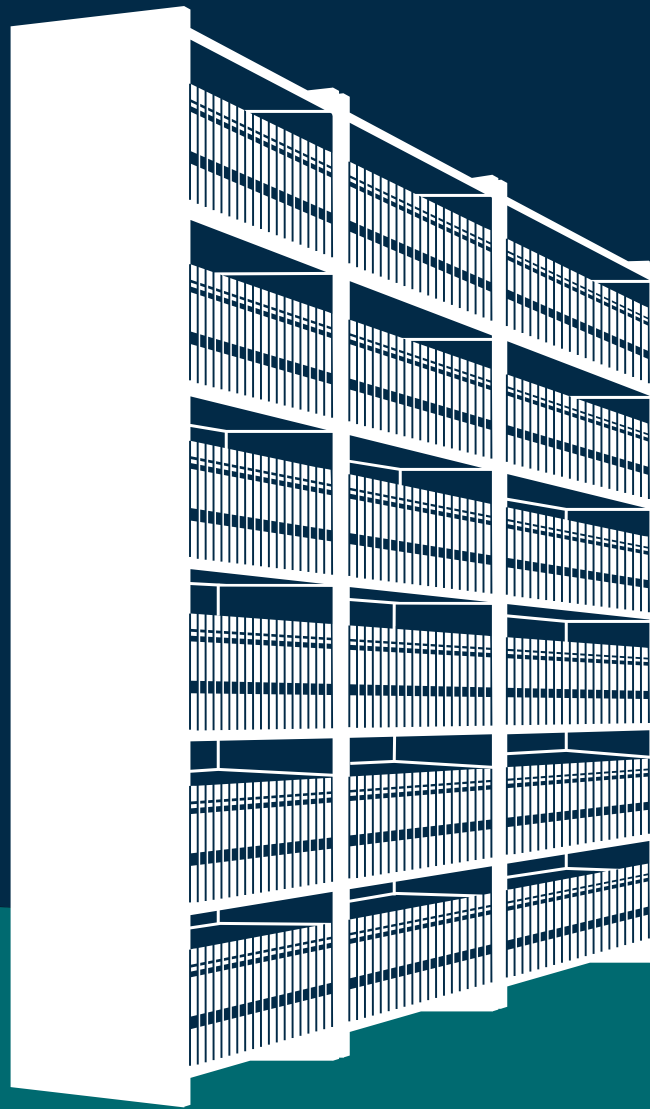




# Legislating for Health and Human Rights: Model Law on Drug Use and HIV/AIDS

Heroin prescription programs



Canadian  
HIV/AIDS  
Legal  
Network

Réseau  
juridique  
canadien  
VIH/sida

# 8

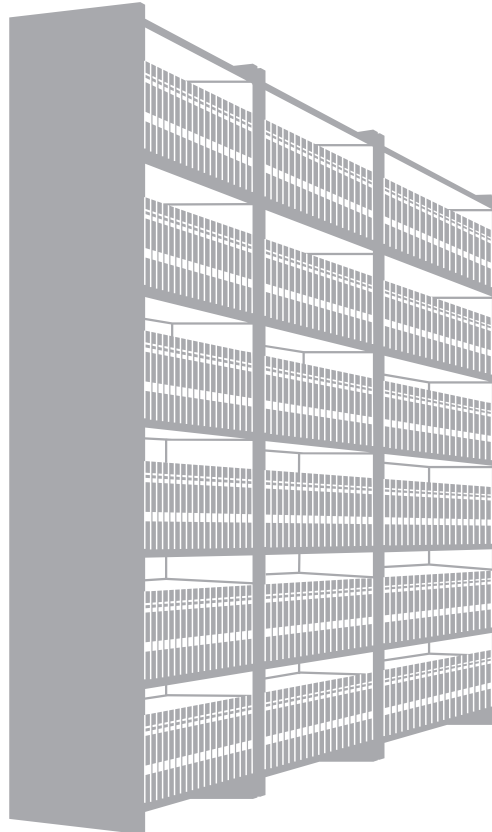
This model law resource consists of eight modules, addressing the following issues:

1. Criminal law issues
2. Treatment for drug dependence
3. Sterile syringe programs
4. Supervised drug consumption facilities
5. Prisons
6. Outreach and information
7. Stigma and discrimination
8. Heroin prescription programs

This module, and the other modules, are available in multiple languages on the website of the Canadian HIV/AIDS Legal Network at [www.aidslaw.ca/drugpolicy](http://www.aidslaw.ca/drugpolicy).



Canadian  
HIV/AIDS  
Legal  
Network | Réseau  
juridique  
canadien  
VIH/sida



# **Legislating for Health and Human Rights: Model Law on Drug Use and HIV/AIDS**

Heroin prescription programs



# **Legislating on Health and Human Rights: Model Law on Drug Use and HIV/AIDS Module 8: Heroin prescription programs**

© 2006 Canadian HIV/AIDS Legal Network

Further copies can be retrieved at [www.aidslaw.ca/drugpolicy](http://www.aidslaw.ca/drugpolicy)  
or obtained through the Canadian HIV/AIDS Information Centre  
([www.aidsida.cpha.ca](http://www.aidsida.cpha.ca))

## **Canadian cataloguing in publication data**

Module 8: ISBN 978-1-896735-72-6  
Complete series: ISBN 978-1-896735-64-1

## **Authorship and acknowledgements**

Richard Pearshouse is the primary author of this resource. Richard Elliott and Joanne Csete wrote text of legal provisions and prefatory notes, and reviewed the entire resource. Invaluable research assistance was provided by Tim Franklin, Sarom Bahk, Katie Gibson and Sara Kushner.

This resource was reviewed by a number of outside reviewers. Special thanks go to Scott Burris and Anya Sarang. Thanks also to the participants of the consultation meeting in Vilnius, Lithuania (7–8 November 2005) who provided feedback and advice on a draft version of this resource: Larisa Bashmakova, Holly Catania, Eszter Csernus, Rumen Donski, Joze Hren, Erik Iriskulbekov, Ainagul Isakova, Murtazokul Khidirov, Vlad Klisha, Tommaso Marilli, David Otiashvili, Ekaterina Paniklova, Alexandr Rumantsyev, Atanas Rusev, Vera Sergunina, Alex Shoshikelashvili, Raminta Stuikyte, Rusudan Tabatadze, Andrey Tolopilo and Thomas Zabransky. We also thank others who provided additional comments on the draft.

Thanks to Glenn Betteridge for his assistance. Lada Mirzalieva provided useful references to legislation from former Soviet Union countries. Thanks to David Garmaise for copyediting the English text, to Liana Ibragimova for translating the resource into Russian, and to Leah Utyasheva for editing the resource in Russian. Cover design was done by Oblik Communications, and layout by Vajdon Sohaili.

Funding for this project was provided by UNAIDS, the International Affairs Directorate of Health Canada, the John M. Lloyd Foundation, and the Open Society Institute. Funding for the consultation meeting in Vilnius, Lithuania was provided by the Conference Secretariat of the Canadian International Development Agency and the Open Society Institute. The opinions expressed in this publication are those of the authors and do not necessarily reflect the official views of Health Canada.

## **About the Canadian HIV/AIDS Legal Network**

The Canadian HIV/AIDS Legal Network ([www.aidslaw.ca](http://www.aidslaw.ca)) promotes the human rights of people living with and vulnerable to HIV/AIDS, in Canada and internationally, through research, legal and policy analysis, education, and community mobilization. The Legal Network is Canada's leading advocacy organization working on the legal and human rights issues raised by HIV/AIDS.

## Introduction

UNAIDS (the Joint United Nations Programme on HIV/AIDS) suggests that approximately 30 percent of new HIV infections outside sub-Saharan Africa are due to contaminated injection equipment.<sup>1</sup> In eastern Europe and Central Asia, the use of contaminated injection equipment accounts for more than 80 percent of all HIV cases.<sup>2</sup> Yet, globally, less than five percent of people who inject drugs are estimated to have access to HIV prevention services,<sup>3</sup> and even in regions where they account for the majority of HIV infections, people who use drugs are routinely excluded from HIV/AIDS care and treatment.

