

# Reducing harm associated with drugs of abuse

## The role of pharmacists

2017



International  
Pharmaceutical  
Federation

## Colophon

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Recommended citation: International Pharmaceutical Federation. Reducing harm associated with drugs of abuse: The role of pharmacists. The Hague, the Netherlands: International Pharmaceutical Federation, 2017.

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## Introduction

In September 2015, the International Pharmaceutical Federation (FIP) Bureau approved the terms of reference for a Working Group on Pharmacists' Role in Harm Reduction, with the terms of reference as shown in Appendix 1. The specific impetus for this working group was provided by the 2014 resolution, proposed by the FIP member organisation, the Uruguayan Association of Chemistry and Pharmacy (*Asociación de Química y Farmacia del Uruguay, AQFU*), and supported unanimously by the FIP Council: "The FIP Council requests the Bureau (through FIP ExCo) to develop a reference document — possibly leading to a FIP policy statement — on the role of pharmacists in discouraging the use of potentially harmful substances for recreational purposes, and in fighting substance abuse and addictions. Such a document could also discuss the distribution of marijuana and other potentially harmful substances used for recreational purposes through community pharmacies."

The working group has mostly worked electronically, with one face-to-face meeting during the FIP congress in Buenos Aires in September 2016.

The members of the working group were:

- Andy Gray (South Africa; chair)
- Carlos Lacava (Uruguay)
- Anabela Madeira (Portugal)
- Marwan Akel (Lebanon)
- Jamie Earnest (USA)
- Liezl Channing (Switzerland)

Secretariat support was provided by Zuzana Kusynová (FIP).

The objectives set for the working group were to:

- Collect and comment on the available evidence for the role and impact of pharmacists and their associations in harm reduction programmes;
- Provide an overview of existing national and regional policies around harm reduction that support pharmacists' involvement in such activities;
- Address specifically the question of the sale of marijuana for recreational use, and how this might involve pharmacists, as part of a harm reduction approach;
- Review the continued relevance of existing FIP Statements on any harm reduction programmes or policies.

A draft report was prepared by the working group and submitted to the FIP Bureau for consideration at its March 2017 meeting. Following input from the Bureau, the draft report was circulated to FIP member organisations, with input elicited by June 2017. A revised report was then developed, based on the inputs received from the Bureau and member organisations, and was adopted by the Bureau in September 2017.

Although the term "harm reduction" has a specific meaning in relation to drugs of abuse, it can also be understood to apply to a broader health promotion effort. Contrary to the initial proposed terms of reference, the working group decided to focus specifically on the issue of harm reduction as applied to drugs of abuse, and not on the broader questions of abuse of alcohol, tobacco, or prescription-only or non-prescription medicines. The major issue at hand, as outlined in the 2014 FIP Council resolution, relates to drugs of abuse, and, in particular, to the potential role of pharmacists in controlling and supplying substances that might previously have been considered illicit. This focus is reflected in the amended title of the report of the working group: "**Reducing harm associated with drugs of abuse — The role of pharmacists**".

With regard to the broader issues, FIP already has a statement on the role of pharmacists in smoking cessation.<sup>1</sup> That statement may need updating with regard to the vexing issue of electronic nicotine delivery devices (such as e-cigarettes). However, that topic is worthy of a separate working group, as the questions are far from resolved and public policy is still evolving. Although they are somewhat dated, FIP also has joint

statements in relation to the role of the pharmacist in HIV (with the World Health Organization)<sup>2</sup> and in relation to responsible self-medication (with World Self-Medication Industry).<sup>3</sup>

### Structure of this report

This report represents the outcome of the literature search conducted by the working group, their deliberations and engagement, and the insights gained from the direct involvement of some working group members in the provision of harm reduction services and/or the development of national policies in this regard, as well as the inputs provided to the initial draft. It is structured as follows:

- Introduction to the concept of harm reduction, as applied to drugs of abuse
- Brief explanation of the scale of the problem and the global response
- Literature review of the role of pharmacists in harm reduction
- Case studies of particular country and regional responses:
  - Uruguay
  - Eastern Europe and Central Asia
  - Lebanon
  - Portugal
  - Additional inputs
- Limitations
- Summary and recommendations
- Additional reading materials
- Appendices

# 1 Harm reduction

## 1.1 Definition of harm reduction

The term “harm reduction” in public health terms does not mean, but is often confused with, the ordinary dictionary meaning of “reduction of harm”, relating to efforts to mitigate against or reduce the harm that may come to any person, of any age, from any external source. Such harmful external agents may vary from specific substances, such as tobacco and alcohol, to the deleterious effects associated with obesity, poor diet, excessive sugar and/or salt consumption, inactivity, or be specific to the sorts of behaviours that are normally associated with pharmacists’ health promotion roles, particularly in the community pharmacy setting. The term “harm reduction” used by FIP’s Working Group on the Pharmacists’ Role in Harm Reduction, and in this report, is specifically focused on drugs of abuse, as specified in public health terminology.

Nonetheless, as a concept, “harm reduction” does fall within the broader rubric of “health promotion”. The Ottawa Charter defined health promotion as “the process of enabling people to increase control over, and to improve, their health”. Further, the Charter explains that “[t]o reach a state of complete physical, mental and social well-being, an individual or group must be able to identify and to realise aspirations, to satisfy needs, and to change or cope with the environment. Health is, therefore, seen as a resource for everyday life, not the objective of living. Health is a positive concept emphasising social and personal resources, as well as physical capacities. Therefore, health promotion is not just the responsibility of the health sector, but goes beyond healthy life-styles to well-being”.<sup>4</sup>

Harm reduction is more specifically defined as “policies, programmes and practices that aim primarily to reduce the adverse health, social and economic consequences of the use of legal and illegal psychoactive drugs without necessarily reducing drug consumption”.<sup>5</sup> The International Harm Reduction Association also points out that the “harm reduction approach to drugs is based on a strong commitment to public health and human rights”.

The US-based Harm Reduction Coalition has defined a set of principles that underpin harm reduction. These principles are described in detail as follows:<sup>6</sup>

- Accepts, for better and/or worse, that licit and illicit drug use is part of our world and chooses to work to minimise its harmful effects rather than simply ignore or condemn them
- Understands drug use as a complex, multi-faceted phenomenon that encompasses a continuum of behaviours from severe abuse to total abstinence, and acknowledges that some ways of using drugs are clearly safer than others
- Establishes quality of individual and community life and well-being — not necessarily cessation of all drug use — as the criteria for successful interventions and policies
- Calls for the non-judgmental, non-coercive provision of services and resources to people who use drugs and the communities in which they live in order to assist them in reducing attendant harm
- Ensures that drug users and those with a history of drug use routinely have a real voice in the creation of programmes and policies designed to serve them
- Affirms drug users themselves as the primary agents of reducing the harms of their drug use, and seeks to empower users to share information and support each other in strategies which meet their actual conditions of use
- Recognises that the realities of poverty, class, racism, social isolation, past trauma, sex-based discrimination and other social inequalities affect both people’s vulnerability to and capacity for effectively dealing with drug-related harm
- Does not attempt to minimise or ignore the real and tragic harm and danger associated with licit and illicit drug use

Many of these principles are challenging to traditional concepts of pharmacy practice, including pharmaceutical care. However, as will be argued in this report, they can be used to inform pharmacists’ role in the provision of appropriate harm reduction services, particularly with regard to illicit drugs. It has been argued, for instance, that pharmacists are well-positioned to screen, assess and refer individual cases, to collaborate with other prescribers in the provision of pharmacological interventions, and to be “agents of change in their communities”.<sup>7</sup> Based on experiences in the Greater Glasgow area, Roberts and Hunter described the evolution of a “comprehensive system of pharmaceutical care for drug misusers”, based predominantly on community pharmacy provision of methadone and needle exchange.<sup>8</sup> This

programme was not only important in terms of penetration (involving 184 of 215 community pharmacies in the region), but also in terms of its integration into management, supervision and support structures.

Accordingly, the benefits of a harm reduction approach can be summarised as follows:

- Individual benefits
  - Prevention of infection by HIV, hepatitis C and other blood-borne pathogens
  - Increased capacity for self-care
  - Reduced chaos associated with drug use through methadone maintenance treatment
  - Fewer overdoses
  - Increased sense of control
  - Options to a person who may not have perceived any choices
  - Opportunities to link with sources of support
- Community benefits
  - Decreased incidence of HIV, hepatitis C and other blood-borne pathogens in the whole community
  - Decreased number of discarded used needles in the community
  - Reduced negative consequences of drug use, such as drug-related criminal activity, and reduced prostitution
  - Fewer overdoses and deaths
  - Reduced strain on social, health, income and employment services
  - Increased number of people who use drugs and feel less marginalised
  - Cost savings

Importantly, this report is firmly located in the human rights approach to drug policy. It has been argued that drug policy represents an endless discussion between “speakers of incommensurable languages”, between those who advocate abstinence above all, and those who value the reduction of harms to drug users’ health.<sup>9</sup> The way out of this cycle of “repetitive call and contradictory response” lies in the acceptance of a human rights approach.

## 1.2 The scale of the problem and response

Drugs are a major social and public health problem and are linked to the major socio-economic issues of our time. It is estimated that almost a quarter of a billion people between the ages of 15 and 64 years used an illicit drug in 2013. If we consider that more than one out of 10 drug users is a problem drug user (suffering from drug use disorders or drug dependence) then the global burden of the problem is of the order of 27 million people who are problem drug users. Almost 12.19 million of those problem drug users inject drugs, and an estimated 1.65 million of those who inject drugs were living with HIV in 2013.<sup>10</sup> In recent years, the estimated number of people who inject illicit drugs has been declining in certain countries of Europe.<sup>11</sup> Although heroin remains the main injected drug in most European countries, new injection patterns and new illicit drugs, such as cathinone and other new stimulant substances, are emerging. These substances are often associated with a high frequency of injection (10 to 20 times per day) which increases the risk of transmission of HIV and hepatitis viruses when injection equipment is shared or reused. Use of stimulants has also been linked with reduced sexual inhibition, high-risk sexual behaviours and with high risk of other drug use.

