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## Reviewing legal aspects of substitution treatment at international level

Prepared by the EMCDDA at the request of  
the Pompidou Group Secretariat

EMCDDA

ELDD Comparative Study

August 2000

Published at

[http://eldd.emcdda.org/databases/eldd\\_comparative\\_analyses.cfm](http://eldd.emcdda.org/databases/eldd_comparative_analyses.cfm)

# Reviewing legal aspects of substitution treatment at international level

## ***Introduction***

Treatment for drug addiction was seen as a measure to reduce drug abuse as early as 1961 when the UN Single Convention was signed. However, the only recognised concept of drug treatment mentioned by the Convention concerned the detoxification of the individual through 'drug-free treatment'.

Therapeutic measures aimed at treating drug addictions through maintenance and related distributions of alternative substances are not expressly mentioned by the UN Conventions of 1961, 1971 and 1988.

However, therapeutic measures, mainly based on the distribution of methadone or similar antagonists to heavy heroin addicts, tentatively started in some European countries already in the late sixties and in the seventies, and developed and expanded during the eighties and in the nineties.

Therefore, reviewing at international level the legitimacy of substitution treatment interventions and programmes comes up against one key obstacle; that the United Nations Conventions - ruling on the production and use of illicit drugs - do not expressly regulate the distribution of narcotics for reducing drug abuse or related harms.

## ***Medical and scientific purposes***

The main objective of the 1961 and 1971 UN Drugs Conventions was to create an international control system to monitor the production of narcotic and psychotropic drugs, prohibiting any use of substances not being previously permitted by the national authorities. Basically under the Conventions any use, possession, production, etc. of scheduled substances is forbidden except when exclusively intended for '*medical and scientific purposes*' (art.4c. 1961 Convention; art.5.2 1971 Convention).

From the Convention of 1961, we can assume that the intention of the legislator was to prohibit the abuse of drugs, allowing their use only for '*medical reasons*' which were mainly intended to be the '*relief of pain and suffering*'.

The preamble of the 1961 Single Convention in fact recognises '*that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes.*' Art.4c confirms that '*the production, manufacture, export, import, distribution of, trade in, use and possession of drugs*' should be limited '*exclusively to medical and scientific purposes*'.

Thus, it is evident that the legislator, while building up a system based on a general prohibitive approach towards drugs, was concerned with allowing the availability of some of those substances to be used in pain therapy. However, the Conventions do not clarify the concept of 'medical and scientific purposes' and do not specify which substances can derogate from strict prohibition, even if for medical reasons.

## **Controlled Substances**

Narcotic and psycotropic substances are listed in 8 schedules (4 in each Convention - 1961 and 1971), according to their therapeutic value, risk of abuse and health dangers. Art.2 of the 1961 UN Convention introduces control measures for these schedules.

In Schedule I (containing among others: methadone, opium, heroin, morphine, cocaine, cannabis) *'the drugs ...are subject to all measures of control applicable to drugs foreseen by the Convention'*.

In Schedules II and III controls are less strict due to the therapeutic properties of the substances therein listed: Schedule II codeine, propiram, etc; Schedule III preparations based on opium, morphine, codeine, etc.

In Schedule IV are listed the most dangerous drugs already listed in Schedule I being particularly harmful and having extremely limited medical and therapeutic value, among others: acetorphine, cannabis, heroin.

Addressing the question of *'Trade and Distribution'* of narcotics, the Convention introduces a control system based on authorisations and licences. Permission for certain individual international transactions, detailed record-keeping, a system for limiting the quantities of those drugs available by licit manufacture or importation, and requirement of medical prescriptions for the supply or dispensation of controlled drugs to individuals.

Art. 30 rules that if countries deem medical prescription of controlled substances *'necessary or desirable'*, even of Schedule I substances, they must require a *'written official form (...) to be issued by the competent governmental authorities or by authorised professional associations'* as prescriptions (art.30bii).

From this article we can assume that the choice to prescribe or not methadone or other controlled drugs is contained in the expression *'necessary or desirable'*. If a country considers that the prescription of a controlled drug is *'necessary'* and not contrary to the general purposes of the Convention, the only requirement consist in applying strict rules such as written official forms, keeping records, and other control measures.

Nevertheless, having regarded the various regimes of control that the Convention foresees for the different Schedules, countries *are required to adopt any special measures of control for drugs in Schedule IV* (inter alia heroin) *which in its opinion are necessary, having regard to the particularly dangerous properties of those drugs* (article 2, paragraph 5 (a)). The medical use of heroin and its controlled supply to addicts, while not expressly forbidden by the Convention, is a controversial issue amongst European countries.

## **Therapeutic Treatment**

The 1961 UN Convention calls on signatory States to take *'all practicable measures'* to *'treat drug abusers'* in order to *'reduce the abuse of drugs'*.