Many countries with injection-driven HIV/AIDS epidemics continue to emphasize criminal enforcement of drug laws over public health approaches, thereby missing or even hindering effective responses to HIV/AIDS. There is considerable evidence that numerous interventions to prevent HIV transmission and reduce other harms associated with injection drug use are feasible, effective as public health measures and cost-effective.<sup>4</sup> Despite such evidence, millions of people around the world who use drugs do not have access to such services because of legal and social barriers.

International human rights law establishes an obligation on states to respect, protect and fulfill the right to the highest attainable standard of health of all persons, including those who use drugs. Other human rights are equally relevant in the context of the HIV/AIDS epidemic. When human rights are not promoted and protected, it is harder to prevent HIV transmission, and the impact of the epidemic on individuals and communities is worse. Consequently, UN member states have committed to

enact, strengthen or enforce, as appropriate, legislation, regulations and other measures to eliminate all forms of discrimination against and to ensure the full enjoyment of all human rights and fundamental freedoms by people living with HIV/AIDS and members of vulnerable groups ....<sup>5</sup>

---

<sup>1</sup> UNAIDS, *2006 Report on the Global AIDS Epidemic*, May 2006, p. 114. At [www.unaids.org/en/HIV\\_data/2006GlobalReport/default.asp](http://www.unaids.org/en/HIV_data/2006GlobalReport/default.asp).

<sup>2</sup> UNAIDS, *2006 Report on the Global AIDS Epidemic*, p. 114.

<sup>3</sup> United States Agency for International Development et al, *Coverage of selected services for HIV/AIDS prevention, care and support in low and middle income countries in 2003*, June 2004. At [www.futuresgroup.com/Documents/CoverageSurveyReport.pdf](http://www.futuresgroup.com/Documents/CoverageSurveyReport.pdf).

<sup>4</sup> See, for example, N. Hunt, *A review of the evidence-base for harm reduction approaches to drug use*, Forward Thinking on Drugs, 2003. At [www.forward-thinking-on-drugs.org/review2-print.html](http://www.forward-thinking-on-drugs.org/review2-print.html).

<sup>5</sup> *Declaration of Commitment on HIV/AIDS*, UN General Assembly, Res/S-26/2, 27 June 2001, para. 58. At [www.un.org/ga/aids/docs/aress262.pdf](http://www.un.org/ga/aids/docs/aress262.pdf).

UN member states have also committed to ensuring that a wide range of HIV prevention programs is available, including the provision of sterile injecting equipment and harm reduction efforts related to drug use.<sup>6</sup>

The widespread legal, social and political ramifications of the HIV/AIDS epidemic make it necessary to review and reform a broad range of laws. Some countries have adopted national HIV/AIDS laws, but these laws often ignore crucial policy issues, as well as human rights abuses that perpetuate the HIV epidemic. This is particularly true with respect to illegal drug use. HIV prevention, care and treatment services operate best within a clear legal framework that specifically protects the human rights of people who use drugs and enables harm reduction measures to mitigate the impact of HIV. A legislative framework can provide clarity and sustainability for such services. This is particularly important, given the often dominant approach of criminalizing illegal drug use and people who use drugs, which creates additional barriers to delivering health services. Law reform is not a complete solution to effectively addressing the HIV epidemic among people who use illegal drugs, but it is a necessary and often neglected step.

## **The model law project**

In early 2005, the Legal Network established a project advisory committee and, in consultation with the committee, developed a plan to produce model law that would assist states in more effectively addressing the HIV epidemic (and other harms) among people who use drugs, based on evidence of proven health protection and promotion measures, and in accordance with states' human rights obligations.

Comprehensive consultations were conducted during the drafting of the model law. A draft version of the model law was reviewed by a group of legal experts, harm reduction advocates and government representatives from central and eastern Europe, and countries of the former Soviet Union, during a meeting in Vilnius, Lithuania (7–8 November 2005). The document was modified in line with this feedback and recommendations. In early 2006, the model law was circulated in electronic form to a large number of people and organizations, providing a further opportunity to modify and strengthen the resource. This final document has, therefore, benefited from the thinking of a wide range of experts in the fields of HIV/AIDS, human rights and drug policy.

## **About this resource**

This model law resource is a detailed framework of legal provisions and accompanying commentary. It makes reference to examples of law from those jurisdictions that have attempted to establish a clear legal framework for addressing HIV/AIDS issues among people who use drugs.<sup>7</sup> This resource also incorporates human rights principles and

---

<sup>6</sup> *Declaration of Commitment on HIV/AIDS*, para. 52.

<sup>7</sup> References to national legal instruments are included in order to demonstrate the feasibility of establishing progressive legal frameworks so that law reform in other jurisdictions can be informed by such examples.

obligations of states throughout the document. It is annotated in order to highlight critical issues and evidence that supports the measures proposed.

This model law resource is designed to inform and assist policy-makers and advocates as they approach the task of reforming or making laws to meet the legal challenges posed by the HIV epidemic among people who use drugs. The model law resource is not intended for any one country or set of countries. Rather, it is designed to be adaptable to the needs of any of a wide number of jurisdictions. In some instances, the model law presents different legislative options for implementing states' human rights obligations. It is hoped that this resource can be most useful for those countries where injection drug use is a significant factor driving the HIV epidemic, and particularly for developing countries and countries in transition where legislative drafting resources may be scarce.

The model law resource consists of eight modules, addressing the following issues:

- (1) Criminal law issues
- (2) Treatment for drug dependence
- (3) Sterile syringe programs
- (4) Supervised drug consumption facilities
- (5) Prisons
- (6) Outreach and information
- (7) Stigma and discrimination
- (8) Heroin prescription programs

Each of the eight modules in this series is a stand-alone document. Each module begins with the introduction that you are reading now; the text of the introduction is identical in all of the modules.

Following the introduction, each model provides a prefatory note, model statutory provisions and a list of selected resources. (Taken together, the model statutory provisions in all eight modules would form a model law addressing HIV/AIDS and drug use.)

The prefatory note presents a rationale for reforming laws and policies in the area covered by the module. This is followed by a discussion of the relevant UN conventions on drug control, and of states' human rights obligations in this area.

The section on model statutory provisions contains provisions that could be included in a model law on HIV/AIDS and drug use. The provisions are divided into chapters, articles, sections and subsections. The first chapter ("General Provisions") describes the purpose of that Part of the model law, and provides definitions for many of the terms included in the provisions.

---

These references do not imply that the actual practice in the jurisdictions cited represents "best practice." There is often a long way to go in ensuring that actual practice conforms to these legal undertakings.

Some of the provisions are accompanied by a commentary. The commentary provides additional information on, or rationale for, the provision in question. For some model statutory provisions, two options are presented; a note inserted into the text indicates either (a) that one or the other option should be selected, but not both; or (b) that one or the other option, or both options, can be selected. As well, some of the provisions have been labelled as “optional.” This means that these provisions may or may not be applicable, depending on the situation in the country.

The section on selected resources contains a short list of resources which the Legal Network considers to be particularly useful. There are two subsections: one on articles, reports and policy documents, and one on legal documents.

The model law resource is heavily footnoted. The notes provide additional information on the issues being addressed, as well as full references. If the same source is cited more than once in a module, the second and subsequent references to that source are somewhat abbreviated (usually just the name of the author, or organization, and the title of the article or report).