Injecting drug users (IDUs) are particularly vulnerable to infectious diseases, like HIV, hepatitis C virus (HCV), hepatitis B virus (HBV), and other blood-borne infections because of sharing contaminated injecting equipment and having sexual contact. In addition, bacterial infections can also be related to drug injection, through poor hygiene, and contaminated drugs or injection paraphernalia. All these infections result in a large burden on health systems, significant individual suffering, as well as high treatment costs.

A wide variety of measures have been developed to improve the access to and use of sterile injecting equipment at different settings, like drug services, pharmacy-based distribution, sale or exchange schemes, vending or distribution machines that operate from a range of fixed, mobile and outreach sites. Some drug services provide both prevention and treatment programmes, including testing for HIV and HCV. Given the settings in which injecting drug users engage in such practices, mobile needle and syringe programmes (NSPs) have been created which operate from a van or a bus, with needles and syringes distributed through a door or window. Mobile NSPs can be more accessible than fixed NSPs and often face less opposition from the surrounding community. In some countries, such as the Netherlands, Germany, Italy and Australia, syringe

vending machines have been provided, in addition to other forms of NSPs. In Australia, packs include several needles and syringes as well as alcohol swabs, cotton wool, sterile water and spoons. Others contain educational materials. There are, however, several barriers to NSPs, including restrictive laws, policing and law enforcement practices, and community opposition to NSPs. Such programmes are also associated with significant stigma. In many countries, injecting drug use is specifically criminalised. Criminalisation of possession of illicit substances and injecting equipment often forces people who inject drugs to hide their equipment, and this may force them to engage in unsafe injecting practices, with many being threatened or abused, having money extorted from them, or being arrested by the authorities. Legal age restrictions may prevent access to those under 18 years of age, despite evidence that injecting drugs can start at an earlier age. Mandatory detention of injecting drug users in drug detention centres is also a barrier. Even in countries where it is legal to purchase needles and syringes, stigma, discrimination or disapproval from the community prevents many people who inject drugs from accessing NSP services. IDUs also experience stigma and discrimination from health care workers, or receive services that are not delivered in a culturally sensitive way. Where countries depend on donor funding for NSPs, withdrawal of international funding can hamper access.

In 2014, 158 countries worldwide reported having people who inject drugs, but just 90 of these countries implemented NSPs to address this problem. Since the emergence of the HIV epidemic among IDUs in the 1980s, many European countries have been implementing evidence-based measures to prevent and control infectious diseases among this group. In the 1990s, European Union (EU) countries started to develop common prevention policies both in the fields of HIV/AIDS and drugs and drug addiction, which included the establishment of EU agencies to monitor the drug situation (European Monitoring Centre for Drugs and Drug Addiction [EMCDDA], in 1993) and to prevent and control infections (European Centre for Disease Prevention and Control [ECDC], in 2005). In the past two decades, prevention and treatment interventions have been expanded and many European countries have established NSPs, which increased the coverage among IDUs. Many of these programmes have included pharmacy-based NSPs, notably in Belgium, Spain, France, the Netherlands, Portugal and the United Kingdom. However, pharmacy-based NSPs are very limited in low-income countries.

## 2 Pharmacists and harm reduction

In 2012, a systematic review of the literature from 1995 to 2011 dealing specifically with the role of pharmacists in harm reduction was published by Watson and Hughes.<sup>12</sup> This review highlighted a number of areas in which pharmacists were providing harm reduction services aimed specifically at reducing the adverse health, social and economic consequences of drug use. These included:

- Syringe and needle exchange programmes
- Opioid substitution therapy, including supervised administration of oral methadone
- Sexual health services, ranging from testing for chlamydia, HIV and hepatitis C to safe-sex advice

Additional literature was accessed on the provision of the two major forms of drug-related harm reduction services — syringe/needle exchange and opioid substitution therapy — but this was also expanded to cover the emerging issues of naloxone provision and the provision of marijuana/cannabis, both for medicinal and non-medicinal purposes. An explanation of the Uruguayan model was provided by Carlos Lacava. In order to illustrate the changing drug policy environment, specific details were provided on the challenges in Eastern Europe and Central Asia (by Liezl Channing), Lebanon (by Marwan Akel) and Portugal (by Anabela Madeira).

In response to the circulation of the draft report, additional materials and comments were received from the European Association of Hospital Pharmacists, and FIP member organisations in Ireland, Spain, Canada and Brazil. An update on the situation in Portugal was also submitted.

### 2.1 Pharmacists and the provision of syringe and needle exchange services

The provision of syringe and needle exchange programmes (NSPs) is well-developed in high-income countries. In Scotland, a user survey identified a number of characteristics of a desirable service, including “friendly, approachable staff”, “evening opening hours” and “weekend opening hours”, but also the availability of additional services, such as “antibiotic prescribing”, “advice from staff on safer injecting” and “dressings for wounds/sores”.<sup>13</sup> Some, if not all, of these could presumably be met by a well-trained and empowered community pharmacy network, with suitable collaborative practice models. One of the concerns often expressed by pharmacists is whether other clients/patients would perceive their practices/premises differently if they were to provide such services. The experience from Scotland is that this fear is not well-founded, and that the majority of pharmacy customers are supportive of such services being offered by pharmacies.<sup>14</sup> However, New Zealand pharmacists did report some problems, including shop-lifting, which they associated with the provision of NSPs.<sup>15</sup> On the other hand, data from California, USA, showed a negative correlation between over-the-counter pharmacy syringe sales and reported crime.<sup>16</sup> Legal enablement of such pharmacy sales can improve use of the service,<sup>17</sup> but restricted sales may still limit access by certain ethnic groups.<sup>18</sup> As expected, the attitudes of pharmacy staff are an important determinant of access for injection drug users.<sup>19</sup> The types of syringes provided by pharmacies is also important, as low dead space versions can assist in reducing the risk of disease transmission.<sup>20</sup> Although described in more detail below, the experience in Portugal has also been reported in the peer-reviewed literature.<sup>21</sup>

The situation in low- and middle-income countries is very different.<sup>22</sup> Opportunities to integrate HIV and drug services for particular vulnerable populations have been identified in South Africa, but remain rare and seldom, if ever, involve community pharmacies.<sup>23</sup> An urgent need to pilot pharmacy-based distribution and exchange programmes in the Russian Federation was identified as long ago as 2008.<sup>24</sup> Limited access to legally available syringes from pharmacies was also identified as a barrier to safe injection practice in Mexico.<sup>25</sup> There have also been calls to scale up access to NSPs in China, but progress has been slow and barriers of remuneration and appropriate training persist.<sup>26,27</sup>

Viewed from the perspective of the key question posed to this working group, which relates to the distribution of a psychoactive substance on demand for recreational use, the provision of NSPs in pharmacies may at first glance appear to be less controversial. However, there remain settings where access to any product regarded as “drug paraphernalia” is restricted, and where a punitive or prohibitive approach prevents or hinders the implementation of harm reduction services.



## 2.2 Pharmacists and the provision of opioid substitution services

The concept of supervised administration of methadone by pharmacists is far from new. In 1994, staff of the Glasgow Drug Problem Service, Scotland, reported on the implementation of the 1993 recommendations of the Advisory Council on the Misuse of Drugs, which has supported the introduction of methadone maintenance programmes across the United Kingdom.<sup>28</sup> Only a year later, 45% of all community pharmacies in Glasgow were offering the service. The feasibility of pharmacy-based supervision of methadone maintenance was demonstrated in a pilot study in London.<sup>29</sup> A 1995 national survey showed that, by then, 50.1% of pharmacies in England and Wales were dispensing controlled drugs (mostly methadone), 34.5% were selling injection equipment, but only 18.9% were providing needle exchange facilities.<sup>30</sup> After a decade, those differences were still evident in Scotland, with dispensing services having improved to a greater extent than needle exchange.<sup>31</sup> Even after two decades of the service in Scotland, it was noted that pharmacy workforce attitudes and service engagement could be improved.<sup>32</sup> However, what this survey also noted was the emergence of pharmacists who were enabled to prescribe for opioid dependence. It should not be assumed that all users of community pharmacies are comfortable with the provision of harm reduction services, even where these are well-established. A series of focus groups with members of the public in the West of Scotland identified evidence of stigmatisation of drug users, with some of the strongest negative attitudes being to needle exchange services.<sup>33</sup> With training, pharmacists are better able to manage difficult situations with methadone patients.<sup>34</sup> The sort of training that would be required might focus on reducing stigma, the proper disposal of used needles and syringes, as well as on the care pathways to which users might be referred.

Although the available literature is dominated by the experience in the United Kingdom, and Scotland in particular, there are reports from other countries. A high demand for opioid substitution services was identified in Australia, but the pharmacy response was characterised as “overlooked, under-rated” in a review of the available literature.<sup>35</sup> As in other countries, users of the service in Australia expressed concerns, particularly about being treated differently from other customers.<sup>36</sup> Opioid substitution therapy (OST) is the predominant therapy option for opioid users in Europe and the effectiveness of this therapy is recognised in most developed countries. All EU countries have adopted a legal basis for substitution therapy. It is estimated that there were about 730,000 people on OST in the EU and Norway in 2011.<sup>37</sup> OST is generally provided in specialist outpatient settings and in some prisons. Office-based general practitioners (often in shared-care arrangements with specialist centres) increasingly play an important role and are the main providers of OST in France, Germany, Norway, Luxembourg, Croatia and Belgium.

