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for Drugs and Drug Addiction

Legal aspects of substitution treatment

An insight into nine EU countries

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Introduction

This report contains the findings and conclusions of a study of the legal aspects of substitution treatment for drug users in Europe. The study was conducted during 2001 by the Catholic University of Leuven (K.U.Leuven), Belgium, for the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA).

The report is divided into two parts. Part I outlines the general findings and conclusions of the study, whereas Part II presents the specific information provided by the participating experts.

Part I consists of five chapters and these present a general synthesis of the legal aspects of substitution treatment in Europe, highlighting the different concepts and definitions used by the participating European countries. The first chapter outlines the objectives of the study and the methodology used to collect, analyse and present the information. The second and third chapters give an overview of the legal basis for substitution treatment at international level and the legal basis for substitution treatment in the European countries participating in the research. The fourth chapter looks at the application of substitution treatment regulations. The fifth chapter summarises the national experts' comments and recommendations on substitution treatment policy in their country. A list of references is presented at the end of Part I.

Part II starts by listing the topics used for data collection by the different participating countries. This is followed by a summary of each of the reports written by the national experts of the participating European countries.

Executive summary

Substitution treatment programmes for drug addicts are available in all the European countries, mainly based on the widespread scientific consensus on the benefits of such programmes in improving the health and psychological and social well-being of drug users. A recent study conducted by the EMCDDA on current practices in drug substitution treatment in the EU Member States highlighted the highly complex nature of this issue: there are considerable differences in practical approach throughout Europe. This made it imperative to look at the ways in which drug policy, legislation and regulations are responsible for these differences.

Consequently, the EMCDDA directed the Catholic University of Leuven to conduct this study of the legal aspects of substitution treatment in Europe. The main goal of the study was to analyse the ways in which international and national laws and directives in the field of substitution treatment are being enforced, in order to show their impact on the status, design, organisation and acceptance of substitution treatment programmes in the European countries participating in the study. In this study, 'substitution treatment' is defined as: 'a form of medical care offered to opiate addicts based on a similar or identical substance to the drug normally used, i.e. methadone or other substitution substances, including medically prescribed heroin'.

The information presented here was collected by experts in a number of European countries (Austria, Belgium, Finland, France, Greece, Ireland, Italy, Norway and Spain). These experts contributed to the study by means of country reports, in which they describe their national laws and regulations and the application of these rules in practice, including policies and public attitude towards the issue of substitution treatment. The following conclusions and recommendations are based on analysis of these national reports by the research team.

Legislation

On an international level, the 1961 and 1971 UN conventions contain no explicit regulations concerning substitution treatment, leaving it to the competence of national governments to legislate in this area. This is probably one of the reasons why national regulations and practices differ so much between countries. Although substitution treatment in the European Member States dates back to the 1960s and 1970s, the development of legislation is often a much more recent matter (sometimes not until the 1990s).

Regulation by means of laws and guidelines exists nowadays right across Europe, but it differs substantially between countries.

Regulation of substitution treatment has been subject to change over time. Originally, the laws and regulations were quite restrictive and very general in content. Later on, changes and adjustments to existing legislation made these laws less restrictive and more detailed.

Purposes

Substitution treatment never serves just one purpose. As far as (public) health is concerned, the aim is to reduce the risk of infectious diseases among injecting drug users, to stabilise drug use and to increase the variety of effective treatment programmes. Furthermore, substitution treatment helps to improve the general health and social well-being of drug users. It also helps to prevent the negative consequences of drug use for society as a whole, by reducing public nuisance and criminal activity among dependent drug users. Differences between countries exist according to the specific emphasis on one or other of these goals. In some countries, the approach to substitution treatment remains ambiguous. Whereas, in most countries, the therapeutic framework is based on reducing drug-related harm, some countries still adhere to abstinence as the ultimate goal.

Prescription and distribution

There are many discrepancies between the public and private sectors in the area of prescription and administration of substitution substances. In most countries, substitution treatment is prescribed and administered either by specialised/licensed centres or by general practitioners (GPs) and community pharmacists, sometimes within the framework of a practical relationship with specialised centres. Control of prescribing and dispensing of substitutes is usually achieved by means of central registration and/or special prescription forms for doctors.

Modalities, entry criteria and substances

The criteria for accessing treatment have relaxed over the years in a lot of countries (low threshold), but some countries and programmes still limit access by strict criteria (high threshold). The modalities of substitution treatment (i.e., the forms it can take) range from detoxification, often on a short-term basis (gradually cutting the quantity of the drugs to zero), to maintenance, mostly on a long-term basis (providing the user with enough of the substance to reduce risky or harmful behaviour). The most common admission criteria are: minimum age, indication or proof of heroin dependence and previous unsuccessful attempts at detoxification. However, no consensus exists between countries with regard to the implementation of these criteria. Methadone is the substitution product 'par excellence', but, over the years, other substitution products have been added to the list, such as buprenorphine and levo-alpha-acetylmethadol (LAAM). The use of heroin to stabilise chronic opiate users has been under trial in Switzerland since 1994, in the Netherlands since 1997 and in Germany and Spain more recently. Heroin has been prescribed on a small-scale, selective basis in the UK for some decades.

In many countries, the law requires that substitution treatment is always accompanied by psychosocial treatment.

Provision of treatment in special settings and situations

Rules for the provision of substitution treatment in special settings or situations are rare in the countries studied. Some countries only provide substitution treatment in specialised or licensed treatment centres or hospitals. In these countries, general

hospitals and community pharmacies are not involved in substitution treatment or are only authorised to continue treatment that has been initiated in a specialised centre. In countries where pharmacies, hospitals and drug services are equally involved, two trends can be observed:

- The number of services dealing with some form of substitution treatment has increased.
- Psychiatric institutions are under-represented in the treatment of drug use in general and, consequently, in the practice of substitution treatment in particular. The role of psychiatric institutions in drug treatment needs to be looked at, in view of the problem of 'dual diagnosis' among drug users.

It is becoming more common for substitution programmes to be offered in prisons, but a number of different problems (reluctance of medical practitioners in prisons to cooperate in substitution treatment, lack of staff for dispensing, etc.) are influencing this trend.

Pregnancy and serious health risks, like HIV or hepatitis infection, are often an indication for prioritising treatment or relaxing the rules. Some countries run special programmes for pregnant women and drug-using mothers with children, but there is still much work to be done in this field.

Public and political attitudes

Although often accompanied by heated debate, one can observe a cultural change across Europe towards a broader acceptance of substitution treatment. Substitution treatment is broadly endorsed by governments as well as the general public. In most of the countries studied here, professional bodies, such as the police force and justice system and the medical profession, have become increasingly supportive of this kind of treatment.

However, some opposition remains. A general consensus rarely exists. Some negative attitudes result from the fact that abstinence is often not achieved after treatment. Indeed, from the abstinence perspective, substitution treatment is not very successful.

Drug users are mostly positive about substitution treatment, but their main concerns relate to its limitations: there are often few centres and practitioners providing substitution treatment and there is limited availability of substances for substitution.

Application of laws and regulations

Actual practice often precedes laws and regulations, which means that it often deviates considerably from what is stipulated in official documents. Consequently, in the same way that the legislation in Member States varies from country to country, application of the legislation differs even more.

In some countries, legal (and political) uncertainty about substitution treatment engenders reluctance among doctors and social services to take part in substitution treatment. In others, a proper legal framework may exist, but this is sometimes not

translated into daily practice. Sometimes substitution treatment, although permitted in law, in practice is still not fully accepted as an appropriate treatment method and thus is rarely practised.

Even within one country, the application of legislation and substitution treatment practices can vary significantly between actors, centres or regions. Indeed, it makes sense for national legislation to allow local policy-makers and fieldworkers to tailor treatment for drug users according to specific situations and localities.

More generally, many of the experts who participated in this study stated that some national regulations are still too restrictive with respect to admission and exclusion criteria, modalities, control measures, range of substances and practitioners who are allowed to be involved in providing substitution treatment.

Conclusions of the expert group

On the basis of the opinions of the participating national experts and analysis by the research team, the following conclusions have been drawn:

- To reduce drug-related crime and the spread of infectious diseases, substitution treatment needs to be expanded, including low-threshold services and harm-reduction initiatives in general.
- Substitution treatment should be provided for within the legal framework, with some flexibility built in allowing practitioners to differentiate according to the specific situation.
- In order to maximise the benefits for drug addicts, admission criteria and regulations in general should be less strict.
- Working methods should be specified more clearly and, in particular, the benefits of maintenance treatment need to be promoted.
- The range of possible substitution substances should be extended, in particular the possibility of introducing controlled heroin prescription as a means of substitution treatment for the most problematic and marginalised patients who are not able to stay in substitution treatment programmes.
- It should be possible to provide substitution treatment in a wide range of facilities, such as health centres, drug services, hospitals (general and psychiatric) and especially in prisons. Apart from specialised centres, general practitioners and community pharmacists should also be (more) involved in substitution treatment.
- Medical substitution treatment should always be complemented by adequate psychosocial support, which is often not the case at present.
- More scientific research and evaluation of substitution programmes is needed.
- More doctors and fieldworkers in general need training and education in substitution treatment.

PART I. LEGAL ASPECTS OF SUBSTITUTION TREATMENT IN EUROPE

Objectives and methodology

The study described in this report focuses on the legal basis, legal constraints and possible problems concerning the issue of substitution treatment for problem drug users in Europe. In this study, 'substitution treatment' is defined as 'a form of medical care offered to opiate addicts based on a similar or identical substance to the drug normally used (i.e., methadone or other substitution substances such as buprenorphine or LAAM), including medically prescribed heroin' (EMCDDA, 'Key role of substitution in drug treatment', *Drugs in Focus*, 2002).

The purpose of this research is to describe if, and to what extent, treatment facilities and services are, in practice, shaped by legal constraints and what could or should be done to improve substitution treatment services from a legal point of view.

More specifically, the study aims to analyse the way in which national laws and directives in the field of substitution treatment are being interpreted and/or enforced, in order to show how they impact on the status, design, organisation and acceptance of substitution treatment. In order to ascertain the impact of social and/or political attitudes on the interaction between the legal framework and actual practice, key figures in the field of distribution of controlled drugs are asked for their opinions and possible problem-solving strategies.

The methodology of the study consists of two important strategies: data collection by national experts on the one hand and analysis of available data by the research team on the other.

1. National experts

In order to study and analyse the legal basis of substitution treatment in different European countries, the first important task was to establish a group of experts in the domain of drug research. These experts from different Member States and other European countries have been the contact persons for the research team throughout this study and have contributed enormously by collecting the required information at national level. The aim was to include experts from as many European countries as possible. Nevertheless, due to the limited financial resources and time constraints of the project, not all the EU Member States have been included.

The following experts participated in the project: Stefan Ebensperger and Verena Murschetz (Austria), Sven Todts (Belgium), Yrjö Nuorvala and Jouni Tourunen (Finland), Anne Coppel (France), Calliope Spinellis and Paraskevi Zagoura (Greece), Barry Cullen and Síle O'Connor (Ireland), Francesca Marchi (Italy), Astrid Skretting (Norway) and Marta Torrens (Spain).

It is important to emphasise that all the findings and conclusions of this study, as presented in this report, are based on information from the nine European countries participating in the project only.¹

2. Data analysis

National level

All the national experts involved in the study were asked to write a report describing the legal status of substitution treatment in their country, following a list of topics. This list was the basic framework developed in order to classify, compare and analyse the country-specific information.

The topics (and, consequently, each country report) focused on three important aspects of substitution treatment. The first part consists of a description of the national, regional and local laws, as well as the regulations and political and professional guidelines governing substitution treatment. The second part concerns the application and interpretation of these laws and regulations in practice, and also looks at public and political attitudes to substitution treatment. Finally, national experts were asked to give their opinion about the substitution treatment policy in their respective countries and to offer suggestions for improving the legal and/or practical situation concerning substitution treatment.

The findings and conclusions of the study are presented according to the structure of the original topic list. However, the first, more general, part of this report does not present the information country by country but provides a general overview of all the relevant issues, highlighting common factors and differences. Country-specific information is only given by means of examples.²

International level

As well as analysing the legal status of substitution treatment in the participating European countries, the researchers also studied the impact of international legislation on the design of national legislation, with particular reference to the guiding principles of the UN conventions on drugs.

The legal basis for substitution treatment at international level³

The most significant legal basis for substitution treatment at international level can be found in the United Nations conventions on drugs of 1961 (Single Convention on Narcotic Drugs), 1971 (Convention on Psychotropic Substances) and 1988 (Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances),

¹ As a consequence, the following countries were *not* involved in this study: Denmark, Germany, Luxembourg, the Netherlands, Portugal, Sweden, the United Kingdom.

² The second part of this report presents all the national country reports upon which this study is based.

³ With many thanks to Jacques Franquet, a member of the International Narcotics Control Board, for providing the relevant data. See also 'Reviewing legal aspects of substitution treatment at international level', EMCDDA (http://eldd.emcdda.org/databases/eldd_comparative_analyses.cfm#).

although these conventions do not explicitly regulate the distribution of narcotics for reducing drug (ab)use or related harms. The main objective of the 1961 and 1971 UN drugs conventions was to create an international system to monitor the production of narcotic and psychotropic substances, whereby any use, possession, production, etc., of scheduled substances is prohibited, *except* when exclusively intended for medical and scientific purposes (Art. 4c Convention 1961; Art. 5.2 Convention 1971). However, none of the conventions clarify the concept of ‘medical and scientific purposes’.

Narcotic drugs and psychotropic substances are scheduled according to their therapeutic value, risk of abuse and health dangers. Article 2 of the 1961 Convention outlines control measures based on these schedules. Drugs listed in Schedule I (which include, among others, methadone, heroin, cocaine, cannabis) ‘are subject to all measures of control applicable to drugs under this Convention’. Controls for substances listed in Schedules II and III are less strict according to the therapeutic properties of these substances (among others, codeine, propiram and preparations based on opium, morphine, codeine, etc.). The drugs listed in Schedule IV are considered to be the most dangerous, having only limited medical and therapeutic value. These substances (such as heroin and cannabis) are subject to the strictest controls.

To regulate the trade in and distribution of narcotics used for medical purposes, the Single Convention introduced a control system based on authorisation and licences, including the requirement that medical prescriptions be used to supply or dispense controlled drugs to individuals. Thus, according to Article 30, if a country deems the prescription of a controlled drug (even Schedule I substances such as methadone) to be ‘necessary’, the only requirement is that strict rules are applied, such as the use of official forms, registration and other control measures. Moreover, for drugs in Schedule IV (heroin, cannabis), Article 2.5a states that ‘a Party shall adopt any special measures of control which in its opinion are necessary having regard to the particularly dangerous properties of a drug so included’. The use of heroin in the treatment of drug addicts is thus not specifically forbidden by the Single Convention, but it remains a controversial issue in European countries.

Concerning therapeutic treatment, the 1961 Single Convention calls on its signatories to take all practicable measures for the treatment of drug abusers in order to reduce the abuse of drugs (see Art. 38). However, the convention does not specify what those measures should be, leaving this to the individual signatories to define. The Second Resolution of the UN Conference for the Adoption of the 1961 Single Convention (annexed to the latter) advises ‘treatment in a hospital institution having a drug free atmosphere’, but this resolution does not appear to exclude recourse to other ‘practicable measures’. Since the 1961 Convention also clearly permits the authorised provision and use of drugs, including methadone, for medical and scientific purposes, substitution treatment is seen by most policy-makers and practitioners as a legitimate type of treatment that responds to the objective of Article 38 to reduce drug abuse.

In conclusion, the UN conventions do not explicitly forbid the controlled use of drugs for medical purposes. However, the question as to whether or not substitution treatment – and particularly the controlled prescription of heroin – is legitimate,

according to international legislation, remains a problem of interpretation. This is probably due to the fact that these conventions are somewhat out of date, because they date back to a time when substitution treatment was not yet considered as a form of treatment.

The legal basis for substitution treatment in the European countries

1. Historical background

The introduction of substitution treatment into European countries dates back to the 1960s and 1970s. However, this was on a very small scale until the mid-1980s, when the advent of the HIV epidemic became an important impetus for the expansion of substitution treatment programmes across Europe. Although the relationship between HIV infection, injecting drug use and the practice of substitution treatment is a complex one, sufficient sound data exist to support the case that substitution treatment is an effective component of HIV prevention.

In countries such as Norway, where the prevalence of HIV infection has always been fairly low, it was the lack of drug-free treatment that encouraged the adoption of substitution treatment.

Historically, the organisation and nature of drug services in each country are predominantly defined by the cultural background and legislative framework of each country (Farrell et al., 1995).

In the European countries (in contrast to the United States, for example), the idea that the negative effects of drug use are, to a large extent, attributable to the illegality of drugs (i.e., a strictly prohibitive drug policy) has become widespread. As a result, substitution treatment has rapidly gained acceptance by policy-makers as well as the general public. Over the last five years, many Member States have reported an increase in drug substitution treatment programmes and this trend is still rising. Currently, it is estimated that around 300 000 drug users are enrolled in substitution treatment programmes throughout Europe (EMCDDA, Insight No. 3, 2000).

Because international legislation does not explicitly regulate substitution treatment (see above), the legal framework for its practice is the responsibility of national governments. This situation is also influenced by a general political tendency for health policy to be regulated by local authorities. There is considerable variation in the availability and nature of substitution treatment, both within and between countries. Moreover, the contrast between legal requirements and the daily practice of substitution treatment is often striking.

As mentioned above, actual practice often preceded laws and regulations. As certain practices became more prevalent and accepted (although without a legal framework), fieldworkers pressured governments and politicians to create a proper legal framework. Even as late as the 1990s, in countries such as France and Belgium, general practitioners (GPs) were still prosecuted for prescribing methadone and other substitutes. More generally, the lack of a secure legal foundation is not very encouraging for practitioners who are willing to provide drug users with substitution

medication. In the past, substitution treatment was implicitly or explicitly forbidden by law in some countries (e.g., France, Greece). Nowadays, the ban on medical substitution treatment has, to a large extent, vanished in Europe.

Substitution treatment in the 1960s and 1970s rarely had a legal basis, and the development of relevant legislation has often been very recent (the 1990s). The exception is Spain, where the first laws in this domain date from 1983. Belgium is at the other extreme, where a specific legal framework was still lacking in 2002, although guidelines existed, based on such a large consensus that they were almost regarded as law ('Consensus Conference').⁴ Table 1 shows the year of adoption of legislation related to substitution treatment in the countries analysed in this study.

Table 1: Year of establishment of substitution treatment legislation, by country

Austria	1998: Federal Narcotics Act
Belgium	1994 (Consensus Conference) + 2002 (Law on legal recognition of substitution treatment)
Finland	1997: Orders of the Ministry of Social Affairs and Health 1997 (28)
France	1994: Circular letter ('relative au cadre d'utilisation de la méthadone')
Greece	1993: Law 2161/1993
Ireland	1998: Misuse of Drugs (Supervision of Prescriptions and Supply of Methadone) Regulations
Italy	1990: Law 309/1990 ('in materia di disciplina degli stupefacenti e sostanze psicotrope')
Norway	1997: Bill + guidelines of Ministry of Health and Social Affairs, I-25, 1998
Spain	1983: Ministerial Order about Regulation of Methadone Maintenance Treatment for Opioid Dependent Subjects

Source: Country reports.

2. National, regional and local laws, regulations and political and professional orientations and guidelines, including regulation of medical practice, prescription and provision

Regulation by laws and guidelines exists right across Europe, but the content of such legislation differs significantly between countries. Over time, the regulation of substitution treatment has been subject to considerable change. Originally, the laws and regulations were often restrictive and very general in content. Complementary legislation and changes to existing legislation have since become increasingly less restrictive and more detailed.

2.1. Who is allowed to prescribe, provide and control prescription?

Prescribing

In some of the countries that participated in this study, only physicians in a specialised/licensed centre are allowed to prescribe substitution medication; in other countries, physicians in the public health system and private physicians are also

⁴ Recently, however, a Belgian law has been developed concerning substitution treatment, but a Royal Decision for its practical application is still lacking. See 'Wet van 22 augustus 2002 strekkende tot de wettelijke erkenning van behandeling met vervangingsmiddelen en tot wijziging van de wet van 24 februari 1921 betreffende het verhandelen van de giftstoffen, slaapmiddelen en verdovende middelen, ontsmettingsstoffen en antiseptica', B.S. 1 October 2002.

involved in prescription. In some cases, substitution treatment always has to be initiated in a specialised centre.

- Physicians in a specialised/licensed centre: Finland (only a designated physician in a nominated unit or hospital), France (methadone is prescribed in specialised centres), Greece (special public units with a licence), Norway (social services specifically authorised to offer medicine-assisted rehabilitation, or a GP can offer treatment, in close cooperation with an authorised centre).
- Private physicians and others: Austria (practitioners who are listed by the state and drug outpatient departments in state hospitals), Belgium (all physicians, in cooperation with a specialised treatment centre), France (buprenorphine can be prescribed by GPs, by means of a secured prescription form), Ireland (GPs who have undergone training; a registered patient is linked to one GP), Italy (public drug treatment centres and GPs, in liaison with a centre), Spain (doctors in licensed prescribing centres and all licensed private doctors).
- Initiation of treatment in a specialised centre: Finland (afterwards, treatment can be continued by means of specialised medical care, health centres, drugs services, outpatient care and prisons), France (for methadone, when substitution has stabilised, it is possible to refer the patient to a GP).

Providing/dispensing

In some cases, substitution medication can only be dispensed in treatment centres. In other countries covered by this study, community pharmacists can also distribute methadone and/or other substitution substances.

- Only in treatment centres: Finland and Greece (dispensing occurs within the same services as prescription; see above), France (methadone is strictly regulated and is only dispensed in a specialised centre, in contrast to buprenorphine/Subutex), Italy (GPs collaborate with drug treatment centres for dispensing).
- Community pharmacies and others: Austria (any pharmacy, but also doctors listed by the state and drug outpatient departments of state hospitals), Belgium (all pharmacies as well as specialised treatment settings), France (buprenorphine: any pharmacy), Ireland (every pharmacy, but a registered patient is linked to one pharmacist), Norway (when client is stabilised, dispensing can take place in a pharmacy), Spain (pharmacists in licensed prescribing centres and all licensed private pharmacists).

Controls

Control of prescribing and dispensing substitutes is achieved mainly by means of central registration (countries that legally demand registration are Austria, Finland, France for methadone, Ireland, Spain) and/or through special prescription forms for doctors (France, Ireland). Registration can also be used for evaluation purposes.

2.2. Goals, working methods, entry criteria, choice of substances prescribed (including opiates such as heroin)

It is an overall trend in the countries studied that legal modalities, entry criteria and range of substances used have relaxed over recent years.

Goals

All the experts participating in this study outlined different goals at various levels with regard to substitution treatment. As far as public health is concerned, the aims include: reducing the risk of HIV and hepatitis infection and other health risks among injecting drug users; involving drug users in a therapeutic process; facilitating medical follow-up of certain pathologies; increasing the variety of effective treatment programmes; stabilising drug use. Social aims include: development of social and professional skills, particularly returning to employment; reintegration into society as a 'normal' citizen. Finally, some countries also mentioned reducing crime as an explicit goal.

Remarkably, general trends in countries can be distinguished according to the overall goal. In some countries, a drug-free life remains the ultimate goal (e.g., Norway and Italy), whereas, in others, the basic aim is to reduce the negative consequences of drug abuse, known generally as 'harm reduction' (e.g., Austria, Belgium, Ireland, Spain). Some approaches fall somewhere in between (in Finland and Greece, detoxification aims at abstinence and maintenance aims at harm reduction) and others reveal ambiguous goals (in France, the ultimate goal is abstinence but, in practice, GPs can do 'as they please' and there are maintenance programmes based on reducing drug-related harm).

In general, there has been an evolution which parallels the one in legislation: from abstinence to reduction of drug-related harm as the primary aim (e.g., in Norway, the goal was abstinence and resocialisation in 1994, whereas the 2000 guidelines include 'reducing harmful effects of drug use').

Modalities

Not all countries employ different modalities of substitution treatment. In some countries, a distinction is made based on the duration of treatment (e.g., short-term detoxification, long-term maintenance). In general, however, no consensus exists within or between countries with regard to the definition of goals, modalities and duration of treatment.

Table 2 highlights a few countries as an illustration.

Table 2: Illustration of possible modalities of substitution treatment

	Short-term	Middle/long-term	Long-term
Belgium	3 weeks–3 months	2 years–5 years	unlimited
Finland	max. 1 month	> 1 month, when previous detox was unsuccessful	> 1 month, when special need (prevention of disease, improving quality of life, preparation for detox)

Italy	detox short-term: max. 1 month detox long-term: > 1 month = reducing dosage (aim is to introduce in another programme)		short-term maintenance: max. 6 months long-term maintenance: > 6 months = stable dosage (aim remains final abstinence)
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Source: Country reports.

In Ireland and Spain, the law stipulates no limit to duration of treatment.

National reports seem to show that, in general, methadone is used for longer-term programmes and buprenorphine for short-term treatment.

Admission (entry) criteria

The most common admission criteria are: minimum age, indication or proof of opiate dependence and previous unsuccessful detoxification attempts. However, no consensus exists between countries with regard to the implementation of these criteria.

In some countries, more criteria have been added or special criteria have been formulated for special cases, such as pregnant women and people with serious health problems.

In all the countries covered in this study, the admission criteria have been relaxed over the years.

Table 3: Admission criteria for substitution treatment, by country

	Opiate dependence	Minimum age	Failed detox	Other criteria	Priority criteria
Austria	min. 1 year	20 years	x	consent of patient (to medical surveillance, to psychosocial treatment, to abstain from drug abuse)	HIV, pregnancy: no minimum duration of H-addiction
Belgium	min. 1 year	18 years	x (also spontaneously)	no contraindications	–
Finland	opioid addiction criteria of ICD-10 classification of diseases	–	x	treatment plan	–
France ⁵	1994: min. 5 years 1995: serious opioid dependence	–	1994: different previous detox attempts 1995: –		
Greece	physical and	20 years	serious but	- contract	HIV,

⁵ Some centres adhere to the 1994 criteria.

	psychosocial dependence		unsuccessful previous treatment in another programme	<ul style="list-style-type: none"> - no serious psychopathology - prohibition of use of other narcotic substances 	pregnancy, serious somatic or psychosocial disorder in general, high risk of death
Ireland	–	16 years (relaxed)	–	–	pregnancy
Italy	x (long-term methadone maintenance: long-term addiction to opiates)	–	– (except for long-term methadone maintenance: previous unsuccessful interventions)	–	–
Norway	long career	25 years (relaxed)	reasonable amount of drug-free treatment	holistic treatment plan	serious or life-threatening illness
Spain	x	–	– (relaxed)	no medical contraindication	pregnancy, AIDS, severe physical illness

Source: Country reports.

In many countries, substitution treatment always has to be accompanied by psychosocial treatment (Austria, Finland, Greece, Italy, Norway) and sometimes urine testing (France, Greece, Italy, Norway).

Substances

In most of the countries participating in this study, methadone is the substitution product 'par excellence'. The exceptions to this rule are France (where buprenorphine/Subutex is far more common, due to the fact that few legal obligations surround its use, unlike methadone), and Finland (where methadone and buprenorphine are used more or less equally).

Over the years, various countries have included other substitution products, such as buprenorphine and LAAM (Levo-Alpha-Acetylmethadol). However, LAAM – which was used fairly infrequently – has now been suspended on the recommendation of the European Agency for the Evaluation of Medicinal Products (EMA), following life-threatening cardiac disorders among subjects in LAAM therapy (EMCDDA, 'Key role of substitution in drug treatment', *Drugs in Focus*, 2002).

So far, none of the nine countries analysed in this study have engaged in any form of medically controlled distribution of heroin, except Spain, where two clinical trials are being set up (in Andalucía and Catalonia). In some of the countries not involved in this study, however, medical prescription of heroin to chronic opiate users is under trial: in the Netherlands since 1997 and in Germany more recently. Heroin has also been prescribed on a small-scale, selective basis in the UK for some decades (EMCDDA, 'Key role of substitution in drug treatment', *Drugs in Focus*, 2002).

Table 4: Substances prescribed for substitution treatment, by country

	Methadone	Buprenorphine	Other substances	Heroin
Austria	x (max. 0.1 gram per day)	x (mostly for pregnant women)	- morphine (Substitol): max. 2 gms per day - codeine (Kapatol)	–
Belgium	x	x		–
Finland	x	x	LAAM (not for detox) (never used)	–
France	x (specialised centres)	x (GPs)	Morphine sulphate (for patients who cannot fulfil the strict conditions of specialised centres, like prostitutes or professional people)	– (proposed for experiment, but not yet decided)
Greece	x	x (for use that is not heavy or chronic) (not yet dispensed because awaiting ministerial decision)	- LAAM (not used) - Naltrexone (after methadone treatment, to abstain from methadone)	–
Ireland	x (only 1 mg/ml) (syrup)	– (pending)	- Naltrexone (occasionally, but no guidelines) - Lofexidine (occasionally, but no guidelines)	–
Italy	x (syrup)	x (not used)	–	–
Norway	x	x		
Spain	x	x (not usual)	- LAAM - 14 other substances (not usual)	Two heroin trials

Source: Country reports.

2.3. Rules for the provision of substitution treatment in special settings or situations (hospitals, pharmacies, treatment centres, prisons, pregnancy)

Rules for the provision of substitution treatment in special settings or situations are rare in the countries studied. As described above, some countries only provide substitution treatment in specialised or licensed *treatment centres* or *hospitals*. In those countries, general hospitals and community *pharmacies* are not involved in substitution treatment (e.g., Greece up to 2001) or are only authorised to continue treatment that has been initiated in a specialised centre (e.g., Finland, Norway).

In countries where pharmacies, hospitals and drug services are equally involved, two developments can be observed:

- The number of services dealing with some form of substitution treatment has increased (more services have obtained a licence or more are willing to cooperate; e.g., Ireland, Spain).
- Psychiatric institutions still remain under-represented in the treatment of drug use in general and, consequently, in the practice of substitution treatment in particular. The role of psychiatric institutions in drug treatment has become more relevant, because of the problem of 'dual diagnosis' among drug users (furthermore, the few psychiatric institutions involved only provide treatment with the goal of abstinence).

Belgium has developed low-threshold mobile centres which organise their own methadone distribution, in combination with psychosocial support.

There seems to be a trend towards more substitution programmes being offered in prisons,⁶ but this development is not very clear, because of problems such as the reluctance of medical practitioners in prisons to cooperate in substitution treatment, lack of staff for dispensing, etc.

In several of the countries studied, substitution treatment is offered in prisons (Austria, Belgium, Finland, France, Ireland, Norway, Spain), but this is usually as a continuation of an existing programme (i.e., no initiation of treatment in prison) and it is, in general, aimed at short-term abstinence from methadone (decreasing doses for short periods of time). An exception is the situation in Spain, where it is possible to start a new methadone programme in prison, not necessarily aimed at abstinence.

Pregnancy (and serious health risks such as HIV or hepatitis infection) is often an indication for priority or for the application of less stringent rules, whether such conditions are explicitly regulated or not. Some countries provide special programmes for pregnant women and drug-using mothers with children (Belgium, France, Ireland), but there is still much work to be done in this field.

2.4. Potential infractions and the sanctions applied

The most prevalent potential infraction is the persistent use of heroin or other illegal drugs while enrolled in some kind of substitution programme. In Austria, Finland, France, Italy and Norway, this will or can lead to suspension of the treatment (depending on the specific centre and the legal situation). In Ireland, continued use of illegal drugs can lead to a reduction of the daily methadone dosage or withdrawal of take-home privileges. In Belgium and Spain, the use of heroin during treatment with methadone is *not* a sufficient reason to end the programme.

Other infractions can be: drug trafficking (including of the substitution substance) inside or outside the walls of the treatment service; refusal to cooperate in the programme; refusing urinalysis or tampering with urine samples; and violent

⁶ See *An overview study: Assistance to drug users in European Union prisons*, a study by the EMCDDA, published by the European Network for Drug and HIV/AIDS Services in Prison (ENDHASP); see also http://www.emcdda.eu.int/responses/themes/assistance_prisons.shtml.

behaviour (mostly inside the centre). Sanctions for these kinds of infraction generally means discharge from the programme. In Spain, people who are excluded from one service can present themselves at another centre. In Ireland, excluded patients are detoxified from methadone over 5–7 days prior to discontinuation of the treatment. In Austria, the sanctions depend on the criminal charges.

Application of substitution treatment regulations

1. Daily practice

We have already mentioned that practice often precedes laws and regulations. Daily practice can deviate considerably from what is stipulated in official documents. Consequently, just as the legislation in European countries varies considerably, actual practice can differ even more. However, although it is not easy to detect general trends, we have tried to present a general overview in what follows.

- *Practice has expanded*

Apart from legislation, the practice of substitution treatment has increased (more or less rapidly) in all the countries studied, with more actors prescribing and an increased number of patients enrolled in treatment.

- *The lack of (or limitations of) a legal framework does not imply that the practice does not exist*

In Belgium, a formal legal basis for substitution treatment has not yet been established.⁷ Nevertheless, it has been a relatively widespread practice for several years, by private physicians as well as in public treatment centres.

In France, the prescription and distribution of methadone is very strictly regulated, unlike buprenorphine, for which few regulations exist. In practice, more than 75% of substitution patients are treated with buprenorphine by GPs and less than 5% are treated in a treatment centre.

- *Sometimes the legal framework is not translated into daily practice*

In many of the countries studied, LAAM is a legal substitution product. However, it is hardly used anywhere, except for Portugal. It has even been withdrawn from the market in many cases.

In Finland, the law foresees three modalities with regard to substitution programmes (detox, substitution and maintenance), though maintenance is not practised except in one treatment unit and in a few special cases. In practice, substitution treatment is still not fully accepted as an appropriate treatment method, by policy-makers as well as by practitioners.

In Italy, it is the other way around. Four modalities exist in theory (short-term detox, long-term detox, short-term maintenance, long-term maintenance), but long-term treatment has been common practice for several years now.

⁷ Although, at the time of writing – February 2002 – legislation is being developed.

As in other countries, substitution treatment is legally permitted in Norway, but waiting periods for entry to a substitution programme can be lengthy (up to 1 or 2 years), because the number of available slots does not meet demand.

- *The practices within one country can be manifold*

Apart from the differences between countries, daily practice can vary between actors, centres or communities, even within one country.

In France, many GPs and pharmacists are involved in substitution treatment on a voluntary basis and are organised in dynamic networks. However, hardly any specialised treatment centres participate in these networks, although such centres practice substitution treatment as well. French treatment centres can be divided into 'old-school centres' (they work in isolation; mainly prescribe methadone in low doses; no maintenance) and 'new-school centres' (basic approach is harm reduction; methadone maintenance is possible; larger number of patients; more transferring of patients to GPs when stabilised).

In Italy, different treatment centres ('Sert') have different approaches. Some centres regard substitution treatment as the first step in treatment and so focus on psychosocial interventions. For other centres, the primary aim of substitution is abstinence. Finally, treatment centres exist along a harm reduction approach, where methadone is provided in high doses and for long periods of time, where the use of heroin is tolerated and the primary aim for users is to normalise their social life.

In Spain, views on substitution treatment (more or less in favour) and practices vary considerably between Autonomous Communities.

2. Legal problems in prescribing or providing substitution substances

As already mentioned, the legal provisions differ between the countries studied. Consequently, any judicial problems or difficulties will vary too. However, it is possible to formulate a few general characteristics.

- *Lack of legal basis*

There is a need for a proper legal framework in countries such as Belgium, where there is no formal legal basis for substitution treatment. Although substitution has been practiced without a specific legal basis, the resulting legal uncertainty causes much reluctance among doctors and social services to take part in such treatment.

- *Lack of involvement of the private sector*

In countries where only public treatment services are authorised to practise substitution treatment (e.g., Finland, Ireland), it is important that the private sector (GPs and pharmacists) should also be allowed to participate (this would help alleviate the long waiting lists). Differentiation is necessary between GPs and pharmacies within the public health service and private doctors/pharmacies. Even in countries where GPs are involved in substitution treatment (e.g., Austria), more and better training is needed for them.

In general, more actors should be involved.

- *Too many restrictions with respect to admission criteria and/or controls*

Admission criteria (minimum age, minimum period of dependence, minimum number of previous detox attempts), exclusion criteria (using heroin or other drugs during treatment) and requirements such as urinalysis are often very stringent (e.g., Austria, Finland). When patients are prohibited from using heroin or other drugs during treatment, users who are not able to quit their drug use are excluded. However, these are often the people who need treatment the most, being the most marginalised.

A minimum amount of government control on prescriptions is desirable, but sometimes such controls can result in interference with the treatment itself (e.g., in Austria).

- *Limited range of substitution products*

The prescription and provision of substitution substances other than methadone should be encouraged, as well as the option to dispense higher doses.

3. Social, political and public attitudes (including both the police force and users) towards treatment, treatment provision and distribution centres

It is possible to observe a cultural change across Europe towards a broader acceptance of substitution treatment, although this is often accompanied by heated debate. Substitution treatment is broadly endorsed by governments, as well as the general public. In most of the countries studied, professional actors such as law enforcement organs (police force and justice system) and the medical profession have become considerably more supportive of such treatment.

Some opposition remains, however. Sometimes, negative attitudes arise from the fact that decision-makers and/or the general public expect drug users to become abstinent very quickly. Indeed, from the abstinence perspective, substitution treatment is not very successful. The new government in Austria has expressed disapproval of substitution treatment, whereas the public attitude is quite positive. In Finland, the general attitude of the public is ambiguous, as prejudice towards drug (mis)users is still very common. The same is true of Ireland, where people expect abstinence to be the end result of substitution treatment and there is also some community resistance towards new dispensing centres.⁸ In Norway, many GPs and pharmacists are opposed to having drug users on their registers and do not wish to participate in substitution treatment. The government in Italy recently announced a major shift in policy regarding treatment for drug addiction. 'Harm reduction' strategies are to be abandoned and methadone treatment will only be offered as part of a detoxification schedule and only within a high-threshold, drug-free programme. Scientific researchers as well as fieldworkers have expressed their disapproval of this change of policy.

Drug users who are receiving substitution treatment are mostly positive about the fact that such treatment has become more common. Their main concerns relate to its limitations: the fact that, in some countries or localities, there are insufficient centres and practitioners offering substitution treatment and that there is limited availability of certain substances. They feel that it is important to complement treatment with

⁸ An example of the 'NIMBY' syndrome (Not In My Back Yard).

psychosocial support. They also feel that opening hours are too limited for those who work, on-site drinking of methadone in a community pharmacy is embarrassing and waiting lists are sometimes too long.

Comments and recommendations of national experts

The national experts of the countries participating in this study have formulated the following suggestions and recommendations to inspire future debate. Although there is no general consensus between all the experts on every one of these suggestions, they have been expressed by the majority.

The executive summary should also be referred to for clarification of some of these points.

- *Substitution treatment should be expanded*

Evaluation research shows that, in practice, substitution treatment programmes are successful (to a greater or lesser extent depending on the country) in reducing the harmful consequences of opiate addiction. A lot of substitution treatment programmes in the European countries are not able to meet the demand. It is, therefore, imperative that substitution treatment be expanded, including low-threshold services and harm-reduction initiatives in general.

- *Substitution treatment should have a proper legal foundation*

A proper legal foundation should be in place for substitution treatment and this should be balanced, with clear guidelines, and allow practitioners flexibility, since contexts differ according to users, local situations, etc.

- *Substitution treatment regulations should be less restrictive*

Admission criteria and regulations in general should be less restrictive. Strict admission criteria (high-threshold) leads to long waiting lists.

Modalities should be specified more clearly. In particular, maintenance treatment as the final objective in substitution treatment should be an option for clients who fail to detox in short-term substitution programmes.

The range of substitution substances should be extended, in order to facilitate tailoring treatment. Special attention should be given – especially by researchers – to the option of controlled prescribing of heroin for problematic and marginalised patients who are not able to stay in substitution treatment programmes.