# Module 8:

## Heroin Prescription Programs

*Module 8 contains a prefatory note which discusses the rationale for providing heroin prescription programs as a form of medical care for the purpose of improving the physical and psychological health and social well-being of people who are dependent on opioids. The prefatory note describes the relevant international laws and policies, including human rights obligations. This is followed by a section on model statutory provisions designed to enable heroin prescription programs. Module 8 concludes with a list of recommended resources.*

### Prefatory Note

#### Rationale for reform

An estimated 80 million people worldwide use opioid-type substances, of which about 11 million use heroin.<sup>8</sup> Untreated opioid dependence can have negative consequences at both an individual and a societal level. Studies have consistently estimated the mortality of untreated heroin dependence at 1–3 percent per year, at least half of which is the result of heroin overdose.<sup>9</sup>

Heroin prescription is a form of medical care that involves strictly regulated and controlled prescription of heroin. Offered on its own or as a complement to treatment programs, it is often targeted for use by people for whom opioid substitution treatment and other programs have not succeeded.<sup>10</sup> Outcome goals for patients receiving

---

<sup>8</sup> An estimated 3.3 million people use heroin in Europe and 1.5 million in the Americas. The largest number of people who use heroin is in Asia (an estimated 5.4 million). See United Nations Office on Drugs and Crime (UNODC), *World Drug Report 2006*. At [www.unodc.org/unodc/en/world\\_drug\\_report.html](http://www.unodc.org/unodc/en/world_drug_report.html). See, also, B. Fischer et al, “Heroin-assisted treatment as a response to the public health problem of opiate dependence,” *European Journal of Public Health* 12(3) (2002).

<sup>9</sup> S. Darke et al, “Heroin overdose: research and evidence-based intervention,” *Journal of Urban Health* 80 (2003): 189–200; K. Sporer, “Acute heroin overdose,” *Annals of Internal Medicine* 130 (1999): 584–590; M. Davoli et al, “A persistent rise in mortality among injecting drug users in Rome, 1980 through 1992,” *American Journal of Public Health* 87 (1997): 852–853; G. Hulse et al, “The quantification of mortality resulting from the regular use of illicit opiates,” *Addiction* 94 (1999): 221–229.

<sup>10</sup> Studies show that 10–20 percent of patients benefit minimally from opioid substitution treatment. See Das bundesdeutsche Modellprojekt zur heroingestützten Behandlung Opiatabhängiger (The German project of heroin assisted treatment of opioid dependent patients), March 2002. At [www.heroinstudie.de/english.html](http://www.heroinstudie.de/english.html). See, also, P. Blanken et al, “Matching of treatment-resistant heroin-dependent patients to medical prescription of heroin or oral methadone treatment; results from two randomized controlled trials,” *Addiction* 100 (2005): 89–95. It was shown in these trials that people who had previously participated in abstinence-oriented treatment and were found to be resistant to treatment responded more favourably to heroin treatment compared to methadone. In May 2003, the National

prescription heroin vary depending on the individual. Heroin prescription may lead to abstinence, it may be a stepping stone to opioid substitution treatment, or it may provide increased stability and greater personal autonomy while continuing to use heroin. Heroin prescription programs also aim to address health risks associated with heroin dependence by promoting safe injection practices, providing HIV/AIDS prevention education, and helping people to use the health-care system.

Several countries have implemented or have been studying heroin prescription programs, often as part of a comprehensive program of psychosocial care and medical treatment.<sup>11</sup> Findings show such programs are feasible and are associated with a number of positive outcomes,<sup>12</sup> including:

Health benefits:

- helping people to stop or reduce their illegal drug use;<sup>13</sup>
- avoiding illness and death as a result of overdose by ensuring access to a drug of known quality and strength;<sup>14</sup>

---

Treatment Agency for Substance Misuse in the U.K. acknowledged that prescribing injectable opioid drugs may be beneficial for a group of people who use opioids, in particular, those who do not respond to optimised oral methadone treatment. See [U.K.] National Treatment Agency for Substance Misuse, *Injectable heroin (and injectable methadone): Potential roles in drug treatment — Full Guidance Report*, May 2003. At [www.nta.nhs.uk/publications/prescribing/HeroinFullGuideFINAL.pdf](http://www.nta.nhs.uk/publications/prescribing/HeroinFullGuideFINAL.pdf).

<sup>11</sup> The Netherlands, the U.K. and Switzerland have prescription heroin programs. Initial exploration, pilot programs or research trials of heroin prescription have been undertaken in Australia, Belgium, Canada, Germany, Italy and Spain. Examples of study descriptions include *Kurzdarstellung des Forschungsdesigns des Modellprojekts zur opiatgestützten Behandlung* (The German project of heroin assisted treatment of opioid dependent patients) at [www.heroinstudie.de/forschungsdesign\\_kurzfassung\\_english.pdf](http://www.heroinstudie.de/forschungsdesign_kurzfassung_english.pdf) and *The North American Opiate Medication Study*, at [www.naomistudy.ca/](http://www.naomistudy.ca/).

<sup>12</sup> T.V. Perneger et al, “Randomized trial of heroin maintenance program for addicts who fail in conventional drug treatments,” *British Medical Journal* 317 (1998): 13–18. In this study, participants received intravenous heroin in addition to mandatory psychosocial support. Functioning of the participants was significantly better after six months. See, also, J. Rehm et al, “Feasibility, safety, and efficacy of injectable heroin prescription for refractory opioid addicts: a follow-up study,” *Lancet* 358(9291) (2001): 1417–1420; U. Vontobel, “Psycho-social assistance in one of the Swiss Heroin Trials,” in G. Bammer, *International Perspectives on the Prescription of Heroin to Dependent Users: A collection of papers from the United Kingdom, Switzerland, the Netherlands and Australia: Feasibility Research into the Controlled Availability of Opioids*, Stage 2 Working Paper, No. 14, National Centre for Epidemiology and Population Health, Australian National University, January 1997, p. 25; WHO, *Report of the external panel on the evaluation of the Swiss scientific studies of medically prescribed narcotics to drug addicts*, April 1999. Available via [www.druglibrary.org/schaffer](http://www.druglibrary.org/schaffer); W. Van den Brink et al, “Medical prescription of heroin to treatment resistant heroin addicts: two randomized controlled trials,” *British Medical Journal* 327 (2003).

<sup>13</sup> J. Rehm et al, “Feasibility, safety, and efficacy of injectable heroin prescription for refractory opioid addicts: a follow-up study,” p. 1419. Participants demonstrated a reduction in their illegal heroin use and criminal activities. See, also, A. Uchtenhagen et al, *Prescription of Narcotics for Heroin Addicts: Main Results of Swiss National Cohort Study — Vol. 1: Medical Prescription of Narcotics* (Basel: Karger, 1999); WHO, *Report of the external panel on the evaluation of the Swiss scientific studies of medically prescribed narcotics to drug addicts*, April 1999. Available via [www.druglibrary.org/schaffer](http://www.druglibrary.org/schaffer).

- retention in medical care;<sup>15</sup>
- facilitating a gradual change from heroin to opioid substitution therapy;<sup>16</sup>
- reducing the risk of HIV and hepatitis resulting from unsafe injection practices;<sup>17</sup> and
- promoting general health and well-being.<sup>18</sup>

#### Social benefits:

- reducing crime related to the acquisition of drugs;<sup>19</sup>

---

<sup>14</sup> In the Netherlands, administration of heroin in a health facility greatly reduced the risk of overdose and other life-threatening consequences compared to the risks normally faced by people who use heroin. See W. Van den Brink et al, *Medical co-prescription of heroin: two randomized controlled trials*, Utrecht: Central Committee on the Treatment of Heroin Addicts, Health Council of the Netherlands, 2002, p. 145–152 (available at [www.ccbh.nl](http://www.ccbh.nl)); W. Van den Brink, “Medical Co-prescription of heroin to chronic, treatment-resistant methadone patients in the Netherlands.,” *Journal of Drug Issues* 29(3) (1999): 587–608.