Opioid substitution services have expanded to include products other than oral methadone. However, there are also negative experiences. For example, increased diversion of sublingual buprenorphine among clients of community pharmacy-based services has been identified in Australia.<sup>38</sup> Since 2008, Finnish community pharmacists have been able to dispense buprenorphine-naloxone, but they do not supervise dosing.<sup>39,40</sup> Single-ingredient buprenorphine and methadone remain restricted to treatment units that supervise dosing.

Though not strictly a form of opioid substitution, the provision of the opioid receptor antagonist naloxone has been used to prevent deaths from overdose. Community pharmacy-based distribution of naloxone has been described in both the US,<sup>41</sup> and in two central Asian developing countries, Kyrgyzstan and Tajikistan.<sup>42</sup> However, as was pointed out by FIP’s Canadian member organisation, differences in reimbursement practices can hamper access to naloxone, even where legal changes have enabled its sale without a prescription. A clinical guideline for the management of opioid use disorder has been developed by the health authorities in British Columbia, but is now being considered as a potential national guideline for Canada.<sup>43</sup>

If the provision of drug paraphernalia poses challenges for pharmacists, then the provision of long-term opioids for maintenance purposes, in the form of substitution therapy, would be expected to be more problematic. However, as shown, such services have been well-established in some settings, and have become part of the expected services provided in some community pharmacies. While the provision of methadone or other opioids for long-term use is perhaps better accepted, there are still barriers to the provision of heroin itself, although a harm reduction argument can be made for safe provision of heroin, which is backed by many years of evidence from Europe.<sup>44,45</sup> Although such provision would be more safely done in specialist clinics, the point that needs to be made is that there is no difference between substances labelled as “drugs of abuse” and

those that might be used therapeutically. Pharmacists need to keep an open mind about the options that might be developed over time, and about their potential role in the safe and responsible use of such options.

## 2.3 Pharmacists and the provision of (medical) marijuana

This working group was created in response to a particular challenge experienced by pharmacists in Uruguay, and related to a major shift in national policy to the regulation of marijuana (cannabis) for recreational rather than medical use. In the time since the 2014 resolution taken by the FIP Council, this policy arena has seen seismic shifts on an international scale. A comprehensive description of this set of shifts in thinking and practice is beyond the scope of this reference paper. Several extensive reviews have traced the development of law and policy in this regard, notably in the US.<sup>46,47,48,49</sup> In summary, there has been widespread recognition, despite poor evidence of efficacy or safety,<sup>50,51</sup> of the societal demand for and support of the concept of “medical marijuana”. However, wherever advice has been sought on how health professionals should meet this need, the problem of legal access to marijuana products, apart from those that are registered as medicines and supplied in pharmaceutical form, has been raised.<sup>52,53</sup>

An exhaustive comparison of the legal reforms in two US states (Colorado and Washington) and Uruguay, published in 2014, noted that only in the latter country were licensed pharmacies identified as the commercial retail outlet.<sup>54</sup> In each case, though, provision is made for licensed commercial cultivation and processing.

Canada has allowed access to marijuana since 2001, but a 2007 survey showed that only 8% of respondents obtained their marijuana from Health Canada, with 66% growing their own and more than 50% using illegal and unregulated “compassion clubs and dispensaries”.<sup>55</sup> Unregulated community-based suppliers (often referred to as “dispensaries”, though this does not imply the involvement of pharmacies or pharmacists) were at the time vulnerable to arrest and prosecution, despite the existence of a medical marijuana policy in Canada.<sup>56</sup> It is, therefore, striking that a 2016 submission by the Canadian Pharmacists Association (CPhA) to the Task Force on Marijuana Legalization and Regulation has argued for the “benefits of pharmacist management and distribution of medical marijuana”.<sup>57</sup> It is worth reviewing the arguments advanced in some detail:

- “As health care professionals, Canadian pharmacists are concerned with minimising the harms of use associated with all forms of marijuana. With respect to medical cannabis, the Association has clearly articulated its position that management and dispensing by pharmacists is in the best interest of patient safety. In addition to providing secure and safe access to medications, pharmacists have the necessary expertise to mitigate the potential risks associated with medical marijuana, including harmful drug interactions, contraindications, and potential addictive behaviour.”
- “It is widely recognised that cannabis legalisation for non-medical purposes would have significant implications for the medical system. Given the continuing need for patients to continue to access safe, medical-grade cannabis, under the supervision of a licensed health care professional, once recreational marijuana is available, CPhA advises the Task Force to ensure the integrity of the medical system going forward and take immediate action to mitigate any unintended effects of legalisation. Pharmacist management and dispensing of medical cannabis is the best option to strengthen any future framework and protect patient and public safety.”
- “CPhA is particularly concerned about medical cannabis patients who may choose to access marijuana through recreational channels in the self-management and treatment of their condition. To help address this concern, any retail personnel with direct contact with users should receive training from accredited health care professionals on the differentiation between medical and recreational products. Furthermore, all staff should be trained to direct users, particularly medical marijuana patients, to licensed health care professionals. This is critical in maintaining a clear distinction between medical and recreational cannabis markets, which will ensure that medical cannabis patients have access to therapeutically appropriate products under the oversight of a licensed health care professional.”
- “While maintaining a separate stream for medical cannabis users is in the best interest of patients, it also offers clear advantages in the enforcement of public safety and protection. Pharmacy offers a safe and secure supply chain with top-level security and tracking for narcotics and controlled substances already in place to ensure that medical cannabis is not diverted for the purpose of recreational use. Given that recreational marijuana should be priced at levels greater than medical cannabis, the importance of secure management and distribution of medical cannabis will take on even greater importance following legalisation of recreational marijuana.”
- “CPhA’s proposal would authorise pharmacists to dispense cannabis for medical purposes to an individual with a medical document. The proposed framework would not only enhance the safety,



quality and accessibility of medical cannabis, but would also benefit patients by providing access to medication counselling and chronic disease management by a licensed pharmacist. Pharmacists have the necessary expertise to mitigate the potential risks associated with medical marijuana, including harmful drug interactions, contraindications, and potential addictive behaviour. Under the proposed framework, Canadians who require cannabis for medical purposes would be able to access the product in person at urban, rural and remote locations across Canada, building on pre-existing relationships with patients and prescribers, through an established distribution system proven to protect patient and public safety.”

The CPhA proposal is, therefore, specific to the control over the supply of marijuana for medical not recreational purposes, and is based on the established role of pharmacy in relation to all medicines. The European Association of Hospital Pharmacists (EAHP) input specifically responded to this issue: “Regarding the recreational use of marijuana, EAHP would like to highlight that we can't see hospital pharmacies as the source of marijuana for recreational use. Thus, EAHP would welcome a continued discussion on this matter, particularly since the report suggests that the sources of marijuana for recreational use are to be developed in conjunction with professional bodies, etc.”

The Canadian position seems to be in line with earlier predictions of the “pharmaceuticalisation of marijuana”, which anticipated two medical distribution channels, one (legal) for cannabinoid pharmaceuticals and another (illegal) for street or home-grown marijuana.<sup>58</sup> Nonetheless, there are even earlier proposals to separate the markets for “hard” and “soft” drugs in Germany, including the sale of marijuana for recreational use by pharmacies.<sup>59,60</sup> The arguments are similar: “Pharmacies are good distribution points because they are familiar with the dispensation of narcotics and are under strict control. They are also experienced in preventive drug policies, such as the distribution of disposable syringes. They are not at all affiliated with the drug scene and are outside the federal sphere. The former is important for separating groups of drug users, the latter to increase acceptance among project participants.”<sup>60</sup>

The potential involvement of the tobacco industry, as an alternative source for marijuana, has been identified, as with the supply of electronic nicotine delivery systems such as e-cigarettes.<sup>61</sup> The Milbank Memorial Fund (2014) has warned about the risk for a “tobacco-style public health epidemic”, and has supported the Uruguayan model of regulated production and distribution.<sup>61</sup>

Although the medical marijuana movement has been most evident in developed countries, there has been movement in developing countries, such as South Africa.<sup>62,63</sup> As with the Saatchi Bill in the United Kingdom (which did not pass), the South African Parliament is currently considering a Private Member's Bill which aims to ease access to medical marijuana.<sup>64</sup> The legal provisions to allow for exceptional access exist, but as in other countries, South African patients face the challenge of procuring marijuana from a legal and trustworthy source.<sup>65</sup>

## 3 Country case studies

### 3.1 Regulation of marijuana: the Uruguayan model

#### Introduction

At the end of 2013, the Uruguayan Parliament approved a new law (Law 19.172) that regulates the trade of marijuana. Up to that time, marijuana regulation was under the Narcotics Law (Law 14.294, modified by Law 17.016). In this summary, the legal aspects of these two laws and the technical points of pharmaceutical scope are discussed. An English translation of the introductory remarks to the new law is provided in Appendix 2, as this provides a cogent argument for the policy approach taken.

The old law followed the directions of international agreements about this matter and prohibited the sowing, cultivation, harvesting and trade of marijuana among other plants from which narcotics can be obtained. Nevertheless, use for scientific purposes and medical indications was allowed. This law did not penalise the consumption of these products for recreational purposes.

#### Regulation model

Since the new law came into force, the sowing, cultivation and harvesting of marijuana for any purpose is allowed, under regulated conditions. This law has created a regulatory body, the Institute of Regulation and Control of Cannabis (Instituto de Regulación y Control del Cannabis, IRCCA). Among other tasks, this Institute must issue licences to sow, cultivate and harvest marijuana for different purposes. Those who will be allowed to produce marijuana for recreational use will not be allowed to produce the plant for medical use. On the other hand, the production of cannabis for medical and/or scientific use will need a special licence. Nevertheless, both products will have to fulfil the regulations of the Ministry of Public Health (Ministerio de Salud Pública, MSP). Up to 2017, only two licences to produce recreational marijuana have been issued and none for any other purpose. The two licensed enterprises are allowed to produce up to two tonnes of marijuana each per year.