A wider range of modalities and substances would make it possible for doctors to decide, on a case-by-case basis, which treatment and which substance is appropriate for an individual client.

- *More actors should be involved in substitution treatment*

It should be possible to implement substitution treatment in a wider range of services, such as health centres, drug services, (psychiatric) hospitals and, in particular, in prisons. Apart from specialised centres, general practitioners and community pharmacists should also be (more) involved in substitution treatment, in order to

make it more accessible. As things stand, there are often long waiting lists in specialised treatment centres.

- *Substitution treatment should be accompanied by psychosocial care*

Medical substitution treatment should always be accompanied by adequate psychosocial support, which is often not the case at present.

- *More scientific research*

More scientific research and evaluation of substitution programmes is needed.

- *More training and education*

There is a need for more training and education of doctors, and fieldworkers in general, regarding substitution treatment.

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PART II. COUNTRY REPORTS

Topic list of the data collection

In this second part of the report the country reports of the national experts participating in the study are extensively presented. In order to offer the experts a basis framework for their reports and to facilitate the analysis of the country-specific information afterwards, the following list of topics was elaborated.

- 1) *National, regional and local laws, regulations and political and professional orientations and guidelines, including regulations to medical practice and prescription and provision rules*
 - 1.1) *Actors allowed to prescribe, provide and control prescription*
 - 1.2) *Purposes and modalities of execution, entry criteria, choice of the substances prescribed (including opiates such as heroin)*
 - 1.3) *Rules for the provision of substitution treatment in special settings or situations (hospitals, pharmacies, treatment centres, prisons, pregnancy)*
 - 1.4) *Potential infractions and sanctions applied*
 - 1.5) *Rules for substitution treatment as an alternative to punishment*
- 2) *Information on the daily practices on the application of prescriptions or provisions approaches*
 - 2.1) *Problems or difficulties of juridical nature in prescribing or providing substances because of the legal framework*
 - 2.2) *Social, political and public attitude (including police force at the one hand and users on the other hand) towards treatment, treatment provisions and distribution centres*
- 3) *Comments and recommendations of national experts*

Belgium

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Introduction

Methadone has been prescribed in Belgium since the mid-1970s. The amount prescribed increased from less than 5 kgs in 1975 to 19 kgs in 1992 and 117.5 kgs in 1997.^{9 10 11} Private physicians and psychiatrists, as well as residential or mobile specialised treatment facilities, are now prescribing methadone or buprenorphine.¹² In spite of all this activity, a legal framework for this practice is still lacking. Until only a few years ago, doctors were prosecuted and imprisoned for prescribing substitution treatment. However, substitution treatment is now accepted by politicians and the medical community.

In this report, we will describe the different laws and decrees regulating substitution treatment. We will also discuss the different initiatives that have attempted to clarify the legal and medical status of substitution treatment.

1. Laws regulating the use of substitution treatment in Belgium

1.1. Legislation

1.1.1. Belgian law

The law that regulates the use of methadone in Belgium dates back to 1921.¹³ This law, from now on referred to as the drug law, was intended as a framework to cover all aspects of trade in poisons, antiseptics, soporifics and narcotics. It was written after the ratification of the opium treaty of The Hague in 1912. Legal opinion at the time was that the existing law of 1818 regulating medical practice in general was insufficient in respect of the the Hague treaty.¹⁴ With regard to substitution treatment, the drug law prohibited any physician from maintaining an existing dependence by prescribing narcotics.

The implementation of several aspects of the drug law was achieved through the royal decree of 1930.¹⁵ This decree was important because it enumerated the actual

⁹ Jacques, J.P. and Raedemaeker, A.F., 'Le projet Lama' in *Drugbeleid 2000*, De Ruyver, B. en De Leenheer, A. (ed.), Antwerpen, MAKLU, 1994, 275.

¹⁰ Vandenbosch, B. and Ledoux, Y., Inspection générale de la pharmacie et conseil supérieur d'hygiène, working group assuétudes, procès-verbal de la séance du 04/03/1998.

¹¹ Tecco, J. and Pelc, I., 'Country report: Belgium' in *Reviewing current practice in drug-substitution treatment in the European Union*, EMCDDA, Luxemburg, Office for official publications of the European Communities, 2000, 52-58.

¹² High-dose buprenorphine has been commercially available in Belgium since October 2001.

¹³ Wet van 21/02/1921 betreffende het verhandelen van giftstoffen, slaapmiddelen en verdovende middelen, ontsmettingsstoffen of antiseptica, *B.S.*, 06 maart 1921.

¹⁴ De Nauw, A., *Drugs*, Antwerpen, Kluwer, 1998, nr. 1.

¹⁵ Koninklijk besluit van 31 december 1930 omtrent den handel in slaap- en verdoovende middelen, *B.S.*, 10 januari 1931.

molecules that were targeted by the drug law.¹⁶ Furthermore, Article 23 stated that every physician, veterinary surgeon or dentist that buys or prescribes excessive amounts of narcotics has to answer to the provincial medical commission. This same article states that any physician who starts, maintains or aggravates a pre-existing dependence will be prosecuted. The provincial medical commissions are administrative bodies under the authority of the Ministry of Public Health. Although these commissions have no actual authority and cannot impose sanctions, they do nevertheless have some impact on the behaviour of the doctors under their jurisdiction, as they can withdraw their licence or denounce them to the Belgian Medical Association or the justice department.¹⁷ From 1982 onwards, most of these commissions took it upon themselves to publish often very detailed guidelines on prescribing narcotics.¹⁸

In 1975, the drug law was thoroughly revised. The government had two primary goals in the revision process. First, it wanted to refine the definitions of which molecules exactly were meant by the drug law. From then on, not only narcotics and soporifics were targeted, but also 'other psychotropic substances that can create dependence'. Secondly, the government wanted to extend their control system in order to be able to combat the rising drug problem more efficiently.

A secondary objective seems to have been to bring in specific legislation on the status of antiseptics and poisons. For a number of reasons, this goal was not achieved and the revised drug law still regulates the trade in psychotropics as well as in poisons or antiseptics (an example is a less important revision of the drug law dealing with the problem of hormonal residues in meat products).¹⁹ Another revision was necessary in 1998 to allow syringe exchange to be offered by people who are not pharmacists. Syringe exchange is a measure to prevent HIV transmission in injecting drug users.²⁰ New legislation has recently been proposed to allow for the medicinal use of cannabis.²¹

¹⁶ Another important royal decree (Koninklijk Besluit van 22 januari 1998 tot reglementering van sommige psychotrope stoffen, *B.S.*, 14 januari 1999) supplemented the decree of 1930 with a new list of molecules. New molecules are regularly added by means of executive decrees. Although this allows for rapid adjustments to be made, it also means that neither the principle of putting a certain item on the list nor the eventual dose at which the said item would become 'dangerous' can be discussed in parliament. Finally, a less important decree of 1946 (Besluit van de regent van 6 februari 1946 houdende reglement op het bewaren en het verkopen van giftstoffen, *B.S.*, 18–19 februari 1946) also contains some regulations that are legally important.

¹⁷ Balthazar, T., 'De methadonarresten van de Raad van State en de normatieve bevoegdheid van de Orde van Geneesheren', *VI. T. Gez.*, 1993, noot 27, 67.

¹⁸ An overview of these guidelines can be found in De Ruyver, B., De Moerloose, E., Balthazar, T., Vermeulen, G., Van Bouchaute, J. en Reisinger, M., *Drugsubstitutiebehandelingen*, Gent, Universiteit Gent en Koning Boudewijnstichting, 1993.

¹⁹ Voorstel van wet tot wijziging van de wet van 24 februari 1921 betreffende het verhandelen van de giftstoffen, slaapmiddelen en verdovende middelen, ontsmettingsstoffen en antiseptica, *Gedr. St.*, senaat, B.Z. 1991, nr. 447/1.

²⁰ Wet van 17 november 1998 tot wijziging van de wet van 24 februari 1921 betreffende het verhandelen van de giftstoffen, slaapmiddelen en verdovende middelen, ontsmettingsmiddelen en antiseptica en het Koninklijk Besluit nr. 78 van 10 november 1967 betreffende de uitoefening van de geneeskunst, de verpleegkunde, de paramedische beroepen en de geneeskundige commissies, *B.S.*, 12 december 1998.

²¹ Wetsvoorstel tot wijziging van de wet van 24 februari 1921 betreffende het verhandelen van de giftstoffen, slaapmiddelen en verdovende middelen, ontsmettingsstoffen en antiseptica ten einde het

The 1975 revision changed the articles that cover the area of maintaining dependence. Under the law of 1975, physicians, veterinary surgeons, dentists and paramedics can be punished if they abuse their authority to prescribe, deliver or administer any product that can establish, maintain or aggravate dependence. It is, in other words, no longer necessary to prove that dependence was already established; it is sufficient that this could have happened.²² The revision also gives more authority to prescribers, because they are only punishable if their act constitutes an abuse of privilege. However, what actually constitutes such abuse was not adequately defined and this has been the source of a lot of problems since 1975 and has often been criticised by legal experts.²³

1.1.2. International treaties

Belgian legislation aims at meeting the requirements of the various international treaties. Three treaties are important in this regard: the New York single convention on narcotic drugs, the Vienna convention on psychotropic substances and the United Nations convention against illicit traffic in narcotic drugs and psychotropic substances.^{24 25 26}

1.2. The Belgian Medical Association (BMA)

Every physician who practises medicine in Belgium has to be a member of the Belgian Medical Association. Through its provincial councils and one national council, the BMA has disciplinary authority over its members.

In response to the growing drug problem, since 1976 the BMA has issued various guidelines on treating addicts. The original 1976 guidelines were quite liberal and stated that, 'in accordance with the principle of therapeutic freedom, the physician who undertakes to treat a drug addict is free to choose the type of treatment to be administered'.²⁷ In later years, this original text was repeatedly revised and each

gebruik van cannabis voor therapeutische doeleinden te reglementeren, *Gedr. St.*, Kamer, 1998, nr.1755/1.

Wetsvoorstel tot wijziging de wet van 24 februari 1921 betreffende het verhandelen van de giftstoffen, slaapmiddelen en verdovende middelen, ontsmettingsstoffen en antiseptica, ten einde het bezit van cannabis en derivaten ervan gedeeltelijk uit het strafrecht te halen, *Gedr. St.*, Kamer, 2000, nr. 0461/1. Wetsvoorstel tot wijziging de wet van 24 februari 1921 betreffende het verhandelen van de giftstoffen, slaapmiddelen en verdovende middelen, ontsmettingsstoffen en antiseptica, *Gedr. St.*, Senaat, 2000, 585/1.

²² Boutmans, E., 'Drugsdelinquentie volgens strafwet en rechtspraak' in *De illegale drugsgebruiker tussen strafrechtspleging en hulpverlening*, Christiaensen, S. en Goethals, J. (ed.), Leuven, Acco, 1994, 40.

²³ De Nauw, A., o.c., 19-21.

²⁴ Wet van 20 augustus 1969 houdende goedkeuring van het Enkelvoudig Verdrag inzake verdovende middelen, en van de bijlagen, opgemaakt te New York op 30 maart 1961, *B.S.*, 27 november 1969.

²⁵ Wet van 25 juni 1992 houdende instemming met het Verdrag inzake psychotrope stoffen en van de Bijlagen, opgemaakt te Wenen op 21 februari 1971, *B.S.*, 21 maart 1996.

²⁶ Wet van 06 augustus 1993 houdende goedkeuring van het Verdrag van de Verenigde Naties tegen de sluikhandel in verdovende middelen, psychotrope stoffen, en van de Bijlage, opgemaakt te Wenen op 20 december 1988, *B.S.*, 21 maart 1993.

²⁷ Citation in Picard, E., 'Legal action against the Belgian Medical Association's restriction of methadone treatment' in *AIDS and drugs in the European Community*, Reisinger, M. (ed), Lisbon, EMCDDA, 1993, 42.

revision brought in new restrictions on therapy. In 1982, the provincial council of Brabant (which includes Brussels) and, later, the national council introduced prescription standards copied from those used in American specialist treatment centres. Since it was virtually impossible for private physicians to comply with these standards, they became increasingly at risk of being disciplined.²⁸ In 1986, the national council stated that, since the term ‘abuse’ was not defined in the drug law, it was up to the BMA and the judicial authorities to decide what constitutes abuse.²⁹ In 1988, the national council stated: ‘When in detox, the treating physician must take care not to replace dependence on one product with dependence on another. Ambulatory and/or long-term prescription of methadone or an analogous narcotic is therapeutically irresponsible, except in exceptional cases.’³⁰ In this climate, the prescription of methadone by private physicians became very rare.

In 1993, the BMA lost two court cases against private physicians who insisted on prescribing methadone, thereby forcing the BMA to relax its policies.

The present policy of the BMA on substitution treatment can be found in Article 37b of the Medical Ethics Code.³¹ The national council approved the revised article on 28 August 1993. The article states that a physician has to do all that is possible to discourage dependence. Within the limits of his competence, he/she will undertake whatever is necessary to treat addicts and to end their dependence:

- a) He/she will discourage abuse of medication and dependence of medication that can lead to toxicomania.
- b) A physician who wishes to prescribe a substitution treatment that may lead to dependence for an addict cannot limit the intervention simply to supplying a prescription. He/she will first evaluate whether substitution treatment is necessary:
 - He/she will ask a multidisciplinary team to evaluate the patient’s dependence, psychosocial situation and treatment options.
 - He/she will treat the patient holistically, assisted by specialists who are competent to assess the medical, psychological and social problems of the patient and who do not simply limit themselves to prescribing substitution when requested by the patient.
 - He/she will make sure that the patient does not get other prescriptions for substitution treatment from another source.
 - He/she will make sure that outpatients are only prescribed oral medication. He/she will do everything necessary to avoid accumulation, manipulation, exchange, sale or any other abuse of the said medication.
 - With the help of a multidisciplinary team, he/she will regularly evaluate the patient’s ongoing treatment and make any necessary adjustments.

1.3. Substance treatment in special settings or situations

1.3.1. Substitution treatment in ambulatory low-threshold services

²⁸ Reisinger, M., ‘Arrêter l’héroïne’, Bruxelles, Editions complexe, 1990, 163.

²⁹ Orde van Geneesheren, ‘Gebruik en misbruik van geneesmiddelen’, Officieel tijdschrift, nr. 35, 1986, 6p.

³⁰ Orde van Geneesheren, Provinciale Raad van Antwerpen, *mededelingen*, 31 maart 1988.

³¹ Orde van Geneesheren, Code van medische plichtenleer, Brussel, 1998.

A large part of all substitution treatment is prescribed in more or less specialised ambulatory low-threshold services. Most prominent are the so-called medical–social reception centres which were created by the federal government in 1997 to alleviate the most pressing drug problems in inner cities. Prescribing procedures in these centres are different from those of general physicians. The biggest difference lies in the fact that most of these facilities organise their own methadone distribution. General physicians or private psychiatrists only prescribe and the patients then collect their methadone at their preferred local pharmacy.

Distribution of methadone by the treatment centres poses a number of legal problems. Article 12 of the 1885 royal decree on pharmacies forbids doctors to take part in the production and distribution of medication.³² Although there are some exceptions to this law, the distribution of substitution medication is not one of them. Article 26 of the same royal decree forbids pharmacists to deliver medication to anyone other than the patient for whom the medication is intended. The royal decree does allow the delivery of medication to an intermediary in a number of specific cases (homes for the elderly, prisons), but, again, treatment centres are not among the exceptions.³³

The result is that the current practice in methadone clinics of buying large quantities of methadone and then distributing this among the patients is in fact illegal. Regional officials of the Pharmaceutical Inspectorate, which is the administrative body that enforces the laws and decrees in question, have responded in different ways to this problem. In most regions, the inspectors have so far not reacted to the delivery of large quantities of methadone to treatment facilities. However, in some regions the use of (computer-driven) methadone pump installations has been forbidden, since only a pharmacist is allowed to divide a larger quantity of prepared methadone syrup into individual doses. In a few regions, even the delivery of individual doses to the centre by one pharmacy is not allowed: each patient has to buy a number of doses of his own methadone at a pharmacy and bring them to the centre in order to receive his/her daily dose administered.

Until now, there has not been a concerted effort by the treatment centres to find a solution to this problem. There are a number of reasons for this. First of all, there is no consensus: at least one centre believes that treatment facilities have no role in the delivery of methadone and it therefore opposes a unanimous effort. Also, the other centres are very uncertain about the pros and cons of delivery. In most cases, delivery has been organised because local pharmacists have either refused to deliver methadone or have created other obstacles to treatment. Although the situation still differs from region to region, pharmacists tend to be less of a problem than in the past. Because of the rising demand for treatment and limited personnel resources, on the one hand, and neighbourhood complaints about loitering or dealing in the vicinity of the treatment centres, on the other, the need for on-site delivery is being re-

³² Koninklijk besluit van 31 mei 1885 houdende de goedkeuring der onderrichtingen voor de geneesheren, de apothekers en de drogisten, *B.S.*, 19 juni 1885.

³³ Koninklijk besluit van 21 oktober 1999 tot wijziging van het Koninklijk besluit van 31 mei 1885 houdende de goedkeuring der nieuwe onderrichtingen voor de geneesheren, de apothekers en de drogisten, *B.S.*, 1 december 1999.

evaluated. Whatever the outcome, the present practice of on-site delivery is absolutely illegal and puts treatment staff in a very vulnerable position.

1.3.2. Substitution treatment in prisons

With the increase in substitution treatment in Belgium, the demand for such treatment programmes in prisons has also increased. Traditionally, the prison health authorities have been opposed to methadone treatment. Minister of Justice S. De Clerck summed up the reasons in 1996:

- Methadone treatment is supposed to reduce criminal behaviour. The fact that the user has ended up in prison is proof that the treatment has failed.
- The supply of heroin in prison is limited and irregular, therefore use will diminish anyway.
- Users of other drugs (cocaine, amphetamines) also have to detoxify when in prison. To offer substitution to one group but not to another would be unfair.
- The large numbers of heroin users entering the prison system makes it impractical to provide the necessary psychological and social follow-up.
- In society, methadone is used as a tool to lower the threshold of treatment. In prison, there is no need for such a tool.³⁴

At a hearing of the parliamentary working group studying substance abuse in 1996, the medical director of the Belgian prison system, F. Van Mol, supported these ideas.³⁵ Since 1995, however, some prisons have adopted the practice of continuing methadone treatment for prisoners who were already receiving methadone before incarceration. This procedure applies to suspects as well as to convicts. With only a few exceptions (pregnancy, people with AIDS), the doses are decreased over a period of a few days to a few weeks. In almost all cases, the medication is prescribed by the medical officer. In only a few prisons are external physicians allowed to treat prisoners and, in these cases, the physician discusses the case with the prison medical officer, who will then prescribe.

Physicians and psychiatrists have sometimes tried to gain access to their patients in prison and force the medical officers to administer methadone, but this has not proved to be easy. In a summary judgment in 1995, a Brussels judge ruled in favour of a local psychiatrist. Since this psychiatrist later retired from the case before it could be appealed, this can hardly count as a precedent.³⁶ In support of external agencies and physicians, representatives of the people, Biefnot, Minne and Moock, proposed a bill in 1996 to 'end this therapeutic discrimination'.³⁷ The same bill was again proposed by representative of the people Giet in 2000.³⁸

³⁴ De Clerck, S., *Speech to the third Drugbeleid 2000 conference*, in: *Veiligheids- en medische benadering: complementair of tegengesteld*, De Ruyver e.a. (ed.), Antwerp, MAKLU, 1996, 43.

³⁵ Verslag namens de werkgroep belast met het bestuderen van de drugproblematiek, *Gedr. St.*, kamer, 1062/1, 318.

³⁶ Rb., Brussel, 16 november 1995, *T. Gez.*, 1995– d1996, 368–372.

³⁷ Wetsvoorstel tot instelling en bescherming van de vrije keuze van arts en van de therapeutische vrijheid in de strafinrichtingen, *Gedr. St.*, kamer, 1996, Nr. 876/1.

³⁸ Wetsvoorstel tot instelling en bescherming van de vrije keuze van arts en van de therapeutische vrijheid in de strafinrichtingen, *Gedr. St.*, kamer, 2000, nr. 534/1.

Belgian law does not explicitly acknowledge the right to choose a doctor, but the fact that the principle is mentioned in different regulations ‘can be considered to be the expression of an unwritten rule that contains freedom of choice as far as the patient is concerned’.³⁹ The right of free choice is explicitly inscribed in a new bill on patients’ rights, with the exception of certain specified situations and groups, including prisoners.⁴⁰ Belgian prison regulations only offered the option to choose one’s own doctor to a prisoner awaiting trial. Permission had to be obtained from the prison director and the prisoner had to pay for the visit and any resulting prescriptions. The medical officer could oppose the decision of his colleague, at which point the medical director of the prison health service would arbitrate.⁴¹ In 1985, the principle of free choice was extended to all prisoners, including those that had been convicted.⁴² The problem with this regulation is that it is unclear whether the phrase ‘to call on one’s own doctor’ means that the doctor can implement treatment or if it just means that the prisoner can ask for his doctor for advice, while the medical officer remains in charge. Medical officers have almost always chosen to follow the more strict interpretation, arguing that allowing external physicians to provide treatment would make prisons unmanageable. The penitentiary health service has tried to alleviate the situation by employing several independent physicians per prison as medical officers. This at least ensures that the prisoner has some degree of choice, between the different medical officers.

The Belgian Medical Association also recognises the general principle of free choice, but allows for restrictions in Article 31 of its code of ethics.⁴³ It also explicitly recognises the fact that the medical officer is the physician in charge and has sole responsibility for treatment of prisoners.⁴⁴

Finally, some international regulations are relevant here. The European Prison Rules state that ‘untried prisoners shall be given the opportunity of being visited and treated by their own doctor or dentist if there is reasonable ground for the application. Reasons should be given if the application is refused. Such costs as are incurred shall not be the responsibility of the prison administration.’⁴⁵ In an explanatory memorandum, the Council of Europe acknowledges the difficulties that can arise: ‘Prison medical officers have a difficult dual responsibility. They are clearly responsible to the governor for the adequate fulfilment of their duties. They also have a direct duty towards prisoners who are their patients, and for the health of prisoners in general. It is not always easy to reconcile these roles. Apart from that, prison medical services are the special focus of contentious philosophical views about the nature of the relationships between medical staff, institutional management and

³⁹ Nys, H., ‘Advies aangaande het voorontwerp van Beginselwet Gevangeniswezen’, 1999, n.p.

⁴⁰ Voorontwerp van wet betreffende de rechten van de patiënt, Minister van Consumentenzaken, Volksgezondheid en Leefmilieu, 2001, in: Compendium 2001, deel I, Brussel, Penitentiare Gezondheidsdienst, 2001.

⁴¹ Artikel 96 van het K.B. van 21 mei 1965 houdende Algemeen Reglement van de strafinrichtingen, B.S., 25 mei 1965.

⁴² M.O. 1495/XII van 16 oktober 1985: Vrije keuze van geneesheer.

⁴³ Orde van Geneesheren, Code van Medische plichtenleer, Brussel, 1986.

⁴⁴ Tijdschrift Nationale Raad Orde van Geneesheren, september 1996, vol. V nr. 73, 24, geciteerd in: Van Mol, F., *Gezondheid en detentie*, Brussel, Penitentiare gezondheidsdienst, 80.

⁴⁵ Article 98 of recommendation No. R(87)3 adopted by the Committee of Ministers of the Council of Europe on 12 February 1987.

prisoners, as patients in what is seen as a coercive environment. These arguments extend to the question of compulsory or voluntary treatment and the right of choice in regard to a doctor. It is not possible to assert a universally acceptable response to those complicated and sometimes emotive issues. Each society, and the prison system within it, must decide on its own approach. However, certain principles are immutable and should be regarded as paramount. These are that the medical officers and their staff have a primary responsibility for the medical care of the prisoners in their charge; that medical treatment and decisions should be made on professional advice and solely in the interests of the health and well-being of the patients. For prison management and administration, any executive decision that overrides or conflicts with a medical view should be reported to a higher authority and be susceptible to review.⁴⁶

A new bill is currently under discussion that seeks to offer a legal framework for all the existing Belgian prison rules.⁴⁷ Article 89 of this proposal affirms the right of every prisoner to have access to his/her own doctor. The preparatory commission has considered the objections made against external physicians, but is still willing to allow external doctors not only to advise their patients but also to treat them. In an explanatory memorandum, the commission states: 'Notwithstanding the many practical objections and counter-arguments, the Commission has found it necessary to endorse the principle of the free choice of one's own doctor in the prison context.' Medical director F. Van Mol of the penitentiary health service has recently published an extensive critique of this proposal.⁴⁸

As a result of external pressure, some medical officers have adopted a more liberal attitude towards prescribing substitution treatment in prisons. They are supported by a new ministerial circular letter on drug problems in prisons, which cautiously suggests new possibilities.⁴⁹ The basic aim is still abstinence, but the following exceptions are possible: pregnant women, patients with HIV or hepatitis and prisoners who will only be in prison for a short period (which is not defined). Furthermore, the circular letter states that 'the decision to start substitution treatment or continue a maintenance or detox programme is the sole responsibility of the medical officer'. It recommends that any treatment should be in line with treatment that had already begun before imprisonment.⁵⁰

⁴⁶ Explanatory memorandum of recommendation No. R(87)3 adopted by the Committee of Ministers of the Council of Europe on 12 February 1987.

⁴⁷ *Voorontwerp van Basiswet gevangeniswezen* in: *Compendium 2001*, Brussel, Penitenciaire Gezondheidsdienst, 2001.

⁴⁸ Van Mol, F., 'Gevangenis en detentie', Brussel, Penitenciaire Gezondheidsdienst, 2001.

⁴⁹ M.O. No 1722 van 18 december 2000 met betrekking tot de integrale aanpak van de drugproblematiek in de penitenciaire instellingen.

⁵⁰ *Ibidem*, p. 6.

2. Actual practice

2.1. The fight for substitution treatment

2.1.1. The legal battle

As in other European countries, drug abuse first became apparent in Belgium in the late 1960s. From the mid-1970s, it was considered to be a serious threat to society. At that time, a small number of private physicians in Brussels started prescribing substitution treatment. Not only was methadone prescribed, but also bezitramide and dextromoramide. It is estimated that, in Brussels in the early 1980s, as many as 500 addicts were in maintenance treatment.⁵¹ Some patients were prescribed large quantities of medication, resulting in a number of overdoses involving methadone.⁵² A concerned public prosecutor notified the Belgian Medical Association and initiated prosecution of the prescribers. In February of 1984, Dr. Baudour, who had been arrested four months before, was sentenced for the systematic prescription of methadone to heroin addicts.⁵³ In 1985, Dr. Nystrom was also sentenced, this time for the prescription of bezitramide.⁵⁴ The courts did not totally condemn substitution treatment but argued that, in both cases, the doctors involved had been careless. In the case of Dr. Baudour, for example, the court held that he had prescribed injectable solutions, that he had prescribed large quantities and that he had also prescribed amphetamines.

The BMA also started trying to discipline its members. The provincial council of Brabant was particularly active in this regard. Proponents of substitution treatment argued that the BMA does not have the authority to restrict the therapeutic freedom of physicians; it can only give advice. A number of Brussels-based physicians cooperated in the 'Initiative Déontologique Médicale' (IDM), with the aim of having the BMA's directives annulled by the State Council. The State Council is a special court that can test the legality of different directives. In October 1990, 170 physicians signed a petition demanding that the substitution treatment directives of the BMA be annulled.⁵⁵ In two consecutive cases in 1993, the State Council decided that the directives of, respectively, the provincial councils and the national council were, indeed, invalid.^{56 57}

Physicians, meanwhile, had not waited for the results of all these legal battles. Under pressure from a growing drug epidemic and an even more serious HIV epidemic in injecting drug users, they had again started prescribing bezitramide, methadone and the newer substance, buprenorphine, in larger quantities. Where the total quantity of methadone used in Belgium in 1990 was only 5.5 kms, it increased to 19 kms in 1992

⁵¹ Picard, E., o.c., 41.

⁵² Reisinger, M. and Picard, E., 'Methadone in Belgium: regaining therapeutic freedom', *Addiction Research*, 1996 (396), 369.

⁵³ Corr. Brussel, 16 februari 1984, *J.Proc.*, 2 maart 1984, 25–33.

⁵⁴ Brussel, 7 november 1985, *J.T.*, 1986, 371.

⁵⁵ Reisinger, M. and Picard, E., o.c., 399.

⁵⁶ R.v. St., Picard, nr. 41.825, 29 januari 1993.

⁵⁷ R. v. St., Picard en Reisinger, nr. 43.258, 9 juni 1993.

and 45 kms in 1994.⁵⁸ Substitution treatment was also spreading to more regions: whereas, in 1990, more than 80% of all patients were from the Brussels region, this percentage was down to 45% in 1996.⁵⁹ ‘Harm reduction’ had reached Belgium. Confronted with this new situation, on one hand, and with the fact that the State Council had upheld the rights of physicians to prescribe substitution treatment, on the other, it was clear to everybody involved that the drug law needed to be revised:

- The State Council’s 1993 rulings had made it clear that neither the BMA provincial council nor national council recommendations could be used as instruments to regulate prescription practices.
- By the same logic, the revised Article 37b of the medical ethics code would prove insufficient if it were to be put to the test in court.⁶⁰
- Maintenance therapy as a means of harm reduction is not possible, because it can still be construed as ‘abuse of competence’ under the existing drug law.⁶¹

Senators Lallemand and Erdman had already proposed a bill, in 1991, that resurfaced in 1993.⁶² Lallemand and Erdman proposed altering Article 3 of the drug law to state explicitly that ‘substitution treatment prescribed by a physician cannot be punished’. Substitution treatment would then be defined as ‘the delivery, within a framework of therapy, of narcotics as medication in order to protect the health and quality of life of the patient, with the ultimate goal of abstinence’.

The bill had many critics. As Balthazar stated: ‘the simplicity [of the proposal] has the advantage of being very clear but the disadvantage of lacking in nuance’.⁶³ In his opinion, the bill should also have included more detail concerning the conditions in which prescribing would be allowed, such as patient registration, education and supervision of prescribers, limitation of the number of patients per doctor and the nature of the relationship between doctors and specialised treatment facilities.

On 8 October 1993, the Council of Ministers decided to support the bill after amending it.⁶⁴ At the same time, the government decided to convene a panel of medical experts before presenting the amendments, which had already been approved, and described in more detail the circumstances in which maintenance treatment would be allowed. The conclusions of this panel (the so-called consensus committee) would prove to be very important (they are discussed in more detail in the next section).

⁵⁸ Vandenbosch, B. and Ledoux, Y., *Inspection générale de la pharmacie et conseil supérieur d’hygiène*, working group assuétudes, procès-verbal de la séance du 04/03/1998.

⁵⁹ Ibidem.

⁶⁰ Balthazar, T., ‘De methadonarresten van de Raad van State en de normatieve bevoegdheid van de Orde van Geneesheren’, *VI. T. Gez.*, 1993, 63–69.

⁶¹ Balthazar, T., ‘Substitutieproducten: een wijziging van de Drugwet is even moeilijk als noodzakelijk’ in *Drugbeleid 2000*, De Ruyver, B. en De Leenheer, A. (ed.), Antwerpen, MAKLU, 1994, 285–294.

⁶² Voorstel van wet tot wijziging van de wet van 24 februari 1921 betreffende het verhandelen van de giftstoffen, slaapmiddelen en verdovende middelen, ontsmettingsstoffen en antiseptica, *Gedr. St.*, senaat, B.Z. 1991, nr. 447/1.

⁶³ Ibidem, 288.

⁶⁴ Balthazar, T., ‘Substitutieproducten: een wijziging van de Drugwet is even moeilijk als noodzakelijk’ in *Drugbeleid 2000*, De Ruyver, B. en De Leenheer, A. (ed.), Antwerpen, MAKLU, 1994, 286.

Lallemand and Erdman reintroduced their bill in 1995. In the course of discussion of the bill, experts were called to testify. Among many others, Vincent Dole, honorary professor of Rockefeller University of New York, testified to the senatorial committee. Soon after Lallemand's proposal, the government presented its amendments,^{65 66} stating that the conditions under which substitution would be possible would be outlined in a royal decree to include:

- which substances would be allowed for substitution treatment;
- the modalities of administration of said medication;
- registration for treatment;
- the number of patients per doctor;
- supervision and follow-up of treatment;
- postgraduate training of physicians; and
- the relationship between physicians and specialised treatment facilities.

Neither of the two proposals was ever put to the vote. In 1996, the government apparently decided to wait for the conclusions of a parliamentary working group that was studying substance abuse problems in general.⁶⁷ Since then, different versions of the governmental bill have been introduced and even reintroduced, but to no avail. Senator Foret introduced a bill in 1992 (and again in 1995) which closely resembled the governmental proposal, but which also stipulated that the purpose of substitution treatment must be to gradually taper off the dose.^{68 69}

In 1998, representatives of the people Van Deurzen, Brouns, Van Kessel and Van Parijs introduced a bill that was identical to the governmental bill of 1996, in the hope of reactivating the debate.⁷⁰ In 1999, the same bill was again proposed to the senate as well as to the representatives of the people.^{71 72 73} A final proposal, by

⁶⁵ Wetsvoorstel strekkende tot de wettelijke erkenning van behandelingen met vervangingsmiddelen en tot wijziging van de wet van 24 februari 1921 betreffende het verhandelen van giftstoffen, slaapmiddelen en verdoovende middelen, ontsmettende stoffen en antiseptica, *Gedr. St.*, senaat, B.Z., 1995, nr 111/1.

⁶⁶ Wetsvoorstel strekkende tot de wettelijke erkenning van behandelingen met vervangingsmiddelen en tot wijziging van de wet van 24 februari 1921 betreffende het verhandelen van giftstoffen, slaapmiddelen en verdoovende middelen, ontsmettende stoffen en antiseptica, *Gedr. St.*, senaat, B.Z., 1995, nr 111/2.

⁶⁷ Verslag namens de werkgroep belast met het bestuderen van de drugproblematiek, *Gedr. St.*, Kamer, 1996, 1062/1–1062/3, 1023 p.

⁶⁸ Wetsvoorstel tot wijziging van de wet van 24 februari 1921 betreffende het verhandelen van de giftstoffen, slaapmiddelen en verdoovende middelen, ontsmettingsstoffen, en antiseptica, *Gedr. St.*, senaat, 1992, nr. 703/1.

⁶⁹ Wetsvoorstel tot wijziging van de wet van 24 februari 1921 betreffende het verhandelen van de giftstoffen, slaapmiddelen en verdoovende middelen, ontsmettingsstoffen, en antiseptica, *Gedr. St.*, senaat, B.Z., 1995, nr. 56/1.

⁷⁰ Wetsvoorstel strekkende tot wettelijke regeling van het gebruik van substitutiemiddelen in de behandeling van heroïneverslaafden, *Gedr. St.*, kamer, 1498/1, 1998.

⁷¹ Wetsvoorstel tot wijziging, wat de behandeling met vervangingsmiddelen betreft, van artikel drie van de wet van 24 februari 1921 betreffende het verhandelen van de giftstoffen, slaapmiddelen en verdoovende middelen, ontsmettingsstoffen en antiseptica, *Gedr. St.*, senaat, 1999, 131/1.

⁷² Wetsvoorstel strekkende tot wettelijke regeling van het gebruik van substitutiemiddelen in de behandeling van heroïneverslaafden, *Gedr. St.*, kamer, 71/1, 1999.

⁷³ Wetsvoorstel strekkende tot de wettelijke erkenning van behandelingen met vervangingsmiddelen en tot wijziging van de wet van 24 februari 1921 betreffende het verhandelen van de giftstoffen, slaapmiddelen en verdoovende middelen, ontsmettingsstoffen en antiseptica, *Gedr. St.*, senaat, 1999, 11/1.

representative of the people Bacquelaine, was introduced in 1996 and again in 1999. This returned to the original proposal of Lallemand, omitting most of the specifications that are contained in the 1996 governmental bill but specifying in more general terms that ‘prescribed oral formulations have to be prescribed by physicians who have followed a specific postgraduate training recognised by the Ministry of Public Health and who are capable of bringing the patient into contact with a specialised treatment facility’.^{74 75}

The current federal government published a policy paper on substance abuse in 2001. This document once more stresses the need for a revision of the drug law.⁷⁶ As a consequence, this government has prepared a new bill, which is presently before the State Council for recommendations.⁷⁷ It differs very little from the earlier proposals. The accompanying royal decree (which has so far not been made public) will introduce some new conditions. The government will probably not stipulate a maximum number of patients that one doctor can treat at the same time. It is more likely that it will leave it up to a supervision group or peer review group to control its members. This will be compulsory. Also, patients will have to be registered. According to the government, registration is necessary to avoid ‘double prescriptions’ (i.e., two or more doctors prescribing maintenance medication to the same patient at the same time). Opponents of registration argue that this is a specious argument, because double prescriptions are a very rare occurrence, and that registration is just another infringement of a drug user’s privacy.⁷⁸ At any rate, the very strict Belgian privacy law should guarantee that all registered data are treated with the utmost discretion. Finally, the royal decree will have to say something about what exactly is meant by the relationship between the prescriber and a specialised treatment facility. It is very unlikely that the government would require every patient to contact a treatment facility if he/she is receiving maintenance treatment from his/her own doctor. It is more likely that there will have to be some kind of contact between a doctor and a treatment facility, so that the doctor can ask for help from the facility if needed. The treatment facilities should also be able to provide continuity of care if the private physician cannot continue to treat the patient.

2.1.2. The consensus conference

As we have already seen, the government were planning in 1995 to revise the drug law in order to permit maintenance treatment. Information obtained from experts convinced government advisers at the time had that there were significant differences in prescription practices across the country. More specifically, there were large differences between the more liberal practices in Brussels and the south of the country (where the Initiative Déontologique Médicale had been very influential), on the one hand, and the more cautious Flemish region, where maintenance treatment

⁷⁴ Wetsvoorstel tot wijziging van de wet van 24 februari 1921 betreffende het verhandelen van giftstoffen, slaapmiddelen en verdoovende middelen, ontsmettende stoffen en antiseptica, *Gedr. St.*, kamer, 1996, 391/1.

⁷⁵ Wetsvoorstel tot wijziging van de wet van 24 februari 1921 betreffende het verhandelen van de giftstoffen, slaapmiddelen en verdoovende middelen, ontsmettingsstoffen en antiseptica, *Gedr. St.*, kamer, 1999, 135/1.

⁷⁶ Ministerie van Volksgezondheid, ‘Beleidsnota van de federale regering in verband met de drugproblematiek’, Brussel, p. 61.

⁷⁷ Minister of Public Health adviser B. Cools, personal communication.

⁷⁸ Reisinger, M., personal communication.

was still exceptional and where therapeutic communities were still influential, on the other. The Minister of Public Health at the time, J. Santkin, therefore decided to establish a consensus conference with all the involved experts. The conference was organised by a committee on which all relevant organisations were represented: the High Council of Health, the Union of Belgian neuropsychiatrists, the Scientific Union of Flemish General Physicians (WVVH), the Flemish Union for Alcohol and Drug Problems, the Ministry of Health and, last but not least, the Belgian Medical Association. The jury of the consensus conference convened in Brussels on 8 October 1994 in order to come up with answers to a number of questions that had been put to them by the government. In the absence of a legal framework, these answers have been regulating the prescription of maintenance treatment until the present day.⁷⁹

The consensus statement starts by confirming that 'long-term treatment with adequately dosed methadone is medically safe' and that 'methadone is effective in the treatment of opiate dependence by reducing heroin intake'. It further states that methadone treatment is effective in lowering the death rate associated with heroin use, in diminishing the risk of infection with HIV and hepatitis B and C, and in slowing the progression of HIV to AIDS in seropositive patients. It also confirms that methadone treatment facilitates improvements in social and professional skills and reduces criminal behaviour.