<sup>15</sup> Heroin on its own has been shown to be more effective than methadone in retaining patients. See L. Amato et al, “An overview of systematic reviews of the effectiveness of opiate maintenance therapies: available evidence to inform clinical practice and research,” *Journal of Substance Abuse and Treatment* 28 (2005), 324; R. Room, “Heroin maintenance and attraction into treatment,” *European Journal of Public Health* 3 (2002): 234–235; M. Ashton et al, “Role reversal,” *Drug and Alcohol* 9 (2003); N. Matrebian, “Prescribing drug of choice to opiate dependent drug users: a comparison of clients receiving heroin with those receiving injectable methadone at a West London drug clinic,” *Drug and Alcohol Review* 20(3) (2001): 267–276; A. Uchtenhagen et al, *Prescription of Narcotics for Heroin Addicts: Main Results of Swiss National Cohort Study — Vol. 1: Medical Prescription of Narcotics*.

<sup>16</sup> Swiss researchers found that the stability enjoyed in the heroin prescription program by some patients enabled them to make the transition to opioid substitution or to abstinence. See C. Brehmer et al, “Medical prescription of heroin to chronic heroin addicts in Switzerland — a review,” *Forensic Science International* 121 (2001): 23–26; J. Rehm et al, “Feasibility, safety, and efficacy of injectable heroin prescription for refractory opioid addicts: a follow-up study.”

<sup>17</sup> Prescription heroin programs facilitate regular access to sterile syringes, thus reducing the risk of transmission of HIV and hepatitis C. See, for example, T. Steffen et al, “HIV and hepatitis virus infections among injecting drug users in a medically controlled heroin prescription programme,” *European Journal of Public Health* 11 (2001): 425–30.

<sup>18</sup> Other health benefits have been documented, including a reduction in injection-related infections, fewer epileptic episodes and less depression and anxiety among those who received prescription heroin compared to other people who use illegal heroin. See C. Brehmer et al, “Medical prescription of heroin to chronic heroin addicts in Switzerland – a review,” p. 24; J. Rehm et al, “Feasibility, safety, and efficacy of injectable heroin prescription for refractory opioid addicts: a follow-up study”; R. Hartnoll, “Evaluation of heroin maintenance in controlled trial,” *Archives of General Psychiatry* 37(8) (1980): 877–883; W. Van den Brink et al, “Medical prescription of heroin to treatment resistant heroin addicts: two randomized controlled trials.”

<sup>19</sup> D. Ribeaud, “Long-term impacts of the Swiss Heroin Prescription Trials on crime of treated heroin users,” *Journal of Drug Issues* 34 (2004): 163–194; W. Van den Brink et al, “Medical prescription of heroin to treatment resistant heroin addicts: two randomized controlled trials”; A. Uchtenhagen et al, *Prescription of Narcotics for Heroin Addicts: Main Results of Swiss National Cohort Study — Vol. 1: Medical Prescription of Narcotics*; T.V. Perneger et al, “Randomized trial of heroin maintenance program for addicts who fail in conventional drug treatments.”

- reducing the number or visibility of drug markets and public drug use;
- lowering costs associated with health care, social welfare, criminal justice and prisons;<sup>20</sup> and
- promoting social integration, including with respect to employment, accommodation and family life.<sup>21</sup>

## International law and policy

### UN conventions on drug control

Under Article 4(c) of the 1961 *UN Single Convention on Narcotic Drugs*, parties to the Convention are required to “limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs.”<sup>22</sup> As the term “medical” is not defined further in the Convention, states bound by the treaty are free to determine that the prescription of heroin constitutes legitimate “medical purpose.” The Convention neither delimits the boundaries of “medical and scientific” purposes, nor substantially restricts the individual state parties in their implementation of activities within these fields. According to Article 30 of the 1961 Convention, a state may deem the prescription of a controlled substance in Schedule I to the Convention to be “necessary,” and must regulate the prescription through the use of official forms, registration and other control measures.

The 1988 *United Nations Convention Against Illicit Traffic in Narcotic and Psychotropic Substances* requires parties to “adopt appropriate measures aimed at eliminating or reducing illicit demand for narcotic drugs and psychotropic substances, with a view to reducing human suffering and eliminating financial incentives for illicit traffic.”<sup>23</sup> Designed to help individuals eliminate, reduce or manage their dependence on opioids, heroin prescription aims to promote physical and mental well being, rehabilitation and social reintegration of people who are dependent on opioids. It also falls within the scope of measures intended to reduce illegal demand for drugs and human suffering by

---

<sup>20</sup> J. Rehm et al, “Feasibility, safety, and efficacy of injectable heroin prescription for refractory opioid addicts: a follow-up study.” The financial benefits from less crime, less health-care use and improvements in social functioning were found to be higher than the costs of operating a prescription heroin program (p. 1420). See, also, WHO, *Report of the external panel on the evaluation of the Swiss scientific studies of medically prescribed narcotics to drug addicts*.

<sup>21</sup> See C. Brehmer, “Medical prescription of heroin to chronic heroin addicts in Switzerland — a review”; A. Uchtenhagen et al, *Prescription of Narcotics for Heroin Addicts: Main Results of Swiss National Cohort Study — Vol. 1: Medical Prescription of Narcotics*.

<sup>22</sup> *Single Convention on Narcotic Drugs*, 1961, UN, 520 UNTS 331, as amended by the 1972 *Protocol Amending the Single Convention on Narcotic Drugs*, art. 38.1. This approach, limiting activities concerning drugs to those with medical and scientific purposes, is repeated in the *Convention on Psychotropic Substances*, 1971, UN, 1019 UNTS 175, art. 5.

<sup>23</sup> *United Nations Convention Against Illicit Traffic in Narcotic and Psychotropic Substances*, 1988, UN Doc. E/CONF.82/15 (1988), 28 ILM 493 (1989), art. 14.4.

removing the need to purchase illegal drugs, by enabling people to avoid participating in crime often associated with drug use, and by helping people to avoid the health risks associated with the sharing of drug consumption equipment.

Heroin prescription programs focus on addressing negative health and social risks associated with opioid dependence and cannot be construed to promote drug use generally. Nor are they necessarily associated with efforts to decriminalize or legalize heroin.

## Human rights obligations

Heroin prescription is consistent with a number of state responsibilities under international human rights instruments. The *Universal Declaration of Human Rights* states that “everyone has the right to a standard of living adequate for the health and well-being of himself ... including ... medical care and necessary social services.”<sup>24</sup> Similarly, the *International Convention on Economic, Social and Cultural Rights* (ICESCR) recognizes the “right of everyone to the highest attainable standard of physical and mental health.”<sup>25</sup> The UNAIDS/OHCHR *International Guidelines on HIV/AIDS and Human Rights* recommend that states ensure the “widespread availability of qualitative prevention measures and services, adequate HIV prevention and care information” in order to protect the human rights of people living with HIV/AIDS and stem the spread of the virus.<sup>26</sup> By reaching out to a particularly vulnerable group of people, heroin prescription programs facilitate the right to health and well-being and help ensure that the right of people who use opioids to the highest attainable standards of health is respected. Furthermore, they promote the widespread availability of adequate HIV prevention and care information by facilitating contact with health practitioners and services, and by helping people who use opioids to take steps to prevent blood-borne diseases, such as HIV and hepatitis.

---

<sup>24</sup> *Universal Declaration of Human Rights*, UN General Assembly, adopted and proclaimed by General Assembly resolution 217 A (III) of 10 December 1948, art. 25.

<sup>25</sup> *International Covenant on Economic, Social and Cultural Rights* (ICESCR), UN General Assembly, 993 UNTS 3 (1966), art. 12. General Comment 14 to Article 12 states that “every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity. The realization of the right to health may be pursued through numerous, complementary approaches, such as the formulation of health policies, or the implementation of health programmes developed by the World Health Organization (WHO), or the adoption of specific legal instruments.” See, UNESCR, Substantive issues arising in the implementation of the International Covenant on Economic, Social and Cultural Rights, General Comment No. 14 (2000), para. 1.