Although medical use was allowed by the previous law, and is also allowed by the new one, there is still no production of marijuana for medical use in Uruguay and there are no pharmaceutical products with active principles derived from cannabis in the market.

What is different about the new law is its approach to the legal production and distribution of marijuana. According to the new law, users can choose between three ways to acquire the product: self-cultivation, membership clubs or procurement in community pharmacies. Each one of these ways exclude the others, and the IRCCA will maintain registers of each type of user.

Self-cultivators are allowed to sow up to six plants per house and to harvest up to 480 grams per year. They must be natural or legal Uruguayan citizens with permanent residence in the country, legally competent, over 18 years of age, and enrolled in the specific IRCCA register for that purpose. Up to 19 July 2016 there were 4,970 self-cultivators registered.

Cannabis clubs are membership clubs for marijuana cultivation. They must be civil associations with statutes and legal status approved by the Ministry of Culture and Education (Ministerio de Educación y Cultura, MEC) with at least 15 and no more than 45 members. Individual members of the club must be natural or legal Uruguayan citizens with permanent residence in the country, legally competent, and over 18 years of age. Membership clubs as well as their members must be enrolled in the specific IRCCA register for that purpose. Each cannabis club may sow up to 99 plants of cannabis and the production per member should not be more than 480 grams per year. The final destination of any excessive production should be decided by the IRCCA. Up to 19 July 2016 there were 17 membership clubs registered.

Users who decide not to cultivate their own plants or become members of a cannabis club will be able to buy the marijuana produced by allowed enterprises. The retail selling points will be community pharmacies with a special licence issued by the IRCCA. To buy marijuana in a community pharmacy, a user must be a natural or legal Uruguayan citizen with permanent residence in the country, legally competent, over 18 years of age, and enrolled in the specific IRCCA register for that purpose. Up to August 2016, the register for buyers in pharmacies

has not been open and there is not any ready marijuana to be sold. The government's initial intent was to issue 100 licences to community pharmacies strategically selected all over the country. Later (by about June 2016) they started talking of a pilot plan with only 50 pharmacies. After three calls, only around 20 pharmacies applied for a licence to sell marijuana, most of them (near 90%) in the capital city, Montevideo. So, by the end of August 2016, the government was considering adding new selling points to the system.

### Harm reduction (risk management) basis of the regulation model

Even though the consumption of any psychoactive substance is legal in Uruguay, the trafficking of such substances is prohibited, which means that users must obtain the substances on the black market. Furthermore, the previous law did not define the amount of any listed substance that was considered to constitute "personal use", so judges applied different criteria and sometimes persons who were found in possession of small amounts were prosecuted as traffickers. Those and other problems were kept in mind when legislators passed the new bill.

The whole regulation and control model for marijuana in Uruguay is based on the premises of risk management for users and this is the public health basis of the project. These premises are:

- The separation of the marijuana market from that for other drugs in order to significantly reduce the number of individuals seeking more toxicologically dangerous substances, such as cocaine base paste (CBP) or cocaine
- The normalisation and social inclusion of marijuana use, to avoid the stigmatisation of users or their criminal conviction and, instead, create the conditions for working with said users and society at large in programmes and educational campaigns aimed at providing factual and reliable information on the matter, empowering users to make informed, responsible decisions and to anticipate and manage the risks of using this substance in an efficient manner
- Control of the identity and the purity as well as the content of psychoactive active principles of the marijuana consumed by the users, avoiding the harm produced by adulterated products
- Use of the money received by the state from the legal market in marijuana to improve prevention and treatment programmes
- Reducing the economic power of drug traffickers as well as reducing the potential source of corruption and social violence that this illegal market may produce

### The role of pharmacists in the supply and control of marijuana

In Uruguay, pharmacists graduate from the Faculty of Chemistry of the University of the Republic (Universidad de la República, UdelaR). This is the only public university in Uruguay, and the only one to produce graduate pharmacists. The graduation title of Uruguayan pharmacists is "pharmaceutical chemists". In Uruguay there is no compulsory college for pharmacists so Uruguayan pharmaceutical chemists are organised as part of the Uruguayan Association of Chemistry and Pharmacy (Asociación de Química y Farmacia del Uruguay, AQFU).

As a professional body, the AQFU was never consulted about selling recreational marijuana in community pharmacies and is opposed to doing so. This position has been supported by FIP, FEFAS (the South American Pharmacist Federation), FEPAFAR (the Pan American Pharmacist Federation), AUDU (the Association of Uruguayan University Professions), and the Faculty of Chemistry (UdelaR). The main point of this position is that, as a health centre, a community pharmacy cannot be a provider of recreational substances. Community pharmacies do not sell alcoholic beverages or tobacco products and it is therefore seen as illogical to sell marijuana.

However, as health professionals, Uruguayan pharmaceutical chemists are prepared to and want to work in collaborative inter-professional groups involved in the risk management of psychoactive substance use.

## 3.2 Harm reduction in Eastern Europe and central Asia

The Eastern Europe and Central Asia (EECA) region comprises of 29 countries, including 11 European Union member states. The EECA is the only region in the world where HIV incidence is still increasing. In 2013, there were an estimated 1.1 million people living with HIV in the region, representing 3% of the global total. In the same year, there were roughly 110,000 new HIV infections and 53,000 AIDS-related deaths. Between 2005 and

2013, AIDS-related deaths increased by 5%. The HIV epidemic in this region continues to grow, particularly in Russia, Ukraine and Uzbekistan. Russia and Ukraine alone account for 85% of people living with HIV in the region. Russia also accounts for eight out of 10 new HIV infections and in 2016 was reclassified as having a generalised epidemic. There are roughly 2.9 million people who inject drugs in the EECA region. Russia has the highest number of people who inject drugs in the region (1.8 million), representing about 2.3% of the adult population. Moldova (1%), Belarus (1.1%) and Ukraine (0.8–1.2%) also have significant numbers of people who inject drugs. Across this region, HIV prevalence is much higher among people who inject drugs than among the general population. For example, in Russia, between 18% and 31% of this group are thought to be living with HIV. Regionally, HIV prevalence among men and women who inject drugs is similar, at 9% and 10%, respectively. Between 2006 and 2010, one in three new cases of HIV were reported to be attributable to a lack of access to sterile injecting equipment. The EECA region also has very high rates of hepatitis, particularly hepatitis C, among people who inject drugs — 23–96% have hepatitis C — and co-infection with HIV is estimated to be 10–60%.

Within the region, 26 countries or territories have national HIV or drug policies explicitly supporting harm reduction. However, drug policy across the region is marked by an overreliance on criminalisation, and political hostility towards harm reduction is common. Although most countries in the region now provide access to harm reduction services, coverage remains low and, where they do exist, services are not always comprehensive. Furthermore, harm reduction programmes are primarily implemented by NGOs with funding from international donors and with little or no support from national governments. With the exception of those in Kazakhstan and the member countries of the European Union, many harm reduction programmes in EECA countries are financed through extra-budgetary resources — primarily from the Global Fund grants. At the same time, the improved economic indicators of a growing number of EECA countries make them no longer eligible for funding from the Global Fund. However, following the departure of international donors, governments are reluctant to invest in harm reduction.

Although the provision of needle and syringe programmes (NSPs) has expanded across the region since 2012, coverage levels continue to remain lower than internationally recommended targets. The number of service sites ranges from just two in Albania to 1,667 in Ukraine. Regionally, only 10% of injecting drug users (IDUs) can access such services. Between 2011 and 2013, there was a 30% increase in the number of syringes distributed across the region and an increase in the number of syringes distributed per IDU. However, coverage varies significantly between among countries — 50% in Kazakhstan compared with 22% in Tajikistan. Moreover, the regional average is only 106 syringes per each IDU — half the recommended target for effective harm reduction programmes.

Overdose continues to be a major cause of morbidity and mortality for IDUs across the EECA. The most significant progress has been made in Central Asia, where a regional project has been initiated to make naloxone available through pharmacies using a voucher system. In Tajikistan, local and international non-governmental organisations were successful in their advocacy to the ministry of health to allow harm reduction programmes to store naloxone legally on site, enabling a significant increase in its distribution.

In 2014, opioid substitution therapy (OST) was available in nine countries in the region, provided at 263 sites reaching nearly 17,000 IDUs — less than 1% of this group. Armenia, Belarus, Georgia, Kyrgyzstan and Ukraine have all significantly scaled up access to OST. By comparison, in Azerbaijan, Kazakhstan, Moldova and Tajikistan, access to OST is limited. In Russia and Turkmenistan, OST remains illegal and, in 2009, Uzbekistan stopped its OST programmes. There is some government commitment to providing OST through official “State Narcological Centres”. Country examples include Belarus, Georgia, Azerbaijan and Albania.