Methadone treatment is indicated if heroin dependence has been established by anamnesis and clinical examination (and, if necessary, other tests such as urine analysis). The patient has to be at least 18 years old, with a proven history of heroin use over a period of at least one year. Failure to detoxify (either spontaneously or with the help of professionals) is partly proof of dependence. Exceptions (under 18, less than one year of addiction, no proven history, etc.) need specialised care, requiring specialised skills of the caregiver. There are no contraindications and there is no need whatsoever to limit the total number of patients.

The consensus statement not only recognises methadone but also buprenorphine as suitable substances for substitution treatment.

So far, it is clear that the 1994 consensus statement is very liberal: it does not require urine testing or one or more stays in a residential facility as proof of dependence. It also does not require that 'special cases' (minors, pregnant women, etc.) be treated in specialised settings, but only states that the caregiver must have the necessary specific skills (the caregiver may very well be an experienced general physician). The conference only recognises two molecules. During the discussion, different specialists argued for adding bezitramide to this list, but this was eventually rejected because of insufficient scientific literature on this substance. After the consensus statement, less and less bezitramide was prescribed and it was eventually withdrawn from the market.

The next part of the consensus statement deals with treatment modalities. First of all, the statement confirms that 'methadone treatment is either of middle/long duration (two to five years) or without a set duration'. Short-term detoxification (three weeks to

⁷⁹ Consensusconferentie, 'Substitutiebehandeling met methadon', promotor J. Santkin, Minister van Volksgezondheid, Hache, R. (ed.), s.l., 1994, 8p.

three months) can be indicated, usually requiring a change of environment and a change in the availability of heroin. Daily doses mostly start at around 30 to 40 mgs, and a mean daily dose is 60 to 80 mgs, but this has to be adjusted to the individual situation of each patient. The oral form of medication, which is most likely to prevent further abuse, has to be prescribed. Occasional use of heroin is no reason to stop treatment or lower the dose. The dose may have to be adjusted in some cases of combination with other products. In the introductory phase, and until a stable dosage is reached, administration of the substance will be supervised daily by the pharmacist or in a specialised treatment setting. Methadone should not be stopped in cases of pregnancy.

This section is also quite liberal, and suggests that, when the treatment is stable, methadone take-home doses should be allowed. The paragraph on short-term detoxification was primarily intended for residential drug-free treatment settings and hospitals. It has, however, also been used in prisons, as it is argued that there is a change of environment and a change of availability of heroin in that setting. The consensus statement does not mention anything about the fact that a patient also has to agree to the dosage being gradually reduced, because this was understood to be self-evident. However, in the prison setting this is often not the case.

The last section of the consensus statement deals with registration and the need for other therapeutic interventions. According to the statement, 'psychosocial care and support are essential to achieve results with substitution treatment'. This kind of care has to be adjusted to the requirements of each individual patient. Support and psychosocial care can be offered by a multidisciplinary team, a general physician or a specialist. Physicians need to be trained and have to attend follow-ups of training, for example with supervision. They also have to establish a working relationship with a specialised treatment facility or a care network, in order to avoid any isolation that might negatively influence medical practice. Finally, the statement affirms that methadone treatment has to be registered, to avoid double prescriptions as well as to allow for ongoing evaluation. The laws on privacy and medical secrecy have to be observed, however.⁸⁰

Again, the consensus is quite liberal. Although it alludes to the importance of support for prescribers, these prescribers only need to establish a 'functional relationship' with caregivers. This rather curious phrase meant that the prescriber was free to decide whether or not (and in what circumstances) he or she would ask for support.

Opponents of registration have remarked that it is not at all necessary to hold identity data on methadone patients in order to continuously evaluate the situation and that it is therefore not necessary to have registration.⁸¹

⁸⁰ Wet van 11 december 1998 tot omzetting van de richtlijn 95/46/EG van 24 oktober 1995 van het Europees Parlement en de raad betreffende de bescherming van natuurlijke personen in verband met de verwerking van persoonsgegevens en betreffende het vrij verkeer van die gegevens, *B. S.*, 03 februari 1999.

⁸¹ As an example of the attitude of prescribers, see: Van Breuseghem, P., 'Open brief aan de voorzitter van de Provinciale Geneeskundige Commissie Vlaams-Brabant en aan de voorzitter van de Provinciale Orde van Geneesheren van Vlaams-Brabant betreffende controle op methadonverstrekking en heroïneverslaving', Brussels, may 23d, 1999, n.p.

As has already been mentioned, the response to the consensus statement was considerable, mostly because the authority of the consensus panel was recognised by everybody. According to the Minister of Public Health, J. Santkin, the long overdue legal framework was no longer necessary: 'If I must describe the text of the statement, I could not do better than by stating that it is an explicit plea for non-intervention by the legislator or by any other regulatory body. It appears to have confidence in the medical corps and to confer responsibility on them to treat heroin addicts in a safe, efficient and continuous way, under the control of their own professional bodies.' Finally, he adds: 'I cannot imagine that, if experts were to be asked to advise on these matters in the course of a legal action, they would not confront the medical acts in question with the consensus statement and evaluate the actions of the physician in the spirit of the consensus statement.'⁸²

This optimistic point of view was immediately criticised by legal experts. Pieters remarked that 'pseudo-law' can never supersede true law.⁸³ He specifically mentioned a judgment of the Court of Cassation that stated that the drug law of 1921 does not require that a prejudicial question is put to the provincial council of the Belgian Medical Association to decide whether a prescription does or does not constitute abuse.⁸⁴ De Ruyver referred to the continuing difficulties that a network of prescribing general physicians in the Brussels region were experiencing at the time, and warned that 'speculating on the principle of opportunity, in the sense of not prosecuting doctors who prescribe maintenance treatment, seems to me to be a bad idea in the light of earlier experiences with, for example, abortion legislation'.⁸⁵ As discussed earlier, later governments have tried (so far to no avail) to construct a legal framework for maintenance treatment.

In 1997, the High Council of Health, a body under the authority of the Ministry of Public Health, was asked to evaluate the situation regarding substitution treatment. Between 1997 and 1999, around one hundred experts were heard at different hearings. A report was published last year.⁸⁶ The follow-up report concludes that, in general, methadone treatment seems to be efficient and that few problems exist. The original text of 1994 has only been changed in a few places:

- The statement that methadone is an effective treatment for heroin addiction is revised to: 'for addiction to heroin or other opiates'. A similar adjustment is made when indications are discussed: 'the indication for methadone treatment is addiction to heroin or other powerful opiate agonists'.
- The statement that methadone treatment slows the progression of HIV to AIDS (a statement that was made in 1994 on the basis of literature) has proven to be premature and is consequently omitted.

⁸² Santkin, J., *Speech to the second Drugbeleid 2000 conference*, in: *Op weg naar een geïntegreerd drugbeleid in België?*, De Ruyver, B. e.a. (ed.), Antwerp, MAKLU, 1995, 23.

⁸³ Pieters, F., 'Dura lex, sed lex, Minister van Volksgezondheid J. Santkin en methadonverstrekking', *Panopticon*, 1995, 69–71.

⁸⁴ Cass, 15 september 1987, nr. 1174, geciteerd in Pieters, F., o.c., 70.

⁸⁵ De Ruyver, B., *België op weg naar een geïntegreerd drugbeleid?* In *Op weg naar een geïntegreerd drugbeleid in België*, De Ruyver, B. e.a. (ed.), Antwerpen, MAKLU, 1996, 44.

⁸⁶ Hoge Gezondheidsraad, 'Follow-up van de conferentie over de methadone consensus van 1994', Hoge gezondheidsraad, s.o., 2000, 23 p.

- The statement that methadone treatment reduces criminal activity is changed to: 'reduces criminal activity linked to drug use'.
- Instead of the statement that methadone treatment is of either middle–long duration or without set duration', the new text states: 'methadone treatment can be of middle–long duration or without set duration'.

The follow-up report concludes this critical review of the 1994 text as follows: 'The low number of revisions to the text of the consensus conference is an indication of the very broad acceptance by all the actors in the field of substance abuse treatment.'⁸⁷

The follow-up report also makes some recommendations. The first concern individual practice. More guidelines are given on how to prescribe methadone: the first dose should be a maximum of 30 mgs, methadone should be stored beyond the reach of children, etc. The follow-up report acknowledges that it is not always easy to determine when the induction phase is over and the patient has reached a stable state. It is therefore prudent to supervise daily methadone intake for at least six weeks (although exceptions must be allowed for). As was the case with the 1994 conference, the follow-up statement declines to suggest a limit to the number of methadone patients per doctor but notes that a high number (10 patients) can lead to exhaustion. Most importantly, it is stressed that it can take years to achieve results and that, therefore, 'the premature termination of therapy must be considered a mistake'.

Relationships between doctors are also dealt with. As in 1994, the follow-up refuses to define in detail the nature of a 'functional relationship'. Instead, it offers a whole range of possibilities: from one-on-one telephone calls with an experienced colleague to postgraduate training. What is important is that this section starts by affirming that these options are only possible for those doctors who have a certain number of cases, and is not a realistic proposal for those who only treat one or very few methadone patients.

A final section outlines more detailed proposals on how to organise registration. It also suggests that the current systems, developed by either the provincial councils of the BMA or the provincial medical commissions, need to be improved in terms of the quality of registration as well as with regard to coding systems.

2.2. Social, political and public attitudes

2.2.1. The political world

We have already described the evolution of political attitudes to substitution treatment. In a climate where the number of heroin addicts is steadily increasing, the attitude of politicians has changed considerably over the last twenty years. Nowadays, almost every political party agrees with harm reduction policies. Only the very conservative 'Vlaams Blok' party still opposes harm reduction measures such as

⁸⁷ Ibidem, p. 16.

needle exchange and substitution treatment. Its members of parliament regularly introduce bills that aim to increase the severity of sentencing for drug offences.⁸⁸

The evolution of political thinking can be traced through the contributions of politicians at the annual 'Drug policy 2000' conferences that were held from 1993 onwards.⁸⁹ These conferences enabled policy-makers and professionals to debate the drug situation, and, as such, they were instrumental in shaping Belgian drug policies in the 1990s.

In 1997, a parliamentary working group reported on their two years' studying drug problems. They concluded by stating that 'two components [of harm reduction] are needle exchange and substitution treatment for heroin addicts. These need to be extended'.⁹⁰

2.2.2. The general public

Little data exists on public attitudes to harm reduction strategies. Some treatment facilities have experienced problems when attempting to establish themselves in certain neighbourhoods. Typically, the objections subside after a couple of months, when the expected rise in problems in that neighbourhood does not materialise.

In a large-scale national survey of attitudes to drug use, only 3.5% of the general population spontaneously mentions methadone as a product of abuse. When asked specifically, a total of 28% of the population believes that methadone is not a product of abuse (as against 60.3% who do).⁹¹ More to the point, more than 64% characterise people who regularly abuse drugs as 'people who need help'. Only 0.4% of the population characterises them as 'people who should be punished or put in prison'.⁹²

2.2.3. The police

There are no specific regulations regarding methadone within the various policing bodies. The general attitude of the police has mirrored the attitudes of society in general. In the beginning, methadone prescribers were often regarded as 'dealers in white coats', and many police officers considered methadone to be 'just another drug'. As a result, low-threshold treatment facilities at that time were not treated with much respect: police officers would enter the facility without permission or the premises would be put under surveillance for several days in the pursuit of suspects. In later years, the police came to appreciate the work of these facilities and to be more cooperative. Nowadays, all the police academies include courses on drug

⁸⁸ Wetsvoorstel tot verstrenging van de straffen zoals bepaald in de wet van 24 februari 1921 betreffende het verhandelen van de giftstoffen, slaapmiddelen en verdovende middelen, ontsmettingsstoffen en antiseptica, *Gedr. St.*, Kamer, 2000, nr. 389/1 (Annemans en De Man). Wetsvoorstel tot wijziging van de wet van 24 februari 1921 betreffende het verhandelen van de giftstoffen, slaapmiddelen en verdovende middelen, ontsmettingsstoffen en antiseptica, *Gedr. St.*, Kamer, 1999, nr. 252/1 (De Man).

⁸⁹ 'Drugbeleid 2000/Gestion des drogues en 2000'.

⁹⁰ Verslag namens de werkgroep belast met het bestuderen van de drugproblematiek, *Gedr. St.*, Kamer, 1996, p. 992.

⁹¹ Patesson, R. and Steinberg, P., *Rapport concernant les résultats de l'enquête Les Belges et les drogues*, Brussels, Fondation Rodin, Drogue 2000, Le Soir et ULB, 2000, p. 9.

⁹² Patesson, R. and Steinberg, P., o.c., p. 18.

treatment (including substitution programmes) in their curriculum. Often these courses are presented by co-operators of the treatment centres. At least in the larger cities, suspects on substitution treatment who have been apprehended are often given the opportunity to obtain their medication: the police will either take the patient to the clinic or pharmacy, or a drug worker is given access to the patient in the police holding cells.

It is not only drug treatment that has become harm-reduction oriented. The objectives of police interventions have also changed over the years and, in many cases, these too have become more harm-reduction oriented. One of the possible harms of drug use is traffic accidents while under the influence of psychotropics. Until 1999, alcohol was the only molecule explicitly mentioned in the road traffic laws.⁹³ In 1999, four new illegal substances (seven molecules) were added: THC-COOH, amphetamine, MDMA, MDEA, MBDB, morphine and cocaine.⁹⁴ This does not imply that driving under the influence of other psychotropic substances is allowed: the term 'drunkenness' in the road traffic law of 1968 is applicable to all kinds of intoxication that present clinically (for example, slurred speech or coordination problems). Therefore, methadone users who show clinical signs of intoxication have always been punishable for driving under the influence, although methadone in itself is not considered a dangerous drug in this respect. In a Belgian Institute for Traffic Safety publication, methadone is classified as a class II/2 drug, which includes 'drugs that are probably able to have a moderate influence on driving capability. Some negative influence on driving skills or related skills has been established in experimental settings.'⁹⁵

New molecules were added to the traffic law to provide a legal base for urine testing and blood sampling of drivers presumed to be abusing a substance. In short, substance abuse in car drivers is traced through three stages: first of all, a police officer will administer a standard clinical test battery; secondly, urine that tests positive will be tested with a qualitative immuno-assay; and finally, positive tests will be confirmed with a blood test. The Chamber of Representatives commission studied the bill and their report explicitly stated that this procedure would exclude methadone patients from being a victim of the new law, as there are no external signs of intoxication in methadone users. Furthermore, there are no cross-reactions with tests on morphine.⁹⁶ The same report stated that a methadone patient could even refuse to be tested, on medical grounds.

3. Expert opinions

Belgian physicians have gained a lot of experience in prescribing substitution treatment over the past ten years. Thousands of heroin users are currently being treated with either methadone or buprenorphine. Through exchanging knowledge and experiences and organising consensus meetings, efficient prescription policies have

⁹³ Koninklijk besluit van 16 maart 1968 tot coördinatie van de wetten betreffende de politie over het wegverkeer, *B.S.*, 27 maart 1968.

⁹⁴ Wet van 16 maart 1999 tot wijziging van de wet betreffende de politie over het wegverkeer, gecoördineerd op 16 maart 1968, *B.S.*, 30 maart 1999.

⁹⁵ Grenez, O., *Invloed van geneesmiddelen op de rijvaardigheid*, Brussel, Belgisch Instituut voor de Verkeersveiligheid vzw, 1999, VI-12.

⁹⁶ Verslag namens de commissie voor de infrastructuur, het verkeer en de overheidsbedrijven, *Gedr. St.*, Kamer, 1999, 1840/2.

been established. Nevertheless, adequate legal frameworks are still lacking, even though the first parliamentary initiatives date back to 1991.

Only a small minority of expert methadone prescribers are against changing the law. They contend that the drug law of 1921 already permits substitution treatment. We have shown elsewhere in this article that most legal experts do not share this view. Resistance to new legislation in this field can often result from the fear that new legislation will result in more restrictions, for example in the number of patients that one doctor may treat at the same time. For GPs who are considering becoming involved in substitution treatment, on the other hand, the lack of a clear set of rules continues to be a threshold, and most experts therefore agree that the need for new legislation, as well as for clear regulations, remains.⁹⁷

It is hard to imagine how further progress in the field of substitution treatment (and, more specifically, heroin prescription) can be achieved without new legislation. Although the current federal government is not actively promoting the development of heroin prescription, it is not radically opposed either.⁹⁸ Since 1994, several research groups have been looking into the possibility of providing heroin prescription in Belgium and have prepared research protocols.⁹⁹ At the fifth national drug conference in Ghent in 1997, where these projects were discussed, the Minister of Public health stressed that 'the legal possibilities for prescribing are very limited'.¹⁰⁰ Since then, nothing has changed. Given the fact that almost every government in the last fifteen years has declared that tackling the drug problem is a priority, this is a very sad conclusion. It is difficult to understand why the Belgian state is unwilling to protect and support those doctors who are willing to take on one of medicine's most daunting problems.

⁹⁷ De Ruyver, B. and Casselman, J., *Het Belgisch drugbeleid anno 2000: een stand van zaken drie jaar na de aanbevelingen van de parlementaire werkgroep drugs*, Leuven, Katholieke Universiteit Leuven, 2000, p. 29.

⁹⁸ Ministerie van Volksgezondheid, *Beleidsnota van 19 januari 2001 van de federale regering in verband met de drugsproblematiek*, p. 54.

⁹⁹ Lequarré, F., Prescription contrôlée d'héroïne en province de Liège, in : *Het Drugbeleid in België : actuele ontwikkelingen*, De Ruyver, B.e.a. (ed.), Antwerpen, MAKLU, 1998, p. 275. Le Bon, O., traitement de la dépendance à l'héroïne : vers un nouveau paradigme, in : *Het Drugbeleid in België : actuele ontwikkelingen*, De Ruyver, B.e.a. (ed.), Antwerpen, MAKLU, 1998, p. 283.

¹⁰⁰ Colla, M., Speech to the fifth national conference, in : *Het Drugbeleid in België : actuele ontwikkelingen*, De Ruyver, B.e.a. (ed.), Antwerpen, MAKLU, 1998, p. 35.

Greece

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1. Introduction: the general legal framework ¹⁰¹

Law 1729/1987, entitled the ‘Law on the Suppression of the Propagation of Narcotic Drugs and on the Protection of Youth’¹⁰² is the basic law that regulates narcotic substances in Greece. This law has been amended several times (by Law 1821/1988, Law 1941/1991, Law 2161/1993, Law 2331/1995, Law 2408/1996, Law 2479/1997, Law 2716/1999 and Law 2721/1999). This national law is supplemented by all the relevant UN conventions that Greece has signed up to and ratified: the conventions of 1966 (Legislative Decree 1105/1972), of 1971 (Law 348/1976) and of 1988 (Law 1990/1991).

The Organisation to Combat Drugs (OKANA),¹⁰³ which was established by Law 2161/1993, has played a crucial role in the issue of substitution. In fact, OKANA has been charged with planning, organising, controlling and enforcing national drug policy related to prevention, treatment and the reintegration into society of drug users. OKANA, up to the present time, is the only institution providing substitution treatment – mainly methadone.

1.1. Actors allowed to prescribe, provide and control dispensing

1.1.1. The period 1987–1995: before substitution programmes

The use of substitution substances in Greece is regulated by a penal law (Law on drugs 1729/1987, mentioned above). Before it was amended, Article 7 § 2 of this law stated: (i) it is absolutely prohibited for anyone to dispense drug substances for substitution purposes in general, and also (ii) in special cases for purposes of dealing with withdrawal syndrome, unless this is done under conditions, and with the use of a method and procedure, that are determined by a Ministerial Decision.

Moreover, violation of the relevant prohibitions was considered as an ‘abuse of the status of being a physician or a pharmacist’ and the law meted out to them penal sanctions as severe as those that were administered to drug traffickers.

It is interesting to note that, when the Minister of Health introduced the relevant bill (now Law 1729/1987) to the Greek parliament, he faced a considerable amount of dissent,¹⁰⁴ especially with respect to the penal sanctions being considered for

¹⁰¹ A considerable number of changes in the substitution policy took place after the completion of this report. The most significant ones are added in footnotes. In general, one notices a shift from an abstinence policy to a policy which is oriented more and more towards harm reduction after 2001.

¹⁰² For more on this law, see: Mavris, Spinellis, Zagoura, in: N.Dorn (ed.) *Regulating European Drug Problems, Administrative Measures and Civil Law in the Control of Drug Trafficking, Nuisance and Use*, Kluwer Law International, 1999, pp. 159 et seq.

¹⁰³ OKANA is a legal person or entity of private law, with its own administration but under the auspices of the Ministry of Health and Welfare which is also financing it. One of its main goals is the coordination of the work of various Ministries involving drugs as well as the enforcement of national policy on drug issues. (articles 1 and 2 of Law 2161/1993).

¹⁰⁴ Statheas, (1988), pp. 43–48 (In Greek).

physicians and pharmacists. It was felt that the proposed law would severely restrict these scientists in the exercise of their profession. The minister was under such pressure that he was almost persuaded to delete the relevant provision and retain the sanctions only in cases where physicians dispensed substitutes for maintenance and not for the purposes of treatment.¹⁰⁵ However, the more conservative point of view prevailed (prohibition of dispensation of certain drugs by certain professionals). The reason behind this prohibition was the fear that illegal drugs would not be dispensed and used for treatment but for other purposes.

Another issue – namely, the prescription of drugs or drug substitutes to addicts who are registered in special registers in various specialised centres – has also been discussed by the politicians, especially members of the so-called Parliamentary Inter-party Committee on Drugs. This committee, in its report of 3 March 1992, stated that the prescription of methadone to opiate/heroin drug addicts was deemed desirable for the following reasons: a) the drug-dependent users would be removed from the illegal demand/supply networks; b) their criminal behaviour will decrease; and c) they will be protected from HIV and AIDS.

The amendment of 1993

Almost one year later, the Introductory Report and Explanatory Memorandum to the Law 2161/1993 (which amended Law 1729/1987) seemed to associate the issue of substitution substances with the existence of a variety of treatment models (with and without substitutes). It was the state's responsibility to provide a variety of treatment models and programmes. Moreover, the above amendment considered it to be futile and almost against medical ethics to prescribe illegal drugs to drug addicts for daily maintenance.

Thus, the new Law 2161/1993 (Article 12, amending Article 7 § 2 of the Law 1729/1987) prohibited the dispensation of substitute substances. However, it allowed, as an exception, the dispensation of substances for substitution. These substances would be dispensed by special public units, as they would be regulated by a new Ministerial Decision which would grant a licence and specify the substances and the conditions under which they are dispensed.

Violations of the above provisions ('abuse of the status of a physician or a pharmacist') were still punishable by the same severe sanctions provided for drug traffickers.

1.1.2. The period 1993 up to the present: pilot and regular substitution programmes

Ministerial Decisions

In order to implement the above, the Minister of Health and Welfare issued:

- i) Decision 25 on 20 March 1995, which set down the general principles relevant to the operation of the Pilot Programmes of Substitution for treating heroin addicts within the special public units; and

¹⁰⁵ Minutes of parliament: 88th Meeting, 12 March 1987, pp. 4509.

ii) Decision 35 on 13 April 1995, which defined the agencies that would implement these Pilot Substitution Programmes (OKANA, in cooperation with the public mental health services of the cities of Athens and Thessaloniki).

The amendment of 1999

Article 7 § 2 of Law 1729/87 was again amended, by Article 19 of Law 2716/1999 (this law referred to ‘the development and modernisation of the mental health services and other provisions’). According to this amendment, the dispensation of substitute substances is only allowed in exceptional cases and only by special public units which will operate under the control of OKANA, which can grant a licence according to a decision of the Minister of Health and Welfare ¹⁰⁶. Violations of the above provisions (i.e., ‘abuse of the status of a physician or of a pharmacist’) are still punishable by the same sanctions as those provided for drug traffickers.

1.2. Purposes and modalities of execution, criteria and substances

1.2.1. Purposes and modalities

As mentioned above (section 1.1.2.), in 1995 the Minister of Health and Welfare issued the Ministerial Decision 25 of 1995, which in fact constituted a regulation ¹⁰⁷. This decision outlined the requirements for setting up *pilot* substitution treatment programmes for users of heroin, including their structure and functions. It also detailed the principles that will govern these programmes. After one year of operation and on completion of positive internal and external evaluations, the two pilot programmes (one in Athens and another in Thessaloniki) would change their status from ‘pilot’ to ‘regular’ programmes and new treatment programmes would be added.

The Pilot Programmes of Substitution had the following aims ¹⁰⁸:

- to treat drug dependence, so that chronic intravenous users of heroin who participate will ultimately be in a position to live not only without heroin but also without methadone (in other words, these programmes were clearly targeting abstinence and not just maintenance);
- to reduce harm at the level of the individual and in society in general; and
- to provide quality psychosocial and medical services to all heroin users participating in the programme (an indication of the quality of the services is the proportion of therapists to participants: one therapist to every fifteen patients).

The pilot programmes set the following goals for chronic heroin users selected to participate in them:

¹⁰⁶ The same is regulated by law 2955/2001 (art.12).

¹⁰⁷ These issues are by now being treated by the ministerial decision Y5γ/Γ.Π.Οικ. 100847 (14-10-2002) which does not differ from the previous 25 of 1995 regarding the general principles.

¹⁰⁸ The therapeutic priorities have recently been moved towards harm reduction more than to abstinence (Ministerial Decision of 2002). Emphasis is now given to keep the patient in the programme through incentives, to reduce his/her parallel drug use, to decrease his/her criminal activity, to stabilize a normal way of life through better family and social relations, education and professional rehabilitation and to reduce the risk of contraction of various diseases.

- they must not use opiates or other narcotic substances;
- they must not abuse alcohol;
- their criminal activities must decrease;
- they must be employed or be productive in some way, or be encouraged to continue their education and so acquire vocational qualifications;
- they must address their clinical and mental health problems; and
- they must be encouraged to stay in the programme and complete it.

With respect to the basic principles for the operation of these substitution programmes, the same Ministerial Decision specified that:

- the units operate as outpatient clinics, where clinical and laboratory checks and preparation of the prospective participant take place before he/she is selected to participate in the programme;
- the programmes are to be situated, for the convenience of the patients, in the centre of the two biggest cities in Greece and chronic heroin users must attend them every day;
- under strict conditions and only in exceptional circumstances, a participant may take the substitution substance in a schedule other than daily;
- psychological services and social support must be provided;
- urine samples are to be analysed both randomly and whenever requested by the therapeutic team;
- it is desirable that the programmes operate beyond usual working hours, in order to assist the participants; and
- the programmes must operate 365 days a year.

1.2.2. Entry criteria

In order to be accepted on the programme, chronic intravenous users of heroin must meet the following entry criteria:

- they should be over 22 years of age ¹⁰⁹;
- they must have a somatic and psychological dependence;
- they must accept, in writing, the conditions and obligations arising from participation in the programme (i.e., they sign a relevant 'contract'); if the therapeutic team decides that there has been a violation of the obligations specified in the contract, certain consequences or sanctions will follow, including exclusion from the programme, with the option to re-apply for admission, although his/her case will go to the end of the waiting list;
- they must not use other narcotic substances;
- they must not have a serious psychopathology; and
- they should have made a previous serious but unsuccessful attempt at treatment in another programme, corroborated by the therapeutic team.

In exceptional cases, heroin users who are above 35 years of age and are suffering from serious somatic or psychological diseases/disorders that endanger their lives (HIV positive users, pregnant women, etc.) may participate in the programme.

¹⁰⁹ There is change from 22 to 20 years after 2002.

Priority

As both pilot programmes had long waiting lists, criteria were formulated prioritising certain applicants, including: the results of the toxicological test, laboratory tests and a medical examination, the patient's prior penal history, demographic characteristics, the motivation of the user, prior unsuccessful participation in therapeutic programmes, etc. In other words, priority is given to individuals who are in a bad physical condition, who are at high risk of dying or of committing an offence, or individuals who are deemed to be likely to complete the substitution/abstinence treatment successfully.

1.2.3. Choice of substances

Methadone is the substance 'par excellence'

Methadone was selected for use in the pilot substitution programmes, in accordance with the aforementioned Ministerial Decision 25 of 1995. This decision determined: a) that the underlying philosophy and goals of substitution programmes were treatment/abstinence and not maintenance; b) the general principles governing the operation of the programmes; and c) the conditions or requirements of admission to the programmes.

LAAM, despite the option to dispense it, is not used, for the reasons outlined below¹¹⁰

In 1997, a new Ministerial Decision (270) granted permission for a new substance to be dispensed. Accordingly, in October 2000, OKANA prepared a treatment protocol for LAAM.¹¹¹ The use of LAAM was considered desirable and necessary, given the fact that, from a pharmacological point of view, LAAM is a substance equivalent to methadone. Moreover, LAAM has an additional advantage: it is possible to dispense it every two or three days. Thus, in certain cases, LAAM is preferable to methadone. This is partly because it has certain financial advantages and partly because it contributes to the effectiveness of the therapeutic units: less drug addicts would be attending the units each day and so the therapeutic team could accept drug users from remote areas for treatment (as they would only need to travel every two or three days) or could spend more time working on the social rehabilitation and vocational motivation of the drug users already participating in the programme.

The protocol regulating the dispensation of LAAM sets new and different criteria for admission to this programme to the ones required for methadone treatment (see above, section 1.2.2):

- the drug user should be fully stabilised on a specific dose of methadone;
- the programme participant must agree to the change¹¹² from methadone to LAAM and will be informed and educated accordingly by his/her therapeutic team; and
- it must be shown that daily attendance at the unit is extremely difficult.

¹¹⁰ Information given to the authors during the first months of 2001 and 2003.

¹¹¹ Decision of the Board of Directors of OKANA dated 25 October 2000.

¹¹² This is the point of view of Psychiatrist Dr. Ch.Kokkoris, responsible for the Long Term - Maintenance- Unit. Dr. Kokkoris believes that therapy should not start with LAAM because it requires a longer period for stabilisation of the dose than methadone. However, this substance is considered appropriate for maintenance and for assisting to abstain from other substances after completion of the methadone programme.

Despite the above decision and protocols, LAAM is still not used in Greece, for two reasons: first, the pharmaceutical product that goes under the name of ORLAAM is not still available in Greece and, second, in April 2001 the European Medicines Evaluation Agency (EMA) announced that the marketing authorisation for ORLAAM in the European Union was to be suspended. This was decided on the grounds that it has the potential to significantly increase the QTc interval and to be pro-arrhythmic.

Buprenorphine has been approved by OKANA, but it is not yet dispensed because the required Ministerial Decision has been issued.

In October 2000, OKANA¹¹³ presented a protocol for setting up programmes that would dispense buprenorphine, in the form of Subutex (Ministerial Decision 3183 of 12 May 2000). According to this protocol, and in addition to or contrary to the requirements set for the dispensation of methadone (see above under 1.2.2), those who qualify to participate in the Subutex programme should not be chronic or heavy users of heroin and should be especially motivated to achieve their treatment goal.¹¹⁴ Also, it must be shown that daily attendance at the unit is extremely difficult. It must be understood that users that present a clinical situation that does not conform with the dispensation of this particular substance will be excluded from using Subutex.

Naltrexone is in use

Since 1998, within the framework of the Programme of Social Rehabilitation, naltrexone has been used to assist those who have already been treated with methadone – i.e., participants in the programme who are no longer dependent on methadone – to abstain from methadone and other substances. Naltrexone is dispensed under supervision and with concurrent and continuous sociopsychological support¹¹⁵.

Heroin is not used in substitution programmes

The Board of Directors of OKANA are quite sceptical¹¹⁶ about the controlled prescription of heroin, for two reasons: first, this has not been proved to be more effective than other methods used for treating heroin addicts and, second, because AIDS is still not very prevalent among drug addicts in Greece.

¹¹³ Decision of the Board of Directors of OKANA, dated 25 October 2000.

¹¹⁴ Given the fact that detoxification from buprenorphine is easier than from methadone, because of the mild withdrawal symptoms, it was proposed that this substance be given immediately to participants who have a good prognosis for abstinence.

¹¹⁵ The law 2955/2001 enacted after the completion of this report provides for dispensation of antagonizers by public and private agencies as well as by physicians. The details regarding such dispensation (kind of substances, conditions for dispensation, prescriptions etc.) are regulated via a ministerial decision.

¹¹⁶ OKANA, 2000, p. 11.

1.3. Rules for the provision of substitution treatment in special settings or situations (treatment centres)

The relevant professionals in Greece are still in the process of discussing and preparing more detailed guidelines and procedures for treatment units and programmes than the ones already operating according to the aforementioned legislation and Ministerial Decisions.

On the basis of the rules and regulations up until 1999, four quality substitution programmes with places for 600 individuals have been set up and are in operation: two in each of the large urban centres, Athens and Thessaloniki ¹¹⁷.

Discussion of the possibility of expanding the substitution programmes has been simultaneously advanced by two different groups: at the level of the executive sector, by the Board of Directors of OKANA; and, at the level of the legislative sector, by the Parliamentary Inter-party Committee on Drugs (see also above, section 1.1.1).

The proposals that have been put forward by OKANA are based on: a) a general evaluation of the effectiveness (according to the goals set and the degree to which they have been reached) of the Pilot Substitution Programmes and b) the finding that both drug addiction and the demand for detoxification programmes have increased significantly, while the supply of relevant services has remained constant and programmes are not geared to take addicts who are only motivated to follow a maintenance programme.

It was found that the programmes that are already in operation are relatively long-term programmes (three years) and have been moderately effective. In fact, approximately 10% (ranging from 8.5% to 12.5%) had left the programme having no further need for methadone or any other narcotic substance, while 60–70% of the participants have achieved the goal of harm reduction only (i.e., they still need some methadone). The findings suggest that the programmes have been quite expensive, if one is to take into consideration the goal that has been reached (i.e., harm reduction). In other words, more people (65%) needed a maintenance programme and less (10%) an expensive treatment programme. The economic resources are not sufficient to provide these high-quality programmes and significantly reduce the long waiting lists (around 1 900 drug users; see also below, under section 3.1.3) and the adverse individual and social consequences. A reconciliation between the abstinence and maintenance programmes has been attempted by adopting a more realistic policy, which will increase the supply of services while not abandoning the goal of achieving adequate treatment and abstinence. ¹¹⁸

The writers of this report are of the opinion that a brief description of OKANA's deliberations might be of interest. Therefore, the various approaches that have been proposed have been grouped into three categories and are outlined below:

¹¹⁷ OKANA operates nowadays five programmes. The fifth is in Piraeus (2001).

¹¹⁸ Decision of the Board of Directors of OKANA, dated 15 November 1999, based on a proposal of its President, Prof.Dr.A.Kokkevi.

1. One alternative would be to increase the number of substitution units that aim at abstinence. At the same time, the duration of these programmes should decrease (e.g., to 18 months, instead of three years; according to internal evaluation reports, those who successfully achieve abstinence do so within the first 18 months). In addition to quantitative changes, qualitative changes are also needed, so that the sociopsychological services provided are improved. In this case, drug users should be committed to working towards achieving complete abstinence and thus neutralise the so-called comorbidity.¹¹⁹ Certain professionals are of the opinion that the motivation of each applicant should be evaluated and only those who are, from the very beginning, highly motivated to quit drugs should be admitted to the programmes and not just those who merely want to achieve harm reduction and maintenance.
2. A second possibility would be to set up a network of substitution services aimed at harm reduction in the short term and abstinence from all substitution substances in the long term. With this option, the substitution services would be outpatient clinics that dispense the substance under strict controls (on the basis of a register that includes the names of all the drug addicts on the programme). Moreover, these clinics would offer psychosocial support at the same time in order to motivate participants to eventually abstain from all substances. In this respect, policy-makers would be faced with decisions concerning:
 - i) the danger of parallel use of other substances by the users, a factor that either neutralises the goal of harm reduction or is, on the contrary, in conformity with this goal because it keeps a great number of drug addicts within the health system; and
 - ii) how the harm reduction and maintenance programmes would be structured: with specialised high-quality programmes that operate within the framework of OKANA (as with the methadone units), or with the involvement of a considerable number of physicians and national health services, on the one hand, and the local communities under the supervision of OKANA, on the other.
3. A third alternative would be to expand and develop both ‘drug-free’ programmes and substitution programmes.

Over this same period, the need to redraft the goals of substitution programmes became obvious. The three-member Evaluation Committee of the Pilot Substitution Programmes has discussed the relevant issues.¹²⁰ This committee, in its initial report (1997), posed the question: ‘is it possible to provide a high-quality programme to participants in substitution programmes for the rest of their lives because they are not motivated to enter a detoxification process?’ Furthermore, the committee stated that this issue is in fact a matter of wider concern, both for the political leaders and the general public.

¹¹⁹ The terms ‘comorbidity’ or ‘dual diagnosis patients’ usually ‘refer to the presence of additional psychiatric diagnosis in a person who has a diagnosis of substance-related disorder’. J.Liappas, Drug Addiction: A Multidimensional Therapeutic Problem, in *Revista ITACA*, March 2001, pp. 11 and 12.

¹²⁰ This committee consists of the National Coordinator for drugs and Deputy of the Greek Parliament Dr. M. Giannakou, member of the Academy and Professor of Psychiatry Dr. C. Stefanis and Professor Dr. C.D. Spinellis.

This same committee, in its second report (1999), made a number of concrete suggestions. They recommended that:

- a) the substitution programmes should continue as short-term programmes of abstinence and psychological and psychosocial support should be intensified;
- b) on a pilot basis, multi-faceted centres with a) 'drug-free programmes', b) 'semi-drug-free programmes' and c) 'substitution programmes' (using a variety of substances and not just methadone) be established; and
- c) a study be conducted into the possibility of setting up a small number of maintenance programmes with substitution substances.

The Parliamentary Inter-Party Committee on Drugs, in its March 2000 report, put forward very similar proposals. Furthermore, this committee indicated that the state should consider the option of prescription and dispensation of substances by the public health services.

The combination of the possibilities described above and the consideration of article 6 of Law 2256/1994 (which refers to the by-laws that regulate OKANA) have finally led to the drafting of a treatment framework and by-laws regulating the substitution units. These rules and regulations state that abstinence is the ultimate goal of treatment. However, as already pointed out, two kinds of treatment units are considered necessary in order to meet all the needs of drug addicts, taking into account the clients' potential for achieving abstinence, their previous history and the seriousness of their psychopathology: a) units aiming at abstinence in the short term (18 months) and b) units aiming at abstinence in the long term (three years).

Thus, after a short process of preparation (lasting a couple of months) in one programme ¹²¹, aimed at motivating the drug addicts, the patients are referred on to high-quality programmes, ¹²² according to their needs and the type of treatment that will best suit them (either a short-term or a long-term unit; see the Table). In both units:

- the criteria for selection and admission are almost the same, with more lenient criteria in the long-term unit than the short-term ¹²³;
- the treatment aim is always abstinence-oriented (in the long-term maintenance programmes, abstinence is still the ultimate goal) ¹²⁴;
- the parallel use of opiates is not tolerated (at most, three times is tolerated) and participants in the programme are followed up (e.g. urine analysis) ¹²⁵; and

¹²¹ This distinction does not exist any more. Heroin addicts are consulted in a special unit and they are referred for admission to the appropriate programme (2002).

¹²² In accordance with the definition given in the Euromethwork 2000 (guidelines for methadone).

¹²³ Not any more. (2002). Certain categories of addicts (those above 50 years of age or suffering from physical or psychological disorders) are referred to a maintenance programme.

¹²⁴ Not any more (2002). Criteria for success are a) stabilisation of use into a low dose and b) psychosocial improvement.

¹²⁵ Emphasis in harm reduction makes the therapeutic team more tolerant towards some drug use, especially in the maintenance programme. Individuals have also access to a low expectations/threshold programme (2002).

- counselling and psychotherapy are compulsory (the ratio between therapists and patients is 1:15 in the abstinence units and 1:40 in the maintenance units).

The following table describes the various stages of treatment.