<sup>26</sup> Office of the High Commissioner of Human Rights (OHCHR) and UNAIDS, *International Guidelines on HIV/AIDS and Human Rights: Revised Guideline 6 — Access to prevention, treatment, care and support*. Available via [www.ohchr.org](http://www.ohchr.org).

# Model Statutory Provisions

## Chapter I. General Provisions

### Article 1. Purpose of this Part

The purpose of this Part is to authorize heroin prescription programs, with the object of improving the physical and psychological health and social well-being of people who are dependent on opioids. Its aim is to:

- (a) enable programs providing heroin by prescription for people for whom it is medically indicated;
- (b) provide the legal structure for clinic-based, and physician- and pharmacy-based service provision;
- (c) protect the human rights of people receiving prescription heroin; and
- (d) ensure quality of care in the programs.

### Article 2. Definitions

For the purposes of this Part, the following definitions are used:

“Dependence” means the criteria for dependence in the International Classification of Diseases (ICD-10) or the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) criteria.<sup>27</sup>

“Clinic” means any facility authorized by [the relevant public health authority] to treat multiple heroin-dependent patients.

“Health practitioner” means a person entitled under the [relevant health law] to provide health services. Health practitioners include accredited physicians, registered nurses and other trained medical staff.

“Heroin” means diamorphine, its salts and any preparation or other product containing diamorphine or its salts.<sup>28</sup> It may be in any form, including but not limited to injectable, inhalable and oral form. It may be prescribed alone or in conjunction with other substances, including but not limited to methadone.

---

<sup>27</sup> The ICD-10 diagnostic guidelines can be found at [www.who.int/substance\\_abuse/terminology/definition1/en/](http://www.who.int/substance_abuse/terminology/definition1/en/). The DSM-IV definition is provided in *DSM-IV, Diagnostic and Statistical Manual of Mental Disorders*, ed. 4. (Washington DC: American Psychiatric Association, 1994). At <http://allpsych.com/disorders/substance/substancedependence.html>.

<sup>28</sup> This definition is derived from *The Misuse of Drugs (Supply to Addicts) Regulations*, U.K., 1997, s. 3(3)(b). Available via [www.opsi.gov.uk](http://www.opsi.gov.uk).

“Heroin prescription” means the prescription of heroin by an authorized physician to patients who are dependent on heroin.

“Patient” means any person on a course of medically prescribed heroin.

“Pharmacist” means an accredited pharmacist who is authorized to dispense heroin.

“Prescribing physician” means an accredited physician who is authorized to prescribe heroin.

“Staff” of the heroin prescription program includes the following persons:

- (a) the operator or manager of the program;
- (b) a person engaged by the operator or manager of the program to provide services at the facility, whether under a contract of employment or otherwise; and
- (c) a person engaged by the operator or manager of the program to provide voluntary assistance at the facility.

“Supervised consumption” means the consumption of prescribed heroin under observation at a specialist opioid substitution clinic, physician’s office, pharmacy, hospital or other medical facility.

“Take-away dose” means any dose of heroin given to the patient as part of a heroin prescription program, for which supervised consumption by a health professional is not required.

## Chapter II. Patients' Rights

### Article 3. Basic rights of patients

Every patient has the right:

- (a) to clinical management of heroin dependence with prescribed heroin in accordance with good clinical practice;
- (b) to clinical management of heroin dependence without discrimination;
- (c) to meaningful participation in determining his or her own goals of clinical management of heroin dependence, which may include, but are not limited to, abstinence or changes in drug use that minimize the harms of dependence;
- (d) to meaningful participation in all decisions regarding clinical management of heroin dependence, including when and how clinical management of heroin dependence is initiated and withdrawal from clinical management of heroin dependence;
- (e) to exercise his or her rights as a patient, including:
  - (i) reporting without retribution any instances of suspected abuse, neglect, or exploitation suffered of patients of heroin prescription programs;
  - (ii) a grievance and appeal process, in accordance with national laws and regulations;
  - (iii) input into the policies and services of heroin prescription program; and
  - (iv) voluntary withdrawal from clinical management of heroin dependence at any time.
- (f) to confidentiality of medical records and clinical test results; and
- (g) to be fully informed, including but not limited to the right to receive information on:
  - (i) his or her state of health;
  - (ii) his or her rights and obligations as a patient, as specified in this Part and in other applicable law;
  - (iii) the procedure for making a complaint about the services received through the heroin prescription program; and
  - (iv) cost and payment conditions and the availability of medical insurance and other possible subsidies.<sup>29</sup>

### Article 4. Informed consent

- (1) Informed voluntary consent of a patient is a necessary preliminary condition for initiating the clinical management of heroin dependence.

---

<sup>29</sup> For other sources that establish patients' rights, see WHO Europe, *A Declaration on the Promotion of Patients' Rights in Europe*, ICP/HLE 121, 28 June 1994. Available via [www.who.int/genomics/public/patientrights/en/](http://www.who.int/genomics/public/patientrights/en/). Documents on patients' rights from a variety of countries are also available via the site.

(2) The following elements are required for consent to clinical management of heroin dependence:

- (a) the consent must relate specifically to the clinical management of heroin dependence;
- (b) the consent must be fully informed;
- (c) the consent must be given voluntarily;
- (d) the consent must be provided in writing; and
- (e) the consent must not be obtained through misrepresentation or fraud.

(3) A consent to treatment is fully informed if, before giving it:

- (a) the person received the information about the matters set out in Section (4) that a reasonable person in the same circumstances would require in order to make a decision about the clinical management of heroin dependence; and
- (b) the person received responses to his or her requests for additional information about those matters.

(4) The matters referred to in Section (3) are:

- (a) the nature of the clinical management of heroin dependence;
- (b) the expected benefits of the clinical management of heroin dependence;
- (c) the material risks of the clinical management of heroin dependence;
- (d) the material side effects of the clinical management of heroin dependence;
- (e) alternative courses of action; and
- (f) the likely consequences of not having the clinical management of heroin dependence.<sup>30</sup>

## **Article 5. Withdrawal from clinical management of heroin dependence**

- (1) A patient shall have the right to withdraw voluntarily from clinical management of heroin dependence at any time.
- (2) The health practitioner shall fully inform the patient of the potential risks and benefits of withdrawal from clinical management of heroin dependence, and shall work with the patient to ensure the patient's safety and comfort during the withdrawal process.
- (3) The health practitioner shall not discontinue services that are needed unless the patient requests the discontinuation, alternate services are arranged, or the patient is given a reasonable opportunity to arrange alternate services.

---

<sup>30</sup> This wording is derived from the *Health Care Consent Act*, 1996, Ontario [Canada], s. 11.

- (4) The withdrawal from clinical management of heroin dependence, with an explanation of likely consequences, shall be recorded or registered in medical documentation and signed by the patient and health practitioner.
- (5) Involuntary withdrawal from clinical management of heroin dependence shall be avoided except where compelling reasons exist. Regulations governing grounds for involuntary withdrawal shall be clearly communicated to patients at the outset of clinical management of heroin dependence.

## Article 6. Confidentiality

- (1) The confidentiality of all health care information shall be respected. Records of the identity, diagnosis, prognosis or treatment of any patient which are obtained in the course of clinical management of heroin dependence:
  - (a) are confidential;
  - (b) are not open to public inspection or disclosure;
  - (c) shall not be shared with other individuals or agencies; and
  - (d) shall not be discoverable or admissible during legal proceedings;
- (2) No record referred to in Section (1) may be used to:
  - (a) initiate or substantiate any criminal charges against a patient; or
  - (b) act as grounds for conducting any investigation of a patient.
- (3) Program staff cannot be compelled under [relevant criminal procedure code] to provide evidence concerning the information that was entrusted to them or became known to them in this capacity.<sup>31</sup>
- (4) All use of personal information of patients and program staff in research and evaluation shall be undertaken in conditions guaranteeing anonymity, and any such information shall also be governed by Section (2).