Select pharmacies in Ukraine, mainly in the public sector, are contracted to act as distribution points for OST and needles/syringes. OST distribution occurs through the filling of prescriptions and funding is through donor funds or through out-of-pocket payments. Pharmacies across the region are also involved with the distribution of naloxone, mostly through prescription or voucher schemes rather than as part of OTC programmes. The barriers to pharmacists’ involvement in harm reduction in the region include stigma, discrimination and regressive drug policies. The highly vertical system for delivering OST (through State Narcological Centres, for example) makes the broader involvement of community and hospital pharmacists difficult. There is a lack of political commitment to harm reduction programming, including financing for interventions. Given the significant number of IDUs, the increasing HIV incidence, and the high degree of HIV/hepatitis co-infection, there is room to expand the scope and involvement of pharmacists in harm reduction programmes in the EECA region. Government services alone will not be able to meet the demand

from IDUs. To successfully address the HIV and hepatitis epidemics, it is necessary to involve private sector pharmacies. WHO/United National Office on Drugs and Crime (UNODC) guidance advocates a comprehensive package of harm reduction services, including: NSPs; OST and other drug dependence treatment; HIV testing and counselling; antiretroviral therapy (ART); prevention and treatment of sexually transmitted infections; condom programmes for IDUs and their sexual partners; targeted information, education and communication for IDUs and their sexual partners; vaccination, diagnosis and treatment of viral hepatitis; and prevention, diagnosis and treatment of tuberculosis. Recently, access to overdose prevention activities (e.g., provision of naloxone) has also been recommended. Pharmacists can play a role in all facets of comprehensive harm reduction programming and can directly fulfil a number of harm reduction roles, including the sale of condoms, educating on safer sex practice, selling clean needles and syringes and dispensing oral methadone for opioid dependence. Many argue that pharmacies are an important but under-utilised resource in preventing the transmission of HIV and other blood-borne infections among IDUs. Pharmacists are one of the most accessible health care professionals and are in an ideal position to reach this group, who are often socially marginalised and wish to remain anonymous.

Key barriers include stigma and discrimination, unavailability of low-threshold testing and counselling services and a lack of comprehensive care and treatment, including evidence-based drug treatment. Currently, ART is financed through a combination of domestic budget allocations and out-of-pocket spending. However, in cases where treatment is covered by the state, IDUs face heightened barriers to access. For example, around 30–50% of IDUs in Estonia do not have health care insurance and are therefore unable to access ART. Other barriers include limited geographical reach of service provision (e.g., in Belarus, fewer than 20 medical professionals can prescribe ART), poor case management and a lack of joined-up service provision between drug treatment services and HIV clinics, as well as TB and hepatitis issues. Other barriers include unequal coverage between urban and rural settings, high threshold criteria for acquiring naloxone, a lack of legislative regulation of services, the criminalisation of people who use drugs, restricted opening hours and poor-quality equipment. Additional barriers to accessing NSPs for specific groups include age restrictions for those under 18 years and a lack of gender-sensitive services for women who use drugs. Political hostility towards harm reduction is also a growing concern, and has led to the closure of the biggest NSP programme in Hungary, which provided around 40% of the country's clean needles. A lack of funding remains a significant barrier to the scale-up of HIV prevention programmes to tackle the epidemic effectively in this region. Indeed, many countries are heavily reliant on international financing from donors such as the Global Fund to Fight AIDS, Malaria and TB, which provides most HIV prevention funding for this region. Any domestic financing usually comes from medical insurance funding, with key affected populations likely to have less access to health insurance. Domestic financing for HIV, in general, goes to OST and ART and seldom goes to prevention programming.

### 3.3 Harm reduction in Lebanon

The approach to harm reduction in Lebanon and the broader Middle East/North Africa region can be described as “timid”. Since 2007, the issue has been addressed by the Middle East and North Africa Harm Reduction Association (MENAHRRA). To date, six countries in the region have instituted OST: Bahrain, Iran, Morocco, United Arab Emirates, Palestine and Lebanon. In addition, five countries operate needle and syringe exchange programmes: Egypt, Morocco, Palestine, Tunisia and Lebanon. It is estimated that some 626,000 people inject drugs in the region.

Lebanon was one of the first countries in the region to introduce an OST programme in 2011. The use of heroin (the primary substance of abuse, alone or in combination) has been decriminalised (by Official decree 899/1), so users are referred to an addiction committee and then to treatment rather than punishment. The partial opioid agonist buprenorphine is used in the OST programme, coupled with counselling and/or contingency management. Buprenorphine (2 and 8mg) and Methadone (1, 5, 10, 20 and 50mg) were registered by the Ministry of Public Health (MOPH) in Lebanon from 2011. Implementation of a web-based information system (OSTIS) by the MOPH and funded with the support of the UNODC has enabled close collaboration between prescribers (psychiatrists), dispensers (pharmacists) and coordinators at the MOPH Narcotics Department. Patients are required to provide a weekly toxicology sample and meet with the prescribers, in order to receive a supply of buprenorphine for one week. Once adherence has been established, a three-month provision is allowed. Non-adherence is managed by modification of the treatment plan or referral to a treatment centre, but can also result in termination of OST. The patient retention rate is considered to be a major outcome and is closely



monitored using the centralised data system. Between December 2011 and December 2014, 1,244 patients were referred to the OST programme. Most of the referred patients were males between 26 and 35 years of age, with only 6% being female. In the rehabilitation centres, the majority of users are aged 29–38 years, with males also being predominant. In 2012, among 956 users tested for communicable diseases, 27.7% tested positive for hepatitis C and 0.67% for hepatitis B. None tested positive for HIV.

Initially, the programme relied on four pharmacists located at two governmental hospitals who were trained to provide buprenorphine. However, the growth of the programme and the burden on the central coordinator (also a pharmacist) has resulted in a plan to increase the number of sites. The absence of local prescribing guidelines is a challenge leading to a wide variability in prescribing habits, reflected in the variable retention rates among different prescribers. Retention appears to be highest among patients receiving doses of 16mg/day of buprenorphine or more. Decentralisation of the dispensing centres is expected to improve outcomes, as patients will be able to access OST at more than just the two government hospitals. This will also ease the burden on the existing four pharmacists. Communication between prescribers and dispensers also needs to improve, and it is suggested that the OSTIS programme be upgraded to generate more alerts and notifications. A gap in the OST programme has been the lack of coordination with the security forces and, in particular, service provision in prisons. Although many NGOs are working in prisons to ensure that existing patients continue their treatment during their incarceration, initiation of new patients on OST in prisons is still lacking. The increased number of patients in the programme also increases the risk of diversion of product and perhaps the emergence of inappropriate intravenous use.

## 3.4 Harm reduction in Portugal<sup>1</sup>

### The legal situation

The main drug law in Portugal is the Decree Law no. 15/93 of 22 January 1993, which defines the legal regime applicable to trafficking and consumption of narcotic drugs and psychoactive substances. The Portuguese legal framework on drugs changed in November 2000 with the adoption of Law no. 30/2000, in place since July 2001, which decriminalised illicit drug use and related acts, but maintained drug use as an illegal behaviour, with respect to all drugs included in the relevant United Nations conventions. In Portugal, although drug possession is still illegal, it is now treated as a civil/administrative issue in certain cases. If someone is found using or possessing a small quantity of drugs for personal use (note that according to law, this shall not exceed the quantity required for average individual consumption over a period of 10 days), where there is no suspicion of involvement in drug trafficking, the focus will be on treatment and the need to promote healthy recovery. For example, the maximum daily limit for heroin is 0.1g, that for cocaine 0.2g and for cannabis 2.5g (leaves), 0.5g (resin) or 0.25g (oil). These principles have shown that a pragmatic public health prevention approach can have a strong effect on reducing the spread of blood-borne and other infections among people who inject drugs.

Drug trafficking may incur a sentence of one to 12 years' imprisonment, depending on specific criteria, one of these being the nature of the substance supplied. The penalty is reduced for users who sell drugs to finance their own consumption.

A new Decree Law no. 54/2013, adopted in April 2013, prohibits the production, exportation, advertisement, distribution, sale or simple dispensing of new psychoactive substances (NPSs). Administrative sanctions, including fines up to EUR45,000, are anticipated for offences against this law, while a person caught using NPSs without a suspicion of another offence is referred to a local Commission for the Dissuasion of Drug Addiction.

Syringe exchange schemes are clearly regulated by Articles 50 to 57 of Decree Law no. 183/2001. This includes provisions on management, access rights, working hours and procedures, premises and location (including the possibility of dispensing machines), coordination with other bodies and assessment.

## Syringe exchange programme

Community pharmacists have always had frequent contact with persons who misuse drugs, providing them with syringes. Besides this, as health professionals, pharmacists have a specific responsibility to improve people's knowledge and awareness, with the aim of reducing risk behaviours in this field. In response to this need, Portugal developed a syringe exchange programme (SEP) entitled "Say NO! to a used syringe". This programme was set up by the Health Ministry National Committee Against AIDS (CNSIDA/Minister of Health) and the National Association of Pharmacies (ANF), a non-governmental organisation that represents most Portuguese pharmacies, pharmaceutical wholesalers and local municipalities. The Portuguese Syringe Exchange Programme (SEP) was launched in 1993 involving community pharmacies and, later, was extended to different governmental and non-governmental organisations. The CNSIDA funds the production, delivery and destruction of sharps waste generated, and pharmaceutical wholesalers deliver (free) kits and sharps waste for collection of used injection equipment to the community pharmacies involved in the programme. Pharmacies' participation is voluntary and no fee-for-service was provided in the beginning. Since 2017, pharmacies are remunerated for the service. Besides that, pharmacies have the responsibility to ensure the safe disposal of the used injecting equipment returned.

The main tool of the programme is the prevention kit, which is provided to IDUs and exchanged for used syringes and needles. Initially, in 1993, the kit included one sterile syringe, one swab, one condom and an information leaflet. However, the analysis of current behaviours of the IDU population and the experience of almost six years in syringes exchange indicated a need to reformulate the kit contents in order to adjust it to current behaviours. Therefore, in 1998, double-distilled water and filters were included and, in 2007, receptacles and citric acid also started to be part of the kit. The provision of this kit has the following harm reduction goals:

- To prevent HIV and hepatitis B and C infections via sexual and intravenous route among IDUs
- To avoid sharing needles and syringes
- To facilitate access to sterile needles and syringes
- To avoid the reuse of syringes
- To protect civil society by collecting and destroying potentially infected syringes
- To promote the use of condoms
- To provide information on HIV/AIDS by a leaflet
- To refer IDUs to health care units (when necessary)

While exchanging syringes, the pharmacist has a chance to talk with the clients to warn of the risks and consequences of their behaviour and to motivate them to take effective preventive measures to improve self-care.