A detailed description of the stages of treatment ¹²⁶

Phase and Duration	Methods of Entry	Purpose	Means
1 Phase A in short-term drug treatment unit ¹²⁷	From the waiting list, on a priority basis or by case basis (e.g., pregnant women)	Preparation: information, motivation, prevention of relapse, stabilisation of dosage	Individual and group therapy
2 Phase B in short-term drug treatment unit (up to 12 months) ¹²⁸	Assessment committee for transition from the previous stage and request by the patient	Physical drug treatment Psychological drug treatment Social motivation	Systematic reduction to zero-level dose Group and individual therapy and prevention of relapse Education, employment.
2 ₁ Phase of preliminary integration (1 month)	Completion of Phase B and stabilisation of abstinence (substitute substance free)	Reinforcement: stabilisation of abstinence, preparation for social integration	Individual sessions Possibility of dispensing naltrexone
2 ₂ Phase of social integration (12–24 months)	Completion of preliminary integration phase and stabilisation of abstinence (substitute substance free)	Psychological treatment of drug dependence Family and social integration Exploring job prospects	
2 ₃ . Drug treatment Completion of the programme	Completion of previous phases One full year of abstinence (completely substance free)		
3 Long-term maintenance unit	Assessment committee and request by the participant Serious problems with physical and mental health	Reduction of doses Reinforcement of abstinence incentive Motivation for employment and education	Individual and group therapy Health education seminars

1.4. Potential infractions and sanctions applied.

Non compliance with agreed therapeutic contracts may lead to the suspension of the programme (see also 1.2.2. entry criteria). Thus, the patient has to adjust to the specific therapeutic procedures and methods, to avoid using physical or phrasal violence and additional drugs ¹²⁹.

¹²⁶ Options: From 1 to 2 or to 3. From 2 to 2₁, from 2₁ to 2₂ and vice versa. From 3 to 2, etc.

¹²⁷ This unit is now replaced by a service organised for the intake of patients, granting information to them and making a first evaluation of their situation; the team of this service assigns each patient to the appropriate unit according to his/her needs (2002).

¹²⁸ The short duration drug treatment unit after 2000 consists of the motivation phase (up to 3 months) and the phase of psychosocial improvement which means that the person under treatment has managed either to stabilise his/her use or to abstain entirely (3 to 12 months).

¹²⁹ Under the new treatment policy (2002), the system of privileges/ rewards and sanctions applied is regulated in a detailed way.

1.5. Rules for substitution treatment as an alternative to punishment.

Addicted drug users who voluntarily and systematically attend the substitution programme (as well as any treatment programme) and happens to be accused either for offending against the drug law (law 1729/87) or committing crimes in order to finance their drug habit (robbery and violent crimes accepted) enjoy several benefits: postponement of the trial, potential suspension of the arrest warrant and potential postponement of the penal prosecution (law 2331/1995 article 21).

The rehabilitated drug users enjoy also crucial benefits: possibility of the permanent setting aside of penal prosecution, obligatory suspension of sanction for three to six years (law 2331/1995 article 21).

2. Practices

2.1. Legal problems in prescribing or providing substances

See sections 1.1 and 1.3, above. Both the scientific experts and public opinion regard these restrictions as positive. In other words, the Greek state is implementing substitution programmes with caution and some reservations.

2.2. Interviews

For the purposes of this study, thorough interviews were conducted a) with therapists and directors of substitution centres located in Athens (eight interviews of almost one-hour duration based on both open-ended and closed questions), b) with members of the Greek parliament, members of the Parliamentary Inter-Party Committee during the years 1997–2000 and 2001 (eight¹³⁰ answered questionnaires, including open-ended questions, were returned) and c) with other scientists. Finally, documents written by therapists in or administrators of 'drug-free programmes' have been taken into account.

The background against which the interviews were conducted featured the following developments:

- (a) The relatively recent (2000) report of the Parliamentary Inter-Party Committee (see also 1.3 above), by virtue of which, *inter alia*, the piloting of a limited number of maintenance programmes was recommended.
- (b) The recent bill (23/5/2001) concerning drugs submitted by five members of parliament from various political parties. According to this bill, the state should adopt a liberal policy on referral to substitution substances (including heroin). In other words, the state should allow the dispensation of substitution substances: a) by public hospitals, public health centres, etc., that are under its supervision and control and b) by psychiatrists in private practice who usually treat drug addicts.
- (c) The recent (28/6/2001) decisions of the Ministerial Council concerning drugs and alcohol, according to which a five-year National Action Plan would be drafted with interministerial cooperation. With respect to substitution programmes, it was

¹³⁰ The research team approached 38 members of the Greek parliament. Despite the assiduity and diligent efforts of the team, there was some disappointment, since very few bothered to respond.

recommended that new units be created: a) within the framework of existing drug treatment facilities (OKANA) and b) on a pilot basis within the framework of the wider healthcare services (National Health System). These initiatives will be oriented towards a) the development of a wide range of programmes for the treatment of drug users, b) the reduction of harm and c) social integration and employment.¹³¹

2.3. Conclusions from the interviews with therapists

2.3.1. Main points raised

Dispensation of substitution substances and the ideological, practical and other issues connected with such treatment, as well as the prerequisites set by the law for participation in substitution programmes, have already been discussed here (see section 1.2.2 above).

According to one view, the minimum age for entry to the programme should be set at 18 – instead of 22 – since the average age of drug abuse is lower now than before. There was a consensus of agreement that the duration of participation in the programme should depend on a) the degree of addiction and b) the overall health of the drug addict – factors that vary from person to person.

A specific period of time (e.g., a two-year period or a period of between three and five years) was suggested as the minimum for participation in methadone treatment. Some negative views have been expressed about the existing interpretation of ‘long-term use’.

It was observed that, although intravenous use is the usual method of use for the majority of patients, other methods (such as inhaling, smoking heroin) should not be excluded.

With regard to the exclusion of cases of acute psychopathology, the following view was stressed. Although the coexistence of psychiatric symptomatology and drug addiction is a typical phenomenon (comorbidity; see footnote 12 above), the methadone centres are not equipped to effectively treat acute psychiatric disorders that are discovered during the course of treatment. It was suggested that there is a need to create a department of experts capable of diagnosing both drug addiction and psychiatric symptoms and to treat such patients individually and not with group therapy methods.

As mentioned above, one of the requirements for eligibility to participate in a methadone programme is ‘the existence of a document certifying that the applicant for admission in the programme has made at least an effort to treat himself/herself in a drug-free programme’ (without substitutes). This prerequisite is considered by some therapists to be obsolete – a certificate showing that the applicant has undergone counselling, however simple and short-term, should suffice, according to their view. However, the majority of therapists believe that a conscientious and systematic attempt to follow treatment in a ‘drug-free programme’, and the subsequent failure of such an attempt, should precede acceptance for treatment.

¹³¹ Decisions of the Ministerial Council concerning Drugs and Alcohol, pp. 11 and 12.

With respect to the consequences of ‘breach of the therapy contract’ – i.e., expulsion from the programme and the option to reapply and be placed at the end of the waiting list – therapists agreed that the programme should continue to have some kind of contact with those patients and provide them with health and psychological support. Therefore, therapists proposed: a) that the emergency care units be developed or that these patients be referred to simple maintenance substitution programmes, and b) that another chance be given to these patients to re-enter the same substitution programme and that the present treatment procedure should be more lenient.

2.3.2 Programme effectiveness

The effectiveness of these programmes was one subject of discussion, focusing on the goals of drug treatment, harm reduction and psychosocial support. Therapists agree with the general conclusions expressed by OKANA¹³² (i.e., that harm reduction is usually successful: 60–70%); however, the primary goal of achieving ‘complete treatment/abstinence’ for drug addicts is reached in a minority of cases (8.5–12%). Furthermore, therapists share the opinion that the goals of ‘abstinence from alcohol abuse’ and ‘reduction of criminal activity’ have been reached. (In a study conducted in 1998 by members of OKANA, it was found that delinquent behaviour and contacts with the criminal justice system had been reduced by at least 90%.) On the other hand, although there has been a steady improvement in family and social relations and in health, the goal of ‘vocational rehabilitation’ has not been reached. Therefore, there is a need for intensifying efforts concerning vocational education and securing employment. In such cases, ex-drug addicts should be given priority in employment opportunities. (However, parents who have both children who are ex-drug addicts and law-abiding ones who have never tried drugs do not agree with this positive discrimination.) Finally, the goal of ‘retaining high percentages of participants in a programme’ is only reached in the programmes operating in Thessaloniki. It seems that therapists there are more lenient than those in Athens and they tolerate more relapses and breaches of contracts.

2.3.3 Suggestions for improvement

- Proposals for short-term and long-term programmes and the effectiveness of the units were considered.
- The issue of ‘waiting lists’ was another subject of discussion. In the year 2000, there were 1 900 applicants on the waiting lists: 110 of these dated back to 1996, while often applicants died before they were actually called to participate in a programme. As the rate of applications for treatment increases, the ability of the existing programmes to reduce the waiting list decreases. Therapists were naturally led to demand that substitution treatment programmes be expanded and simple maintenance programmes set up. Therapists, in general, feel that, at present, there is considerable confusion concerning the goals and methods of the substitution programmes and the possibility of expanding them.
- The need for greater flexibility and independence in the administration of the individual units and the distinction between scientific and administrative duties was raised.

¹³² The Reality about Drugs: Action Plan 2000–2003, p. 13.

- The need for equal development of substitution treatment services and establishment of independent social services was stressed.
- The therapists also believe that it is necessary to make quantitative and qualitative changes in the treatment staff and to distinguish between the therapeutic roles in accordance with the specialisation. Moreover, they emphasised that drug counsellors need to be educated in the field over a period of a few months before being charged with any responsibility and that this education should be continuously updated.
- New substances should be introduced, according to the views expressed, but also new programmes should be set up for special groups (prisoners, pregnant women, patients with heart conditions, etc.).
- There is an urgent need for aftercare services for stabilising the treatment results.
- The controlled dispensation of drugs by state-run hospitals within a predetermined framework was regarded as positive.

3. In lieu of an epilogue

The writers of this report have simply recorded the views listed above. Some of the points raised by the interviewees may be somewhat naïve or oversimplified; others do not distinguish between a methadone programme supported by psychological therapy and the simple implementation of a methadone programme without any kind of psychological treatment.

The opinion of professionals working in or for ‘abstinence’ or ‘drug-free programmes’ does not appear in this study, although it is evident that they do not always share the opinions stated above. Most of them – if not all – believe that substitution programmes have the full support of the state – which is true – and that government policy is to promote these programmes at the expense of ‘drug-free’ programmes (Ch. Pouloupoulos, ‘The development of therapeutic communities: Risks and difficulties in transition’, in *Magazine of the European Society of Professionals Working with Drug Dependences*, ITACA, March 2001, p. 32).

On the other hand, a well-known psychiatrist who has been working in a state psychiatric mental hospital for more than 25 years writes: ‘Drug addiction is not a disease in the medical sense of the term.’ She continues: ‘To reduce a social phenomenon to a biological one, to reduce a complex and complicated human problem to a medical one, means to support those who believe that drug addiction is nothing but a simple behaviour disorder. All these people are of the opinion that, in order to cope with drug addiction, it suffices to “control” this behaviour via substituting a legal substance (methadone, naltrexone, buprenorphine and others) for an illegal one, without even touching on the other parameters of the problem’ (K. Matsa, *We were looking for human beings and we have found shadows: The riddle of drug addiction*, Athens, 2001, p. 326).

Spain

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Introduction

Spain is one of the EU countries that has extensive substitution treatment services (see 'Insight' number 3)(1). At the end of 1999, there were 72 236 patients in methadone maintenance treatment (2). This situation was the result of an active policy, over the last 10 years, to encourage opioid addicts to avail of this kind of treatment because of the high prevalence of HIV infection among Spanish drug abusers. Spain was the EU country with the highest incidence of HIV infection, and most of the HIV-positive cases were related to the use of intravenous drugs (mainly heroin). At the end of the 1980s, about 65% of AIDS patients were drug users. This was a decisive factor in changing the treatment policy for opioid dependence. At the beginning of 1990, the 'Royal Decree 75/1990 of 19 January, about regulation of opioid treatment for opioid-dependent subjects' came into force. The most relevant effect of this new regulation was a general change in the orientation of treatment for opioid dependence in Spain, and substitution treatment was the preferred option.

1. National, regional and local laws, regulations and political and professional orientations and guidelines

The heroin epidemic began in Spain in the late 1970s. At that time, opioid maintenance treatment was only available for pain relief in terminally ill patients and their use in opioid addiction had not yet been legislated on. Later, in 1983, legislation recognised the use of methadone in the treatment of opioid dependence ('Ministerial Order/1983 of 23 October about the regulation of methadone maintenance treatment for opioid-dependent subjects') (3) and it became possible to prescribe methadone for substitution treatment in opioid dependence. Methadone prescription had to be provided both in the public and private sector, using the usual prescription forms for narcotic substances provided by the Official College of Physicians. Methadone was dispensed by pharmacies, and these did not need a special licence. However, the majority of prescribing was by doctors located within the private sector and concern was expressed that, in some cases, this was for personal gain.

In response, new legislation subsequently appeared in 1985 ('Ministerial Order 269/1985 of 31 October about regulation of methadone maintenance treatment for opioid-dependent subjects' and the 'Resolution of 22 November about dosage and admission criteria of methadone treatment in opioid-dependent subjects') (4) restricting prescription of methadone within the private sector. This legislation established that methadone treatment had to be prescribed by doctors working in the public sector, in specially licensed centres ('prescribing centres'). The doctors had to propose candidate patients for methadone treatment to a special Autonomous Commission constituted by representatives of both the autonomous and national administrations. This commission assessed every new case. Once approved, the subject had to receive methadone in a centre designated for the administration of methadone ('dispensing centres') belonging to the autonomous administration. There was an upper limit of 40 mg of methadone per dosage, and doses could only be increased with the commission's authorisation. Compulsory weekly urinalysis for

detecting illegal drug use also had to be conducted and, when a specified number tested positive, the patient was discharged from methadone treatment. This resulted in a long period when there was a highly restrictive policy for methadone maintenance treatment and drug-free programmes and substitution with naltrexone were practically the only treatments available for opioid dependence (there were very few places for methadone treatment and at least a 12-month waiting list).

However, because the HIV epidemic was extremely severe among drug addicts in Spain (65% of AIDS diagnosis were established in opioid dependent patients) and there was growing evidence that harm-reduction strategies were useful in decreasing both the spread and morbidity of HIV infection, it was decided to change the national drug strategy, and the regulations governing opioid maintenance programmes were substantially modified ('Royal Decree 75/1990 of 19 January, about regulation of opioid treatments for opioid-dependent subjects') (5).

'Royal Decree 75/1990 of 19 January, about regulation of opioid treatments for opioid-dependent subjects'

This law regulates the use, for a period of more than 21 days, of certain opioid drugs for treating opioid dependence. Drugs included in the regulation are: buprenorphine, butorphanol, codeine, dextropropoxyphen, dihydrocodeine, etilmorphine, folcodine, methadone, morphine, noscapine, opium, pentazocine, petidine, tilidine.

According to this new law, all the substitution treatment for opioid dependence has to be carried out in public or non-profit-making centres or services licensed by the health services (of the autonomous government or the National Ministry of Health). Other institutions, not strictly for health (such as prisons), could also be licensed for provision of substitution treatment. Certain centres, and not professionals, were licensed for both prescribing and dispensing opioid substitution treatment, and only doctors working in these centres could order this treatment. Furthermore, opioid drug formulations have to be prepared by a pharmacist working in the centre. The drugs used are usually formulated and administered as an oral solution.

Authorisation of centres or services depends on the Special Autonomous Commission and the specific requirements are established by every autonomous community. However, this Royal Decree made some general recommendations: the availability of substitution treatment had to be increased (more patients had to be admitted to this kind of treatment), priority had to be given for public and non-profit-making centres to provide treatment, professionals working in the centres should have had previous experience in treating drug abuse, and the treatment objectives should be planned according to the available resources. The licence had to be renewed every two years.

Criteria for admission to treatment include diagnosis of opioid dependence and that patients must have tried and failed at least one other previous intervention. In cases of pregnancy, HIV infection or serious systemic disease, these criteria do not apply. There is no limit on dosage and length of opioid treatment.

Every three months, the licensed centre has to notify the Autonomous Commission of the number of patients it has in substitution treatment, the number of new admissions

and patients that have been discharged (giving reasons for both) and the kind of opioid drug used for treatment.

This modification in the legislation facilitated the involvement of many centres in opioid substitution treatment and the number of patients increased significantly. Although this Royal Decree regulated for the use of a number of opioid drugs (see below), methadone was the main drug used in opioid substitution treatment. Furthermore, many new drug abuse outpatient treatment centres were founded (6).

Although this new regulation was much more liberal, the long waiting lists and evidence that methadone maintenance treatment prevents the spread of HIV infection among opioid drug users brought about another change in the legislation in 1996 ('Royal Decree 5/1996 of 15 January, about modification of Royal Decree 75/1990 of January 19 th, about regulation of opioid treatments for opioid-dependent subjects, and the extension of its annexe') (7). This new change made it easier to gain admission to opiate maintenance programmes.

'Royal Decree 5/1996 of 15 January, about modification of Royal Decree 75/1990 of January 19 th, about regulation of opioid treatments for opioid-dependent subjects, and the extension of its annexe'

According to this modification of the regulation, some professionals not working in licensed centres can be independently authorised to prescribe substitution treatment for opioid addicts by the same special Autonomous Commission, and under the same conditions as licensed centres. Furthermore, the opioid drug can be formulated and dispensed by a licensed pharmacist who does not necessarily work in the centre. According to this new regulation, only a diagnosis of opioid dependence is required for enrolment in opioid maintenance treatment (it is not necessary to have already received treatment for opiate addiction). The regulation also recommends the inclusion of intravenous drug users who have tested seronegative for HIV. This legislation included LAAM as a new drug allowed for treatment of opiate addiction. In addition, the regional administrations could also license doctors in private practice to prescribe methadone and pharmacies to dispense it.

All specialised centres or services, private doctors and pharmacies involved in opiate substitution treatment programmes are required to report to the autonomous authority when individuals enter and leave the programme and to give the reasons for both. This information is collated by the 'Observatorio Español de la Droga y de las Toxicomanías' into a national report. This data-gathering system covers any form of drug prescribing and not specifically methadone, although methadone is by far the most commonly used drug for substitution.

1.1. Who is allowed to prescribe, provide and control prescription?

Methadone substitution is currently available in all Spanish autonomous communities, although the distribution and organisation of centres is somewhat different in each community. In some, methadone prescribing and dispensing activities are both carried out at the same centre, whereas, in other communities, these activities can take place in different centres and even in different networks (from specific drug-addiction networks to general health networks). Centres involved in methadone

treatment can be ranked according to their particular activity: 'prescribing and dispensing', 'dispensing only', 'prescribing only'.

'Prescribing and dispensing' centres carried out a variety of treatment activities, including methadone provision (i.e., dosage, treatment duration, urinalysis, counselling, dispensing). 'Prescribing only' centres were also involved in most of the aforementioned activities, except for dispensing. 'Dispensing only' centres were exclusively involved in providing patients with their daily dose of methadone.

At present, most 'prescribing only' and 'prescribing and dispensing' centres are located in specific drug-addiction services where other treatment modalities for drug addiction are also offered (i.e., naltrexone, drug-free programmes, detoxification, etc.). The majority of 'dispensing only' centres are located in primary healthcare services. At the end of 1999, there were 1 654 centres for drug addiction in Spain, all of which were involved in methadone treatment. There were 190 'prescribing only' centres, 283 'prescribing and dispensing' centres and 1 181 'dispensing only' centres (2). Current figures for the private sector are not available, but, in general, there are few institutions involved.

1.2. Goals, modalities, entry criteria, choice of substances prescribed

Substitution clients

According to current legislation, drug policy in Spain relating to treatment with opioid agonists is not restrictive and diagnosis of opioid dependence is the only criterion for entry into a methadone treatment programme. However, when the specific policy of each centre was assessed, it was found that the criteria of pregnancy and diagnosis of AIDS and other severe physical illness were prioritised over HIV negativity or a patient's request for treatment. Most of the centres considered violence, drug use and trafficking in the centre to be criteria for expelling a patient from the programme. When a patient is expelled from a centre, she/he can be admitted to another. In fact, staff at one centre often make contact with another centre in order to 'transfer' the patient.

Substances prescribed

At present, methadone is by far the most frequently prescribed drug for maintenance treatment. Methadone is usually administered orally, in the form of a syrup or tablets, which are made by licensed pharmacies and dispensed free to the patients. One drug company has recently begun marketing methadone in tablets of 30 and 40 mg (5-mg tablets have been available for more than 20 years for general medicine, but not specifically for drug addicts). However, there are some problems in administering them, because the law only allows them to be dispensed in a hospital environment. The law does not regulate on maximum doses or take-home policies.

LAAM was the other opioid agonist available for substitution treatment in Spain, but a recent EMEA recommendation (19 April 2001) has resulted in it being withdrawn from the market. Patients who were on LAAM have had to change to other substitutes (mainly methadone).

At present, buprenorphine is marketed in very small doses (tablets of 0.2 mg) and, in general, it is not used for maintenance treatment. A few clinical trials have been performed using buprenorphine. Buprenorphine in greater doses (as in other European countries such as France) will be marketed in the future.

There are two autonomous communities (Andalucía and Catalonia) interested in developing clinical trials with heroin. Because the current legislation for opioid treatment for opioid-dependent subjects (Royal Decrees 75/1990 and 5/1996) does not include heroin as a drug for treatment, a special licence was needed for using heroin in a clinical research project. The licence has now been approved and both clinical trials will begin soon.

Both clinical trials have similar inclusion criteria (mainly failure of previous treatment and urinalysis confirming illegal opioid use) and exclusion criteria (pregnancy and severe somatic illness). In both trials, heroin will be dispensed, under direct supervision, daily (a minimum of twice a day) for seven days a week, and there will also be a methadone control group. The Catalonia trial will also include a group receiving sustained-release oral morphine, for comparison. In the Andalucía trial, the heroin will be administered intravenously, whereas all the substances (heroin, sustained-release oral morphine and methadone) will be administered orally (double-blind method) in the Catalonia trial. Psychosocial services will be included in both studies.

1.3. Rules for the provision of substitution treatment in special settings or situations (hospitals, pharmacies, treatment centres, prisons, pregnancy)

Methadone treatment is provided in treatment centres according to the rules described above. Subjects in special situations, such as patients hospitalised for medical or mental illness or prisoners, can continue their methadone maintenance treatment.

Prisons

It is estimated that, in Spain, about 30–50% of prisoners are drug addicts. The 1990 law included a paragraph on methadone in prisons and, since December 1999, all prisons except one have methadone maintenance programmes. The figures for December 1999 showed that 21 851 (49%) prisoners were enrolled in methadone treatment (2).

General hospitals

Methadone maintenance patients are often admitted to general hospitals for medical illness related to drug use, mainly HIV infection. However, in recent years, concomitant cocaine use is also a factor. In either case, methadone treatment is guaranteed after contact with the treatment centre to obtain information regarding the patient's previous methadone dosage and when it was last administered. Similarly, when a patient is discharged from hospital, the hospital staff inform the methadone centre of the time and amount of the patient's last dose of methadone at the hospital. Whilst in hospital, patients can receive methadone intravenously if their medical condition demands it.

Psychiatric hospitals

For a long time, to be in receipt of methadone maintenance treatment was an exclusion criterion for admission to the majority of psychiatric hospitals. As it is now generally accepted that there is a high prevalence of psychiatric comorbidity among these patients, methadone treatment is no longer a reason for exclusion and methadone is provided as needed.

Pharmacies

Since the 1996 legislation, private pharmacies have been progressively involved in dispensing methadone. In these cases, the methadone is usually prescribed by public drug addiction centres and the regional administration pays the pharmacies for every patient receiving methadone. At the end of 1999, 633 pharmacies were involved in methadone dispensing.

Primary care involvement

In general, primary care centres are rarely involved in methadone treatment programmes. Most of the patients are treated in specific drug treatment centres. The main exception is Andalucía (in the south of Spain), where methadone is generally provided in primary health care settings (as dispensing centres).

1.4. Potential infractions and the sanctions applied

Infractions in the area of substitution treatment only relate to offences such as trafficking of substitution drugs and diversion to illegal markets. The sanctions applied are the same as for other illegal drugs (heroin, LSD, cocaine), all of which are public health offences.

2. Information on actual practice in regard to prescription and provision

In 1994 and 1997, the National Plan on Drugs commissioned two extensive studies on substitution treatment (6,9). For both studies, a specially designed self-administered questionnaire was mailed to all the centres in Spain involved in methadone treatment. More than 85% of eligible centres participated in both studies. The questionnaire collected information on the following three areas:

- Organisation: the centre's facilities, its financing and managing arrangements, hours of operation, staff composition, and security arrangements.
- Patients: the number of patients in the programme and their characteristics.
- Treatment provided: the centre's treatment policy, any other services provided, the mean daily methadone dose for centre patients, treatment duration, urinalysis procedures and admission and forced discharge criteria.

The coordinator of each prescribing centre was asked to rate every item on the list of admission criteria and forced discharge criteria according to its importance in that particular programme (from '0', not important, to '9', very important). The results of both studies have been published (6, 9) and are freely available.

2.1. Legal problems in prescribing or providing substances

All the services, centres and private professionals involved in substitution treatment have to be licensed by the Autonomous Commission. Substitution drugs have to be administered in the context of a treatment programme where other related aspects (social, medical, related problems) are also addressed. Each individual Autonomous Plan on Drug Abuse determines the specific characteristics of the treatment programme required to be granted the licence. One of the objectives of the National Plan on Drugs during the current period 2000–2008 is to develop the basic criteria needed for other services in the substitution maintenance programmes. This will result in a 'National Commission of Agonists', based on the National Plan on Drugs and representative Autonomous Plans on Drugs.

2.2. Social, political and public attitudes (including both the police force and users) towards treatment, treatment provision and distribution centres

Public opinion shows a positive attitude towards substitution treatment. In a study conducted in the general population, opinions about some measures related to drug policy were assessed using a 1–3 rating score. The results of this study found that attitudes to methadone treatment had a mean score of 2.45 in favour, and medical treatment with heroin had a mean score of 2.08. Attitudes towards drug abuse centres were also evaluated and the results showed that 21% of the general population supported these centres, while 30% rejected them and 36% were indifferent (8). Another study on methadone maintenance treatment in Spain reported that all centres involved in methadone maintenance treatment were generally well accepted in their neighbourhood (a mean score of 7 on a scale of 0–10), although 'dispensing only' centres rated less than 'prescribing only' and 'prescribing and dispensing' centres less than other types of centres (a mean score of 5.7) (9). When public opinion has been more negative about dispensing centres, other alternatives, such as mobile services (methadone-bus), have been developed in some places.

In general, methadone maintenance is well accepted by the police. In many parts of the country, the local police have actively cooperated in the rapid spread of substitution treatment. For instance, in Barcelona, where methadone maintenance programmes increased substantially over a relatively short period of time (10), the police force cooperated in helping the centres to avoid problems with neighbours, between patients and with dealers.

There are a number of associations for drug users and relatives across the country. They express their opinions about different aspects of drug addiction at conferences, meetings and congresses. A free magazine, *Meta-morfosis*, edited by a group of opioid users who are in methadone treatment, is a useful voice for their opinions about different aspects of addiction (including treatment offered). The contents include reports about different aspects of methadone substitution treatment written by drug users, interviews with people working in different areas of the drug field, reports of drug user conferences and so on. The magazine published a summary of the third 'Meeting about legal demands for subjects with drug use problems' (Barcelona, 15 December 2000) (11). A workshop about drug users in methadone maintenance treatment concluded that: 1) in general, the ratio between doctors and patients in

methadone maintenance is lower than desirable, as there are too many methadone users to every doctor, 2) there is insufficient psychosocial support offered in most of the methadone programmes and 3) it would be useful to provide 'day centres for drug users' for patients in methadone maintenance treatment.

3. Recommendations of national experts about substitution treatment policy

In general, the national experts in the drug addiction field feel that the legislation regarding substitution treatment is adequate for offering treatment for heroin addiction and related problems in Spain. They emphasise that the law accords with the recommendations of scientific evidence for substitution treatment (i.e., regarding limits on dosage or duration of treatment). Main problems are related to the need for improved mental, social and family support in the programmes. Insufficient funding is reported as the main problem in relation to this.

Recently, a group of 21 national experts from different disciplines (Psychiatry, Psychology, Public Health, Sociology, Anthropology, Philosophy, Theology and Bioethics) worked together, over a period of one year, on a study about the ethical aspects of substitution policy in Spain. The final report included some recommendations about substitution treatment, which are summarised below (12):

1. Substitution treatment must be available for everybody that needs it.
2. Substitution treatment has to be voluntary, after informed consent by the patient.
3. Although substitution treatment might, as a secondary effect, generate some benefits for society (better control of public health, reduction in crime, better management of some infectious diseases), such benefits must never override respect for the human rights of drug abusers.
4. Substitution programmes have to include psychological and social support.
5. Substitution strategy has to be individualised for every patient.
6. Substitution programmes need to receive enough funding to offer sufficient staff, services and resources.
7. Substitution programmes have to be provided even if they do not adequately meet all the medical, psychological and social support needs mentioned previously. Nevertheless, it is important to work on improving all these elements.
8. Substitution programmes are not the definitive solution for drug addiction or HIV infection among drug users.
9. Substitution treatment has to be evaluated, not only in relation to the drug user but also to his/her environment. Side-effects will also be assessed.
10. Substitution treatment should only be curtailed for a subject for the common good, never as a punishment for the patient.
11. At present, availability of substitution programmes must be a priority for problems related to opiate addiction (i.e., HIV infection).
12. The complete and indiscriminate rejection of substitution treatment is wrong from both a scientific and ethical point of view.

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France

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1. General legal framework

In France, no specific legal provisions existed with regard to substitution treatment until 1994. In 1973, two methadone programmes, each with 20 patients, were initiated on an experimental basis. Almost two decades later, in 1990, a third programme was started for 12 patients. Officially, 52 patients received treatment with methadone up to 1993. During the 1980s, however, general practitioners (GPs) had started to treat heroin users with medication such as morphine sulphate and buprenorphine, mostly for the management of pain. These practices led to heated debate at the time, and even to prosecution of GPs. However, this approach yielded results that eventually convinced the medical profession.

Finally, in 1994, a circular letter of 7 March ('relative au cadre d'utilisation de la méthadone') authorised all specialised treatment centres to prescribe methadone; towards the end of the year, the legal status of methadone had shifted from a classified (illicit) drug to a legal medication.

The following year, another circular letter was issued on 31 March 1995 (DGS/SP3/95 'relative au traitement de substitution pour les toxicomanes dépendants d'un opiacé'). This letter explicitly authorised the use of two substitution products: methadone and a new product called 'Subutex', which is based on buprenorphine. In July 1995, Subutex was authorised to be put on the market (AMM: Autorisation de Mise sur le Marché) and in January 1996 it was effectively sold. Like all other medication, both substances are covered by medical insurance (up to 70% for general cases; up to 100% in cases of invalidity, AIDS or hepatitis; opiate dependence does not give the right to a total refund). In specialised drug centres, treatment is free, according to the law of 1970.

In 2000, between 85 000 and 90 000 patients received some form of substitution treatment in France. The majority of these (72 000 to 75 000 clients) were treated with Subutex, while approximately 10 000 were prescribed methadone. Some patients received morphine sulphate, but no official figures exist as to this practice.¹³³ Only around 5 000 clients were in specialised drug-treatment centres, and the others were treated by GPs.

1.1 Actors allowed to prescribe, provide and control prescription

Subutex

The rapid increase in the number of patients treated with Subutex is a result of the absence of stringent legal regulation of its use. As a matter of fact, every GP is allowed to prescribe Subutex. The only requirement for GPs is the use of a 'secured prescription', which is also compulsory for pain treatment with morphine. This special prescription form was created in 1999 to facilitate the prescription of drugs for pain

¹³³ These figures are based on the sale of medication in pharmacies, with an average of 8 mg for Subutex and 60mg for methadone. For morphine sulphate prescription, there could be 1 000 to 2 000 patients.

management. Formerly, the use of such medication was very limited in France, because of the very strict regulations. The form mentions the name and address of both doctor and patient and it obliges the patient to show his/her identity card. Buprenorphine may be prescribed for 28 days, even though the circular letter of 1995 advises doctors to prescribe for shorter periods at the beginning of treatment. Doctors are also advised to participate in a network of GPs, but this is not obligatory. The organisation of these networks is also optional. Finally, doctors are advised to write the name of the pharmacist on the prescription form and to contact the pharmacist to ensure the follow-up of the delivery. Again, this recommendation is not obligatory. The medication is delivered in a pharmacy and the doctor can ask the pharmacist for the medication to be delivered in parts (e.g., weekly).

Methadone

Methadone, on the other hand, remains a very controlled substance. The above-mentioned circular letter of 1994 requires the initiation of methadone treatment to take place in a specialised drug-treatment centre. Afterwards, clients can be referred to a GP, provided the treatment centre considers the client to be 'stabilised'. The medication is dispensed daily in the specialised treatment centre. The option of take-home doses is a clinical decision made by a specialised doctor. Methadone is prescribed weekly and requires a weekly consultation. Since 1999, this is also allowed fortnightly. The methadone protocol includes urinalysis, for which specialised centres receive a subsidy that provides for weekly analysis. In the first protocol of 1973, the dosage was limited to 60 mg. According to the circular letter of March 1994, a doctor had to be authorised by the administration to exceed the dose of 100 mg. However, there is now no limit regarding dosage or duration of treatment. Patients are registered by name and the list of names is managed by the central pharmacy of the hospitals of Public Assistance. Each name has to remain on the list for three years. A national evaluation of methadone treatment is foreseen, but not for the new medication, Subutex.

The circular letter of March 1995 announced the establishment of 'department committees', which are charged with the follow-up of substitution treatment policies. These committees have to safeguard good practice in the use of the two substitution substances. They also have to advise health professionals and encourage the development of networks of doctors and pharmacists. Furthermore, the committees have to estimate the number of patients in treatment and to study the difficulties that arise in the field (e.g., abuse of prescriptions). The committees are composed of administrative staff, medical, psychiatric and pharmacological experts, as well as representatives from the GP networks.

The way the committees function varies according to the department. Some meet regularly and follow the situation very closely; others have a more administrative function and only collect information about the number of patients, without addressing clinical questions such as poly-prescription.

There are few controls on GP prescriptions. Since the authorities are not involved with controls, the social security bodies charged with dispensing the medication have evaluated poly-prescriptions through analysis of the number of prescribing doctors and the amounts prescribed. This analysis shows that approximately 70% of all patients nationwide consult with one prescribing doctor and are regularly followed up,

30% show more erratic follow-up and some patients see up to 30 doctors per month.¹³⁴ However, this is an exception. In such cases, the social security bodies can refuse to dispense the prescribed medication.

In conclusion, administrative controls are moderate, apart from the usual controls on the medical profession. The implementation of substitution programmes is largely organised on a voluntary basis: doctors and pharmacists are organised into networks that are financed by the government. These networks have been very dynamic. They organise regular clinical meetings and try to solve any problems that arise. About half of all prescribing doctors participate in these networks.

The circular letter of March 1995 recommended that specialised treatment centres be integrated into these networks, but this is rarely the case. The position of GPs and specialised treatment centres is the reverse of what it was in the past. The latter have always adopted a rather negative stance towards substitution therapy, but they are currently responsible for the majority of methadone-based substitution therapies. The knowledge that substitution treatment can now include a psychotherapeutic approach – the only appropriate treatment, in their view – has seriously weakened former resistance. However, their relations with GPs is often still troublesome, which is why very few methadone patients are referred to general medicine.

1.2 Objectives of substitution treatment

The principal objectives of substitution treatment in France, regardless of the substance involved (methadone or Subutex), are, according to the circular letter of 1995:

- entry into the therapeutic process and medical monitoring of possible psychiatric or somatic pathologies related to drug (mis)use;
- stabilising the use of illicit drugs (notably heroin) and limiting injecting drug use; and
- social (re)integration.

Beyond these main aims, the ultimate goal of French drug treatment is that users attain a drug-free lifestyle ('sans dépendance'). This means that, in principle, maintenance treatment is not an option, although the duration of treatment is not defined.

Remarkably, the methadone protocol prohibits short-term methadone treatment aimed at abstinence. In reality, maintenance treatment is accepted, although, officially, substitution programmes cannot be distinguished according to their final aims. Every doctor adheres to his/her own approach, which means that the therapeutic choice of a specific centre is predominantly by word of mouth. Furthermore, GPs connected to a network do not limit the duration of treatment (some 'isolated' doctors dispense decreasing prescriptions). The specialised treatment centres are, in general, high-threshold: patients who continue to use illicit drugs on a regular basis can be excluded and some centres apply the lowest possible doses.

¹³⁴ Synthesis of the studies conducted within the scope of the Medical Insurance (22 studies): 'Faits marquants Assurance maladie, Editions 2001'.

A sharp distinction can be made between treatment centres, according to when they were founded. Treatment centres that were started since the spread of the harm reduction movement are, in general, very low-threshold and mostly have a large number of clients (80–120). They also frequently refer patients to GPs. This is in sharp contrast to traditional centres, which are often characterised by low numbers of clients (20–40) and selective admission criteria.

As a result of this, the most problematic drug users (those suffering from psychiatric problems, social exclusion, polydrug abuse) are far more likely to be treated by GPs than in specialised treatment centres, with the exception of centres established after 1994. At present, only two so-called ‘low-threshold’ methadone programmes operate in France: one in Paris, the other in Marseille. These are based on the Amsterdam ‘BUS’ model.

1.3 Execution modalities

Admission criteria

According to the methadone protocol of 1973, potential clients for substitution treatment must apply voluntarily and must have reached adulthood (minors need the authorisation of their parents, except when the doctor considers it to be an emergency). The circular letter of March 1994 still included two conditions for methadone treatment: a minimum period of opiate dependence of five years and ‘several’ previous detoxification attempts. In the circular letter of March 1995, the only admission criterium is ‘a serious dependence on opiates’, without any specific duration. However, some specialised treatment centres continue to adhere to the criteria of March 1994.

The criterium regarding duration of the dependence has not been a problem for patients who are a bit older (an average of 33 years in specialised centres). Patients of GPs on Subutex are slightly younger (around 30).

Range of substances

Two types of substitution medication are officially prescribed in France: Subutex (buprenorphine) and methadone. Clinical considerations are less important than administrative regulations regarding the choice of product.

The majority of GPs do not have the option to prescribe methadone. This is the responsibility of specialised centres. In networks where some form of collaboration with specialised treatment centres exists, GPs can prescribe methadone in cases of injecting drug use or benzodiazepine addiction. Since access to methadone is much more difficult, it is generally reserved for ‘heavy’ drug abusers. On the other hand, because it is subject to so many restrictions, very few heroin addicts seek treatment with it. They prefer to be prescribed morphine sulphate, which some doctors are willing to do. In 1995, approximately 5 000 patients received morphine sulphate treatment. This number has steadily decreased in favour of methadone. Today, these prescriptions are discouraged by pressuring doctors and some social security services to refuse to dispense them.

There has been no evaluation of morphine prescription, but it seems that two types of patients benefit from it:

- very dissipated patients (such as prostitutes) who cannot cope with the restrictions of treatment centres;
- integrated and stabilised patients who refuse to be identified with specialised centres, as the restrictions of these centres are not compatible with an active professional life.

A project for a heroin programme has been proposed to the Ministry of Health, but so far no decision has been made.

1.4. Rules for the provision of substitution treatment in special settings

Only for prisons do any rules concerning substitution treatment exist. In principle, substitution treatment that has been initiated outside prison has to be continued in prison. In practice, however, this is not always possible, either because some prison doctors refuse to prescribe (they are not obliged to) or because the prison administration does not maintain the necessary personnel for dispensation. However, prison doctors are less hostile towards substitution treatment since it has been shown to have positive results. Some prisons will even agree to initialise substitution treatment. In all cases, treatment is with Subutex (apart from a few specific arrangements with specialised treatment centres).

In France, there are no special substitution programmes for prostitutes. One programme is reserved for drug-using mothers with child(ren).