### Commentary: Article 6

The right to privacy is articulated in several international instruments.<sup>32</sup> Many jurisdictions and national institutions, such as hospitals, also have legislation or guidelines concerning patients' rights, including the right to confidentiality.<sup>33</sup> In the

---

<sup>31</sup> This wording is derived from Germany's *Code of Criminal Procedure*, s. 53, para. 1, no. 3b.

<sup>32</sup> See, for instance, Article 12 of the *Universal Declaration of Human Rights*; Article 8(1) of the *European Convention for the Protection of Human Rights and Fundamental Freedoms*; Article 17(1) of the *International Covenant on Civil and Political Rights* (ICCPR), UN General Assembly, 999 UNTS 171, 1966.

<sup>33</sup> For example, [U.K.] National Treatment Agency for Substance Misuse, *Confidentiality and information sharing*, September 2003 (at [www.nta.nhs.uk/publications/docs/Confidentiality1.pdf](http://www.nta.nhs.uk/publications/docs/Confidentiality1.pdf)); WHO Europe, A

context of heroin prescription programs confidentiality is particularly important for a number of reasons. First, drug use is often heavily stigmatized, and people may fear the consequences of their health information being shared, such as discrimination and police attention. Further, the failure to guarantee confidentiality will likely discourage people from seeking care or entering a heroin prescription program, disclosing accurate information, or participating in research for fear that information about their health status, including HIV status, may be released.

---

*Declaration on the Promotion of Patients' Rights in Europe*; Israel's *Patient's Rights Act*, 1996, art. 19, 20 (at <http://waml.haifa.ac.il/index/reference/legislation/israel/israel1.htm>).

## Chapter III. Enabling Heroin Prescription Programs

### Article 7. Authorization to operate heroin prescription programs

(1) The [relevant public health authority] shall be responsible for:

- (a) authorizing clinics, physicians, pharmacists and patients;
- (b) authorizing the acquisition, preparation and circulation of heroin necessary for operation of heroin prescription programs;
- (c) supervising clinics regularly, in collaboration with local authorities;
- (d) making recommendations to physicians, pharmacists and clinics, and establishing policies to ensure quality coordinated heroin prescription programs;
- (e) supporting the training of physicians, pharmacists and clinic personnel; and
- (f) encouraging and supporting research on questions relating to medical prescription of heroin.<sup>34</sup>

### Article 8. Principle of interdisciplinarity

Heroin prescription programs should comprise physical care, mental health care and social care.<sup>35</sup>

### Article 9. Eligibility for heroin prescription

(1) The decision whether to prescribe heroin shall be made after thorough examination of the patient's state of health and consultation with the patient.

(2) Heroin shall not be prescribed unless:

- (a) in the opinion of the prescribing physician, the patient has an established heroin dependence;
- (b) in the opinion of the prescribing physician, the patient suffers physical, psychological or social harm due to his or her established heroin dependence; and
- (c) the patient provides informed voluntary consent.<sup>36</sup>

---

<sup>34</sup> This section is derived from the *Ordonnance sur la prescription médicale d'héroïne*, Le Conseil fédéral suisse, 1999, art 16.

<sup>35</sup> This section is derived from the *Ordonnance sur la prescription médicale d'héroïne*, Le Conseil fédéral suisse, 1999, art. 3(1). A WHO review of heroin trials in Switzerland found that one of the success factors of those trials was engaging "highly qualified, multidisciplinary teams." See WHO, *Report of the external panel on the evaluation of the Swiss scientific studies of medically prescribed narcotics to drug addicts*. Examples of "social care" might include job training, assistance with housing, financial guidance, support from social workers and participation in peer support groups.

<sup>36</sup> This section is derived from the *Ordonnance sur la prescription médicale d'héroïne*, Le Conseil fédéral suisse, 1999, art. 5(3).

## Commentary: Article 9

A question arising from the provision of prescription heroin is whether such programs should be open to all people who have used heroin for some time or only to those for whom dependence treatment has been unsuccessful.<sup>37</sup> Most of the countries offering heroin prescription programs or conducting trials conceive of these programs as a “last resort,” after dependence treatment of some kind, including opioid substitution therapy, has not succeeded.<sup>38</sup> Some experts have recognized that such an approach excludes what is likely to be a significant population of persons who have not sought any kind of drug dependence treatment, or have not sought treatment in recent years or months.<sup>39</sup> This is exactly the kind of population that is most likely to be in need of such services. A few programs have, for example, formally allowed admission to heroin prescription programs of people who have not sought treatment in the last six months.<sup>40</sup>

The position adopted here is that persons who suffer physiological harm, psychological harm or, more generally, social harm due to dependence on heroin should be considered for admission. As a matter of human rights, requiring someone to undergo unsuccessful treatment first — an often painful, even torturous process — is incompatible with the idea of the highest attainable standard of health services. An approach based on human rights would encourage less restrictive admission criteria for a program that offers proven health and social benefits. Similarly, there should be no categorical exclusion of persons from heroin prescription programs. No minimum age, prescribed time of dependence, or

---

<sup>37</sup> With respect to the required duration of dependence, existing trials have varying requirements. Canada’s North American Opiate Medication Initiative (NAOMI) trial requires an addiction to opioids for at least five years and daily injection opioid use for at least one year. Germany’s trials require opioid dependency for at least five years. Trials in the Netherlands require a history of heroin dependency of at least five years. Switzerland’s trials require heroin dependency of at least two years.

<sup>38</sup> For examples of eligibility criteria, see the *Arrêté fédéral sur la prescription médicale d’héroïne*, L’Assemblée fédérale de la Confédération suisse, 9 October 1998, art. 7. Available via [www.admin.ch/](http://www.admin.ch/); Canadian Institutes of Health Research, *North American Opiate Medication Initiative* (at [www.naomistudy.ca/enrolment.html](http://www.naomistudy.ca/enrolment.html)); W. Van den Brink et al, *Medical co-prescription of heroin: two randomized controlled trials*, p. 29.

<sup>39</sup> The U.K. Parliament’s Select Committee on Home Affairs reported, “[T]he suggestion is that diamorphine [heroin] on prescription may offer a way of encouraging these people, too, to enter treatment. Dr [Gerrit] Van Santen [chief physician, City of Amsterdam Department of Mental Health] said: ‘I think the power of the prescribing of heroin lies not among those poor performers on methadone but on those people not reached yet by services, by necessary care.’ Professor [Jürgen] Rehm [professor, University of Zurich] too described this as potentially a much more important role for diamorphine prescription than that explored by the trials: ‘We want to see can they attract non-treatment goers in our society, which is way more a problem in Switzerland.’ ” See Select Committee on Home Affairs, Third Report: *The government’s drug policy: is it working?*, U.K. Parliament, 22 May 2002, para. 193. Available via [www.publications.parliament.uk/pa/cm200102/cmselect/cmhaff/cmhaff.htm](http://www.publications.parliament.uk/pa/cm200102/cmselect/cmhaff/cmhaff.htm).

<sup>40</sup> See, for example, *Das bundesdeutsche Modelprojekt zur heroingestützten Behandlung Opiatabhängiger* (The German project of heroin assisted treatment of opiate dependent patients) at [www.heroinstudie.de/forschungsdesign\\_kurzfassung\\_english.pdf](http://www.heroinstudie.de/forschungsdesign_kurzfassung_english.pdf). Note, however, that the German trial requires “documented previous experience with addiction treatment programmes or negative course of maintenance treatment”, p. 2.

number of failed attempts at treatment should be enforced as criteria for receiving prescription heroin. In order for heroin prescription programs to effectively reduce the health risks associated with injection drug use, they should be made accessible to all persons for whom heroin prescription is medically indicated.