At the beginning of the SEP, a free telephone help-line was available to assist pharmacists to handle the programme. In 2012, due to the economic crisis in the sector, the ANF informed the Ministry of Health (MH) that it would not be possible for pharmacies to continue providing this programme for free. In July 2014, the MH and the ANF signed an agreement which allowed the SEP to be restarted from January 2015. Support materials were developed for the SEP, which included an intervention protocol, poster, door sticker and pharmacy software (SIFARMA) to document the delivered kits. The current kit includes two sterile syringes and needles, two swabs, one condom, two filters, two ampoules of distilled water, two receptacles for the preparation of drugs and two citric acid sachets. In exchange for every two used syringes, IDUs receive one kit, without any limits. The Portuguese SEP has been evaluated by an independent organisation (Faculty of Economics of the University of Porto), commissioned by the MH, and the ANF has also commissioned an evaluation by a research consortium. Due to the demonstrated cost-effectiveness, a government decree (Portaria n.º 301-A/2016) was issued in November 2016, allowing the MH to reimburse pharmacies for the kits dispensed (at a rate of EUR2.40 per kit) as from January 2017.

From 1993 to 2012, more than 50 million syringes were exchanged by pharmacies (of which 40% were in community pharmacies), mobile units and governmental and non-governmental organisations. As of 2012, there were more than 1,300 pharmacies and 49 governmental entities and non-governmental organisations involved in the SEP in Portugal. Since the SEP restarted in January 2015, 1,633 pharmacies have provided a total of 137,261 kits (274,522 syringes) by December 2016.<sup>66,67</sup> Figure 1 shows the number of SEP kits provided by pharmacies per month in 2015. Figure 2 shows the number of kits provided per pharmacy in 2015, by district. By June 2017, the SEP was being provided by 1,184 pharmacy-based sites.

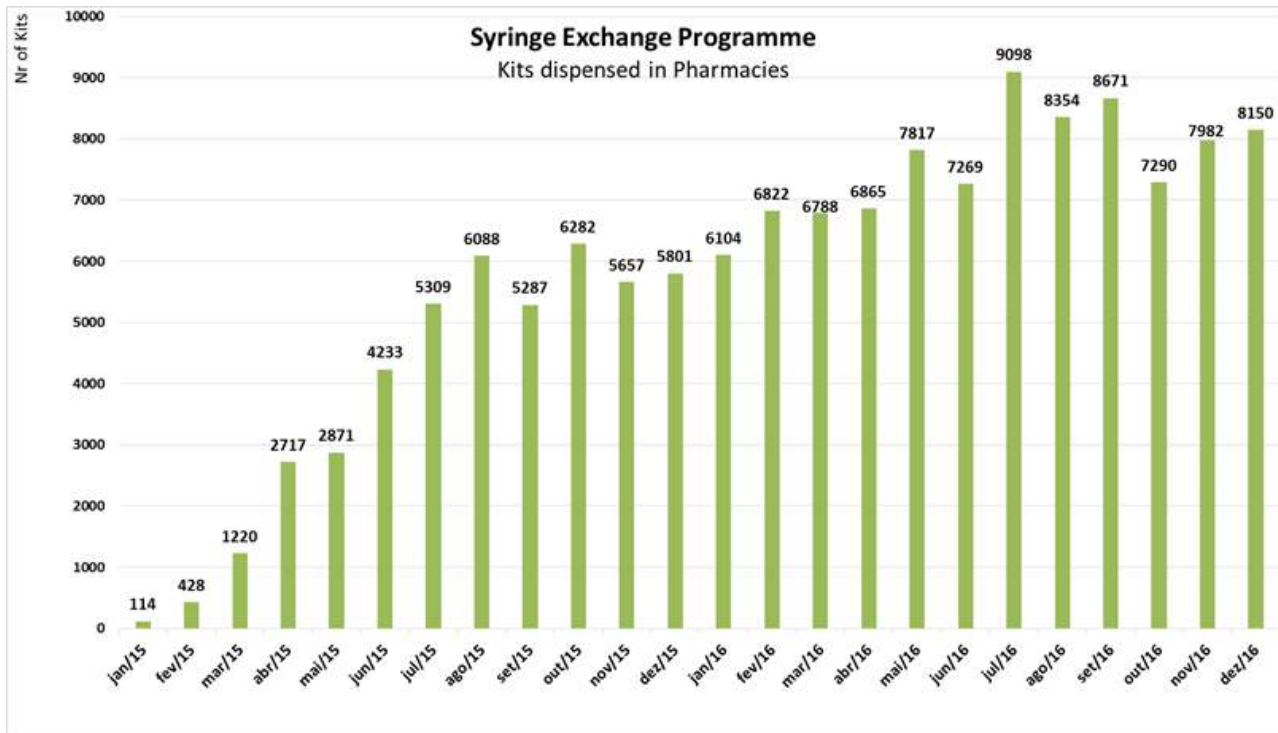


Figure 1 — Number of SEP kits provided per month

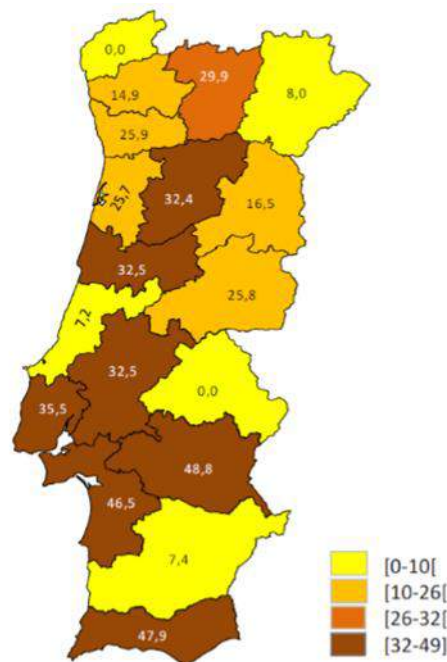


Figure 2 — Average number of kits provided per pharmacy, in 2016, by district.

Community pharmacies, by virtue of their accessibility, convenient locations, extended days and hours of operation are, undoubtedly, an important partner in the Portuguese SEP. Pharmacies' participation improves the equity of geographical access to the programme. As health professionals located closer to the population, pharmacists have a particular responsibility in improving IDUs' knowledge about blood-borne viruses and safe injecting practices, with the aim of reducing risk behaviours and the spread of infection.



In 2001, eight years after the beginning of the SEP, the CNSIDA and the ANF engaged the consulting firm Exigo to evaluate the economic consequences of the intervention.

Between 1993 and 2001, over 23 million syringes were distributed and collected. The programme avoided more than 7,000 new infections per 10,000 users of the SEP, with an investment of EUR8m.<sup>68</sup> According to the most conservative estimates, the programme may have saved over EUR400m in treatment costs of patients infected with HIV. The return on investment from distributing and collecting each syringe is 70-fold, but can be up to 350-fold.<sup>68</sup> A hypothetical delay of one year in the implementation of the programme could have represented more than 1,083 HIV infections and additional expense of EUR270m.

In 2015, results generated by the research consortium showed that pharmacies' participation in the SEP generated health systems savings of over EUR2m over a five-year period, and an EUR3.01 annual net benefit per needle exchanged in a pharmacy, in a setting where pharmacies were provided a reimbursement of EUR2.50 per needle.<sup>66,67,69</sup> In addition, over a five-year period, pharmacies' participation would deliver a reduction of 22 cases of HIV infection and 25 cases of hepatitis C infection.<sup>69</sup>

Initially, in 1993, and as in any programme involving IDUs, the stigma associated to this group was one of the barriers to the implementation of the programme. The typical IDU can be difficult to deal with and hard to involve in ongoing projects that may influence his or her health and position in society. However, despite the initial lack of receptivity from the general public and some health professionals, this problem was overcome.

### Opioid substitution programme

The provision of methadone maintenance therapy (MMT) in community pharmacies is considered to be an effective way to reduce the use of illegal opioid dependence. This programme has also been found to reduce injection-related risk behaviours, sexually transmitted infections and mortality. In order to implement MMT in community pharmacies, a protocol was signed in 1998, between the Institute for Drugs and Drug Addictions (IDT), the Pharmaceutical Society (OF) and the National Association of Pharmacies (ANF). In 2004, the National Authority of Medicines and Health Products (INFARMED) became a partner in this protocol.

Many countries, including Portugal, have encouraged the active participation of community pharmacists in MMT programmes in recent years. However, it is also important to note that pharmacies provide this service free-of-charge. Community pharmacies have long been partners of integrated response centres and IDT treatment teams in the administration of methadone, naltrexone and buprenorphine. The treatment teams, composed of physicians, nurses, psychotherapists and social workers, are outpatient units that act as the first point of contact with the treatment system. MMT at pharmacies targets patients who were previously followed by IDT treatment teams and who had a stabilised dose. Patients go to the pharmacy daily and the pharmacist supervises the administration of methadone solution. The flexibility and the extended opening hours, common in community pharmacies, are very important to MMT adherence.