2. Problems and legal difficulties

Since the new legislation (March 1994 and March 1995), only a few legal problems have arisen. In 2000, there were two court cases:

1) A GP was accused of incitement to drug trafficking. The doctor was located in the suburbs, some distance from Paris. She prescribed Subutex for the majority of heroin addicts in town. After she was put under strict surveillance by the police, she was accused of drug trafficking by a judge who had obviously not understood the new legislation. It became clear that there was no question of trafficking but that she dispensed medical prescriptions. The doctor was subsequently accused of 'incitement to drug use'. The judge considered that the prescribed doses were too high and the consultations too frequent. The doctor was prohibited from practising her profession during the investigation, even though dosage and frequency of consultations are not concerns of the justice system (except for in the case of professional misconduct). As the medical experts have shown, the doctor's practices were in accordance with medical ethics. Consequently, the case against the doctor was dismissed.

2) A second problem occurred as a direct result of the 1970 law that regulates the 'war on drugs' in France. A patient at a methadone treatment centre was accused of cocaine trafficking. He admitted having sold cocaine to other patients in methadone treatment centres. The judge seized the files of all the patients to search for any trace

of cocaine in the patients' urinalysis, as drug use is an offence in France. From a legal point of view, the seizure was legitimate and necessary to provide proof of trafficking. The doctor at the centre, supported by all the health professionals and the harm reduction movement, protested against this violation of medical secrecy, though without winning the case. The law of 1970 guarantees anonymity for patients in treatment, but this anonymity can be repealed in drug trafficking investigations. This problem has not yet been solved. Judges can still confiscate medical files if they think it is necessary. This practice remains rare, but depends on the goodwill of the judge.

3. Programme effectiveness

Substitution treatment has not been questioned in France, because of its outstanding success. In four years (1996–1999), the number of overdoses has decreased by 80% and the number of arrests for heroin use has decreased by 54%. The correlation with substitution treatment has been established by SIAMOIS, founded by the French monitoring centre for drugs to follow up on harm reduction measures.¹³⁵

1) Regarding heroin arrests, when substitution treatment programmes were first started, there was a decrease in the consumption of heroin. This situation has contributed to the successful results, but in an indirect way. The decrease in arrests coincides with the sale of Subutex. It is clear that younger people consume less heroin (they prefer psycho-stimulants), but heroin addicts have not just given up the use of heroin out of the blue. They switched to Subutex. Although the exact number of heroin-dependent patients in treatment is not known, they are estimated at between 130 000 and 170 000. More than half of all heroin addicts are thought to be in treatment at this moment. The decrease in arrests is an indirect indicator of the decrease in crime. Heroin addicts are arrested less frequently because they are less evident on the streets.

2) The decrease in fatal overdoses is again related to substitution treatment. The decrease in deaths from AIDS shows improved access to treatment. Heroin (mis)users are also accepted in hospitals. Hepatitis remains health problem number one, but, in general, the health of heroin users has improved considerably.

There have been a number of studies of patients in treatment with Subutex. These studies all confirm the observations of practitioners.¹³⁶ The results can be summarised as follows:

- a decrease in heroin consumption by an estimated 70%;
- two out of every three patients stay in treatment for up to one year; this could be even higher, since the studies only relate to doctors participating in networks (e.g., from 82.7% to 96% for four treatment networks);
- a very small seroconversion for HIV (e.g., 0.8% in two years) and a bigger one for hepatitis C (4.1% in two years), but still not massive;

¹³⁵ SIAMOIS, *Contribution à l'évaluation de la politique de réduction des risques. Description et analyse des données de ventes officinales de seringues et de produits de substitution de 1996 à 1999*, Institut de Veille Sanitaire.

¹³⁶ The results that are presented here are the synthesis of the SPESUD-studies (*Ann. Med. Interne*, 2001, 152 au n°3 IS26-IS36 ; 'Comparaison entre quatre réseaux de soin', *Ann. Med. Interne* 2000, 151 suppl. B-5 ; 'Le programme OPPIDUM', *Ann. Med. Interne*, 2000, 151, suppl. A A10-A17 ; 'Réseau Ville hôpital Vaucluse', *La revue du Prat*, Médecine générale, n°442, 14 Dec. 1998).

- improved access to treatment for HIV patients (23.4% of HIV patients before treatment with Subutex began and 75% since); and
- improved social integration through remaining in employment, or even through access to employment for approximately 10% of the patients (43% before treatment and 55% during treatment).

In terms of social integration – for people who abuse or are dependent – stabilisation or progress are usually observed and very little deterioration. Only a small number of the very unstable patients do not make progress.

These results have not been contested. However, the situation is very different for studies that have been conducted in the field, on the streets, in syringe exchange programmes or in prisons.

In all the sectors covered by the framework of the TREND project, Subutex is more available, more accessible and cheaper than heroin.¹³⁷ Different types of Subutex use have been described, apart from prescribed use: occasional use of Subutex when there is a lack of heroin; use in association with codeine; and polydrug use in a study on intoxication, particularly with benzodiazepines. These types of use may exist because of the younger users who have never used heroin before. Subutex may also be used to alleviate a user who is 'coming down' from stimulants, cocaine, amphetamines or synthetic drugs.

Subutex can be sniffed or injected. A large percentage (up to 70%) of the participants in the needle exchange programmes (Programmes d'Echange de Seringues; PES) inject Subutex. Some of them are in treatment, while others obtain the medication on the black market (20.8% on average in the PES).¹³⁸ Compulsive recourse to injection has also been used by doctors to support their demands for methadone treatment. In studies based on a clinical evaluation by doctors, injecting drug use during treatment is estimated to be at around 12–30%. The rare studies that are based on statements made by users show a higher percentage. In a study on socialisation trends, 39.3% of the users declared that they were injecting at the beginning of treatment and 31.6% after six months. This percentage decreased further as treatment progressed. In a study conducted by the association AIDES on the satisfaction of users in treatment with Subutex, 55% admitted to injecting and half of these stated that they did not dare to tell their doctor.

How can we interpret these results? Are they contradictory? If one compares the users' perspective on the needle exchange programmes (PES) with that of patients in substitution treatment with a GP, one can see that the latter are better integrated socially. More than 90% of the patients with a GP (94.4% SPESUD; 93.7% SUBTARES) have accommodation, as opposed to 66% of the 'PES users'. Between 48% and 55% of GP patients have jobs, as opposed to only 19% of the PES users. The PES users are more isolated (72% live on their own), whereas between 26% and 29% of GP patients live on their own. Also the substances used differ greatly between these populations: in the first study conducted by the association AIDES,

¹³⁷ TREND, Rapport 2000 et 2002, Observatoire Français des Drogues et de la Toxicomanie.

¹³⁸ EMMANUELLI, J., see 'Programmes d'échange de seringues et réduction des risques chez les usagers de drogues dans le monde développé : états de lieux et mise en perspective', document of CESAMES, N°8, January–April 2001.

36% used cocaine, as opposed to only 5% in the SPESUD study of GP patients (although this could be an under-evaluation, given the fact that the information is based on an evaluation by the doctor, without urinalysis). On the streets, in the needle exchange programmes and in prisons, it is possible to observe precisely who is having difficulties with their treatment with the doctor. According to studies on the follow-up of GP patients, 20–30% are not stabilised. They return to the streets and join the users who are not in treatment but use Subutex from the black market.

A 70% decrease in heroin consumption for those in treatment with Subutex is a very favourable result, similar to the methadone programme. This result is all the more surprising because Subutex is, in theory, not meant for long-term prescription: patients should have abandoned the use of heroin, benzodiazepines and injecting drug use. To comprehend the extraordinary success of substitution treatment in France, it is necessary to understand the relationship between doctor and patient. An ethnographic study conducted by Aude Lalande and Stany Grelet¹³⁹ described doctor–patient relationships where doctors are participating in a network. These cannot be generalised, because the doctors concerned are actively participating in a network, and there are certainly 'isolated' doctors with controversial clinical practices. This study is a good means of understanding the success of Subutex treatment, given the fact that doctors organised in networks treat approximately half of all the patients. These doctors are well trained, they communicate with their patients and they work in partnership with harm reduction teams.

The evolution of drug use itself has also contributed indirectly to the success of Subutex treatment. After 10–15 years of heroin dependence, often incarcerated, ill and in urgent need of treatment, heroin addicts have convinced doctors of the usefulness of substitution treatment programmes. The medical world nowadays no longer disputes this.

4. Recommendations

1) The main problem for the treatment system in France is the difficulty of accessing methadone. Although there are users stabilised on Subutex, 30–40% of them continue to inject (however, it should be remembered that, until 1993/1994, 90% of heroin addicts in France were injecting). Polydrug use also exists, particularly with benzodiazepines, which can be dangerous.¹⁴⁰ Many of these patients would be more stable with methadone treatment. Easier access to methadone has to be prioritised. Two possibilities need to be pursued:

- extending the option to prescribe methadone (e.g., for doctors organised in networks); and
- adapting the working practices of specialised centres in such way that they accept problematic patients and refer stabilised patients on to a GP.

These two possibilities have been examined within the framework of a report that was presented to the Ministry of Health in February 2001.

¹³⁹ LALANDE, A., GRELET, S., *Tensions et transformations des pratiques de substitution en ville*, OFDT, 2001.

¹⁴⁰ Mortality in case of poly drug use, particularly with benzodiazepines, has been well identified: 20 deaths have been registered in 1998 (see the work of Dr. A. TRACQUI, ILM, Strassbourg).

2) More thorough investigations should be conducted into the hepatotoxicity of buprenorphine and the risks related to injection. In some cases, distinctive abscesses have been observed, probably caused by sensitivity to this medication.

3) For the most marginalised patients, medical prescription alone is not enough; such treatment has to be supplemented with social and psychiatric services. Access to these services has to be improved, either through 'normal' health services, when possible, or through specialised services for drug users. Specific responses to specific problems (prostitution, migrants, women) are almost absent. These problems may, to a large extent, fall outside the scope of substitution treatment, but there are still implications for such treatment.

Ireland

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1. Introduction and historical development

Almost all of the opiate abuse in Ireland is confined to the greater Dublin area, which is served by the Eastern Regional Health Authority (ERHA). Historically, the ERHA's Addiction Service (formerly AIDS and Drugs Services under the Eastern Health Board, EHB, until 1999) was the primary institutional force behind the opiate substitution treatment initiatives in Ireland, with a number of voluntary and community drug and HIV services strongly advocating substitution treatments for much longer.

(i) Pre-1992

Until September 1992 – when the first community drug treatment service was set up by the EHB – the National Drug Treatment Centre (NDTC) was the only methadone-prescribing drug treatment centre in Ireland. The centre had mental health clinical direction with a stated objective of assisting clients to achieve a drug-free state. Located in Dublin's city centre, the NDTC, until 1987, operated a strict detoxification policy, with methadone being prescribed for short periods only, and in relatively low doses, and patients subjected to regular supervised urine testing. All of the methadone prescribed at the centre was administered and dispensed on-site by nursing staff, operating under the supervision of clinicians. With the onset of AIDS/HIV in 1987, the centre gradually began to offer methadone maintenance to some of its opiate-dependent clients. However, overall numbers were small.

In 1989, the AIDS Resource Centre was established by the EHB in a city-centre location. This centre was established as a public health measure, ostensibly to provide information, testing and counselling services for persons with HIV/AIDS (including drugs misusers, gay men and other categories perceived to be at high risk). In practice, the centre quite quickly established low-dose substitution treatments for HIV-infected drug users. Clearly, contrasting approaches by institutional services in relation to substitution treatment became evident, reflecting essential differences between the psychotherapeutic treatment of addiction and public health.

Persons who were not HIV-infected and who did not attend NDTC but who required treatment for opiate misuse pre-September 1992 could either undergo a symptomatic detoxification using non-opiate drugs or attend one of a few general practitioners (GPs) who were prepared to prescribe methadone. Community pharmacists dispensed all of this privately prescribed methadone: most of it was dispensed at a few key community pharmacies. At this stage, methadone services were controlled under the Misuse of Drugs Acts 1977 and 1984, which presented no legal obstacles to methadone prescribing. In practice, very few GPs actually prescribed. Up until the advent of AIDS, indeed, treatment policy – at both primary care and other levels – was based upon an unquestioned belief in abstinence. Clearly, as the statutory health authority for the Dublin area, the EHB became involved in treatment, and this gave way to a more pragmatic approach whereby indefinite substitute prescribing became accepted.

Until August 1992, Physeptone® was the only formulation of methadone available on the Irish market. Physeptone® was a 2 mg/ml formulation of methadone, designed and licensed for the treatment of coughs. It was never licensed for use in the treatment of opiate dependence. Physeptone® contained sugar, as well as small quantities of alcohol and chloroform, all of which made it less than ideal for regular long-term use. It was also very bulky, leading to storage problems for pharmacists and difficulties for patients who drank large volumes on a daily basis.

(ii) 1992–1996

The Department of Health and Children's *Government Strategy to Prevent Drug Misuse (1991)* highlighted the need to provide substitution treatment as integral to drug treatment, rather than simply as HIV prevention. It also advocated the involvement of primary carers in treatment. The subsequent *Report of the Expert Group on a Protocol for the Prescribing of Methadone (1993)* highlighted the need to standardise and control the supply of methadone as a way of extending the involvement of primary medical carers, thereby facilitating the provision of better treatment to a greater number of patients.

In September 1992, the first community-based drug treatment centre opened in west Dublin. The centre provided an intensive outpatient detoxification service as well as offering structured methadone maintenance to chronic IV drug users aged 18 years or older. Patients who were HIV positive and pregnant women were prioritised. Methadone prescribing and dispensing took place on-site and regular urinalysis was carried out on patients. Similar centres were subsequently established in various locations around Dublin.

In addition, satellite drug treatment services were established in the course of the following years, which provided GPs with independent premises from which to prescribe methadone. This facilitated GPs who were willing to prescribe methadone but had concerns about seeing patients at their own surgeries. The satellite services also had on-site nursing staff, counsellors, supervised urinalysis facilities and security staff. These services were located in areas where significant numbers of opiate misusers required treatment. Patients prescribed methadone at these satellite services were dispensed methadone at local community pharmacies.

Despite these efforts to provide adequate services for opiate misusers, once established, drug treatment centres and satellite drug services were quickly saturated as increasing numbers of opiate users sought treatment for their addiction. As people were maintained on Physeptone®, treatment programmes filled to capacity and there were no services for additional patients.

It had been envisaged that patients stabilised in these tertiary drug-treatment services would return to the care of their GP and community pharmacist. But, generally, GPs and community pharmacists lacked interest in treating drug misusers because they were seen as chaotic and problematic, and therefore unmanageable within primary care. In addition, opportunities for diversion or abuse were high, as Physeptone® was being dispensed privately in large volumes, which led to fears of drug-related deaths associated with methadone, as was seen in Manchester during the same period (Cairns, 1996).

(iii) 1996–1998

In response to these issues, and in an effort to address the problem of saturation in the drug-treatment centres, two steps were taken:

- (a) Physeptone® was replaced with methadone 1 mg/ml in all statutory drug-treatment centres. This formulation was licensed for the treatment of opiate dependence and was prescribed and dispensed free of charge. Methadone 1 mg/ml was green in colour, while Physeptone® was brown, which helped to clarify sources of methadone sold on the black market for concerned members of the public.
- (b) In March 1996, the EHB established a pilot project to look at the viability of returning stabilised patients to the GP's surgery and the community pharmacy. A number of stable patients were identified within the drug-treatment centres and these were transferred to the care of participating GPs and community pharmacists under this Methadone Pilot Project (MPP). Under the MPP, patients received methadone 1 mg/ml. Details of each patient were held centrally, and each patient was registered to attend a nominated GP and community pharmacy (DoH Report, 1997). A treatment card containing the patient's name, date of birth and registration number and photograph was lodged at his/her nominated community pharmacy. Only patients whose cards were held could be dispensed methadone 1 mg/ml by community pharmacists. In addition, only community pharmacies registered to the MPP could order supplies of methadone 1 mg/ml.

(iv) 1998 onwards

Some of the most significant changes to the provision of methadone treatment for opiate misusers in Ireland were made during 1998 and 1999 (EHB Service Plans 1998 and 1999). In 1998, the EHB's Addiction Service's stated aims were the promotion of a drug-free lifestyle and, in partnership with other statutory and voluntary agencies, the provision of prevention, treatment, rehabilitation and aftercare programmes that minimised the harmful effects of drug addiction and prevented the spread of HIV and other infections (EHB Service Plan 1998).

Following a positive evaluation of the MPP, the Minister of Health and Children signed into law the Misuse of Drugs (Supervision of Prescriptions and Supply of Methadone) Regulations, 1998, which took effect on 1 October 1998. These new regulations effectively brought to an end the previous situation in which all medical practitioners could prescribe methadone for the treatment of opiate-dependent patients. Also, only the 1 mg/ml formulation could legally be dispensed. All methadone prescriptions had to be written on a special prescription form. In addition, all patients were registered on a Central Drug Treatment List (CDTL) and each patient was allocated to a named prescriber and dispenser. Patients in community-based treatment services were all issued with methadone treatment cards. GP coordinators were recruited to support and coordinate GPs who prescribed methadone 1 mg/ml in the community, and liaison pharmacists were appointed within the ERHA to facilitate community pharmacist involvement in the Methadone Protection Scheme (MPS). The MPS advocated the on-site supervision of methadone self-administration by community pharmacists, particularly for unstable patients.

The nationwide introduction of the MPS had three primary effects:

- all patients on Physeptone® were transferred to methadone 1 mg/ml;
- all those being prescribed methadone 1 mg/ml were registered on a central treatment list; and
- all doctors proposing to prescribe methadone 1 mg/ml were obliged to undergo training with the Irish College of General Practitioners (ICGP), register centrally and agree to participate in audit.

In the year May 1998 to May 1999, there was a significant increase in the total number of patients registered in methadone treatment in Ireland. There was also an increase in the number of primary carers (GPs and community pharmacists) participating in the provision of methadone treatment for patients using methadone 1 mg/ml over that time (Keenan, 1999). By July 1999, there were a total of 143 GPs and 190 community pharmacists prescribing and dispensing methadone, respectively, for a total of 2 107 patients nationwide. In addition, there was one inpatient detoxification unit, 13 drug treatment centres and 31 satellite services within the Eastern Health Board region, caring for a further 1 916 patients (statistics from the CDTL, July 1999).

2. Prescribers and dispensers

Only GPs who have undergone specialist training in the provision of methadone treatment with the ICGP and consultant doctors can legally prescribe methadone 1 mg/ml. It can only be dispensed by community pharmacists who are nominated to provide methadone treatment for registered opiate misusers and who hold MPS treatment cards for these registered opiate misusers.

Guidelines for doctors prescribing methadone for opiate misusers were issued by a group of Dublin-based GPs with a special interest in problem drug use (Bradley, 1997). The Pharmaceutical Society of Ireland published dispensing guidelines for community pharmacists in 1999 (Practice of Pharmacy Guide, 1999).

GP recruitment to the MPS has been slow but steady since its introduction in 1998. Community pharmacy involvement in methadone dispensing has also increased steadily since the MPS was introduced. Pharmacists working with the MPS report confidence in their own ability to help patients and they reported receiving adequate support with the majority of the problems they encountered (O'Connor, 2001 (1)).

3. Entry criteria and choice of substances used

The entry criteria for methadone treatment have been relaxed somewhat in recent years, with opiate misusers aged 16 years or older being accepted into treatment. Heroin smokers were also allowed to access treatment services. There is no time limit on the duration of methadone maintenance treatment in Ireland.

Only the 1 mg/ml formulation of methadone is available for use in substitution treatment programmes for opiate misusers in Ireland. Methadone tablets and injections are not available here. Diamorphine is not available either. Lofexidine (Britlofex®) and naltrexone (Narcan®) are prescribed occasionally in Ireland, but

there are no national prescribing guidelines governing their use. A review of the use of buprenorphine in opiate substitution therapy is currently under way.

4. Special settings

The rules governing the supply of methadone via drug-treatment centres, satellite drug services and community pharmacies are outlined above. Methadone treatment is currently available for a limited number of prisoners in the main Irish prisons. More extensive services are planned and the interface between national methadone treatment services and the prison service is currently being examined (Irish Prisons Service, 2000).

Methadone treatment can be initiated or continued for hospital inpatients, although these patients must register with the MPS or attend a drug-treatment centre on discharge. Liaison midwives employed by the ERHA's Addiction Service facilitate the treatment of patients in methadone treatment in the course of their pregnancies by liaising between Irish maternity hospitals and methadone treatment services.

5. Sanctions applied

Patients can be suspended from treatment for non-compliance with agreed contracts or violent or disruptive behaviour. Usual sanctions range from one month to one year. Patients are generally detoxified from methadone over five to seven days prior to the discontinuation of treatment. Where the continual use of additional drugs or medication is apparent from urinalysis, patients' daily methadone dose may be reduced or take-home privileges may be withdrawn (patients are obliged to drink their methadone on-site under the supervision of a pharmacist).

6. Methadone as an alternative to prison

In February 1998, the fifth report of the working group on a Courts Commission was published and this recommended, *inter alia*, the setting up of a drug court. Following this publication, a drug court planning committee was established, which commenced the process of overseeing a pilot drug court. This has been established since December 2000 and covers one geographical area in the inner city of Dublin. The planning committee has brought together all the relevant agencies on an inter-sectoral basis to allocate and target dedicated resources in treatment (including substitution treatment), counselling and rehabilitation for the duration (two years) of the pilot project which is being evaluated.

7. General acceptability of the Irish methadone treatment programme

7.1. Legal issues

There are many practical problems arising from legal aspects of the MPS. Some examples of these problems follow:

- (a) The MPS allows only one nominated prescriber to treat each patient on methadone. This leads to difficulties when this doctor is not contactable (off duty, on holidays, sick, etc.). Pharmacists cannot transfer prescription enquiries or other

concerns to anyone else. Patients may have long periods without a consultation with their prescriber. Community pharmacists have highlighted frequent problems in contacting methadone prescribers, many of whom do not work full-time. No on-call service is available. This can result in a lack of cohesion in primary care methadone treatment services, and can result in delays for patients, which may be associated with disruptive behaviour in community pharmacies.

- (b) The MPS allows only one community pharmacy to dispense methadone for each patient. The nominated pharmacy is usually local to the patient's home address. This can cause problems for patients who work and cannot attend this pharmacy during office hours and for those who do not live at their registered address.
- (c) Such tight controls on the prescribing and dispensing of methadone and the elimination of private methadone prescribing has led to waiting lists for substitution treatment in many parts of Dublin. It has also caused problems outside the Dublin area, when patients need treatment and no local prescribers are trained to provide it.
- (d) There appears to have been an upsurge in private prescribing of other psychoactive medication (other opiates such as dihydrocodeine and morphine, benzodiazepines, etc.) as an alternative to methadone prescribing for GPs who would have previously prescribed Physeptone®. This problem needs to be addressed, as recent research from Dublin showed that multiple drug use (specifically, the use of benzodiazepines) was evident in almost all of the drug-related deaths recorded during 1998, 1999 and 2000 (Ward, Barry and Byrne).
- (e) Take-home methadone doses dispensed at drug-treatment centres and under the MPS may have been involved in incidences of fatal overdose in children (Harkin, 1999). Not all community pharmacists report providing pharmaceutical measures with multi-dose methadone supplies, and not all patients report using these measures even when they are supplied (O'Connor, 2001 (1 & 2)). Health promotion messages need to address this safety issue for pharmacists and for patients.

7.2. Social, political and general public attitudes

There is, in general, some public ambiguity regarding the provision of methadone for opiate misusers under the MPS. The MPS was introduced as the country entered a period of economic prosperity. An associated reduction in unemployment and crime may have contributed in some ways to a reduction in the wider social effects of drugs, leading to an increase in public tolerance of new measures for drug users. However, while the public supports harm-reduction measures, this support seems to be premised on drug misusers becoming abstinent (Bryan et al., 2000).

As opiate misuse has traditionally been a problem based mainly in areas of socio-economic deprivation, the provision of substitution treatment has alleviated many other social problems in these areas. Indeed, many community organisations are directly involved in organising and providing treatment alongside ERHA personnel. However, problems arise in some areas when attempts are made to establish new dispensing treatment centres and some local resident groups make objections. Also, community groups express some frustration that attenders at these clinics do not become abstinent.

The EHB Addiction Service strategy supports three interventions in efforts to address the problems of drug misuse: a) education and prevention, b) treatment and c) rehabilitation (EHB Service Plan, 1999). As a treatment initiative, the Irish government is fully supportive of the MPS and its funding is adequate. The Irish police (the Gardaí) are also fully supportive of methadone treatment programmes nationwide.

The views of patients being treated under the MPS are varied and often conflicting. When the scheme was first introduced, the majority of patients reported that it had a positive impact on their lives. Many received free treatment for the first time, others reported an improvement in the standards of their care, while others reported being able to access a place in treatment for the first time (O'Connor, 2001 (2)). More recent research suggests that, as time has gone by, problems have arisen with the MPS (Larkin, 2000; O'Connor, 2001 (3)). Patients' primary complaints include the following:

- (a) Under the MPS, only the methadone is legally available for use in substitution treatment for opiate misuse. Patients would like to have a choice in the opiate used. Preferred opiates include LAAM, buprenorphine and heroin.
- (b) Given that methadone is the only drug available under the MPS, patients would like to be able to choose from a range of methadone formulations. Many believe that Physeptone® was more effective in treating their addiction. Others would prefer tablets to the 1 mg/ml mixture.
- (c) Patients report problems relating to where they receive methadone treatment. Those in community-based treatment services report a lack of social and personal support, while those attending drug-treatment centres complain of exposure to active or unstable drug misusers.
- (d) Patients attending community pharmacies report having to agree to comply with regimental or punitive pharmacy/patient contracts or risk having their dispensing service withdrawn.
- (f) Pharmacies in drug-treatment centres only dispense methadone for a limited length of time each day, which is generally within office hours. This can be problematic for patients who work.
- (g) Drinking their methadone on-site at community pharmacies can be embarrassing for patients, particularly in community pharmacies that do not have private areas for this purpose. Patient confidentiality may also be breached by the enforcement of obligatory on-site supervision.

8. Conclusions and recommendations

Irish opiate substitution treatment consists of a number of tertiary drug-treatment centres and community-based treatment under the Methadone Protocol Scheme. This is a very effective way of delivering tightly controlled opiate substitution treatment to a significant number of drug misusers. It has eliminated the dangers associated with patients attending multiple methadone prescribers. It has succeeded in increasing public acceptance of methadone treatment and has resulted in the expansion of the involvement of GPs and community pharmacists in the provision of methadone treatment services.

Irish substitution treatment programmes, while relatively low threshold, are tightly controlled, to an extent which may cause personal and social problems for patients.

They are limited to the provision of methadone 1 mg/ml, which reduces their acceptability to patients. Irish substitution treatment programmes should aim to meet the needs of those providing services, while protecting the rights of patients and maximising positive treatment outcomes.

Recent trends towards increased prescribing of psychoactive medicines that have an abuse potential need to be addressed to avoid increased mortality rates among Irish opiate misusers.

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Italy

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Legal aspects of drug-substitution treatment programmes

In Italy, the substitute drugs used in the treatment of drug addiction are methadone and buprenorphine. A trial was undertaken in certain centres in Italy to integrate buprenorphine into the daily running of the drug services (Sert). In Italy, harm-reduction programmes up until now have not used buprenorphine, whereas methadone continues to be the preferred substitute drug. Methadone is always consumed orally.

The regulations for drug substitution treatment are set out in 'Testo unico delle leggi in materia di disciplina degli stupefacenti e sostanze psicotrope', Law n.309/1990. This law classifies methadone syrup as the drug to be used in drug addiction treatment. This law was changed in the national referendum of 1993,¹⁴¹ which concerned the regulations for administering substitute drugs.

The most significant change relates to who administers the substitute drugs. Before the referendum, the drug could only be administered by the Sert centres (public drug treatment centres) and the Minister of Health determined the rules for administering the drug (doses, length of treatment). Since the referendum, general practitioners have been allowed to prescribe the drug. Furthermore, the Sert doctors have been allowed to decide on the details of treatment.

The main rules for substitution treatment are as follows:

- the Minister of Health sets out the guidelines concerning treatment and recovery;
- Article 78,1a (n.309/1990) outlines the medical diagnosis procedures for the regular use of psychoactive substances;
- Articles 20 and 122 give Serts the responsibility of drug addiction diagnosis, along with deciding the details of the therapeutic programme;
- Article 43 states that doctors who prescribe psychoactive drugs must conform to specific regulations (they are not allowed to prescribe more than a certain specified dosage, they must keep copies of prescriptions, etc.); and
- Article 72 states that the aim of prescribing psychoactive drugs must be to treat the specific pathological condition of the individual patient.

There are also other important regulations:

- 1) The substitute drugs must only be used for cases of certified physical drug addiction.
- 2) The Serts are responsible for the substitution treatment programmes, including the dosage, length of treatment and regulation of prescription.
- 3) General practitioners can also prescribe substitute drugs, but the therapeutic programme has to be established in liaison with the Sert in that area. The programmes are drawn up according to the individual needs of the patients and they

¹⁴¹ See Decreto del Presidente della Repubblica 5 juin 1993, N. 171.

may include specialist medical attention, psychological and social interventions, which may be provided by other services.

4) All the programmes must include precise regulations concerning dispensing, in order to prevent illicit use of the prescribed substitute drugs.

In 1994, the Minister of Health set out specific guidelines for treatment with substitute drugs.¹⁴² Following this, the Minister of Health set out the 'Harm reduction guidelines' that were officially presented at the third national conference on drugs and drug addiction in November 2000. This document also looks at substitute drug treatment.

The guidelines

In particular, the guidelines give instructions for the use of methadone for either detoxification or maintenance, the option of taking the drug at home and the duration of treatment. According to the guidelines, doctors may decide to initiate methadone treatment, in their professional and ethical capacity. The patient must be completely informed and must agree with the aims and methods of the programme and also with the criteria of assessment.

The guidelines state that methadone must be taken orally, either in the doctor's surgery or the Sert centre, in the presence of a doctor or another member of the health staff. However, they also regulate on the new option of allowing patients to take the drug in their own home, as explained more fully later on.

The guidelines indicate two objectives for drug substitution:

- detoxification; and
- maintenance.

1) Detoxification is achieved by gradually reducing the dosage. It may be short-term (reduced dosage for no longer than a month) or long-term (reduced dosage for longer than a month). The aim of detoxification treatment is to avoid withdrawal symptoms and to introduce the patient to other programmes.

2) Maintenance treatment may be short-term (with stable doses, for no longer than six months) or long-term (with stable doses, for longer than six months). It aims to stabilise the patient's social situation, thereby preventing further problems. Nevertheless, the final goal is still to bring the patient to complete abstinence from all drugs. Maintenance treatment, as outlined in the guidelines, can only be applied in the case of certified long-term addiction to opiates, when other interventions have proved unsuccessful. The programme for substitution treatment includes social and psychological counselling. Furthermore, the patient must be subjected to regular urine tests. The aim of maintenance treatment is the social rehabilitation of patients and, in particular, their return to employment, including the opportunity to attend training courses.

The guidelines stress the importance and the difficulties for the drug addict on the street of approaching the service and becoming a patient. For this reason, the services should give the patient accurate information showing that methadone

¹⁴²See 'Linee guida per il trattamento della dipendenza da oppiacei con farmaci sostitutivi' (Guidelines for the treatment of opiate addictions with substitute drugs), 2000.

maintenance is the best option for them. Concerning the dosage, the document underlines that it is impossible to prescribe a standard dose decided by ministerial regulations because the dosage must be decided taking the individual into account. Treatment should be considered successful when the patient has stopped taking heroin and has changed his/her lifestyle. Urine tests are done to see whether the patient has stopped taking the drugs. The patient is not informed when these tests will occur and they must be carried out in a room in the centre to avoid cheating by giving the staff someone else's urine. If the test is positive, the staff may implement the following procedures: increasing the methadone dose and provision of further counselling and social interventions. After several relapses, the staff can suspend the substitution treatment.

The document also gives instructions for the 'take-home' method. The drug should only be given to the patient to take home if he/she has been in treatment for a long time, if they have proved that they have stopped taking heroin and other drugs and if they have shown clinical and social improvement. In cases where the patient cannot leave his/her house for documented justifiable reasons, the substitute drug may be assigned to a relative who will act as an intermediary. The relative has to be directly related to the patient and will be considered responsible for the correct use of the drug. The guidelines emphasise that the length of the treatment should be decided by the doctor, according to data collected from past experience. A patient should be considered to have recovered when he/she has stopped using opiates and abusing other drugs, even if they are still taking substitute drugs. An indication of the suitability and efficiency of the programme is the percentage of patients who remain in treatment.

Certain members of staff in the treatment services in Florence were interviewed on which factors positively influence a patient to stay in the treatment. Important factors were felt to be: when it is easy for the patient to access the service, when opening hours are flexible, when the service has a pleasant atmosphere, when there are clear rules for using the service and when the programme provides appropriate doses of methadone along with social support. The dosage is decided on by the staff; however, the guidelines suggest a dosage of between 80 and 120 mg.

Buprenorphine

Legal situation and method of use

Buprenorphine was known under the name Tangesic. Tangesic was already being used for detoxification. Buprenorphine is listed as a class A drug and, like methadone, can be used following certain regulations: for example, it must only be prescribed with specific prescription forms and the prescription cannot exceed eight days. Usually the patient takes the drug orally (under the tongue) in the presence of a nurse on the site of the services. The dose is usually increased to 16 mg when the use of heroin has stopped.

In Italy, the use of buprenorphine as a substitute drug has to be evaluated according to the specific instructions published in international scientific reviews and the specific practices of each service. The guidelines give suggestions concerning the therapeutic use of buprenorphine. It is emphasised that buprenorphine is a very efficient drug for

detoxifying a patient from heroin. It is well received by patients and can be adapted by the doctors to suit individual therapies. Buprenorphine can facilitate transition to antagonist drugs but a potential problem is abuse. Regarding maintenance programmes, the guidelines suggest that buprenorphine may be administered on alternate days, doubling the dose, but daily administration allows better control over the withdrawal symptoms. Administration on alternate days may be suitable for patients who are very motivated and clinically stable.

A 'double blind' trial was conducted in 10 Serts. The patients had either to take a pill (under the tongue) or drink a liquid and they were not told if they had taken methadone or buprenorphine. The conclusions of the trial show that buprenorphine is suitable for young patients with a brief history of drug addiction and no drug-related pathologies and who have never used methadone. BPNF can be used at the highest dose of approximately 16 mg, which is equivalent to 60 of methadone (the higher dose is not advised, because BPNF can have an antagonistic effect). BPNF has been shown to be a useful drug, since there are no strong side-effects: unlike methadone, it does not cause sweats, weight gain, change in sex drive, etc. The majority of drug addicts see BPNF as an effective alternative to methadone, which is perceived as having more long-term undesirable effects. The withdrawal symptoms with BPNF are less intense compared to those of methadone. For this reason, the services often use it when a patient is ending therapy with methadone, in order to minimise the discomfort from withdrawal. There are not many Serts that use BPNF on a regular basis, even if the desire to experiment with this new drug has led to some instances of indiscriminate substitution with it instead of methadone.

We maintain that the correct practice is the one used, for example, in Empoli (Tuscany). The services there select the users according to the duration of their drug addiction, their age and the presence or the absence of drug-related pathologies and crimes. They also undertake a psychological analysis of the patient. On the basis of these criteria, BPNF is used for the younger drug addicts. However, BPNF is not used when the patient has shown improvement on methadone with dosages higher than 60 mg and when, on this dosage, they have stopped injecting heroin.

The trial also tested the hypothesis that BPNF is more efficient than methadone in preventing the use of cocaine, which often occurs during methadone treatment. This hypothesis was not proven and it would be difficult to verify because BPNF is a substitute drug for heroin. For this reason, the evaluation remains subjective. Regarding the dosages, they are usually increased until the patient stops taking heroin. In the initial stages, the patient is invited to attend a session to evaluate their craving (specifying the degree of craving from 0 to 100 on a line of 10 cm). If the subject remains abstinent, the dosage is kept at this level. If, however, they show a high degree of craving, the dosage is increased until the craving disappears.

Methadone

Methadone treatment has two important characteristics:

- it attracts and keeps in treatment those who are less inclined to take part in more rigid programmes, such as those run by therapeutic community centres; and
- it reduces the risks related to drug injection (hepatitis, HIV).

As shown in the literature, the majority of problematic patients approach the services indicating that they urgently need methadone treatment and rejecting other types of therapeutic programmes.

The law allows considerable freedom in the decisions that the staff make in the daily running of drug substitution treatment. Thus, every Sert has its own preferred dosages and methods of treatment, depending on the approach taken in their own area and even, in certain cases, on the specific approach of the head of the service.

In general, methadone treatment is considered by services to be the first step in treatment and this is followed by other psychological and social interventions. In this way, the drug is seen as a useful 'bait' to attract the patient to the service and subsequently keep them in treatment. The different services have very varying approaches to methadone treatment. For some, the only aim is abstinence and the use of heroin, even sporadically, is not tolerated during treatment. For others, the most important aim is to keep the patient in treatment, with the main objective of harm reduction, and occasional use of heroin is tolerated. Some services use methadone at high doses to saturate the receptors and eliminate craving. The dosage is raised until it eliminates the craving for heroin and the patient's mood is more or less stabilised. This dose is maintained for a period of time and is then slowly reduced. Once the craving has been eliminated, the patient can be motivated to focus on getting his life back together (job, house, relationships, etc.).

Short-term methadone treatment (no longer than 30 days) is rare, because it does not eliminate craving, but it is used when a patient has to go into a therapeutic community centre to reduce withdrawal symptoms. Treatment lasting for 30 to 60 days is not used very much.

Methadone maintenance allows for long-term treatment with other interventions. Generally, the treatment begins by adapting the dosage to fit the particular needs of the individual. This period lasts between 6 and 12 months and is followed by a period of stabilisation, with urine tests twice a week, lasting between 8 and 10 months. Finally, the period of reduction of the dosage is determined according to the characteristics of the individual and can vary from 1 year to 6 or 7 years, thus making the reduction process 'gentle' but progressive.

The take-home method

There have been no specific regulations concerning 'take-home' substitute drug treatment since the 1993 referendum. In fact, the 1990 law and the DPR 445 (19.12.90, Article 6) did not mention this method, as the drug was only to be administered in the presence of the Sert staff. However, the referendum of 1993 abolished the DPR 445 and, today, the only national guidelines are in the document already cited.

The normal Sert practice is for the 'take-home' method to be applied either as a reward for a patient who has shown considerable improvement or in cases where the staff believe that the 'take-home' approach may help the patient in the rehabilitation process. Generally, the 'take-home' approach is decided upon when the patient has

regularly come to the Sert, he has complied with the therapeutic regulations, including the interviews with the medical and psychological staff and his urine tests have been negative. In Tuscany, the local authorities of the region set up a commission of experts for extending the guidelines for the take-home method: they stress that the take-home method improves the therapeutic relationship between patient and staff.

The option of taking home the drug is important, because it means that the patient does not have to attend the centre every day. The take-home method and the option of obtaining the prescription from his/her general practitioner are two important opportunities for 'normalising' the drug user's life. Also, if the patient is allowed to take home the substitute drug or go to a GP for a prescription, the volume of people attending the Sert (and the long queues outside) is reduced. Thus, it is useful both for the patient and for the community if the patient does not have to attend the Sert every day, as it lessens the stigma for the patient and avoids the neighbourhood reaction of 'not in my back-yard'. Despite this, the take-home method is not widely practised, as the Sert staff may have concerns about patients dealing the substitute drug on the black market or that patients would not take the drug correctly according to the prescription instructions.

In Italy, substitution treatment has always been subject to heated debate and the staff of the various Serts have been divided in their opinions concerning the use of such treatment. More recently, there has been a cultural change and this treatment, and particularly methadone substitution, is more widely practised, with greater freedom in dosage and the duration of prescribing.