## **Article 10. Duration and dosage of prescription heroin**

- (1) The prescribing physician shall determine the appropriate dose in consultation with the patient and in accordance with best medical practice. The dosage shall aim to achieve an effective level of physical and psychological comfort while minimizing the likelihood of overdose.
- (2) The dosage should never be held out as a reward to the patient, nor withheld as a punishment of the patient.
- (3) The duration of prescription heroin should be adequate to ensure its effectiveness according to best medical practice.

### **Commentary: Article 10**

International studies do not specify the optimal duration of medically prescribed heroin or the dosage to be used.<sup>41</sup> In determining duration and dosage, “best practice” experiences underline the importance of consulting with and listening to the patient and finding solutions that allow him or her to live without physical discomfort.

Considered to be relatively free of long-term adverse health consequences when consumed in a safe manner, heroin has an established history of use in the medical field.<sup>42</sup> It is recognized that consumption of prescribed heroin may continue over a long period and should not, in any case, be thought of as having a predetermined duration.<sup>43</sup> In some situations, people have been able to effectively manage and regulate their use.

---

<sup>41</sup> Dosing practices vary widely between and within countries. Physicians in the U.K. reported prescribing between five and 1500 mg/day of heroin. See N. Metrebian et al, “Survey of doctors prescribing diamorphine (heroin) to opiate-dependent drug users in the United Kingdom,” *Addiction* 97 (2002): 1155–1161. In the Swiss trials, the average dose was 470 mg/day; see C. Brehmer et al, “Medical prescription of heroin to chronic heroin addicts in Switzerland — a review”.

<sup>42</sup> In the United Kingdom, physician prescription of heroin to opioid addicts has been officially endorsed since 1926. Physicians have been required to be specially licensed since 1968. In the U.S., heroin-assisted therapy clinics were operational from 1919–1923. In Canada, in 1972, a commission of inquiry led by Mr. Justice LeDain recommended the implementation of a heroin prescription trial for people who could not be attracted into conventional forms of opioid dependence treatment. See G. LeDain, *Final Report of the Commission of Inquiry into the Non-Medical Use of Drugs*, Information Canada, Ottawa, 1973.

<sup>43</sup> Some studies have indicated that heroin prescription should be long-lasting to obtain stable positive outcomes. See W. Van den Brink et al, “Medical prescription of heroin to treatment resistant heroin addicts: two randomized controlled trials.”

People who are dependent on opioids should be able to remain in heroin prescription programs for as long as those programs are beneficial for them.<sup>44</sup>

In respect of dosage, it is imperative that the adjustment of dosages, especially the reduction of the dose, never be used as punishment or inducement for behavioural change. Thorough patient consultation, respecting basic patient rights, is necessary in order to determine the appropriate dosage. Patients have a right to be involved in decisions affecting their health, including the determination of the dose they receive.

## **Article 11. Central patient list**

- (1) Where a physician intends to prescribe heroin for the first time to a patient, the prescribing physician shall not issue a prescription for the heroin until he or she assigns a unique identifier to the patient and notifies the [responsible public health authority] of that unique identifier.<sup>45</sup>
- (2) The [responsible public health authority] shall maintain a central list, which shall contain the information notified to it under Section (1).
- (3) Where a notification is made to the [responsible public health authority] in accordance with Section (1), the [responsible public health authority] shall inform the prescribing physician as to whether the patient has previously been included in the central list.
- (4) The confidentiality of all providers and patients shall be respected. Any information obtained by the [responsible public health authority] or any other body that would identify patients shall be regulated so as to preserve the right to confidentiality.

---

<sup>44</sup> D. Small et al, "Policy makers ignoring science and scientists ignoring policy: the medical ethical challenges of heroin treatment," *Harm Reduction Journal* 3 (2006): 16.

<sup>45</sup> Some needle exchanges in New York [U.S.] use a form of enrollment card that does not record the full name of the program participant, but rather a unique identifier code formed from letters of their name and numbers from their birthday. No address or other contact information is required.

## Chapter IV. Service Provision

[Two options are presented below: clinic-based service provision (Articles 12-16; or physician- and pharmacy-based service provision (Articles 16-17). One or the other (or both) options can be selected.]

### ***Option 1: Clinic-based service provision***

#### **Article 12. Authorization of clinics**

- (1) The [relevant public health authority] may authorize a clinic to provide medically prescribed heroin.
- (2) In order to be able to continue to provide prescription heroin when a patient is hospitalized or imprisoned, the hospital or the medical service in the correctional facility may be temporarily authorized to provide medically prescribed heroin to the patient.<sup>46</sup>

#### **Article 13. Operational guidelines**

- (1) The [relevant public health authority] shall create operational guidelines for the clinics, describing:
  - (a) management of the clinic;
  - (b) personnel and their qualifications;
  - (c) location(s);
  - (d) number of programs;
  - (e) safety measures;<sup>47</sup>
  - (f) financing;
  - (g) relation to other services;
  - (h) treatment philosophy;
  - (i) modes of collaboration among personnel; and
  - (j) ongoing training practices.

- (2) Any interested person shall be able to consult such plan.<sup>48</sup>

---

<sup>46</sup> This section is derived from the *Ordonnance sur la prescription médicale d'héroïne*, Le Conseil fédéral suisse, art. 18(2).

<sup>47</sup> For example, in the NAOMI trial, “[t]he heroin will be dispensed to subjects in a pre-filled syringe that must be used under the observation of trained health care professionals in the high-security medical clinics developed for the trial.” See Canadian Institutes of Health Research, *Questions & answers: CIHR NAOMI clinical trial*, March 2005. Available via [www.naomistudy.ca](http://www.naomistudy.ca).

<sup>48</sup> This section is derived from the *Ordonnance sur la prescription médicale d'héroïne*, Le Conseil fédéral suisse, art. 15.

## Article 14. Administration of heroin

- (1) As a general rule, the administration of heroin shall be the supervised consumption by a patient on a regular schedule within a clinic or other health care setting while under direct observation.
- (2) The determination of eligibility for take-away doses shall be based solely on:
  - (a) the clinical stability of the patient; and
  - (b) the patient's ability to comply with the procedures of the program.
- (3) The prescribing physician shall have discretion to initiate take-away doses to patients who do not meet the eligibility criteria in Section (2) where:
  - (a) the patient has a medical condition or disability that limits his or her mobility;  
or
  - (b) the distance the patient must travel to the clinic or other health care setting, or other circumstance, restricts his or her ability to have his or her consumption supervised on each occasion.
- (4) The prescribing physician shall specify the procedures of the program for take-away doses in writing and shall ensure that copies are provided to the patient and the dispensing pharmacist.

### Commentary: Article 14

The supervised consumption of heroin in a clinical setting provides the patient with a structured regime and the benefit of medical supervision in the case of an emergency.<sup>49</sup> Supervised consumption can also reduce the risk of diversion to illegal markets.

However, experience in other clinic-based medical care programs, such as opioid substitution treatment, has demonstrated benefits associated with the provision of take-away doses. Recognized benefits include promoting prescription adherence, retention of program participants, reducing congregation at dispensing points, and improving access to treatment by reducing travel difficulties.<sup>50</sup> Such benefits are potentially applicable to the provision of prescription heroin.

---

<sup>49</sup> N. Hunt, *A review of the evidence-base for harm reduction approaches to drug use*, Forward Thinking on Drugs, 2003. At [www.forward-thinking-on-drugs.org/review2.html](http://www.forward-thinking-on-drugs.org/review2.html). See, also, G. Simpson et al, *Prescribing heroin – what is the evidence?*, Joseph Rowntree Foundation, 2003 (at [www.jrf.org.uk/knowledge/findings/socialpolicy/pdf/943.pdf](http://www.jrf.org.uk/knowledge/findings/socialpolicy/pdf/943.pdf)); G. Bammer, “Heroin Prescription — A comparison of the English, Swiss, Dutch and Australia situations,” in G. Bammer, *International Perspectives on the Prescription of Heroin to Dependent Users: A collection of papers from the United Kingdom, Switzerland, the Netherlands and Australia: Feasibility Research into the Controlled Availability of Opioids*, Stage 2 Working Paper, No. 14, National Centre for Epidemiology and Population Health, Australian National University, January 1997, p. 45.