The possibility of continuing MMT at a community pharmacy was restricted to patients who were receiving a defined, stabilised dose of methadone at IDT treatment centres. Community pharmacies cooperated actively with the treatment teams in methadone distribution and patient monitoring. Patients had the opportunity to receive treatment in their area of residence or professional activity. All patients gave written informed consent prior to entering the programme. In addition, a mutual expectations agreement set out guidelines for appropriate behaviour at the pharmacy and was signed by patients and community pharmacies. The provision of MMT in community pharmacies was based on DOT (directly observed therapy), with methadone provided by pharmacists to patients previously referred by treatment teams. Each dose administration at the pharmacy was recorded and signed by both pharmacist and patient to provide proof of dispensing and that the drug had been taken. Patient records were kept confidential. All MMT records filled at community pharmacies were kept for at least five years as per the legal provisions for all psychotropics. Training courses for pharmacists are mandatory and sponsored by the ANF and the IDT. Periodically, multidisciplinary meetings are held with pharmacists, IDT treatment teams and the programme manager. From January 1998 to January 2013, 3,090 patients enrolled in MMT programmes at community pharmacies in Portugal, of whom 76% were male.<sup>70</sup> A total of 792 pharmacists received specific training on OST and DOT and 506 community pharmacies participated in the programme, of which 222 (44%) had 761 patients on follow-up.<sup>70</sup> This was an unpaid service provided by community pharmacies and their pharmacists. In 2012, and due to the economic crisis in the sector, the ANF informed the MH that it would not be possible for pharmacies to continue working for free in this programme.

From December 2012 to January 2013, community pharmacies with patients on follow-up had gradually promoted their referral to treatment centres. In July 2014, the MH and the ANF signed an agreement, which established a plan of work covering several activities and programmes, including the possibility of restarting MMT at pharmacies. The new agreement with the Ministries of Finance and Health signed in 2016 also includes MMT services.

## 3.5 Additional inputs

In response to the circulation of the initial draft, additional inputs were provided by a number of member organisations. These are summarised below:

### Spain

The General Pharmaceutical Council of Spain, the Ministry of Health and Consumer Affairs and the Ministry of the Interior created the National Plan on Drugs in 1985. The goals of this programme were, on the one hand, to train pharmacists and pharmacy assistants in strategies to reduce the risks and damages associated with drug injection and, on the other hand, to promote the implementation of anti-AIDS kit dispensing programmes, syringe exchange programmes (PIJs), and methadone dispensing programmes (PDMs) in pharmacies.

PDMs are aimed at dispensing aqueous methadone hydrochloride solutions to opiate-dependent persons in the pharmacy as a means of reducing the risks associated with drug injection, particularly the risk of acquiring HIV. PDMs have been developed by pharmacies on a voluntary basis since 1996. In that year, a PDM was provided in 17 pharmacies, with a total of 185 patients served. By 2007, 1,237 pharmacies offered the service, reaching 4,442 patients. This trend has been continued over time. The anti-AIDS kit was first distributed in pharmacies in 1989 and consists of an insulin syringe with the appropriate container for disposal, an alcohol-impregnated wipe and a condom. In 2005, 469,778 anti-AIDS kits were dispensed in the 3,480 pharmacies participating in the programme. There are continuing efforts to expand access to this harm reduction initiative. The PIJ was developed in 1991. Its goal is to preserve the health and life of IDUs by making it possible for them to use sterile injection equipment. In 2007, 1,000 pharmacies exchanged syringes.

Since pharmacies are often the only health facilities accessed by IDUs, rapid testing for HIV has been implemented in certain pioneering pharmacies. These tests generate a result in approximately 15 minutes, with a sensitivity of 100%. In 2009, a pilot programme was started in 20 pharmacies in the Basque Country. In the period between May 2009 and December 2010, 5,995 HIV rapid tests were carried out, 53 of which were positive. Most (70%) of the patients who requested an HIV rapid test were men, aged 30–39 years, with more than half (53.4%) not having been tested before. This service has been extended to other communities, including Cantabria, Balears and Castile & Leon, and currently, about 250 Spanish pharmacies offer HIV rapid tests.

### Ireland

FIP's member organisation in Ireland, the Irish Pharmacy Union, provided an extensive report, dated May 2015, on an evaluation of the pilot stage of the Pharmacy Needle Exchange (PNEX) Programme. The PNEX programme was established as a partnership initiative between the Elton John Aids Foundation, Irish Pharmacy Union and the health, safety and environmental PNEX Programme, and began in October 2011. The evaluation was conducted in April 2014. A total of 70 out of 107 pharmacies participated in the study. The majority of pharmacy respondents were positive about the programme, although some challenges were identified, such as the risk of crime and undesirable behaviour in the pharmacy and surrounding area. Importantly, the report noted that "where pharmacies were located within shopping areas, it was apparent that some local businessmen and security objected to the needle exchange".

The survey also included responses from 74 users of the service, most of whom (88%) reported using heroin. The self-reported rates of hepatitis B and C and HIV were 7%, 22% and 5%, respectively, and approximately one-third of clients reported not having been previously tested for these blood-borne viruses. Almost half (49%) of the client sample reported their use of a needle that someone else had already injected with.

Overall, the evaluation was positive and noted increasing numbers of clients accessing the needle exchanges during 2013. However, the need for additional training for pharmacy staff regarding “the nature of drug use and client need” was identified. The evaluation report also noted the need for participating pharmacies to be “better linked in with other health services available to this population” and that “the provision of a range of health interventions and information such as [blood-borne virus] testing, harm reduction, wound care and sexual health advice will further increase the effectiveness of pharmacy needle exchange services”.

## 4 Limitations

This reference paper needs to be read with the following limitations in mind:

- As mentioned above, the working group decided, contrary to the initial proposed terms of reference, to focus specifically on the issue of harm reduction as applied to drugs of abuse, and not on the broader questions of abuse of alcohol, tobacco, and prescription-only or non-prescription medicines. Particular attention was nonetheless paid to the question of supply of marijuana for medical and recreational use, as it was this question that stimulated the debate.
- The literature provided does not represent a comprehensive or systematic review of all available sources, and was limited to publications in English only. There are sure to be many more publications, both in the peer-reviewed and grey literature, of relevance to the topic at hand. In particular, it is noted that the literature in French, Spanish and German has not been adequately reviewed. Nonetheless, it is believed that the literature accessed provides sufficient basis for the development of FIP policy in this regard, and can serve as the basis for ongoing debate.
- The working group did not attempt a globally-representative survey of the provision of harm reduction services by pharmacies. Nonetheless, additional material has been provided by a number of member organisations. There are certainly programmes in countries that are not mentioned in the report. Countries in which pharmacy has long been involved in harm reduction programmes have a wealth of materials available as guidance for policy and practice.

## 5 Summary and considerations

The available literature and the experiences in a number of settings support the involvement of pharmacists, and community pharmacies in particular, in a wide range of harm reduction activities with specific reference to drugs of abuse.

A comprehensive service should be provided that takes into account the needs of the community in each setting, but should include:

- Syringe and needle exchange programmes, including (where possible) the provision of low-dead-space syringes
- Opioid substitution therapy, including (where possible) pharmacist prescribing or dose adjustment under collaborative practice arrangements
- The supply of naloxone as a means to manage inadvertent overdose, including (where possible) pharmacist-initiated supply
- The provision of health promotion services, including sexual and reproductive health services, such as (where possible) testing for and treatment of sexually transmissible infections and pharmacist-initiated supply of hormonal and non-hormonal contraceptives

Careful consideration should also be given, as advanced by the Canadian Pharmacists Association, to the possible role of pharmacists and both community and hospital pharmacies in the supply of marijuana or marijuana-containing products for medicinal use. This would be in addition to those pharmaceutical products containing cannabinoids that are commercially available and authorised in the particular jurisdiction.

The question of whether, with a view to separating the markets for licit and illicit substances, pharmacists and pharmacies (both community and hospital) are the best option as licensed retail outlets for marijuana for recreational purposes poses more challenges. An argument can be made, based on harm reduction principles, for such an arrangement. It might, in fact, represent only a slight difference in approach from that used for long-term opioid substitution as maintenance therapy. However, where such a policy is advanced, it needs to be developed in consultation with pharmacists and their professional associations. Such a policy must also take careful consideration of the concerns of pharmacists about their professional roles, ethical obligations and standing in the public eye. There are strong opinions in opposition to this concept from pharmacy professional associations.

The working group suggests that the following recommendations be considered for a future FIP statement of policy:

1. FIP should:
  - a. Develop a position paper on the role of the pharmacist in harm reduction, based on the evidence provided in this reference paper
  - b. Recommend a considered, pharmacy-inclusive, but evidence-informed, approach to the development of public policy on the concept of medical marijuana
2. FIP member organisations should:
  - a. Engage with policymakers and health authorities regarding any barriers to the increased involvement of pharmacists in the provision of nationally-appropriate harm reduction services, including maximising the potential contribution of pharmacists through collaborative practice arrangements
  - b. Engage, where appropriate, with policymakers and health authorities around the question of medical marijuana and the decriminalisation of the use of marijuana for recreational purposes, with a view to contributing to rational and effective policies on the production, access and needed professional services for these purposes

## 6 Additional reading materials

The Open Society Foundation has provided a comprehensive set of documents on drug policies, including harm reduction approaches, and has summarised the developments in a number of key countries (Switzerland, Portugal, Czech Republic, Netherlands, Spain and Bolivia). These documents can be accessed as follows:

Harm Reduction (September 2015) — <https://www.opensocietyfoundations.org/reports/harm-reduction>

### **Country studies**

From the Mountaintops: What the World Can Learn from Drug Policy Change in Switzerland (October 2010) — <https://www.opensocietyfoundations.org/reports/mountaintops>

Drug Policy in Portugal: The Benefits of Decriminalizing Drug Use (August 2011) — <https://www.opensocietyfoundations.org/reports/drug-policy-portugal-benefits-decriminalizing-drug-use>