Austria

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1. Introduction

Until the mid-1980s, the care and treatment of drug addicts consisted solely of detoxification/withdrawal treatment. At that time, the sudden rise in HIV infection compelled the authorities to take a fresh look at the drug situation. In 1987, the first directive concerning oral substitution treatment of intravenous drug addicts was issued. It allowed narcotic substances to be prescribed if this was medically indicated and other non-narcotic substances were not working. The guidelines stressed that substitution treatment was to be seen as the 'ultima ratio' in therapy and was only to be used in special, severe cases. In 1998, substitution treatment as a form of therapy was incorporated explicitly into the federal narcotics act (SMG) and the idea of the treatment being the 'ultima ratio' was abandoned. At the same time, substitution treatment was adopted as an alternative to punishment (Therapie statt Strafe). Nowadays, substitution treatment is an intrinsic component of the therapies offered in cases of drug abuse.¹⁴³ Since 1987, more than 5 500 people have been treated with substitutes in Austria.¹⁴⁴ At present, 4 300 patients are enrolled in such treatment programmes, most of them in Vienna.

2. National, regional and local laws, regulations and political and professional orientations and guidelines

2.1. Legal framework

The law in Austria is based on written codes of civil law. The legislation that is relevant for this study is as follows:

- a) **Suchtmittelgesetz**,¹⁴⁵ abbreviated SMG, the federal narcotics act (code of drug law).
- b) **Suchtgiftverordnung**,¹⁴⁶ abbreviated SV, includes detailed regulations concerning: illegal substances; cooperation between medical officers; medical practitioners and pharmacists; and federal law.
- c) **Substitutionserlass**,¹⁴⁷ abbreviated SE, are directives concerning substitution treatment published by the Ministry of Health (Bundesministerium für Arbeit, Gesundheit und Soziales). These are binding only for medical officers and health departments but not (state) hospitals and medical practitioners.¹⁴⁸
- d) **Strafprozessordnung**,¹⁴⁹ abbreviated StPO, the code of criminal procedure (federal law).

¹⁴³ Österreichisches Bundesinstitut für Gesundheitswesen (Hrsg.), Bericht zur Drogensituation 1999, 46 f.

¹⁴⁴ Bericht zur Drogensituation 1999, 51.

¹⁴⁵ Bundesgesetz über Suchtgifte, psychotrope Stoffe und Vorläuferstoffe, BGBl I 1997/112 idF BGBl I 1998/30.

¹⁴⁶ BGBl II 1997/374.

¹⁴⁷ Erlass vom 9.6.1998, Z 21.551/6 – VIII/B/12/98, betreffend orale Substitutionsbehandlung von Suchtkranken.

¹⁴⁸ Bertel, Die rechtlichen Grundlagen der Substitution, in: Arbeitskreis für Vorsorgemedizin in Tirol (Hrsg.), Leben mit Drogen ... (1994) 57 (59 ff).

¹⁴⁹ BGBl 1975/631 zuletzt idF BGBl I 2000/128.

- e) **Strafvollzugsgesetz**,¹⁵⁰ § 68, abbreviated StVG, outlines the rules of detention (federal law), 1st **Vollzugserlass**,¹⁵¹ abbreviated VE 1, and 2nd **Vollzugserlass**,¹⁵² abbreviated VE 2, both of which directives legislate on substitution treatment in prisons.
- f) **Drug programmes** of the Austrian (federal) states (state law).

Any suspicion of drug (ab)use leads to a medical examination, performed by a medical officer of health (Bezirksverwaltungsbehörde als Gesundheitsbehörde), to ascertain whether any health-related treatment, such as medical surveillance, psychological therapy or substitution treatment, is necessary.

2.2. Who is allowed to prescribe, provide and control substitution substances?

- a) **Prescription:** According to § 8 of the SMG, substitution substances have to be prescribed by a medical doctor, who is either a medical officer (see c), a psychiatrist or a physician who has had special training in substitution and detoxification treatments. These doctors are listed annually by the state and the ministry of health.¹⁵³ To start the treatment, the doctor and patient have to sign a treatment contract (IV.1. SE). The prescription process is very formal, complicated and strict. The amount, concentration and type of substance have to be specified on the prescription (§§ 18 to 22 SV). A prescription is generally valid for 14 days (§ 20 Abs 1 SV) after the date of issue. It usually prescribes the substance on a daily basis for a 30-day period (long-term prescription).¹⁵⁴ A prescription not complying with these terms is invalid. State hospitals can establish drug outpatient departments, where they offer substitution treatment programmes. Here they prescribe and dispense the substances to the patients.
- b) **Provision:** Any pharmacy can dispense the prescribed substance. Generally, the substance has to be taken orally,¹⁵⁵ under the supervision of the pharmacist (he watches the patient take the drug orally in the pharmacy; VII.1. SE). If the patient refuses to submit to these conditions, the pharmacist has to keep the substance and inform the physician or supervising medical officer (VII.2. SE). The pharmacist is only allowed to dispense the daily dose on a daily basis. If the patient fails to turn up, that dose cannot be dispensed to anyone else (VII.4. SE). The substance can also be dispensed by the doctor in charge of the case or by state hospitals with drug outpatient departments. Again, it has to be taken by the patient in the presence of the doctor.
- c) **Controls:** The most important actor is the 'Amtsarzt', a medical officer of health who is in charge of controlling substitution treatment.¹⁵⁶ He has to examine and sign each long-term prescription. If he refuses to sign it, the

¹⁵⁰ BGBl 1969/144 zuletzt idF BGBl I 1999/146.

¹⁵¹ GZ 61551/20-VI/A/7a/90 Erlass des BKA betreffend orale Substitutionsbehandlung von Suchtkranken vom 8.1.1991.

¹⁵² JMZ 52202/8-V4/91, betreffend Richtlinien über die 'orale Substitutionsbehandlung von Suchtkranken' in den Justizanstalten vom 3.7.1991 – Erlass des BKA vom 8.1.1991.

¹⁵³ V.2. SE.

¹⁵⁴ V.5. SE.

¹⁵⁵ Only oral substances may be prescribed as substitutes.

¹⁵⁶ § 12 Abs 2 SMG.

prescription is invalid. The doctor in charge of the case is obliged to give the state physician all the required information concerning the patient (§ 22 Abs 3 SV, VIII1. and 2. SE). The patient is also monitored through random urinalysis. At the beginning of treatment, this takes place three to four times a week, and subsequently about once a month (V.8. SE).

The doctor in charge has to report when a new client enrolls for treatment and when treatment ends to the Austrian monitoring centre for drugs and drug addiction (the Suchtmittelüberwachungsstelle, in the Ministry of Health) in Vienna (XI. SE).

- d) **Coordination:** Each state has a drug coordinator (Drogenkoordinator), appointed by the state's government. The drug coordinator's role is to see that the aims and goals set forth in that state's individual drug programme are implemented.

2.3. Goals and modalities

Goals: The purpose of the substitution treatment is to cure the patients addiction to the illegal drug by substituting it with methadone (or other substances) or in the long run to cure the drug addiction itself by steadily reducing the substituting substance. Along with that the program is supposed to decrease the patients criminal activity such as drug dealing and supply crimes as well as prostitution. On the other hand it increases the patients resocialisation-process. Also the oral use of the drug reduces HIV and other health risks, as the substituting drugs are considered less damaging. Therefore the treatment goal is to reduce the harm on the individual as well as on society.

Modalities: see above 2.2. Apart from the physical examinations, the controlled prescription and provision of the substances the patient undergoes psychological and psycho-social treatment.¹⁵⁷

Entry criteria: The following criteria (II. SE) apply for a patient to enter treatment.

- a) one year of opiate addiction, as well as a failed detoxification/withdrawal treatment *or*
- b) opiate addiction and HIV infection *or*
- c) opiate addiction and pregnancy *or*
- d) a patient with a one-year opiate addiction who is the spouse/partner of either a) or b)

The following additional criteria are obligatory (III. SE):

- 1) consent of the patient to oral application of the substitute, *and*
- 2) consent of the patient to medical surveillance, such as urinalysis, *and*
- 3) consent of the patient to additional psychological and psychosocial treatment, *and*
- 4) consent of the patient and a declaration that the patient will abstain from abuse of drugs (such as intravenous use) or from passing on the drugs to others, *and*

¹⁵⁷ § 11 SMG.

- 5) consent of the patient to have his/her treatment registered at the Ministry of Health and the health department

For people under 20, the directives concerning substitution treatment (SE) strongly recommend detoxification/withdrawal treatment instead of substitution treatment. Psychological and psychosocial treatment is also necessary (II.2. SE).

Choice of substances prescribed: The primary substance allowed to be prescribed for substitution is methadone, but other substances can be prescribed in cases of pregnancy. Pregnant women are usually given buprenorphine, as it is believed to be less risky for the child. In cases of intolerance or massive physical side-effects, morphine, codeine or buprenorphine may be prescribed. Neither heroin itself nor heroin preparations are permitted. The maximum amounts permitted are defined in § 15 Abs 1 SV. The maximum amount of methadone, for instance, is 0.1 gm and of morphine is 2 gms per day. In practice, between 50 and 60% of the patients receive methadone, between 25 and 40% receive substitol (morphine) and about 10 to 25% receive buprenorphine or kaptol.

2.4. Rules for provision in special settings or situations

a) Prisons: Substitution treatment can be *continued* in prison but not *started*. Treatment is generally based on the agreement of the physician and the consent of the prisoner (voluntary treatment). If the prisoner agrees to continue treatment, he/she has to follow the orders of the physician and submit to frequent urinalysis. Each detention facility in Austria has its own physician, who assesses whether treatment is an option and if it is likely to succeed.¹⁵⁸ Most substitution treatment in prison takes place in the detention facilities of Wien-Josefstadt (Vienna), Innsbruck (Tyrol) and Eisenstadt (Burgenland). In 1998, 270 prisoners were participating in a substitution treatment programme while in detention.¹⁵⁹

b) Hospitals: Substitution treatment is usually offered as an outpatient service, where the patient visits the hospital to receive the substance and have psychological treatment. It can also be performed as an inpatient programme. In many cases, substitution treatment is not imposed as an alternative to punishment but stems from the addict's desire to deal with his/her drug problem. Most of the patients are treated in the outpatient departments of state hospitals.¹⁶⁰

c) Pharmacies: See above (2.2.b).

d) Physicians: See above (2.2.a).

2.5. Potential infractions and the sanctions applied

Possible infringements of the treatment programme are: abuse of the substitution substance, use of other illegal drugs, or sale of the substitution substance, as well as

¹⁵⁸ 2nd VE.

¹⁵⁹ Wiener Drogenkommission (Hrsg), Das neue Suchtmittelgesetz – Zusammenarbeit zwischen Drogeneinrichtungen, Justiz und Gesundheitsbehörde, 1998, 384.

¹⁶⁰ Interview with Prof *Bertel*, Head of the Institute of Criminal Law and Procedure, University of Innsbruck, 16.8.2001.

not participating in the programme or refusing urinalysis. In these cases, it is up to the physician in charge of treatment to decide whether to go on with or stop the treatment. When treatment is terminated, the health department and the Ministry of Health are to be informed. The sanctions applied depend on the criminal charges (see 2.6).

2.6. Rules for substitution treatment as an alternative to punishment

In accordance with § 11 SMG, drug addicts (or abusers) are required to undergo the necessary and appropriate treatment, such as:

- 1) medical surveillance by a physician
- 2) medical treatment, including detoxification/withdrawal treatment or substitution treatment
- 3) clinical/psychological consultation and care
- 4) psychotherapy
- 5) psychosocial consultation and care

Any suspicion of drug (ab)use leads to a compulsory medical examination, performed by the medical officer, in order to determine whether one health-related treatment or a combination of different treatments is necessary.¹⁶¹

a) During the prosecution stage and the trial

In cases where the medical officer deems substitution treatment to be necessary and appropriate and the offender agrees to participate in a substitution programme, the prosecutor can postpone the charge if the following criteria are met:

aa) The offender is charged with use/possession of a small amount of drugs (§ 35 Abs 1 SMG). What constituted 'small' is not a set amount. A 'small' amount of heroin has to be distinctively smaller than the 'large' amount, which is 3 gms. The amount depends on the severity of the drug user's addiction, the daily dose and the dangers inherent in storing the drug.

bb) The offender is charged with use/possession of a regular or large amount of any illegal drug, without intent to sell, or is charged with a supply crime¹⁶² committed without a high degree of culpability (§ 35 Abs 2 SMG).

In both the above cases, if the offender agrees to treatment and the relevant criteria are met, there is no official charge, and therefore no trial before a judge takes place. The offender is sentenced to two years' probation. If the offender completes the treatment (treatment has to be undertaken for two years, but the offender does not have to be drug-free at the end of that

¹⁶¹ § 12 SMG. See *Foregger/Litzka/Matzka*, SMG § 12 Anm. II.1.

¹⁶² *Foregger/Litzka/Matzka*, SMG § 35 Anm. VI. The term 'supply crime' is very strict and is narrower than the term 'drug-related crime'. The code describes supply crimes as crimes committed by a drug user to supply for his drugs, where the sentence is not more than five years in prison or the case is not judged by a jury. In practice, prosecution and courts require, for a drug-related crime to be a supply crime, that the objects gained by it are either the drug itself, money (not an item worth money) or receipts in order to obtain drugs. This very narrow definition means that the specific provisions for supply crimes are rarely applied.

time¹⁶³) and commits no other drug or drug-related crime in the next two years, the case is dropped permanently and there is no criminal record. If the treatment is terminated, the charge is filed before the court.

cc) The same applies to charges brought before the courts (§ 37 SMG).

dd) As a control (§ 36 Abs 2 SMG), depending on the stage of the proceedings, the prosecutor or judge can require the offender to show proof that treatment has been initiated and is in progress.

b) After trial

The courts are given special powers in cases where a drug offender is convicted and applies for postponement of sentence. The following criteria have to be met:¹⁶⁴

aa) If the sentence imposed is not higher than two years of imprisonment or a monetary fine and the offender agrees to substitution treatment, the judge has to postpone the execution of the sentence for up to two years (§ 39 (1) 1st alternative SMG).

bb) If the sentence imposed is not higher than three years of imprisonment and the offender agrees to substitution treatment, the judge can postpone the execution of the sentence for up to two years (§ 39 (1) 2nd alternative SMG).

cc) In the case of a supply crime,¹⁶⁵ where the sentence allowed by law is not higher than five years of imprisonment and the offender agrees to substitution treatment, the judge can postpone the execution of the sentence for up to two years (§ 39 (2) SMG).

In all three cases, the postponement is revoked and the sentence executed if the offender discontinues¹⁶⁶ the substitution treatment or is convicted of another drug or drug-related crime within the imposed time, and if execution of the sentence is believed to be necessary to keep the offender from reoffending (§ 39 (5) SMG).

In all three cases, if the offender successfully completes the substitution treatment, the judge has to set a one- to three-year probation period.¹⁶⁷ If the offender is not convicted of another crime committed during the probation period, the sentence is permanently revoked (§ 40 SMG).

3. Legal problems in prescribing or providing substances

Most experts see substitution treatment itself as positive, as well as being a very important part of the therapies offered and an important alternative to punishment. What has come under criticism from legal and medical experts is that the entry criteria and the choice of substances, as outlined in the Substitutionserlass (SE), are

¹⁶³ *Schwaighofer*, Die Zukunft der österreichischen Drogenpolitik, JRP 1999, 155 (136); EBRV zum SMG, 110 BlgNR XX. GP, 53.

¹⁶⁴ *Foregger/Litzka/Matzka*, SMG § 39 Anm. I ff.

¹⁶⁵ See 2.6.a)bb).

¹⁶⁶ See 2.6.a)bb).

¹⁶⁷ § 40 (1) SMG.

too strict.¹⁶⁸ According to *Bertel*, the requirement of a one-year period of opiate addiction is unreasonable. He believes it is foolish to deny treatment to a person who has 'only' been addicted for half a year on the grounds that he has not been addicted for long enough. Each case should be decided individually. It is also felt that methadone should not necessarily be the first choice of substitution substance. Other substances, such as morphine and buprenorphine, should also be allowed, for instance if the side-effects of methadone are not physical but mental. Each doctor should be able to decide which kind of treatment (detoxification or substitution) and which substance is appropriate on a case-by-case basis.

Another problem is that, although some control is necessary, by refusing to sign a long-term prescription the medical officer could cut short a treatment programme.¹⁶⁹ Some experts criticise the current practice of some medical officers. *Fischer* argues that some of them intervene in the treatment or therapy itself, whereas they are only supposed to check that the prescription is correct.¹⁷⁰ She also mentioned that, in Vienna, medical practitioners may only prescribe methadone, whereas the best treatment for short-term addicts would be buprenorphine. However, this substance may only be prescribed by special drug outpatient departments in hospitals. As these institutions can only take a limited number of patients, not all of them are given the best and most appropriate treatment.¹⁷¹

While many experts feel that more money should be allocated to substitution treatment programmes,¹⁷² a few see such treatment as inappropriate and useless, as it does not lead to abstinence.¹⁷³ Also criticised was the fact that treatment often lasts for many years, sometimes a lifetime¹⁷⁴.

All in all, the majority of experts called for better education and training of medical practitioners and for more money to be allocated to substitution treatment programmes.¹⁷⁵

4. Social, political and public attitudes towards treatment, treatment provision and distribution centres

The current political attitude towards substitution treatment seems to be less than positive. One doctor treating mostly detoxification and substitution patients at his practice in Tyrol argues that the attitude of the new government is jeopardising

¹⁶⁸ *Bertel*, Was könnte man anders machen? Eine neue Drogenpolitik, in: Oberarzbacher/Dornauer (Hrsg.) Das Strafbegehren der Suchtgesellschaft 1999, 13 (18), interview with Prof. *Schwaighofer*, Institute of Criminal Law and Procedure, 14.8.2001.

¹⁶⁹ *Bertel*, Der Erlaß des Bundesministers für Arbeit, Gesundheit und Soziales über die „Substitutionsbehandlung von Suchtkranken“ (GZ 21.551/6-VIII/B/12/98), Stellungnahme vom 4.11.1998, interview with Prof Gabriele *Fischer*, (head of the outpatient department at the Universitätsklinik für Psychiatrie) in Ärztwoche (online magazine), www.infoline.at/drogen/wien.htm.

¹⁷⁰ Interview with Prof Gabriele *Fischer*, www.infoline.at/drogen/wien.htm.

¹⁷¹ Interview with Prof Gabriele *Fischer*, www.infoline.at/drogen/wien.htm.

¹⁷² Interview with Prof *Bertel*, 16.8.2001; interview with Prof Gabriele *Fischer*, www.infoline.at/drogen/wien.htm.

¹⁷³ Some oppose substitution treatment because it does not lead to abstinence: *Hauptmann*, Drogenpolitik ohne Strafrecht 2000, 44 ff.

¹⁷⁴ Interview with Max Wellan, vice-president of the Viennese pharmacists organisation (www.infoline.at/drogen/apotheken.htm).

¹⁷⁵ Interview with Prof Gabriele *Fischer*, www.infoline.at/drogen/wien.htm.

substitution treatment.¹⁷⁶ However, even though the new government's line on drug policy is very stringent (the maximum sentence for drug dealing has been increased and the definition of a 'large' amount of heroin has been altered from 5 to 3 gms, which has implications for sentencing), substitution treatment itself has not been altered and has not even been discussed yet. Public attitudes towards substitution treatment are very positive. A recent study in Vienna shows that 85% are in favour of such treatment.¹⁷⁷

5. Recommendations of the national experts

The experts consider substitution treatment to be a very important part of the treatment offered to drug addicts and a valuable alternative to punishment. Current practices should be retained, as well as expanded. The directives concerning oral substitution treatment (SE) should either be abolished or relaxed, especially regarding the entry criteria. For instance, the requirement of one year's opiate addiction, as well as the recommendation for detoxification for those under 20, should be removed. Controlled prescription and provision of heroin, instead of substitutes, in the most severe cases needs to be considered, according to some experts.¹⁷⁸ It is argued that, not only would the individual benefit, but that social harm would also be reduced. It would also lead to a decrease in supply and in drug-related crimes; heroin dealing would no longer be necessary and the health risks would be minimised, as most deaths are a result of impure heroin and dirty syringes.¹⁷⁹ Heroin prescription would improve the physical, mental and social situation of most of the severely addicted patients. These patients would otherwise, in most cases, not be able to stay in a substitution treatment programme.¹⁸⁰

6. Substitution treatment as applied in the states of Vienna and Vorarlberg

6.1. Vorarlberg¹⁸¹

Substitution treatment has been available in Vorarlberg since 1987. Medical treatment, as well as prescription of the drug, urinalysis, etc., takes place in the outpatient department of the state hospital. Each patient is treated individually. Methadone is used in most cases (47%) (except for pregnant women). Other substances used are Substitol (33%), Subutex (11%) and, in a few cases, Compensan, Mundidol, Kapanol and Vendal are prescribed. Substitution treatment is only possible if the patient also undergoes psychosocial treatment.¹⁸² In 2000, 387 patients (157 of them new patients) were participating in the programme, 71% of

¹⁷⁶ Interview with Dr *Nemec*, www.infoline.at/drogen/tirol.htm.

¹⁷⁷ *IFES* (Hrsg.) Studie: Suchtmittel und Drogenpolitik, Bevölkerungsbefragung Wien Februar 2001, 10.

¹⁷⁸ *Bertel*, in: *Strafbegehren* 16 f, *Killias/Rabasa*, Auswirkungen der Heroinverschreibungen auf die Delinquenz Drogenabhängiger, *Monatsschrift für Kriminologie und Strafrechtsreform* 1998, 1; *Köck*, Entwicklung und Stand des Drogenstrafrechts in Österreich, *ÖJZ* 1998, 94 (102 f).

¹⁷⁹ Compare the positive results of the Swiss experiments, *Köck*, *ÖJZ* 1998 103, interview with *Gutzwiller*, Head of the Institute of Social and Preventive Medicine, University of Zürich, in: *Der Spiegel* 48/1996, 240, as well as 238 f.

¹⁸⁰ Interview with *Gutzwiller*, in: *Der Spiegel* 48/1996, 240.

¹⁸¹ Institut für Suchtgifforschung der Leopold-Franzens-Universität am KH Maria Eberle/Amt der Vorarlberger Landesregierung (Hrsg), *Vorarlberger Drogenbericht* 2000, 17 ff.

¹⁸² Interview with Dr. *Alexander Backer*, specialist in neurology and psychiatry (www.infoline.at/drogen/vorarlberg.htm).

them male. About 50% of the patients were employed.¹⁸³ During the course of the year, 114 of the 387 clients ended the treatment, but only 10% completed it successfully. Of these 114, 49% started inpatient treatment, 23% gave up, 9% were expelled from the programme and 5% were arrested. However, substitution treatment is still considered a success, as crime, HIV infection and prostitution have decreased and some clients have been socially reintegrated.

6.2. Vienna

In Vienna, the number of people undergoing substitution treatment has reached an all time high. In 1999, approximately 2 700 patients were participating in substitution programmes. This means that more than twice as many drug addicts undergo this kind of treatment in Vienna than in all the other Austrian states put together.

About 70 % of these patients are treated with methadone and the remainder receive other substitutes.

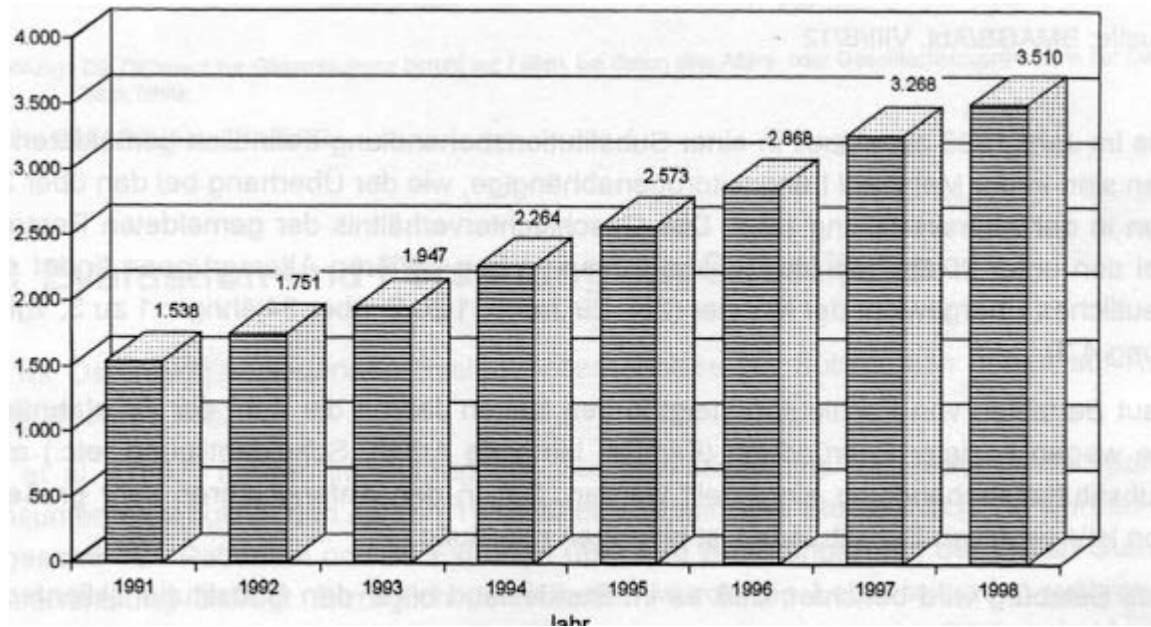
More than half the patients enrolled in substitution treatment programmes are treated by medical practitioners. About two-thirds of all patients are in touch with a drug counselling facility or are in receipt of psychosocial care.¹⁸⁴

¹⁸³ Interview with Dr. *Alexander Backer*.

¹⁸⁴ Wiener Drogenhilfe (Hrsg), Leistungsbilanz der Wiener Drogenarbeit 1999, 2000, 3f.

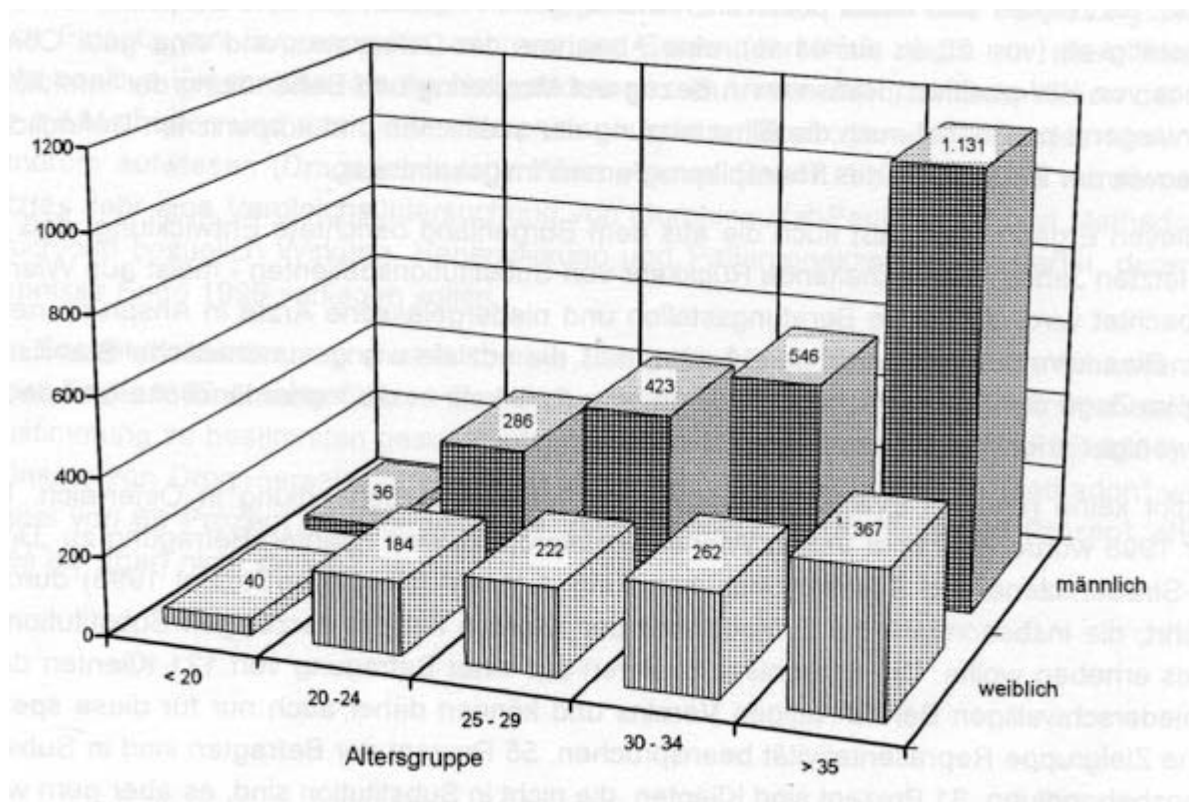
7. Figures¹⁸⁵ and tables

7.1. Participants in substitution treatment programmes per year



The left-hand column indicates the number of patients.

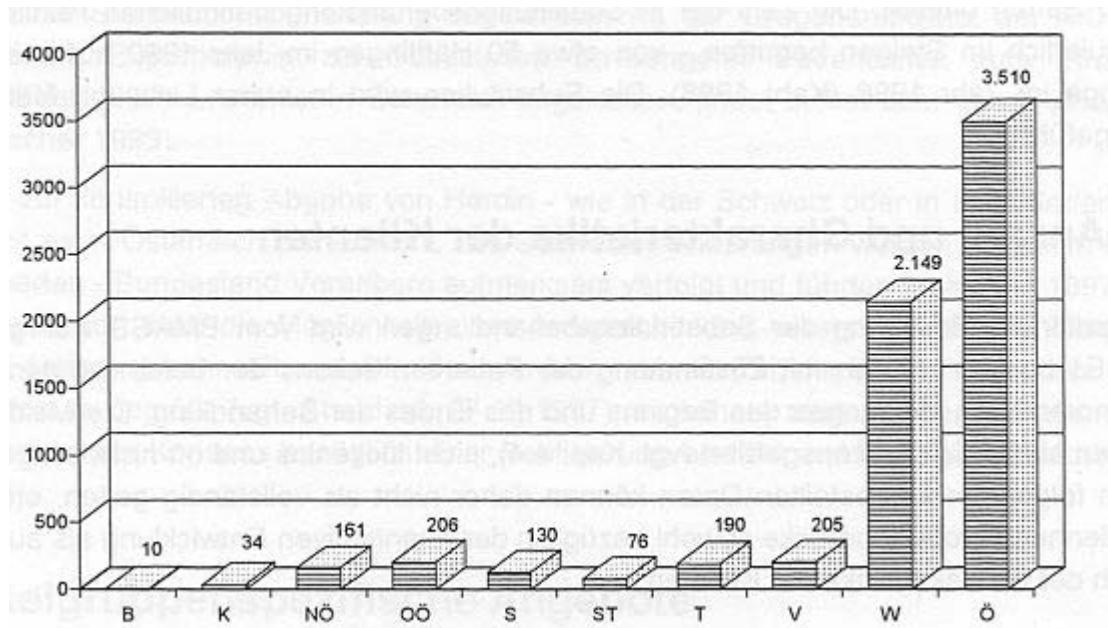
7.2. Substitution patients categorised by age and gender (1998)



The left-hand column indicates the number of patients; 'weiblich' = female; 'männlich' = male.

¹⁸⁵ Figures 1–3: Bericht zur Drogensituation 1999; Graphic 4: Vorarlberger Drogenbericht 2000, 18.

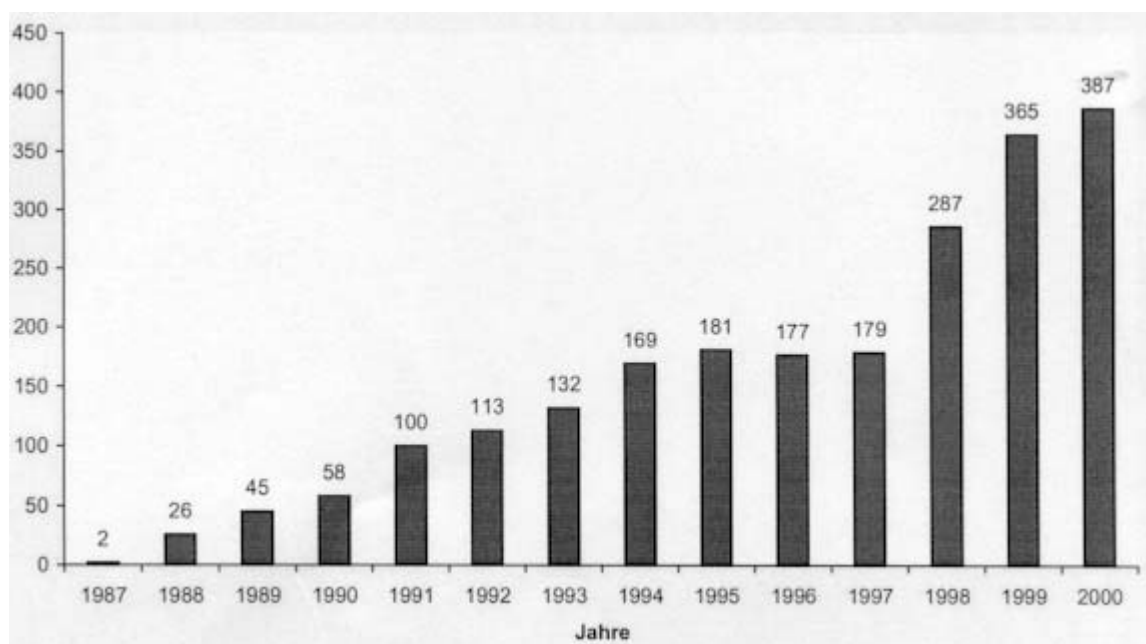
7.3. Participants in substitution treatment programmes in Austria, categorised by state (1998)



The left-hand column indicates the number of patients.

The Austrian states are represented at the bottom of the graph (B: Burgenland, K: Kärnten/Corinthia, NÖ: Niederösterreich/Lower Austria, OÖ: Oberösterreich/Upper Austria, S: Salzburg, St: Steiermark/Styria, T: Tirol/Tyrol, V: Vorarlberg, W: Wien/Vienna, Ö: all of Austria).

7.4. Development of substitution treatment programmes in Vorarlberg between 1990 and 2000



The left-hand column indicates the number of patients.

7.5. Development of substitution treatment programmes in Vienna and the rest of Austria¹⁸⁶

Year	Patients in Vienna	Patients in the rest of Austria
1991	887	492
1993	1 150	657
1996	1 698	842
1997	2 079	921
1998	2 121	961
1999	2 653	about 1 000

¹⁸⁶ Wiener Drogenhilfe (Hrsg), Leistungsbilanz der Wiener Drogenarbeit 1999, 2000, 3.

Finland

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1. Introduction

Use of opioids and treatment of opioid addiction in Finland – the historical background

Before the Second World War, morphine was the most frequently used intoxicant in Finland (Hakkarainen, 1992, 51–61). This phenomenon has been described as upper-class morphinism. In many cases, the users were healthcare professionals such as doctors and nurses. Another user group consisted of artists and still another consisted of persons from wealthy circles. Although there were also working-class morphine users, the average level of education of users was high. Morphine addicts were treated in mental hospitals.

The use of heroin for medicinal purposes was already very common in Finland before the war. However, it was not until after the war that heroin replaced morphine as an intoxicant. At the same time, the user profile changed. Although healthcare professionals, the upper middle classes and artists were still typical users, working-class people now formed the greatest user group. As the sale of heroin in pharmacies became now more strictly controlled, morphine regained its dominant position. Methadone became available in the early 1950s, and many of those who had previously used morphine and heroin began to use this new drug. In addition to opioid use, amphetamines have also been used in Finland. In the 1950s, however, amphetamines were not classified in the same group of intoxicants as opioids.

It has been estimated that the main way of acquiring drugs up to the 1960s was by doctor's prescription, and smuggling did not occur to any great extent. In the early 1960s, the welfare authority records no longer contained any information on heroin or morphine use. It was methadone only that was used, and the users often came from socially disadvantaged groups.

In the mid-1960s, the culture of drug use changed in Finland as the first 'drug wave' hit the country. Cannabis became the most frequently used drug. In 1973, a group of opioid addicts began receiving methadone treatment in the Hesperia Hospital in Helsinki. In 1993, there were only three patients that received this kind of treatment (Memorandum of Working Group on Medicinal Treatment of Opioid Addicts, 1993, 1). In the years between 1974 and 1996 the number of patients in methadone substitution treatment never exceeded 15. Low doses of methadone were used, and the treatment did not include rehabilitation targets or urine test controls (Granström, 1999, 58–59).

Worsening of the drug situation and increased use of opioids in the 1990s

The drug situation got significantly worse after the mid-1990s. This development, referred to as the 'second drug wave' in Finland, has been reflected in several studies, such as population surveys, conscript surveys and school health studies.

Information from other sources, such as the police, customs and crime, court and prison statistics, paints the same kind of picture of the situation.

By combining data from different official registers, it has been estimated that, in 1999, there were between 11 000 and 14 000 users of hard drugs among Finns aged between 15 and 55 (Finland had a population of about 5.2 million in 2001) (Partanen et al., 2001). Of these, 20–30% used opioids. Since 1997, no major changes have occurred in these estimates. There was just a small increase in the estimated number of opioid users.

Worsening of the drug situation is reflected in the care system

The worsening of the drug situation can be seen in the social welfare and healthcare services. Hospital data related to drug diseases show that these have been on the increase throughout the 1990s. In 1999, there were 8 213 hospital cases involving a drug-related disease as the primary or secondary diagnosis (Intoxicant Statistical Yearbook 2000, 106–107).

Substance abuse cases in the social welfare and healthcare services were monitored for a period of 24 hours in Finland on 10 October 1999 (Nuorvala et al., 2000). A total of 11 535 cases were counted during the 24-hour period. Of these, 15% were related to illicit drugs, while the corresponding figure in a similar count conducted in 1995 was 11%. Opioid use had also increased from 2% in 1995 to 5% in 1999.

Each year, a Pompidou data collection on drug treatment is carried out in Finland. In 2000, data were obtained from 113 units providing treatment. Among these were 99 substance-abuse services, 12 units specialising in drug treatment and 2 prisons. In all, data were obtained on 5 685 clients (Partanen, 2001). Among these clients, the intoxicants for which treatment was mostly sought were opioids (29%) and amphetamine (28%). In 2000, a total of 3 200 intravenous drug users attended the health counselling centres in Helsinki (Operation Report 2000, 9).

Changes in Finnish drug policies and increased supply of substitution treatment for opioid addicts in the late 1990s

In 1996, a drug policy committee was set up to assess the drug situation and to create a national drug strategy. When the committee issued its report in 1997 (Committee Report 1997: 10), its most important suggestions were that the drug treatment system should be further developed, in addition to control measures, that the spread of infectious diseases should be prevented and that low-threshold services should be increased and access to medicinal substitution treatment improved. In Finland, the use of drugs is a criminal offence, and the committee did not propose any changes to this situation.

The Council of State Decision-in-Principle on Drug Policy, adopted in 1998, emphasised that detoxification and substitution treatment should be provided for opioid addicts according to the prevailing needs (Council of State Decision-in-Principle, 1998). In 2001, a working group set up by the Ministry of Social Affairs and Health to assess the treatment given to drug users stated that it was imperative that the supply of medicinal treatment for opioid addicts be increased in order to meet the

demand. The working group also suggested that private doctors be used in a controlled manner in the provision of care to complement the public healthcare services (Working Group Memorandum, Ministry of Social Affairs and Health 2001: 8).

Attitudes to drug policies appear to have changed quite dramatically in Finland. Previously, attitudes towards harm-reduction measures such as low-threshold treatment units, syringe exchange programmes and medicinal substitution treatment for opioid addicts were very negative. More recently, however, several major municipalities have established, or at least plan to establish, health counselling centres, where clean injection equipment, for instance, is available. At the same time, the supply of medicinal detoxification, substitution and maintenance treatment has increased and this development is likely to continue.