<sup>50</sup> For example, these advantages are reflected in New South Wales [Australia], *Guidelines for prescribing methadone for unsupervised administration ‘take-away’ doses* and may be transferable to prescription heroin programs. At [www.health.nsw.gov.au/public-health/dpb/publications/pdf/guidelines\\_takeaway.pdf](http://www.health.nsw.gov.au/public-health/dpb/publications/pdf/guidelines_takeaway.pdf).

In designing a treatment schedule, medical practitioners have the responsibility to take into account the needs of individual patients. Take-away doses should be prescribed at the discretion of trained medical staff after undertaking a suitability assessment and appropriate patient education.<sup>51</sup> In addition, take-away doses should never be withheld as a punishment. Risks associated with take-away doses (e.g., diversion, overdose) can be minimized by monitoring progress and reassessing their suitability over time.

### **Article 15. Storage**

Any supply of heroin shall be stored in a secure location in the clinic that has been authorized for this purpose.

### **Article 16. Safety**

- (1) The [relevant public health authority] shall develop health and safety protocols to deal with emergency situations, including overdoses.
- (2) The person responsible for the control and security of the heroin supply must be able to present at any time the clinic's authorization for the acquisition and use of heroin.<sup>52</sup>

– AND/OR –

## ***Option 2: Physician and pharmacy-based service provision***

### **Article 17. Authorization of prescribing physicians**

- (1) The [relevant public health authority] may authorize physicians to prescribe heroin.
- (2) A physician shall apply to the [relevant public health authority] for such an authorization and shall attest in the application to meeting the requirements established by regulations.
- (3) The [relevant public health authority] shall ensure sufficient availability of the requisite training, exam, and clinical attachment opportunities as may be established by Regulations.

---

<sup>51</sup> In the U.K., heroin is prescribed by a doctor and dispensed from a community or hospital pharmacy for unsupervised injection at home. See N. Hunt, *A review of the evidence-base for harm reduction approaches to drug use*.

<sup>52</sup> This section is derived from the *Ordonnance sur la prescription médicale d'héroïne*, Le Conseil fédéral suisse, art. 14.

## Article 18. Authorization of pharmacists

- (1) The [relevant public health authority] shall authorize pharmacists to dispense heroin.
- (2) A pharmacist shall apply to the [relevant public health authority] for such an authorization and shall attest in the application to meeting the requirements established in the Regulations.
- (3) The [relevant public health authority] shall ensure sufficient availability of the requisite training, exam, and clinical attachment opportunities as may be established by Regulations.

### Commentary: Article 17 and 18

Physicians and pharmacists should be authorized to prescribe and dispense prescription heroin by the appropriate health authority. For example, in the United Kingdom, where prescription of heroin to people who are dependent on opioids has been officially endorsed since 1926, physicians have been required to be specially licensed since 1968.<sup>53</sup> Appropriate training and guidelines for physicians and pharmacists is also required.<sup>54</sup>

---

<sup>53</sup> See N. Hunt, *A review of the evidence-base for harm reduction approaches to drug use*; [U.K.] National Treatment Institute, *Injectable Heroin (and injectable methadone): Potential roles in drug treatment*, 2003. At [www.nta.nhs.uk/publications/prescribing/HeroinFullGuideFINAL.pdf](http://www.nta.nhs.uk/publications/prescribing/HeroinFullGuideFINAL.pdf); [U.K.] National Treatment Agency for Substance Misuse, *Prescribing services for drug misuse*, January 2003 (at [www.nta.nhs.uk/publications/prescribing/briefing2.pdf](http://www.nta.nhs.uk/publications/prescribing/briefing2.pdf)).

<sup>54</sup> See, for example, [U.K.] National Treatment Agency for Substance Misuse, *Roles and responsibilities of doctors in the provision of treatment for drug and alcohol misusers*, September 2005 (at [www.nta.nhs.uk/programme/national/docs/Doctors\\_roles\\_and\\_responsibilities.pdf](http://www.nta.nhs.uk/programme/national/docs/Doctors_roles_and_responsibilities.pdf)); [U.K.] National Treatment Agency for Substance Misuse, *Best practice guidance for commissioners and providers of pharmaceutical services for drug users*, February 2006 (at [www.nta.nhs.uk/publications/Prescribing/Pharmaceutical\\_services\\_for\\_drug\\_users.pdf](http://www.nta.nhs.uk/publications/Prescribing/Pharmaceutical_services_for_drug_users.pdf)).

## Selected Resources

*This section provides a list of resources that the Legal Network considers to be particularly relevant.*

### Articles, reports and policy documents

British Institute of International and Comparative Law. *Draft fourth framework convention on risk management*. 2003. At [www.senliscouncil.net/documents/BIICL\\_HR\\_Framework#search=%22Draft%20fourth%20framework%20convention%22](http://www.senliscouncil.net/documents/BIICL_HR_Framework#search=%22Draft%20fourth%20framework%20convention%22).

Council of the European Union. *Recommendation on the prevention and reduction of health-related harm associated with drug dependence* of 18 June 2003. 2003/488/EC.

European Parliament. *Recommendation to the Council and the European Council on the EU drugs strategy (2005-2012)*. A6-0067/2004, 15 December 2004.

Hartnoll, R. et al. "Evaluation of heroin maintenance in controlled trial." *Archives of General Psychiatry* 37 (1980): 877–883.

McCusker, C. et al. "Prescribing drug of choice to illicit heroin users: the experience of a U.K. community drug team." *Journal of Substance Abuse Treatment* 13(6) (1996): 521–531.

Metrebian, N. et al. "Prescribing drug of choice to opiate dependent drug users: a comparison of clients receiving heroin with those receiving injectable methadone at a West London drug clinic." *Drug and Alcohol Review* 20 (2001): 267–276.

Metrebian, N. et al. "Feasibility of prescribing injectable heroin and methadone to opiate dependent drug users: associated health gains and harm reductions." *Medical Journal of Australia* 168 (1998): 596–600.

Perneger, T.V. et al. "Randomised trial of heroin maintenance programme for addicts who fail in conventional drug treatments." *British Medical Journal* 317 (1998): 13–18.

Rehm, J. et al. "Feasibility, safety and efficacy of injectable heroin prescription for refractory opioid addicts: a follow-up study." *Lancet* 358 (2001): 1417–1420.

Uchtenhagen, A. et al. *Prescription of Narcotics for Heroin Addicts: Main Results of Swiss National Cohort Study — Vol. 1: Medical Prescription of Narcotics*. Basel: Karger, 1999.

Van den Brink, W. et al. *Medical co-prescription of heroin: two randomized controlled trials*. Utrecht: Central Committee on the Treatment of Heroin Addicts, Health Council of the Netherlands, 2002.

WHO. *Report of the external panel on the evaluation of the Swiss scientific studies of medically prescribed narcotics to drug addicts*, April 1999.

## **Legal documents**

*Ordonnance sur la prescription médicale d'héroïne*. Le Conseil fédéral suisse, 1999. [Switzerland].

*The Misuse of Drugs Regulations 2001*, Statutory Instrument 2001 No. 3998. [United Kingdom].



Canadian  
HIV/AIDS  
Legal  
Network | Réseau  
juridique  
canadien  
VIH/sida

**Canadian HIV/AIDS Legal Network**  
**1240 Bay Street, Suite 600**  
**Toronto, Ontario**  
**Canada M5R 2A7**  
**Telephone: +1 416 595-1666**  
**Fax: +1 416 595-0094**  
**E-mail: [info@aidslaw.ca](mailto:info@aidslaw.ca)**  
**[www.aidslaw.ca](http://www.aidslaw.ca)**