Art. 38 recognises in fact the importance of applying measures against the abuse of drugs inviting the signatory countries *'to take all practicable measures, for the prevention*

*of abuse of drugs, treatment, education, after-care, rehabilitation and social reintegration*'.

However, the Convention does not specify which are those measures, leaving free choice to the States to define them.

The only reference which defines treatment, within the Convention framework, is the *Resolution II of the United Nations Conference for the Adoption of the 1961 Single Convention* annexed to the latter: '*The Conference... Declares that one of the most effective methods of treatment for addiction is treatment in a hospital institution having a drug free atmosphere*'.

It seems evident that while the legislator calls for the treatment of drug addicts, freedom of choice is left to states to apply '*all practicable measures*' that will not be contrary to the dispositions of the Convention, including administration of controlled substances for medical reasons. The Resolution advising drug-free treatment does not exclude recourse to other '*practicable measures*' as indicated by art.38.

The provisions of the 1988 Convention must be considered in relation to the 1961 Convention and the 1971 Convention. Each Party to the 1988 Convention is required to adopt such measures as may be necessary to establish as criminal offences certain acts under its domestic law. Such offences relate, to actions that are prohibited under the 1961 Convention and the 1971 Convention, for example the illicit manufacture, distribution or sale of any narcotic drug or psychotropic substance. Since the 1961 Convention clearly permits the authorised provision and use of drugs, including heroin, for medical or scientific purposes, the 1988 Convention do not prohibit it for such purposes.

## ***Substitution Treatment***

Substitution treatment is therefore a type of treatment that seems to respond to the objective of article 38 to reduce abuse of drugs, but that was not expressly contemplated by the UN Conventions. Concerning medical prescription of a controlled substance, the Convention of 1961 allows countries '*to require medical prescriptions for the supply or dispensation of drugs to individuals*' including drugs listed in Schedule I (art.30 2b(ii)), unless this provision would be contrary to the general objectives of the Convention.

Concerning the meaning of '*medical and scientific purposes*' to allow the use of controlled drugs, the conventions seem to refer 'expressly' only to pain therapy and suffering, although art. 30 affirms that prescription of narcotics could be allowed under restrictions and using official forms. Thus, this allows for an extensive interpretation of the concept '*medical and scientific purposes*' which includes treatment of drug addictions.

## ***European Member States***

Substitution treatment in Europe developed during the 70s and 80s in a rather 'grey legal area'. Only in the last few years do European countries seem to take formal positions concerning the effectiveness and necessity of substitution treatment programs, moving into a situation where substitute prescriptions of methadone or other opiate agonists are

accepted by practitioners and decision-makers, and often formalised with appropriate laws.

However, although substitution treatment is generally recognised as an effective measure to reduce risk behaviour and drug related criminality, improving health and social well being, major variations can be found in its practical provision among EU countries.

Differences can be encountered in the substances allowed for substitution, the actors allowed to prescribe and control prescription, the purposes and modalities of execution, entry criteria, choice of substances prescribed, etc.

In some Member States substitution treatment is quite recent, while in others it has a relatively long history. As reported in the EMCDDA Insight *Review of the Current Practice in Drug Substitution Treatment in Europe*, for a long time the only legal option for treatment in Europe was detoxification, based on a strict approach. Methadone or other opiates could only be administered to drug users when highly specific indication criteria were met, or in case of pain therapy.

In many countries the 1970s and 1980s were dominated by a rigid adherence to the abstinence paradigm. The therapeutic ideal of permanent abstinence for all opiate users was considered the only valid premise for providing practical survival support and the only valid criterion for successful drug treatment. There was a general opposition towards drug substitution treatment, including from politicians, medical professionals and authorities, and methadone maintenance treatment was considered as being medical malpractice.

Gradually the effectiveness of maintenance therapy in other countries and the increasing awareness of risk factors like HIV infection produced a change in the medical and political approach to maintenance treatment. In many countries during the 80s a new demand for alternative, harm-reduction measures and similarly oriented concepts led to a gradual acceptance of methadone maintenance programs aimed to treat heavy drug addicts.

These new programs often started as treatment trials and pilot projects, outside formal legal recognition, and often under opposition on the part of the public opinion, medical profession and political society.

It was the effectiveness of these pilot programmes in reducing the HIV drugs-related risks and the drug-related crime, as well as in improving the general health conditions for drug addicts, that opened the way for new legislative changes that formalised maintenance treatments with methadone or other opiates agonists.

To date all EU countries have legal provisions and/or guidelines for the administration of methadone or other opiate agonists to drug addicts. However, the organisation of substitution treatment programmes, the availability of places, resources and the related funding, as well as the substances allowed for medical reasons, are strongly associated with public opinion and political views.

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