At least two factors that are related to the worsening of the drug situation have contributed to this change of attitude. Among intravenous drug users, a rapid increase in the incidence of communicable diseases has been observed. Hepatitis infection is common. In 1996, a total of 69 HIV infections were reported. Of these, only 1% were related to intravenous drug use. In 1999, a total of 142 HIV-positive cases were reported, of which drug users already accounted for 57%. The high costs of treating HIV-positive patients have often featured in public debate. Furthermore, there was an increase in the number of drug-related deaths in the 1990s. In 1989, there were 24 drug-related deaths, of which 19 involved the use of opiates. In 1999, the corresponding figure was 113, of which 57 involved opiates (Intoxicant Statistical Yearbook 2000, 103, 115).

The fact that the public authorities now play a more active role in issues related to substitution treatment for opioid addicts may partly be due to one specific case where a doctor working in the private sector started to treat opioid addicts with buprenorphine in the 1990s. The doctor was first denied the right to write prescriptions for CNS medication by the National Authority for Medicolegal Affairs. He was subsequently also denied the right to practise medicine by the same authority. The media has actively followed these developments and the related legal proceedings. Another important player has been an association for the support of opiate addicts (Opiattiriippuvaisten tuki ry), whose members consist of family members and close friends of people who abuse opiates. The association advocates easier access to, and increased availability of, medicinal treatment.

At present, there are about 200 patients in substitution treatment in Finland, of which a little more than 100 are treated with methadone and a little less than 100 with buprenorphine.

2. Regulations concerning medicinal treatment of opioid addicts

General regulations

The Act on Welfare for Alcoholics and Drug Addicts (41/86) confers the responsibility for welfare services for substance users to the municipal authorities, who are obliged to ensure that such services are provided and that their content and scope meet the prevailing need. Both welfare and healthcare authorities are responsible for the

development and provision of these services. The services consist of general services (such as social service offices and health centres) and specialised services for substance abusers, including A-clinics and rehabilitation centres. The act does not distinguish between drugs and other narcotic substances. It defines narcotics substances to include alcohol and other substances used for the purpose of becoming intoxicated.

Provision of treatment is also regulated by the Act on the Status and Rights of Patients (785/1992).

The Narcotics Act (1289/93) stipulates that the use of drugs is prohibited for purposes other than medical or scientific, or those furthering prevention or investigation of narcotics offences. Substitution medicines used in the treatment of opioid addicts are regarded as drugs.

The Act on Health Care Professionals (559/1994) and the Act on Specialised Medical Care (1062/98) give the Ministry of Social Affairs and Health the right to issue any necessary guidelines and provisions.

Orders on the treatment of opiate addicts with medicines, issued by the Ministry of Social Affairs and Health in 1997 and 1998

On 8 July 1997, the Ministry of Social Affairs and Health issued an order on the detoxification and substitution treatment of opioid addicts with medicines (Orders of the Ministry of Social Affairs and Health 1997:28). Referring to the Act on Specialised Medical Care, the order defines such treatments as expert-level medical care in cases where buprenorphine, methadone or levacetylmethadol is used. The use of heroin for treatment is not permitted in Finland.

The stated aim of treatment was, in all cases, *withdrawal* from opioid addiction. All treatment required a treatment plan, made by different cooperating professionals and specifying other medical and psychosocial care received by the patient along with medical treatment.

Initiation of detoxification treatment was centralised in university hospitals and one unit within the psychiatric hospitals of the City of Helsinki. However, treatment could continue in cooperation with another qualified unit specified by the unit that initiated the treatment: a unit providing specialised medical care, a health centre, an institutional substance-abuse service unit, an outpatient care unit, or an inpatient or outpatient unit within prison administration.

Detoxification treatment referred to treatment periods of, at most, three months.

Substitution treatment could be started if previous detoxification treatment with approved care practices and procedures for curing the patient's opioid addiction had not been successful. Assessment of care requirements and initiation of substitution treatment were assigned to the Detoxification Unit in the Helsinki University Central Hospital and in the Psychiatric Department of the Oulu University Central Hospital. Treatment could also be continued in the Outpatient Substance-Abuse Service Unit

of the Helsinki University Central Hospital and other units that qualified for the continuation of detoxification treatment.

Units providing detoxification and substitution treatment were obliged to have a specially assigned physician who was responsible for these activities. Medicines could only be prescribed by this physician or another physician who had been authorised to do this by the assigned physician. Medicines were to be administered to the patient under controlled conditions in the care unit, and they could not be obtained by prescription from a pharmacy.

On 2 November 1998, the Ministry of Social Affairs and Health issued new provisions on the treatment of opioid addicts (Orders of the Ministry of Social Affairs and Health 1998:42). This order no longer states that the aim should always be opioid detoxification.

In addition to the units mentioned above, the Järvenpää Addiction Hospital was authorised to initiate detoxification treatment. Also, the treatment could now be continued beyond three months for up to one year. The decision on continuing treatment was to be made on the basis of a consultation with the patient or a written consultation obtained from the unit that had initiated the treatment.

In addition to the two earlier hospitals, substitution treatment could now also be initiated in the Psychiatric Department of the Kuopio University Central Hospital. Treatment could also be continued in university hospitals.

The order recommended that the detoxification units should monitor waiting times for treatment and that the substitution treatment units should monitor waiting times for assessment of care needs. Furthermore, it was emphasised that the unit that had initiated the treatment and the unit that was responsible for continuing treatment should cooperate on following up the treatment.

Decree on the medical treatment of opioid addicts in 2000 – the present situation

The decree on treatment of opioid addicts (607/2000) that is now in force was issued by the Ministry of Social Affairs and Health on 21 June 2000. It aims at facilitating access to medical treatment for heroin addicts.

The application of the decree

The decree applies to *detoxification*, *substitution* and *maintenance* treatment of opioid addicts with medicines containing buprenorphine, methadone or levacetylmethadol. It does not apply to the supportive medical treatment of somatically ill opioid addicts if the aim is to prevent withdrawal symptoms that would impair the patient's clinical status and complicate his/her treatment.

Detoxification treatment

Detoxification treatment is defined as care in which the care period does not exceed one month and which aims at a drug-free lifestyle, using buprenorphine or methadone but not levacetylmethadol.

Substitution treatment

Substitution treatment is defined as medical care in which the care period exceeds one month and which aims at a drug-free lifestyle. Levacetylmethadol may be used. Substitution treatment can only be started if previous treatment with approved care practices and procedures for curing the patient's opioid addiction have not been successful.

Maintenance treatment

Maintenance treatment is defined as the rehabilitative care of opioid addicts where the care period exceeds one month and where the medicine used is buprenorphine, methadone or levacetylmethadol. It has harm reduction and improvement of the patient's quality of life as its main goals. Maintenance treatment can only be initiated in patients with a specific need for the reduction of harm caused by opioid use. In the case of these patients, it is not likely that the drug use can be terminated. Maintenance treatment aims at preventing the spread of communicable diseases and other health hazards and at improving the patient's quality of life. It also aims at preparing the patient for more ambitious rehabilitative substitution treatment.

Criteria for access to treatment and choice of medication

A precondition for treatment is that the patient has been diagnosed as having an opioid addiction, defined in accordance with the ICD-10 Classification of Diseases F11.2x. Substitution treatment can be initiated provided previous treatment with approved care practices and procedures for curing the patient's opioid addiction have not been successful. Maintenance treatment can only be initiated if reducing the harm caused by opioid use is of particular importance to the patient.

Buprenorphine and methadone can be used in detoxification, substitution and maintenance treatment. There are no guidelines for the choice of medication. It is also possible to use levacetylmethadol for substitution and maintenance treatment. This medicine, however, has not been used or been commercially available in Finland. On 19 April 2001, the National Agency for Medicines reported that the sale of Orlaam had been banned in the EU. The use of heroin for treatment is prohibited in Finland.

Commencement of treatment

Detoxification, substitution and maintenance treatment all require expert medical care, as defined in the Act on Specialised Medical Care. The initiation of all three treatment methods is assigned to the university hospitals, other central hospitals and the Järvenpää Addiction Hospital. Each hospital district can also assign the task to another hospital of a similar level in place of the central hospital.

Continuation of treatment

In liaison with the unit that initiated the treatment, the treatment can be continued at another unit that qualifies for the task according to the information available to the unit that initiated the treatment: an operating unit of a municipal federation within the hospital district, a health centre, an institutional substance-abuse service unit, an outpatient care unit, or an inpatient or outpatient unit that comes under the prison administration. The unit at which the treatment is continued must have a specially assigned physician responsible for the treatment. The unit notifies the unit that initiated the treatment and the National Authority of Medicolegal Affairs of the

assigned physician. As substitution and maintenance treatment are long-term processes, the relevant services should be provided as close to the patient's place of residence as possible.

Treatment plan

Treatment should be based on a treatment plan that specifies other required medical and psychosocial care and follow-up received by the patient along with medical treatment.

The right to prescribe medication and control of the use of medication

Medication for the purposes of treatment can only be prescribed by a physician at the initiating unit and the unit that is continuing the treatment, or another physician especially authorised to do this by that physician. In Finland, private-sector physicians do not have the right to prescribe methadone, buprenorphine or LAAM for detoxification, substitution or maintenance treatment of opioid addicts.

Guidelines for the administration of medication

Medicinal treatment can only be implemented and medicines administered to the patient under controlled conditions in the care unit. If a patient has been cooperative, under special circumstances he or she may be provided with more than one (but no more than seven) daily doses at a time. Medicines used in detoxification, substitution and maintenance treatment cannot be obtained on prescription from a pharmacy.

Obligation to give information and to monitor activities

Units that have been assigned the task of initiating detoxification, substitution and maintenance treatment are obliged to provide the Ministry of Social Affairs and Health with any information it requests on the implementation and provision of treatment. The units that initiate treatment must also monitor waiting times for treatment and evaluate the implementation of the treatment in liaison with the units that continue the treatment. With the patient's consent, information on the treatment given can be made available to the care units participating in the treatment.

Offences committed by the patient and related sanctions

There are no national guidelines or recommendations on follow-up of the patient's heroin use or other substance use, on substance use or on other offences in connection with the treatment.

Substitution treatment as an alternative to punishment

In Finland, substitution treatment cannot be used as an alternative to punishment. Recently, however, a variety of treatment programmes have been developed for prisoners with drug problems. Prisoners can participate in the programmes during their term of imprisonment.

3. Substitution treatment practices

At present, three different care practices are used in Finland in the medical treatment of opioid addicts: detoxification, substitution and maintenance treatment. Either methadone or buprenorphine is used in the treatment, whereas levacetylmethadol is not used. These treatments differ from each other mainly in terms of their duration and aims. As to the content of the treatment, however, the differences and

boundaries are not so clear-cut. So far, maintenance treatment has not been implemented except for in a few special cases. The only care unit that offers maintenance treatment began operating in Helsinki this year. A total of 12 HIV-positive patients addicted to opioids receive methadone treatment in the unit. In practice, however, the methadone substitution treatment received is, in most cases, closer to permanent maintenance treatment than to substitution treatment aimed at opioid withdrawal as defined in the decree.

Implementation of substitution treatment

The substitution treatment process can be divided into five different stages. The drug user who seeks substitution treatment first needs to get a *referral* for assessment of need of care. The referral can be obtained from a social welfare, health care or substance-abuse service unit and it has to be written by a physician. According to the decree (607/2000), the *assessment* of the need for substitution treatment is then to be conducted at a university hospital, another central hospital or corresponding hospital or in the Järvenpää Addiction Hospital. After assessment, the *initiation* of substitution treatment involves a period of inpatient care, the duration of which varies from a few days to a few weeks. If required, a separate detoxification period in a psychiatric ward or a rehabilitative institutional substance-abuse service unit may precede the initiation of substitution treatment or form part of it. The Järvenpää Addiction Hospital has the only specialised rehabilitation department for substitution treatment (buprenorphine) in Finland.

The fourth stage of the treatment process consists of *outpatient care*. Substitution treatment continues in outpatient units in liaison with the unit that conducted the assessment and the unit that initiated the treatment. Outpatient substitution treatment is provided by the outpatient departments of university hospitals, A-clinics, special outpatient units offering medical detoxification or substitution treatment for opioid addicts or municipal health centres. In special cases, substitution treatment can also be implemented in two prisons. According to the information available to the Järvenpää Addiction Hospital, a total of 35 units provided substitution treatment in June 2001 (Table 1). In autumn 2001, a new outpatient care unit for substitution treatment (buprenorphine) will be opened in Helsinki and a new department for the assessment of care needs and the initiation of treatment will be opened in the Järvenpää Addiction Hospital (buprenorphine). The intention is to start substitution treatment (methadone) in two municipal A-clinics in Helsinki and in one other substance-abuse service unit towards the end of the year. While there were only a few detoxification and substitution treatment units at the end of 1998, the number of units has increased rapidly during the last three years (Granström 1999; Holopainen 2000).

Table 1: Care units providing substitution treatment in Finland (6/2001)

Type of unit	Number
Hospital	12
Health centre	7
A-clinic	11
Special outpatient unit	3
Prison	2
Total	35

Finally, the decree on substitution treatment defines the objective of withdrawal, from both drugs and substitution medication. In practice, however, this objective is not attained in many cases, especially not in a short period of time. In the greater Helsinki area, waiting times for assessment of care needs and initiation of treatment have increased, as neither A-clinics nor health centres have not been allowed to implement the treatment as desired. The need for substitution treatment has also increased since a private physician was denied the right to practise medicine, and his patients now need care. This situation is partly due to attitudes (clients addicted to opioids are not desirable) or ideological factors (medical substitution treatment is not regarded as an appropriate treatment method), and partly to the fact that programmes for medical treatment, particularly other care programmes supporting such treatment (psychosocial rehabilitation), are only just being developed and tested. There is no clear overall picture of substitution treatment as a whole, the different treatment methods and the objectives and duration of care.

Outpatient care in substitution treatment

Substitution medication is administered to the client, under the supervision of the care personnel, usually once a day. Methadone is given in liquid form mixed with juice, and buprenorphine in the form of tablets that dissolve in the mouth. As to buprenorphine, the patient's mouth is checked after administration to ensure that the medicine has been absorbed. The administration of medication usually takes place before noon, while the afternoon is reserved for consultation with the assigned nurse, group discussions and other activities. To promote psychosocial rehabilitation, other care units, authorities and projects that promote labour market integration, etc., are encouraged to cooperate. During weekends, administration of medication is usually the only activity. The substitution treatment is mainly implemented by nurses who work under the supervision of the assigned physician. The staff may also include a social worker, occupational therapist, psychologist, etc., on a full-time or part-time basis.

The use of drugs is also monitored and tested as part of the substitution treatment. Urine tests are taken regularly, usually at least once a week. In addition, signs of injection are monitored, occasionally or as agreed. At the beginning of treatment, positive test results are frequent. Such results are followed by more detailed discussion about the use of other drugs, the possibility of reducing such use and the aims of the substitution treatment. If necessary, special discussions on the treatment to be provided or periods of 'intensified care' in other detoxification or rehabilitation units are arranged. Repeated use of other drugs may also lead to interruption of the treatment. According to the care personnel, however, the most common reason for interruption of treatment is that the patient fails to adapt to the treatment: there is no proper cooperation and the relationship between the patient and the care personnel breaks down; the patient misses appointments at the care unit; drug trafficking takes place in the premises of the care unit; or there is violence or a threat of it. Drug use by the substitution patients is tackled with understanding and persistence, even though the establishment and maintenance of care practices requires daily struggles with problems arising from the culture of drug use. Interruption of the treatment does not prevent the patient from seeking again treatment, but the entire process has to be started from the very beginning.

Adherence to substitution treatment

Experience so far indicates that clients have adhered fairly well to substitution treatment with both methadone and buprenorphine. During the year after the new decree, in particular, when the obligation to complete detoxification within a specified period of time was omitted, treatment has been discontinued in only 10–30% of all cases. Before the new decree came into force, a follow-up study of all patients that had received medical detoxification treatment with buprenorphine between 1 January 1998 and 30 June 2000 was conducted in the Järvenpää Addiction Hospital and an outpatient detoxification unit in Helsinki. During this period, there were 95 patients in the Järvenpää Addiction Hospital and 76 in the outpatient detoxification unit.

A total of 76% of patients that had started the period of inpatient care proceeded to the next care unit, and a total of 58% were still receiving some kind of treatment one year after the period of inpatient care. Of the outpatients, 60% received treatment in the detoxification unit for six months or more, 90% were referred to another care unit for continued treatment after the detoxification treatment and 70% were still receiving some treatment after one year. During the one-year observation period, a quarter of the inpatients had succeeded in withdrawing from buprenorphine, the corresponding figure for outpatients being as low as five per cent. Of all patients, only five per cent started to use heroin. Although the use of other drugs was frequent, it was less frequent than before starting the treatment (Baas & Seppänen-Leiman 2001).

After the new decree came into force, between 1 July 2000 and 30 April 2001 a total of 35 patients were admitted to the department of rehabilitative substitution treatment (buprenorphine) in the Järvenpää Addiction Hospital. Of these, the treatment of 10 patients was interrupted and 25 continued in outpatient care after having received inpatient treatment. According to data compiled in the department, 22 of them are still receiving substitution treatment with buprenorphine: the social rehabilitation of 15 patients has advanced markedly and 10 patients have quit using other drugs. One patient now receives methadone treatment, one has died and one has ceased to take substitution medication and is now in community care without medication (Baas 2001b).

Legal problems

Care professionals do not mention any legal problems regarding their work. The decree on substitution treatment and the care practices based on it are mostly regarded as appropriate. There has been some debate on the interpretation of the decree with regard to the new buprenorphine treatment units. It is felt by some that the decree has been interpreted unnecessarily strictly because of traditional approaches to substance abuse services and the relatively critical attitude towards people with drug problems. To a certain extent, the decree in its present form allows substitution treatment to be realised in a more flexible and less controlled way. In some cases, in fact, this has led to the administration of buprenorphine in larger daily doses and to the delivery of medication less frequently than once a day. Attempts have been made to identify less 'rigorous' care practices for patients who have reached an advanced stage of treatment and can manage quite independently. Care professionals nevertheless regard it as advantageous that the implementation of

substitution treatment takes place in a relatively controlled, clearly directed manner and that there are specific care units assigned for the purpose.

On the other hand, patients in substitution treatment may feel that the way in which the treatment is administered involves a too strong element of control. They may feel that the daily delivery of medication is inconvenient and complicates life, especially if they are working or studying. Others may feel that the daily dose of medication is insufficient and might like to be able to take another dose home with them in the evening. Repeated checking of the mouth and looking for injection marks and collecting urine specimens may seem unpleasant and unnecessary and even violate the rights of the patient to privacy. Moreover, some people may regard it as stigmatising that they end up as clients in the public health services.

The ombudsman for drug-related issues and the association for the support of opiate addicts (Opiatiriippuvaisten tuki ry) have criticised the fact that it is difficult to access substitution treatment and it takes a long time to get such treatment, because it only is available in the public sector. They maintain that private-sector physicians should have at least a limited right to prescribe medication for substitution treatment (Viljakainen 2001). As early as 1999, the ombudsman and the chairman of the association presented a petition to the parliamentary ombudsman expressing their concerns over delays in getting substitution treatment and the potential failure of local authorities in the Helsinki metropolitan area to meet the obligation to provide adequate care services as defined in the Act on Welfare for Alcoholics and Drug Addicts. Even though a person with drug problems is not considered to have a subjective right to medical substitution treatment, the above criticisms have contributed to the creation of new care places and to revision of the decree on substitution treatment.

General attitudes towards substitution treatment and towards the units providing it

In Finland, substitution treatment has been officially accepted, through political decision-making and decisions made by competent authorities, as one method of treating people who are addicted to opioids. In spite of this, there is no general consensus about substitution treatment policies. The treatment of opioid addicts with narcotics-like medication is still a source of controversy. Behind it is the ideal of care provision based on avoidance of medication and aimed at a drug-free lifestyle. The question is whether medical substitution treatment can be regarded as a desirable method of treatment for drug addicts, whether it produces adequate care results, whether the positive effects of increased substitution treatment are adequate in relation to the disadvantages or risks and whether appropriate psychosocial support can be provided to complement medical treatment. On the one hand there are those who advocate compulsory treatment for drug addiction (at least as far as minors are concerned), whereas, on the other hand, there are those who favour various low-threshold services, treatment aimed at harm reduction and other forms of treatment, all on a voluntary basis.

There are still fearful and prejudiced attitudes towards both drug users and substance-abuse service units. Even some units in the social and health services have been reluctant to admit anyone with a difficult opioid addiction. It has often been

difficult to find a location for substitution treatment outpatient units or health counselling centres, as nobody wants to have them close to their home or workplace. In the summer of 2001, there were many newspaper articles about the problem of used syringes found near substance-abuse care units and the related risk of contamination for children and outdoor maintenance staff, in particular. Workers in the drug care services have their work cut out combatting the fears and accusations that result from lack of information and prejudice.

4. Views on substitution treatment policies

Medical substitution treatment has been officially accepted and is regarded as appropriate and necessary. Recent reports and expert opinions have emphasised the following aspects:

- the content of substitution treatment programmes should be developed and extended;
- the number of units that assess the need for care and initiate treatment should be increased;
- detoxification, substitution and maintenance treatment should be defined and distinguished from each other more clearly;
- it should be possible to implement substitution treatment in health centres and substance-abuse service units;
- the number of low-threshold and harm-reduction treatment units should be increased; and
- methods and actions for psychosocial rehabilitation should be developed to complement medical treatment.

The increased numbers of opioid addicts and their special needs have not been adequately reflected in the supply of substance-abuse services. Nor have opioid addicts been systematically taken into account in care provision. Substitution treatment has been described as the first step towards rehabilitation, as a transition from 'self-medication' in the street to controlled medical treatment. There are many who think that it will not be possible to rehabilitate opioid addicts without medical treatment. It is hoped that substitution treatment will result in long-term care and, finally, to withdrawal from substitute medication and other drugs in as many cases as possible. Substitution treatment – and other treatment aimed at harm reduction – is believed to reduce the health risks resulting from intravenous drug use and to reduce drug-related deaths, criminal behaviour and other social harm. It is regarded as a safer, more humane and ethically preferable alternative to unrestrained drug use without any interventions or treatment. Substitution treatment is also believed to result in economic savings, through the reduction of health hazards and social harm (see, for example, Holopainen 2001a+b; Salaspuro 2001a+b). During the first few years of operation, the health counselling centres have been shown to have an impact on the prevention of hepatitis C infection, and there have been positive results in the adherence of opioid addicts to substitution treatment practices (Baas & Seppänen-Leiman 2001; Baas 2001; Helsingin Vinkin vuosikertomus 2000).

Criticisms of substitution treatment

Substitution treatment has also been criticised. It has been stated, firstly, that the positive effects claimed by proponents of substitution treatment are by no means self-evident and, secondly, that the possible negative effects or risks of substitution treatment have not, so far, been adequately assessed (e.g., Mäkelä & Poikolainen 2001). The following questions, among others, have been posed:

- Does the treatment of drug addicts with addictive narcotic medication lead to addiction to the medicine? Can buprenorphine be used as a medication for drug users who are already addicted to buprenorphine?
- Is medical substitution treatment offered too readily and too early without first offering other forms of treatment (particularly in the case of young people with a short drug-use career)?
- Can adequate psychosocial rehabilitation be provided to complement medical treatment?
- To what extent are medicines used in substitution treatment (buprenorphine in particular) sold on the streets and used intravenously? Is there any risk of Subutex becoming the first hard drug for some young people experimenting with or habitually using drugs, paving the way for abuse of heroin?
- Is it possible to sufficiently control the use of other intoxicants when substitution treatment is given? How and where will the line be drawn for the use of other drugs when determining adherence to treatment? Will new forms of polydrug use come into being?
- Are some of the models developed and observations made in other countries suitable for use in Finland? Are the special characteristics of Finnish drug users, the Finnish healthcare system and Finnish society in general sufficiently taken into account? Experiences in Finland have been gained over a short period of time and there is hardly any research data available.
- Are the data available on the medication used in substitution treatment adequate and are there resources available for increasing substitution treatment as planned?
- Will less strict criteria be applied over time with respect to access to treatment? Will mere medical treatment followed by maintenance treatment become increasingly common? Does all this eventually lead to heroin treatment?

Concerns related to the development of substitution treatment

One area of concern is linked to the issue of the medicalisation of social problems (e.g., Murto, 2001). Many think that substitution treatment puts too much emphasis on the medical approach in addressing drug problems. For instance, with the exception of one lawyer, an expert group that was set up by the Ministry of Social Affairs and Health to submit proposals for measures to increase substitution treatment and make it more easily available only consists of medical representatives. This may give the impression that only medical substitution treatment can help drug addicts, even though drug addiction is not just a medical problem (to be solved with medication). To a large extent, it is also a societal problem (linked to the structures of

society and social problems) and a political one (focusing on various drug treatment policies). In most cases, people with drug problems who seek treatment come from socially disadvantaged groups, are excluded in various ways and use several different drugs (Baas & Seppänen-Leiman, 2001; Hakkarainen et al., 2000, Nuorvala & Metso, 2001). The worry is that substitution treatment is currently given to drug addicts despite the fact that the appropriateness of such treatment is not yet known, that there is inadequate psychosocial support and there is no overall strategy on drug treatment.

Another area of concern is to be found within the field of medicine: how to distinguish between the various types of substitution medication that can be used. In the Helsinki and Turku metropolitan areas, the dominant medication is methadone, whereas buprenorphine is mostly used in the Järvenpää Addiction Hospital and elsewhere in Finland. Differences in treatment practices largely depend on the preferences of individual physicians. Recently, the pharmacological differences between methadone and buprenorphine have been assessed based on international research. The low toxicity and low peak effect of buprenorphine has been highlighted, as the risk of deaths due to overdose thereby remains low. In addition, the long half-life of buprenorphine reduces the prevalence of withdrawal symptoms. Some studies also suggest that the addiction potential of buprenorphine is lower than that of methadone and that it has a broader applicability in treatment than methadone (Salaspuro, 2001a). The main advantages of methadone are that it has been in use for longer, it is misused for intoxication to a lesser extent, concurrent use of other drugs is less frequent during treatment and patients show a high adherence to substitution treatment when treated with it (Granström, 1999, 2001).

In Finnish legislation, both methadone and buprenorphine are regarded as narcotic substances, although in different categories: methadone is included in List I of the 1961 Convention on Narcotic Drugs and buprenorphine has been on List III of the Convention on Psychotropic Substances since 1989. Some people feel that the pharmacological differences between the two drugs should be better taken into account and that buprenorphine should be defined less strictly as a non-narcotic substance as distinct from methadone (Viljakainen, 2001).

A third concern, shared by many citizens, is that substitution treatment will receive too much attention at the expense of alternative methods of treatment without medication or at the expense of other alcohol or drug addicts in need of care. Therefore, substitution treatment should be expanded in a controlled manner, without sacrificing the development of treatment for people with other drug-related problems.

In particular, attention is often drawn to the problems caused by the use of amphetamines and the use of several intoxicants, as these types of problems are common in Finland. Research shows that most patients in detoxification and substitution treatment are polydrug users who use a variety of intoxicants and medicines. It is regarded as a risk that, in the absence of specific treatment programmes for amphetamine users and polydrug users, not only opioid addicts but also other drugs addicts may seek substitution treatment. Concern has also been expressed that the unlawful sale of buprenorphine (Subutex) and related use may increase. According to an estimation made by the care units, most patients seeking substitution treatment already use buprenorphine (Baas & Seppänen-Leiman, 2001;

Suojasalmi, 2000). A study by Ari Baas and Tuula Seppänen-Leiman (2001) indicates that, out of 181 patients that received medical detoxification treatment in inpatient or outpatient care units, two-thirds had used Subutex and one-third heroin as the primary opioid. There have also been a few reports that suggest that Subutex may constitute the first hard drug for some young people and that this can subsequently lead to opioid addiction.

The core question among all these concerns is: which is the most urgent and important? Those who favour increasing substitution treatment feel that the most important thing is to ensure that as many opioid users as possible can receive treatment as rapidly as possible, that health hazards and other harmful effects can be reduced and that public spending can be limited. In addition, they think that the process of seeking treatment should be made more rapid and flexible (for instance, by allowing the assessment of care needs and initiation of treatment to be carried out at outpatient units, as happens in many other countries).

Those who are more critical of substitution treatment think that it should only be expanded according to the resources, information base, professional skills and other capabilities already available within the care system. All kinds of drug treatment should be developed as a whole, based on planning. Substitution treatment should remain a controlled, limited, expert method of care, and it should not be the primary method of treatment in the care of drug addicts. In addition, doubts have been expressed about the validity of the perceived benefits that have been used to promote substitution treatment, such as successful rehabilitation of opioid addicts and reduction of social problems. More information and experience are needed over a longer period of time before any far-reaching conclusions can be drawn.

The arguments of both those who are in favour and those who are critical of substitution treatment can be upheld by international research findings, because such findings allow even conflicting interpretations to be made. What kind of conclusions are drawn depends largely on the emphasis given to different viewpoints, the studies cited and the criteria the studies are expected to meet to be seen as scientifically valid.

5. Summary, conclusions and recommendations

Summary

Until the mid-1960s, the drug problem in Finland mostly consisted of the use of opioids. As the first drug wave hit Finland, the use of opioids became quite marginal. They were replaced primarily by cannabis and, to some extent, by amphetamines. In the 1990s, however, the use of opioids increased again. As a result, the state authorities, local authorities and the care system became more actively involved. The opioid problem has also gained plenty of attention in the media.

In Finland, medical treatment of opioid addicts was insignificant until 1997, when the Ministry of Social Affairs and Health issued its first order concerning such treatment. In its second order (1998), the number of detoxification and substitution treatment places was increased, the duration of detoxification treatment was extended and the objective of treatment was no longer always withdrawal from opioids. The decree

currently in force defines maintenance treatment as a new care alternative. In this type of treatment, the patient's drug use is accepted. The emphasis is on harm reduction and improvement of the patient's quality of life.

The number of substitution treatment units has increased rapidly, from a few units in the greater Helsinki area in 1998 to over 30 units in different parts of Finland in summer 2001. During this period, the number of patients receiving substitution treatment increased from about 50 to more than 200. Most of the patients who have sought treatment are socially disadvantaged and excluded and long-term users of several different intoxicants (including buprenorphine). Adherence to the treatment has been fairly good. Short-term substitution treatment aiming at detoxification has increasingly been replaced with long-term substitution. As most of the care units are still new, the treatment programmes and care practices are only just beginning to take shape. So far, little research data is available.

Medical substitution treatment is officially recognised as an essential part of drug treatment practices. The aim is to make access to treatment more flexible by increasing the number of places where the assessment of care needs and initiation of treatment can be carried out and by allowing the treatment to be continued in primary healthcare units and specialised substance-abuse service units. The aim of substitution treatment is to prevent and reduce the impact of drug abuse on health and the adverse social and economic effects. Those who criticise substitution treatment believe that the criteria for such treatment should not be made too broad and that the supply of treatment should not be greatly increased. They also hope that the negative consequences of substitution treatment will be analysed more thoroughly. In the debate on substitution treatment, there are tensions between the medical and social approaches, between the different types of medication used in substitution treatment and between the care of people with drug problems and people with other alcohol- and intoxicant-related problems. The right of private physicians to give substitution treatment is likely to be under consideration in the near future.

Conclusions and recommendations

Both the arguments for substitution treatment and the criticisms are understandable and important. Both approaches can be justified with research findings. However, an unambiguous synthesis of the research findings is not easy to arrive at. What is still needed is discussion, cooperation and integrated planning of drug treatment in order to arrive at a system where there is a balanced relationship between medical treatment and psychosocial support.

Medical substitution treatment is needed. The use of opioids has become more frequent, even in Finland, and there is an increased need for treatment for opioid addicts. The number of substitution treatment places needs to be increased to some extent, particularly in the greater Helsinki area. However, the substitution treatment services should be expanded judiciously. It is appropriate to maintain medical substitution treatment as a controlled, expert form of medical care. This is a precondition both for the rehabilitation of patients and for ensuring proper working conditions for care personnel.

Patients in substitution treatment usually comply with the treatment fairly well. Interruptions in treatment and withdrawal from substitution medication occur relatively infrequently. The duration of care periods has increased. As the treatment cannot yet be continued in primary healthcare units and specialised substance-abuse service units, the waiting times for patients to be assessed and for initiation of treatment have increased. There is a need for new units, where the treatment can be initiated and continued. In addition, the definitions, content, objectives and various stages of detoxification, substitution and maintenance treatment need to be clarified. Psychosocial rehabilitation needs to be developed to complement the medical treatment.

A typical feature of Finnish opioid addiction is the mixed use of several intoxicants. According to a number of care units, most of their patients now also use buprenorphine (Subutex) intravenously as an intoxicant and, increasingly, for many the primary intoxicant is buprenorphine. Substitution treatment provides an opportunity to progress from 'self-medication' in the street to controlled medical treatment, social rehabilitation and subsequent withdrawal from substitute medication. In some cases, however, buprenorphine was also probably the first hard drug used by an addict. When substitution treatment is expanded and treatment programmes developed, the fact that the street trade and use of buprenorphine is relatively common should be taken into account.

More research and follow-up is needed. At present, it is difficult to obtain an accurate overall picture of the different medical treatments and related arrangements. There is little information available on care practices and content, such as the criteria for accessing treatment, codes of conduct, interruption of treatment and the role and quality of psychosocial rehabilitation. Qualitative data on patients and treatment is needed, in addition to data on patient numbers, patient characteristics and the treatments available.

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Norway

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1. Introduction

Use of methadone in the treatment of drug addicts has traditionally been regarded with some scepticism in Norway. During the 1970s, methadone was occasionally prescribed by physicians, both in private practice and in conjunction with institutionalised treatment. However, the Norwegian Board of Health was eventually to advise against the use of methadone. This negative action was, first and foremost, grounded in the belief that the goal for the treatment of drug users should be a drug-free and non-addictive lifestyle. The first white paper presented to the parliament on the narcotics problem (St. meld. Nr 66 (1975–76) *Om narkotikaproblemer*) states, for example, that it is the government's opinion that abuse of dependence-inducing substances among both younger as well as older age groups should largely be seen as a symptom of social maladjustment. Treatment should focus on the underlying problems and not the addiction itself. The same parliamentary bill also states that methadone is not recommended as a form of treatment, as this is seen as prolonging chemical dependence.

In 1976, the Norwegian Board of Health presented guidelines that allowed methadone to be prescribed only in conjunction with hospital care, which, in practice, only occurred very rarely (Helsedirektoratet, 1976). This limited practice was also to disappear over time, and the result was that substitution treatment programmes were non-existent in Norway for many years; neither were such programmes the subject of much debate as a treatment alternative. When the Norwegian government, during the 1980s, presented its next white paper on drugs policy (St. meld. Nr. 13 (1985–86) *Om narkotikaproblemene og narkotikapolitikken*), methadone treatment was not mentioned. Neither was there any demand made for methadone by addicts until the early 1990s. Norway was not alone in this position. While substitution treatment programmes using methadone have been utilised for a number of years in countries like the USA, the United Kingdom, Denmark, Switzerland and the Netherlands, other countries, like France, Germany, Belgium and Greece, approach such treatment with the same restrictive attitude as Norway. It was not until the 1990s that substitution treatment with methadone and buprenorphine was introduced (Buning, 1994).

1.1. Treatment optimism – methadone as a negative signal

There was no official debate in Norway on the use of methadone until the HIV epidemic in 1985. When there were clear indications that the spread of the virus among needle injectors could become serious, physicians in the field suggested methadone substitution treatment as a means of preventing the spread of infection. The issue was investigated, but such treatment was still not implemented. Meanwhile, in 1989, the Oslo municipality initiated trials of maintenance treatment for HIV-positive addicts without provoking any serious debate. Rather than treatment of addiction, this was seen allowing HIV-infected drug addicts to end their lives in a dignified way.

That there was never any real discussion of methadone treatment as a means of addressing the HIV epidemic among drug addicts can be related to the fact that it was soon discovered that HIV among substance abusers in Norway was relatively rare. The Ministry of Health and Social Affairs also initiated an extraordinary action plan to expand non-medical treatment measures (Sosialdepartementet, 1988). Additionally, free needle exchanges were established to limit the spread of infection through needle sharing.

The most important factors underlying Norway's resistance to the use of methadone in the treatment of substance abuse can be summarised as follows (Skretting, 1997):

- There was a strong belief in the possibility of overcoming abuse. Both the central authorities and practitioners in the field of abuse believed in drug-free treatment. There was a large degree of optimism about such treatment.
- Methadone signals a negative view of human nature, whereby we give up on abusers and do not believe that they are capable of changing.
- Methadone involves encumbering the abuser with a lifelong dependence.
- The medical community was only marginally engaged in the treatment of drug addicts. It was primarily social workers and, to some extent, psychologists who dominated the field. This resulted in a general lack of awareness about the subject.

1.2. Misery on the rise – the number of overdoses climbs

During the early 1990s, a growing number of reports indicated a general decline in the health of heavy drug users. At the same time, the number of drug-related deaths rose, gaining extensive media coverage. Although drug-free treatment had been expanded substantially, it was clear that this had not reduced the problem. It became increasingly evident that it was necessary to look to other solutions and so it was that methadone treatment, and the extent to which it should be made available, came to be considered. The HIV epidemic was not, however, as important a factor in this debate as it was in many other countries, as the prevalence and incidence rates have continued to remain low in Norway.

Against this background, in November 1991 the Norwegian Research Council organised a 'consensus conference', at the request of the Ministry of Health and Social Affairs, on 'The use of medication in the treatment of the chemically dependent – prescription of habitual pharmaceuticals' (NAVF 1992). Based on the recommendations of this conference, a three-year trial was initiated in Oslo in 1994 using methadone-assisted treatment for the rehabilitation of 50 opium addicts. The project was largely based on a model used in Sweden for methadone treatment and was the object of an extensive evaluation (Ervik, 1997; Frantzen, 1997; Ravndal and Vaglum, 1997; Skretting, 1997). The 50 individuals who were admitted to the project had to fulfil the following criteria:

- they had to be at least 30 years of age;
- they had to have abused heroin for at least 10 years;
- they must have already received a reasonable amount of drug-free treatment; and
- they must not have any cases pending with the police or the courts.

The main goal of the project was that patients would cease using illegal substances and take their place in society as 'normal' citizens. The model was (and is) based on substitution treatment with methadone in conjunction with other measures within the social and medical services, to ensure the necessary psychosocial follow-up. Strict urine testing was an important element of the service. To demonstrate that methadone was part of a comprehensive rehabilitation regime, the project was referred to as 'methadone-assisted rehabilitation'.

Even before the trial was completed and the conclusions of the evaluation were available, the Norwegian parliament adopted a bill in 1997 that made methadone-assisted treatment a nationally available treatment alternative. This treatment was under way during 1998.

2. Legal basis

2.1. Goals, modalities, entry criteria, choice of substances prescribed

The new bill did not put any upper limit on the number of participants that could avail of methadone substitution treatment, but it stated that all addicts who expressed an interest and who met the necessary criteria were to receive such treatment.

The premise underlying substitution treatment in Norway is that methadone (and, since 2000, other relevant pharmaceuticals) should be used as a means of improving the quality of life and functioning of the individual, and that it should be used in conjunction with a holistic treatment programme. In other words, methadone (or any other legal drug) should not be prescribed in isolation as substitution treatment but has to be just one element of treatment, insofar as this is possible in an individual case (i.e., methadone-assisted rehabilitation).

With the initiation of a nationally available methadone-assisted rehabilitation alternative, the Ministry of Health and Social Affairs provided guidelines for treatment (I–25 1998). The criteria for receiving substitution treatment were:

- the client was to be at least 25 years of age (30 for the trial project);
- the client was to have had at least 10 years of opiate-dominated substance abuse;
- the client was to have undergone a reasonable amount of drug-free treatment; and
- an individual treatment plan (aiming at a holistic treatment programme) had to be compiled, signed by the client, the municipal social services and other cooperating authorities.

These guidelines included a passage that allowed the regulations to be disregarded in the event of a serious or life-threatening illness.

During 1998/1999, four regional centres for methadone-assisted rehabilitation were established. The centres had to ensure that clients fulfilled the above criteria and were responsible for authorising individual treatment plans. The regional

centres have also been largely responsible for organising the expansion of substitution treatment.

These guidelines were revised in a circular of 2000 and are now less restrictive (Sosial- og helsedepartementet rundskriv I-35/2000). This circular is reproduced below in its entirety:

Introduction

Pharmaceutical drugs can only be prescribed to a patient as one element in medicine-assisted rehabilitation of drug abusers when the said individual participates in programmes/centres authorised by the provisions set forth by the Ministry of Health and Social Affairs in the regulations of 27 April 1998, number 455 *om rekvirering og utlevering av legemidler fra apotek* (on the requisition and distribution of pharmaceuticals by a pharmacy), paragraph 2-1 subsection 3, paragraph 8-4, subsection 2, revised 4 September 2000. Until the revisions enter into effect on 1 January 2001 [subsequently postponed until 1 April 2001], the provisional guidelines for the care of patients of physicians who have lost their right to prescribe drugs as a result of revisions to the aforementioned provisions shall be in effect, as dictated by the Norwegian Board of Health 18 September 2000 and adopted in the Norwegian Board of Health's circular IK 15/2000 (Statens helsetilsyn IK-15/2000 and IK 24/2000).

These guidelines apply to centres approved for medicine-assisted rehabilitation.

Substantial changes to centres for which approval has been given must be presented to the Ministry of Health and Social Affairs.

Medicine-assisted rehabilitation of substance abusers presumes a close relationship between the health and social service authorities concerning the arrangement of treatment.

Target population for medicine-assisted rehabilitation

1. The target population consists of drug addicts who suffer from a long-term, opiate-dominated abuse pattern and who have not been able to recover from their opiate addiction despite availing of other treatment, rehabilitation and care programmes.
2. The goal of using pharmaceuticals as one of several measures in a holistic treatment programme is to support the relevant abusers by:
 - helping them escape the debilitating world of addiction;
 - helping them take advantage of other treatment, rehabilitation and care measures;
 - reducing the harmful effects of abuse and the danger of overdosing;
 - improving the individual's ability to function physically and socially; and
 - enabling them to achieve a drug-free, better quality of life and, as far as possible, rehabilitating them so that they can lead a more productive working and social life.

Responsibility and organisation

3. The Social Services Act, chapter 6, sets out measures for the treatment of substance abusers. The Social Services Act shall, where need has been demonstrated and in the event that the addict requests it, provide treatment programmes, see paragraph 6-1 (Sosial- og helsedepartementet, *Lov om sosiale tjenester av 13 des. 1991* [Ministry of Health and Social Affairs, Social Services Act of 13 December 1991]). In the event that medicine-assisted rehabilitation is deemed appropriate, it is critical that contact is established with the health services. If the client requires specialist treatment of a somatic or psychiatric nature or specialised services for substance abuse, the client must be referred to these. Such services must be included in a holistic individual treatment plan, as necessary, see point 6.
4. Centres approved for medicine-assisted rehabilitation are responsible for selecting individual clients for treatment. Applications from the municipal social services authority shall be sent via the county, which shall ensure that municipal social and health services and specialised social and health services are coordinated, and that the proper conditions exist for a well-planned and conscientious collaboration. Approved centres within a region (the regional centres) shall assist in developing and giving guidance to the local services that are responsible for following up on the individual substance abuser. An agreement

should be made for cooperation between the centre responsible for approving the individual treatment plan and the physician who will eventually be prescribing the relevant medication.

Admission and discharge

5. Authorisation for admitting and discharging clients from approved centres must follow the laws that apply to the individual centre.
6. Admission criteria:
The client shall:
 - a. be at least 25 years of age
 - b. have a long career behind him/her of drugs abuse. At the time of application, abuse shall have been clearly dominated by opiates.
 - c. to a reasonable degree, have undergone treatment and rehabilitation without the use of methadone and opioids with the aim of achieving a drug-free lifestyle.

As a basis for assessing admission of a client, an application shall be submitted by the municipal social services for evaluation by the county. An individual holistic treatment plan, including information concerning the physician who will prescribe the medication, shall be enclosed with the application. The services to be included in the treatment plan shall be determined in cooperation with the client, insofar as this is possible. The client's wishes shall be paid particular attention; see the Social Services Act, paragraph 8-4 [sosialtjenestelovens §8-4].

7. Exceptions can be made with respect to the admission criteria, point 6 a-c, if the addict suffers from a chronic or life-threatening illness that makes the treatment alternative critical for survival, or if an overall evaluation implies this.

8. Discharge criteria

The client shall be discharged from the programmes in cases of trafficking in illegal drugs and/or addictive substances or well-founded suspicion of this, and where there is use of violence and/or threat of violence, as long as this could not be seen as an inappropriate reaction.

Persistent alcohol and/or drug abuse alongside treatment, tampering with urine samples or medication, failure to appear at meetings/to pick up medication and refusal to cooperate according to agreements, regulations and/or treatment plans can result in ineffective treatment. Such circumstances can provide grounds for discharge.

Appeals

9. Right to appeal is in accordance with the Administrative Act [forvaltningsloven] and with the provisions set forth in the Social Services Act.

2.2. Who is allowed to prescribe, provide and control prescription?

As can be seen, the regulations concerning prescription of medication (forskrift av 27.april 1998 nr 455 med endringer (IK 24/2000, presiserer IK 15-2000 utleveringsforskriften)) indicate that physicians cannot prescribe medication for substitution treatment on their own. However, despite the fact that, in principle, it is not allowed, there have been some general practitioners who have provided unauthorised prescription of opiates to drug addicts. A deadline of 1 April 2001 was given for the patients involved to be submitted for approval by the authorised centres. It is hoped that, once clients are approved for such treatment, they will be referred to the care of a general practitioner and that, after dosage has been stabilised, this general practitioner will assume responsibility for prescribing the relevant medication.

During 1999, three of the centres were authorised to start trials with 'buprenorphine'. In 2000, trials were initiated for the use of naltrexone and all the centres have been

authorised to use both methadone and buprenorphine, according to what is most appropriate for the individual client. For this reason, the term 'medicine-assisted rehabilitation' began to be used rather than 'methadone-assisted rehabilitation'. There has, thus far, been no discussion concerning the use of heroin in maintenance treatment.

2.3. Rules for the provision of substitution treatment in special settings or situations

Beyond the above guidelines for medicine-assisted rehabilitation, there are no special rules for substitution treatment in hospitals, treatment programmes in prisons or treatment during pregnancy. In principle, the same guidelines apply in these situations as well.

2.4. Rules for using substitution treatment as an alternative to punishment

Neither are there any special rules concerning medicine-assisted rehabilitation as an alternative to incarceration. However, the Prison Act includes a general bylaw that states that the final stage of a sentence can be served in a treatment institution. In cases where individuals fulfil the criteria for medicine-assisted rehabilitation, this bylaw can be applied to cover such treatment.

3. Current practice

The procedure for entering medicine-assisted rehabilitation is set out in the guidelines referred to above. Once a client is approved for treatment, he or she undergoes detoxification before methadone is administered. During treatment, the client is monitored, both medically and socially, including testing of supervised urine samples. The frequency of urine samples and the method of delivery of methadone (take-home or attendance at a centre) depend upon how well the client complies with the regulations for treatment.

As mentioned earlier, in 1997 the Norwegian parliament determined that methadone-assisted rehabilitation would become a permanent and nationally offered treatment alternative. From there being at that time a total of just under 100 clients in treatment (including those who were in treatment due to a somatic diagnosis), the numbers have since rapidly increased. At the end of 1998, the number of abusers in methadone rehabilitation in Norway was approximately 200, at the end of 1999 it was approximately 730, at the end of 2000 there were as many as 1 063 and by the end of April 2001 this number had risen to 1 235. There were also approximately 800 individuals on the waiting list for treatment or awaiting approval of their application in order to be admitted to treatment. For various reasons, the waiting time for evaluating an application and for being admitted to such treatment has become unreasonably long (currently 1–2 years).

Although the admission criteria have been somewhat liberalised, they are still quite restrictive when compared with other countries. One argument for establishing a minimum age requirement of 25 years is that experience indicates that a change seems to take place in the abuser's identity around that age. Even if the client has used illegal substances for some time, his/her identity as abuser may not manifest

itself until he/she reaches the age of approximately 25. For this reason, it can be posited that there are greater ethical problems associated with offering substitution treatment to addicts younger than 25.

As mentioned above, in 1998 provisions were made for four regional centres, under the authority of the Ministry of Health and Social Affairs, to serve the entire country. One centre has been awarded national competency, and for this reason can be said to have overall authority for substitution treatment. The internal organisation of the four centres varies from a centralised model, where the regional centre is responsible for prescriptions even after methadone has been initiated, to a more decentralised model, whereby prescription of substitute drugs is gradually assumed by a local physician in cooperation with the centre. The original plan was that a general practitioner would assume responsibility for prescription once the client had completed detoxification and was stabilised on methadone.

3.1. Legal problems in prescribing or providing substances

A common problem has been finding doctors who are willing to take part in the authorised substitute treatment programmes. The reasons for this are, to some extent, economic, but they are also practical and/or professional/ethical in nature. For example, one municipality has chosen to pay physicians 2 500 euro extra per patient to compensate for the extra work associated with treating a methadone patient, in addition to the compensation they already receive in accordance with the standard provisions.

In a letter to the Minister of Social Affairs (20.10.2000), the director of the national competency centre for medically assisted rehabilitation in Norway noted some of the problems:

- It is unclear which pay scales physicians should use in the treatment of patients (for example, for participating in a treatment team).
- It is unclear how treatment controls (urine samples and analysis of samples) should be handled. While the doctor largely regards urine testing as part of the medical treatment, others see it as a behavioural control, which has consequences for how the tests should be funded.
- It is unclear if opiate dependence gives a patient rights with respect to medical leave, rehabilitation and assistance with re-entry into the workforce.
- A physician's or pharmacist's obligation to prescribe drugs for treatment is unclear, even though, in practice, they are free to choose whether they wish to take part in prescribing and delivering drugs in the context of medically assisted rehabilitation.

The problems that are identified here are largely associated with whether opiate addiction can be defined as an illness or as a social maladjustment. However, during the spring of 2001 it was decided, that when a patient has been approved for medically assisted rehabilitation, a physician's participation should be regarded as essential medical help (Municipal Health Services Act § 2-1). With the introduction of the Regular General Practitioner (RGP) reform that entered into force in June 2001, doctors who take part in the RGP scheme are henceforth obliged to participate in such treatment for the patients he/she has been allocated. There are also problems

associated with the participation of pharmacists in dispensing prescriptions for methadone or buprenorphine. Because pharmacies in Norway are privatised, they cannot be obliged to participate in this treatment.

(The problems outlined above may only be partially described as legal in nature. Nevertheless, many of the problems are related to the interpretation of laws and regulations. The fact that substitution treatment cannot be provided by doctors on their own can also be seen as a legal problem.)

4. Informed opinions

Naturally, there are varied opinions concerning substitution treatment in Norway and, similarly, there are mixed views on how substitution treatment is practised in relation to the frameworks and goals that have been established. Based on interviews and articles in newspapers and scientific journals, we will take a closer look at the views of medical doctors, treatment specialists, politicians and clients concerning some of the issues that have been raised.

4.1. General practitioners' refusal to participate in substitution treatment

Although regional centres have been established for medicine-assisted rehabilitation, treatment is still conducted in close cooperation with the Municipal Health and Social Welfare Services. Once a client is approved for such treatment and has been stabilised on methadone (or another relevant drug), a local physician must assume responsibility for prescribing the medication as part of the medical follow-up. An important factor in this not operating as intended in many places is, as mentioned above, the fact that many general practitioners are against participating in this kind of work, for a number of reasons. The objections they put forward are partly professional/ethical in nature, partly economic and partly practical.

For example, one district medical officer gives the following reasons for not participating in methadone treatment:

- this form of treatment has not been adequately tested;
- GPs are too busy to take on methadone patients, as they demand more time and attention; and
- drug addicts embarrass other patients in the waiting-room.

Another reason for such unwillingness to participate in treatment is the amount of polydrug use among many of the clients, as methadone is not very effective in treating such users (Tønsberg blad, 25.10.2000). A chief county medical officer commented that it is difficult to force district medical officers to participate in methadone substitution treatment as long as such treatment is not defined as essential medical assistance (something that has now been legislated on).

Those who work with medicine-assisted rehabilitation on a daily basis are naturally concerned about the fact that general practitioners do not wish to have methadone clients as patients: 'It is ridiculous that individual doctors can sabotage an arrangement that the parliament has declared will be available as a national alternative. This cannot continue. Drug addicts are not a first priority for doctors. It

can be tragic for an individual to miss the opportunity of receiving treatment' (Dagsavisen 4.7.2000). The director of the national competency centre for medicine-assisted rehabilitation has responded to the criticisms put forward by doctors by acknowledging that the benefits of treatment can be exaggerated and that, at both national and international level, there is a danger of over-investing in methadone treatment. Regarding the argument that methadone treatment lacks validation, however, he stated that it is rather pretentious of Norwegian doctors to sit in judgement on international expert evaluations. In response to the charge that methadone clients demand more time and are more difficult, he affirmed that this is an understandable opinion but that it cannot be condoned. He said that methadone clients are also the responsibility of the health services and that refusal to treat them is an expression of the fact that doctors control what and whom they wish to treat (Tidsskr Nor Lægeforen nr 21, 1999:119).

However, some district medical officers are positive about methadone treatment and seem to have been successful in involving doctors in it. The district medical officer for one of Oslo's neighbouring municipalities, for example, has put a lot of work into finding ways of making it advantageous for local doctors to participate. This has resulted in full integration of medically assisted rehabilitation in the local health and social services in this municipality. The majority of patients receive medication that is distributed under the supervision of their local pharmacy. The local social services are supported by social workers who follow up individual clients according to their needs. According to an agreement with the municipality, general practitioners in private practice have responsibility for prescribing methadone to patients. The district medical officer emphasises the importance of specialised training in the medical aspects of substitution treatment and stresses that this has been the key to how antagonism and prejudice have been replaced by interest and active participation in this particular municipality. By becoming involved in this type of work, it appears that doctors discover that they can finally reach, and even help, a target group that, until now, has represented a 'pain in the behind' for the health services (r & a 6.2000).

It should be noted, however, that the municipality in question is also the one that pays doctors an additional subsidy of 2 500 euro per client. It has been questioned whether it is ethical to 'buy' doctors who otherwise would be sceptical to participating. The director of the national competency centre for medicine-assisted rehabilitation maintains that, since Norway has chosen to base its healthcare system on a privatised system for general practitioners, we must be prepared to pay doctors when their efforts are required. At the same time, he points to the problems that face responsible authorities when they pay the standard rate for doctors' participation in medically assisted treatment above and beyond the purely medical (e.g., cooperation with other bodies). It is maintained that, in order to achieve decentralised multi-disciplinary cooperation, it is essential that all aspects of a doctor's participation in cooperative activities should be recognised as medical treatment and approved as such.

As noted earlier, the Ministry of Health and Social Affairs subsequently (in spring 2001) mandated that treatment by a doctor of a patient who qualifies for medicine-assisted rehabilitation must be regarded as an essential health intervention and that such treatment has to be included in the general practitioner's regular work. However,

it is too early to say how this will impact on recruiting local doctors into substitution practices.

There have also been problems with recruiting pharmacists to administer methadone to clients. As a consequence, more clients than necessary have to go to 'their' methadone centre to receive methadone. A representative of the user organisation for clients in medicine-assisted rehabilitation says that it is disappointing that several of Oslo's pharmacies do not wish to have methadone clients as customers. She maintains that 'the road is long' when those we believe know better maintain such prejudices. She questions whether they will be perceived as patients with a chronic illness who require daily medication when so many pharmacies do not want them as customers (r & a 2.2000).

4.2. The framework is inadequate

The Norwegian model for medically assisted rehabilitation is based on the notion that an individual treatment plan will address the different areas of a treatment regime. The premise behind treatment with methadone or other relevant drugs is that medication should always be given within a framework of psychosocial healthcare, as this is deemed essential in order to improve the individual client's situation as much as possible.

Over a relatively short period of time, substitution treatment has become an important part of treatment offered to drug addicts in Norway. In light of the goals set out for using substitute medication in the treatment of heroin abusers, this raises the question as to whether this development has taken place too rapidly, thus leading to a situation where many clients have not received the required psychosocial follow-up. Although the quality of substitution treatment varies, concern has been expressed that clients in many cases do not receive any help other than methadone/buprenorphine. For example, two experienced treatment specialists maintain that: 'Many of those who use methadone have a long history as drug abusers and need basic information on how to live a "normal" life. Today there are too many who do not receive any follow-up beyond giving urine samples, drinking methadone and being offered a talk. Society is not managing to follow up on the needs that need to be met for each individual' (Dagsavisen 28.05.01).

The head of one of the regional centres has pointed out the following:

'[The parliament's] resolution that all those who fulfil the criteria for methadone treatment should be offered treatment has created a lot of pressure for quick expansion. This must be questioned, when one considers the requirement that the Norwegian model be constructed as an active treatment alternative of high quality and with the necessary psychotherapeutic, medical and social resources. ...It is worrying if expansion has to proceed so quickly that there is no opportunity to evaluate how successful the Norwegian model is in facilitating methadone-assisted rehabilitation (i.e., offering abusers an alternative whereby they can become drug-free and take control of their situation) before one relaxes the central criteria and conditions for treatment. As the head of a methadone centre, I see daily how methadone-assisted rehabilitation really does have the

potential to enable many abusers to undergo a normalisation process without abuse of narcotics and criminality.However, it is essential that conditions are created that facilitate this, with respect to housing, employment and medical aspects, and, not least, in relation to treatment that helps the individual to become aware of his/her own self-control and ability to choose and how he/she interacts with other people, among other things. If one is to realise the objectives of methadone-assisted rehabilitation, it is therefore necessary that the social services, for example, give priority to the individual in the areas of follow-up, suitable housing and gainful employment. Claims that methadone clients are given too high a priority by municipal authorities are therefore unwarranted. On the contrary, one should focus on the positive aspects and look at the cooperative structures that operate for methadone-assisted rehabilitation as a model for other treatment alternatives.... I believe it is unfortunate when the intention of a treatment alternative is active rehabilitation but when, in practice, this develops in the direction of harm reduction. This is particularly unfortunate for all those who are not able to realise the opportunities they have for rehabilitation because an alternative is unclear in relation to overriding goals and expectations.’ (r & a 02.2000)

Some dissatisfaction has been expressed with respect to the fact that addicts who, for different reasons, are not eligible for methadone and therefore are denied access to the help that ‘methadone clients’ receive from the social services. The Minister of Health and Social Affairs says that we must be wary of a situation where drug addicts can apply to methadone treatment programmes in order to receive help. We should not accept that the right of the drug addict to assistance from the social services should be dependent upon what type of treatment alternative is being offered (r & a 2.2000).

4.3. One-sided attention given to methadone

The decision to offer medicine-assisted rehabilitation does not mean that drug-free treatment alternatives should be given less priority. In fact, it should complement them. However, some concern has emerged concerning the extent to which such a large investment in medicine-assisted rehabilitation gives economic and professional recourse to both.

For example, two experienced specialists in treatment have stated the following:

We both believe and fear that we in Norway during a relatively short period of time are moving away from the primary aim that there should be a variety of drug-free measures, of which methadone-assisted rehabilitation should be one component. We are afraid that drug-free treatment will soon be an expensive supplement to medically assisted treatment. It is our strong opinion that, without a strong professionally based drug-free treatment apparatus, the content of medicine-assisted rehabilitation will be reduced.

Methadone can represent an important and necessary ‘bait’, a motivational factor that makes it possible for opiate addicts to find the necessary courage to begin the long and painful process that change always involved. The road

to established substance abuse is long, and the way out is equally long. As is well-known, it involves not only achieving control over one's physical and psychological dependence on opiates but, equally, overcoming the power that heroin has, in order to come to believe that it is in fact possible and realistic to live a useful life and experience good meaningful moments without being intoxicated, to learn to cope with the trivia of everyday life, to endure the thought that often nothing exciting or especially rewarding will take place: all the grey days that can be a challenge for us all. It is about finding a meaningful context that makes it possible to get through the day. When one is not equipped with the necessary tools, it is understandable that heroin becomes an important ingredient that can fill a void that seems unbearably empty.

Change requires courage. For one who is powerless or caught in a rut, it is important to meet someone who has faith in you and who can help set in motion a new type of process by which you can rebuild your own strength. Medical support can provide such a source of strength, just as spiritual faith can do the same.

Furthermore, during weak and vulnerable periods, methadone-assisted rehabilitation can help the individual to resist taking heroin, as its desired effects are not achieved. A type of 'antabuse effect' can help an individual to pursue his or her goals for development. Methadone does make one dependent on opiates, but it also puts one in close contact with care workers and removes the opportunity to achieve the kick, or rush, which is so important to many people.

This forms part of the background for why we have both supported methadone-assisted rehabilitation in Norway. Strict regulations and an active treatment approach should prevent methadone from becoming regarded as a 'state drug'. Elimination of nuisance and harm-reduction goals should not be the sole aim here in this country. Methadone should only be a supplement to drug-free alternatives.

The pace at which expansion has taken place blows one away. With 700 patients awaiting treatment (spring 2000), the waiting list is still long. As the government has stated that all who fulfil the criteria shall receive treatment, we are looking at at least a doubling of the number of clients that we may expect to see on methadone. Moreover, there are many who feel that the admission criteria should be loosened up, the age limit of 25 should be lowered, etc....

We see this as a matter of great concern. In Sweden, this process has taken place over several decades and there are now up to 800 people in methadone treatment. Norway has exceeded this limit in the space of two years.

In the near future, the number of heroin abusers in receipt of methadone is likely to be greater than those who do not receive it. Already today we can

see that methadone-assisted rehabilitation is the primary option within the field of rehabilitation of drug addicts. Is this what we want?

Many of us who have worked for a long time in the drugs field daily encounter social services that are striving to effectively plan treatment for and follow up on individual clients. Use of time and resources, prioritising and quality in this work varies greatly. Medically assisted rehabilitation demands treatment plans and follow-up procedures. It is remarkable that the social services are managing to keep pace with the rapid increase in the number of clients receiving methadone. We suddenly find ourselves asking questions about the likelihood that all those who are currently on methadone have expectations that are in line with what was originally intended. Is it disrespectful to suggest that there is no longer the amount of emphasis on a detailed treatment plan as was the case at the outset? Or maybe the plans that were set out initially are not always followed?

These questions also have relevance for clients who have undergone drug-free treatment and are ready to take that critical step towards re-entering society outside of an institution. How is that they cannot find a place to live? Is it because the social services prioritise methadone-assisted rehabilitation? Is it that there is no time, money or resources available for clients that have received drug-free treatment?

We know that many clients get high on other drugs while they are on methadone (as do most patients in a treatment programme), that more and more continue to abuse extensively, that methadone can be bought on the street. Is this part and parcel of what we must accept? Along the same lines, it should also be noted that there is a growing need for a low-tolerance alternative for many of those who benefit from medically assisted rehabilitation. We are witnessing a shift away from rehabilitation towards harm reduction. The treatment goals have been relaxed, so that clients must improve somewhat and escape as much criminal activity as possible. In this way, we relax in the knowledge that Norway's health system is doing something – as best it can.

One client stated that 'to be in methadone treatment is to jump right into aftercare'. Does this mean that treatment is only about drinking methadone, giving a urine sample and having a talk every once in a while?

Methadone substitution, like other alternatives that bring individuals into treatment, should be regarded as an opportunity to prevent relapse and to help them to achieve change. A drug-free life, with or without medication, should still be a goal to work towards. The focus should be on the fact that it is rewarding and the measures implemented to rehabilitate abusers should be effective, with or without medication. We need a professional field that clearly states that we do not wish to see a tendency to move away from the objectives that formed the basis for initiating methadone-assisted rehabilitation. (r & a, 2.2000)

The Minister for Health and Social Affairs has stated that she is largely in agreement with the two treatment specialists. She maintains that it is reasonable to ask questions about whether expansion has been too rapid, about the quality of the methadone alternative and the psychosocial follow-up provided by the municipal social services, whether treatment measures up to the original goals and what consequences such major investment in methadone has had for the drug-free alternatives. She confirms that promoting methadone and buprenorphine substitution was not perceived as an alternative to drug-free assistance and other treatment alternatives. It was to be complementary and a means of helping long-term heroin addicts to take advantage of the available help and treatment facilities. This is reflected in the use of the term 'medically assisted rehabilitation' rather than 'methadone treatment'. She acknowledges that we know too little about the extent of abuse of illegal drugs among 'methadone clients'. She also agrees that it is problematic to focus on methadone and buprenorphine substitution at the expense of other approaches to treatment. This could easily lead to a situation where drug-free treatment is totally overshadowed, added to which there will always only be a few substance abusers who are appropriate for methadone treatment. She also states that a well-functioning assistance and treatment alternative is a prerequisite for achieving the stated goals of treatment for abusers using medication. The vast majority of those who receive methadone or buprenorphine are in need of extensive support, whether this is in the form of outpatient care or in an institutionalised setting (r & a 2.2000).

The largest organisation for the relatives of drug users has expressed concern about the fact that investment in methadone has come at the expense of drug-free treatment measures. The organisation argues that experience has shown that it is essential to see methadone within a holistic treatment perspective and that it is therefore important to maintain and strengthen the drug-free measures that support the individual during methadone treatment (Dagsavisen 29.05.2001).

The fact that the drug-free treatment services are an important supplement to medicine-assisted rehabilitation is also emphasised by the clients. For example, one of the clients who has been in such treatment the longest states that it should be more linked to drug-free measures. He maintains that an important reason why he has managed to handle so many different problems for this long is that he has been in a treatment institution and that this environment offers a backbone of support that has been important at times of crisis. He believes that the social services have little to offer other than money and that this is not enough in such situations (r & a 2.2000).

Treatment staff feel that drug-free treatment has been given a lower priority. One stated that: 'Methadone treatment was meant to be a supplement to traditional treatment. Now we see that the reverse is taking place. Drug-free treatment has become a supplement to methadone' (Dagsavisen 28.05.2001).

However, not all share in their concern that drug-free treatment will become less of a priority. Some methadone clients who currently reside at a treatment institution where there are also clients who are not on methadone maintain that most of them manage without daily medication and that they therefore want to try drug-free treatment first. At the same time, they fear that methadone treatment will become methadone without other treatment; that the rehabilitation element will disappear: 'Downtown it's

just “drink, piss and go”. How this amounts to rehabilitation is difficult to understand’ (r & a 02.2000).

4.4. Are the criteria too strict?

Norway has strict criteria for admission to medicine-assisted rehabilitation, even if these have been relaxed over time. Those admitted to treatment are also subjected to relatively strict prohibition against the use of illegal substances while using methadone/buprenorphine. As experience has begun to show that many individuals are unable to quit using illegal substances, at the same time as an increasing number of drug users are applying for medicine-assisted rehabilitation, varying views are emerging concerning the extent to which the original criteria for qualifying for such treatment should be maintained and how strictly one should enforce the exclusion criteria. While some argue that it is important to uphold the original goals of this kind of treatment, making persistent use of illegal substances unacceptable, others would like to see a greater degree of differentiated goals, such that it would be acknowledged that the most problematic clients might continue to use illegal drugs.

While one leading Oslo politician was responsible for measures pertaining to drug abusers in the municipality of Oslo, he stated that the most problematic abusers must receive methadone even if they have nowhere to live and they also abuse alcohol or other illegal substances at the same time. Given the increase in drug-related deaths, he had changed his opinion as to who should receive methadone treatment and believed that the criteria should be relaxed to make it possible for the most problematic groups to receive a moderate amount of methadone substitution (Dagavisen 24.05.2000). The director of the national competency centre for medically assisted rehabilitation supported him, stating that, in some cases, it would even be advisable to give methadone to abusers who cannot manage to kick their habit (Dagavisen 24.05.2000).

The Minister of Social Affairs at the time that medicine-assisted rehabilitation was introduced as a nationally available alternative disagreed with this view, however. She is sceptical about relaxing the criteria for admission to treatment and allowing continued use of illegal substances. She maintains that the framework for methadone treatment is important, as it gets results (Dagavisen 25.05.2000). A researcher who is active in policy issues in the field of substance use is of the same opinion. He feels that it would be a death wish for drug policy if clients on methadone were allowed to simultaneously use illegal substances. He points to experiences in other countries that indicate that allowing this practice to continue means that the abuser enters into a new abuse pattern of which methadone is one part. In his opinion, little is achieved if abuse is still largely connected to criminal activity. He believes that the quality of other treatment measures is the critical factor in determining whether the client will manage or not, and that there is a danger that too much emphasis on methadone treatment will absorb the resources that would otherwise be available for other measures (Dagsavisen 25.05.2000).

The district medical officer mentioned earlier has also discussed the extent to which one should diversify the goals for treatment (r & a 06.2000). The Minister of Social Affairs notes that, in practice, this involves the question of allowing leeway when illegal substances continue to be used during treatment with

methadone/buprenorphine. While acknowledging that this is a difficult question, as it makes sense that not all clients will be able to follow the guidelines 'to a t', she believes that allowing such a practice will lead to further problems. In what circumstances would we accept continued use of illegal substances? Would such a practice jeopardise the client's chance to quit their use of benzodiazepines and other narcotic substances? To what extent would it be possible to take into account each individual case (r & a 06.2000)?

At the same time, two treatment staff who are critical to the rapidly increasing number of methadone clients question whether it is possible to maintain the anticipated level of quality if the numbers of those receiving methadone continue to increase at the current rate. They note that many of the heaviest drug users neither have the potential to become, nor do they wish to become, drug free. As developments appear to be moving in the direction of using drugs as a means of harm reduction and rehabilitation no longer appears to be the primary goal, they feel that more flexibility might be in order (Dagsavisen 05.2001).

Clients also have different views about the extent to which the criteria for medicine-assisted rehabilitation are too restrictive. Quite naturally, those who are managing well are more positive than those who are not. One client who is doing well admits, however, that he occasionally feels that the controls associated with treatment are difficult: 'It was tough to show up daily to receive methadone and give a urine sample at times when things were not going so well.' However, he maintains that, with hindsight, he can see that this was the only way to give him support: sometimes he needed more strict controls, but these made him feel that he was being taken care of rather than punished. He stresses that control measures can defeat their purpose if they only feel like punishment. However, individual treatment was important to him, and he believes that he would not have coped if his rehabilitation had followed a strict routine and rules (r & a 02.2000).

Another client notes that the tough controls are one more burden in addition to the many often unpleasant side-effects of methadone and the many negative external reactions they experience. She refers, for example, to those clients who during the early period of treatment have to come and drink their methadone under supervision, even at weekends. She describes how they have to give urine samples while someone watches, at first three times a week and later 'only' once a week, and that, for many, this was degrading, especially for a 40-year-old woman who had to urinate in front of a 25-year-old male social worker. Yet, she says, they accept the rules – quite simply, because they do not have a real alternative. They cannot say they just want one part of the package (r & a 02.2000).

In contrast, another methadone user is far more critical and says that it is a problem that the programme is so standardised. Far too little individualisation is given with respect to both control and follow-up alternatives (Dagsavisen 28.05.2001).

The user association for clients in medicine-assisted rehabilitation also expresses concern about strict adherence to the rules, for instance when it comes to refusing to treat those who are not able to quit their abuse of other substances. According to this group, it is important to remember that, for most of these people, this form of treatment is their last hope. For a user who is rejected from the programme, there is

no alternative except the street. Therefore, the association believes that treatment services should be flexible in following the current guidelines on excluding clients for 'continued abuse'. The association would like to see an independent project that does not require clean urine samples (r & a 02.2000).

Some clients are also doubtful about the relevance of the age limit criterion for methadone treatment. They believe that the length of time a person has used narcotics should be more important than their birthday (r & a 02.2000).

5. Conclusions and recommendations

As has been shown here, the expansion of medicine-assisted rehabilitation in Norway has taken place quite rapidly – from approximately 200 clients at the end of 1998 to more than 1 200 individuals as of 30 April 2001. In Sweden, where methadone treatment was introduced in 1966 and which was the model for such treatment in Norway, there is a maximum limit of 800 treatment spaces. The somewhat dramatic shift in policy on the treatment of long-term drug abusers in Norway is largely due to extensive pressure from the media, public opinion and politicians. The newspapers and television have given the issue much attention: there have been innumerable documentaries on drug abusers who present their unfortunate stories and call for methadone treatment. Similarly, the issue has been raised in parliament on numerous occasions. It is probably fair to say that the arguments put forward both by politicians and public opinion/media are founded on the belief that treatment with methadone/buprenorphine more or less represents 'the solution' to the drugs problem.

5.1. Quality in treatment

Such rapid expansion has naturally led to major problems in relation to the continued quality of treatment. The literature on methadone treatment is extensive. A common conclusion is that positive results in achieving rehabilitation using methadone or other appropriate medication is dependent on methadone being part of a holistic programme that offers different forms of psychosocial support (see, for example, Ball & Ross, 1991). Another finding is that methadone can make a bad situation worse if it is not followed up with some form of control and psychosocial support measures. Methadone treatment was centralised in Denmark in 1996 in order to ensure that methadone treatment was administered in the context of other support measures (Narkotikarådet 2000).

The rapid growth in the number of clients in medicine-assisted rehabilitation in Norway has led to many instances in which the necessary psychosocial support measures (such as housing, social input in one form or another and supplementary support) have not been established. This is especially true in Oslo, which has the largest number of clients. Extensive continued abuse of illegal substances by clients whilst in treatment is also reported. It is therefore difficult to believe that the original goals of treatment still apply.

Based on these developments in Norway, 'harm reduction' appears to be a more appropriate term. Even if the majority of abusers in medicine-assisted treatment are

now in a better situation than before they received methadone, there is still reason to question whether one should accept this fundamental shift in emphasis. If nothing else, experience thus far should prompt us to evaluate to what extent one should cling to the term 'medicine-assisted rehabilitation'. Given that many clients continue their illegal use of benzodiazepines and other narcotic substances, it could be argued that it should be possible to pursue a more differentiated set of goals. In this case, the extent to which continued use of illegal substances alongside methadone/buprenorphine would be accepted would be based on an evaluation of the individual client's situation and potential. However, it is clear that such a procedure would be difficult in practice. Under what conditions would one accept continued illegal use? What about the danger of undermining the client's chances of achieving the goal of quitting the use of benzodiazepines or other narcotic substances? Does a situation in which one is both 'in treatment' and continuing one's abuse enhance the client's dignity and sense of self-worth? Enhanced dignity is a common goal in Norway in relation to support measures for addicts. When considering these issues, it is clear that we need to look at the degree to which methadone/buprenorphine treatment actually contributes to a better quality of life and self-worth rather than the opposite.

5.2. What about drug-free treatment approaches?

The current focus on medicine-assisted rehabilitation and the rapid increase in the number of clients in treatment points up other issues. Have the social services and other facilities for substance abusers concentrated too many of their resources on addicts who are in or have applied for medicine-assisted rehabilitation? If this is the case, it could lead to a situation where the treatment apparatus 'forgets' or gives less priority to other addicts. It is also possible that the heavy focus on medically assisted rehabilitation of heroin addicts could result in alcohol addicts becoming even less interesting for the treatment apparatus.

Too much emphasis on methadone/buprenorphine treatment could also lead to a situation where drug-free alternatives are not considered when the municipal care services evaluate potential treatment alternatives for an addict. Given that drug-free treatment alternatives are still meant to be the primary means of treating drug addicts in Norway, and given that drug-free measures are regarded as important if not decisive for achieving the goals of medicine-assisted rehabilitation, this situation demands a lot more thought and discussion. As already mentioned, the literature consistently indicates that substitution treatment must be supplemented with a wide range of psychosocial measures if there is to be any hope of achieving anything like rehabilitation. Even if many would say that rehabilitation is a very ambitious goal for most problematic addicts, it is still valid to retain an emphasis on it.

5.3. Control or help and care?

One could not be blamed for wondering if the media and politicians have hidden motives for the ongoing pressure to get as many heroin addicts as possible into medicine-assisted rehabilitation as quickly as possible. As we know, drug addicts are a group that can create considerable problems for society. They often hang out in large groups in busy places and are a nuisance for most people. They commit crimes in order to get money for drugs. Many of the women addicts are prostitutes. It is not

beyond the realms of possibility that one underlying motive for offering methadone substitution is to have a greater degree of control over a group that is a major social nuisance.

Although such scepticism is understandable, there are, in fact, no grounds to support any claim that Norwegian politicians and the mass media are promoting increased substitution treatment in order to control drug addicts. It would appear that, first and foremost, there is genuine concern about the level of misery to be seen among long-term addicts and the many drug-related deaths (270 in 1998, 220 in 1999, 327 in 2001). The number of injecting drug users appears to have risen dramatically in Norway. Estimates calculate that the figures doubled from 4 000–5 000 at the end of the 1980s to 9 000–12 000 at the end of the 1990s (Betteville-Jensen and Ødegård 1999). Most of these addicts use heroin.

Massive demands are being made that something be done to respond to this development and to achieve better conditions for drug addicts. A greater number of treatment places has generally been put forward as the answer to Norway's drug problems. The fact that methadone and medicine-assisted rehabilitation is currently receiving so much attention must be seen in the context of a situation where the results of drug-free measures are regarded as limited. Even if Norway has invested a relatively large amount of resources in different treatment measures, the number of drug addicts has clearly risen. When methadone and buprenorphine are presented as the new 'wonder cure', it is only natural that this is accompanied by a more or less popular demand for as many addicts as possible to receive such treatment. While only a few years ago it was an increase in the number of 'regular' treatment places that would solve the problem, today it is methadone and buprenorphine.

While the quality of medicine-assisted rehabilitation has not met the original goals, this could also be seen as making it difficult to stop or slow down further expansion. As the situation appears today, it is reasonable to say that use of methadone/buprenorphine has become part of a development that has acquired its own momentum. Despite professional opinions that there need to be renewed efforts to ensure that the use of medication takes place within a framework of more holistic treatment, pressure from politicians and the media for expanding substitution treatment is, as already indicated, massive. At the moment it looks unlikely that the emphasis of the original goals will be reverted to. Many also argue that rehabilitation is an overly ambitious and unrealistic goal for the group of addicts that are targeted by medicine-assisted rehabilitation in Norway. Given the dimensions of the problem, it could be argued that the main goal for using methadone and buprenorphine should be harm reduction and that the use of illegal narcotic substances should cease to be a problem as a treatment criterion.

In this context, the harm reduction approach suggests that at least part of the addict's drug needs can be met through legal sources. Because a heroin addict receives methadone or buprenorphine, his need to obtain illegal narcotics, in this case heroin, is reduced. However, the addict will be able to continue to use other substances in the same way as previously. A positive 'side-effect' of this substitution is that, as the need for heroin is reduced, the need to commit crimes to obtain money for drugs should decrease. This is a benefit of substitution treatment that is often given attention internationally. However, it is legitimate to question who has the most to

gain from this effect. To what extent does a reduction in crime contribute to helping addicts along the road to doing something about their abuse problem? Will not such a reduction in crime benefit society more than the individual addict?

Although there is no proof that the current emphasis on substitution medication in the treatment of addicts in Norway is motivated by a desire to control the drug addict population, it could be argued that abandoning the objective of quality in treatment leads, in practice, to an emphasis on control as a central element. Control is defined here as a means of assisting the addict with achieving a 'rush', such that he/she hopefully will steal less and commit fewer robberies. Although these addicts will probably be less of a nuisance, they will not have received the necessary help to find housing, employment, psychological treatment, etc. (i.e., improve their quality of life). Seen in this light, the rather uncritical demand that 'everyone' should be offered treatment with methadone or buprenorphine may, in practice, lead to a situation where such treatment is a means of controlling drug addicts. Surely, this was not the intention?

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