A Balancing Act: Policymaking on Illicit Drugs in the Czech Republic (February 2012) — <https://www.opensocietyfoundations.org/reports/balancing-act-policymaking-illicit-drugs-czech-republic>

Coffee Shops and Compromise: Separated Illicit Drug Markets in the Netherlands (July 2013) — <https://www.opensocietyfoundations.org/reports/coffee-shops-and-compromise-separated-illicit-drug-markets-netherlands>

Innovation Born of Necessity: Pioneering Drug Policy in Catalonia (March 2015) — <https://www.opensocietyfoundations.org/reports/innovation-born-necessity-pioneering-drug-policy-catalonia>

Habeas Coca: Bolivia's Community Coca Control (July 2015) — <https://www.opensocietyfoundations.org/reports/habeas-coca-bolivia-s-community-coca-control>

### **General drug policy topics**

Drug Courts: Equivocal Evidence on a Popular Intervention (February 2015) — <https://www.opensocietyfoundations.org/reports/drug-courts-equivocal-evidence-popular-intervention>

The Impact of Drug Policy on Women (May 2015) — <https://www.opensocietyfoundations.org/reports/impact-drug-policy-women>

Drugs and the Death Penalty (October 2015) — <https://www.opensocietyfoundations.org/reports/drugs-and-death-penalty>

The Impact of International Drug Policy on Access to Controlled Medicines (November 2015) — <https://www.opensocietyfoundations.org/reports/impact-international-drug-policy-access-controlled-medicines>

Prevention of Drug Use and Problematic Use (November 2015) — <https://www.opensocietyfoundations.org/reports/prevention-drug-use-and-problematic-use>

Drug Crop Production, Poverty, and Development (February 2016) — <https://www.opensocietyfoundations.org/reports/drug-crop-production-poverty-and-development>

Detention and Punishment in the Name of Drug Treatment (March 2016) — <https://www.opensocietyfoundations.org/reports/detention-and-punishment-name-drug-treatment>

The Economics of the Drug War: Unaccounted Costs, Lost Lives, Missed Opportunities (March 2016) —  
<https://www.opensocietyfoundations.org/reports/economics-drug-war-unaccounted-costs-lost-lives-missed-opportunities>

No Health, No Help. Abuse as Drug Rehabilitation in Latin America & the Caribbean (April 2016) —  
<https://www.opensocietyfoundations.org/sites/default/files/no-health-no-help-en-21060403.pdf>

The Impact of Drug Policies on Children and Young People (May 2015) —  
<https://www.opensocietyfoundations.org/reports/impact-drug-policies-children-and-young-people>

# Appendices

## Appendix 1

### Terms of reference for the FIP working group on pharmacists' role in harm reduction

Version 2015-09-21

Adopted by the FIP Bureau (with timetable adjusted afterwards)

#### Introduction

Health promotion is defined by the World Health Organization as “the process of enabling people to increase control over, and to improve, their health”. Harm reduction falls under the broader umbrella of health promotion and traditionally refers to policies or programmes that are aimed at “decreasing the adverse health, social and economic consequences of high-risk behaviours such as psychoactive drugs, tobacco, and alcohol use.”

Community pharmacists continue to be among the most accessible health practitioners, with whom the public interacts on a daily basis.<sup>1</sup> Pharmacists are uniquely positioned to provide meaningful harm reduction services, as part of an expanding role in health promotion, such as by providing clean needles (e.g., a needle exchange programme in Portugal via community pharmacies<sup>2</sup>), administering opioid substitution therapy, tobacco cessation programmes (e.g., evidence suggests that pharmacists' advice to quit smoking can produce significant increases in quit rates among smokers<sup>3</sup>), as well as educating the public on ways to minimise the harm associated with unhealthy practice (transmission of blood-borne pathogens, providing advice to people who inject drugs on preventing acquisition and transmission of HIV, hepatitis B and hepatitis C infections). Such programmes may also involve hospital pharmacists, those working in military and emergency settings, and those engaged in the provisions of health and medicines information.

Studies examining the attitudes of practitioners have found that pharmacists are generally willing to offer harm reduction services.<sup>4</sup> In some countries, community pharmacies are actively recruited into national harm reduction programmes based on regional needs and are subsequently provided with the financial support needed for involvement. Expansion of such services within pharmacies may be achieved through policy changes that provide better central support and guidance as well as remuneration for these programmes. Pharmacists require additional support in the form of better health team and system integration, as well as remuneration models.

Some of the barriers to implementing harm reduction services may be addressed through additional education in basic pharmacy curricula and continuing education programmes, including an increased emphasis on interdisciplinary teamwork.

In 2014, the FIP member organisation, the Asociación de Química y Farmacia del Uruguay (AQFU), requested the federation to develop a reference document, which might lead to a statement, covering the issue of the sale of marijuana in community pharmacy. This was considered at the Council meeting in August 2014 in Bangkok, which passed the following resolution unanimously: “The FIP Council requests the Bureau (through FIP ExCo) to develop a reference document — possibly leading to a FIP policy statement — on the role of pharmacists in discouraging the use of potentially harmful substances for recreational purposes, and in

<sup>1</sup> The World Health Organization (WHO). The Role of the Pharmacist in the Health Care System. (1994; 60 pages). Accessible from: <http://apps.who.int/medicinedocs/en/d/Jh2995e/1.6.2.html> [accessed 22 January 2015]

<sup>2</sup> *Say NO! To A Used Syringe. A Needle Exchange Programme in Portugal*. Nationwide syringe exchange programme, which has been ongoing since October 1993 in order to prevent HIV and other infectious diseases among injecting drug users. [source: FIP internal POPAD database]

<sup>3</sup> Smith MD, McGhan WF, Lauger G: Pharmacist counseling and outcomes of smoking cessation. *American Pharmacy* 1995, NS35(8):20-9

<sup>4</sup> Watson T, Hughes C: Pharmacists and harm reduction: A review of current practices and attitudes. *Can Pharm J* (Ott). May 2012; 145(3): 124-127.e2. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3567507/> [accessed 22 January 2015].



fighting substance abuse and addictions. Such document could also discuss the distribution of marijuana and other potentially harmful substances used for recreational purposes through community pharmacies.”

### Objectives

The FIP Bureau decided to set up the “FIP working group on pharmacists’ role in harm reduction” with the following objectives:

- To collect and comment upon the available evidence for the role and impact of pharmacists and their associations in harm reduction programmes
- To provide an overview of existing national and regional policies around harm reduction that support pharmacists involvement in such activities
- To specifically address the question of the sale of marijuana for recreational use, and how this might involve pharmacists, as part of a harm reduction approach
- To review the continued relevance of existing FIP Statements on any harm reduction programmes or policies

This reference document may possibly lead to an FIP Statement on the role of pharmacists in harm reduction

### Plan of project methodology

To achieve these objectives, the working group will:

- Identify and perform an analysis of existing data:
  - Perform a literature review on this topic
  - If needed, undertake a survey of existing harm reduction activities and policies
  - Gather more information on the specific proposals in Uruguay
- Prepare a draft reference document for submission to the FIP Bureau for consultation
- Finalise the reference document for its adoption by the FIP Bureau
- Prepare an article to be published in the FIP journal (and possibly another journal), after approval by the FIP Executive committee, presenting this work

### Expected final outcomes

The final outcome of this working group will be a reference document.

- For the purpose of this reference document, the scope of harm reduction activities will be limited to:
  - Psychoactive drug use (including marijuana, injectable drugs) and diversion of psychoactive medicines
  - Tobacco use (including tobacco products and electronic devices delivering nicotine)
  - Excessive alcohol use
- An indicative structure of the document is provided below — however, the working group may differ from this suggested structure, if necessary:
  1. Introduction
  2. Methods used for this reference document
    - a. Scope and structure of the reference document
    - b. Evidence used for this document
  3. Definition of harm reduction (within limitations for the purpose of this document)
    - a. Harm reduction policies
  4. Current status of harm reduction policies and programmes in selected countries
    - a. Psychoactive drug use (including marijuana, injectable drugs) and diversion of psychoactive medicines
    - b. Tobacco use (including tobacco products and electronic devices delivering nicotine)
    - c. Excessive alcohol use
  5. Rationale and suitability of the delivery of harm reduction programmes via pharmacists (including measured impact, if available)
    - a. Health promotion (prevention of use of harm products)
    - b. Limiting health impact of the use of such products
      - i. Improving access to safe products/alternatives
      - ii. Screening for suspicious cases
      - iii. Triage (judging the risk)
      - iv. Referring patients with complex issues

- v. Optimising outcomes of pharmacotherapy (of addictions)
    - vi. Educating on coping skills
  - c. Limiting health-related adverse effects
    - i. Dialogue with patients
    - ii. Safe storage and disposal of high-risk medicines
    - iii. Needle exchange programmes
    - iv. Drug replacement therapy
  - d. Stopping use of harm products
    - i. Cessation programmes
6. Identifying barriers and drivers to the implementation of harm reduction activities conducted by pharmacists
  - a. Local support (referrals to and from other health care professionals, collaborative practice)
  - b. National support (government introducing legislative changes, incentives)
  - c. Competence (training, CPD)
  - d. Safety
  - e. Evidence-based documentation
  - f. Individual barriers (pharmacists' attitudes towards harm reduction)
7. Summary table putting in perspective policy objectives and pharmacists' activities
8. Conclusions
9. Annexes with examples of pharmacists activities

The final, approved reference document will be made available to all FIP member organisations and will be publicly available on the FIP website. It may be summarised in a publication, in the *IPJ* and, if appropriate, other peer-reviewed journals. It may also, with the approval of the FIP Bureau, be used to produce an FIP Policy Statement.

### Project team

To ensure this work, the following profiles for the team members should be considered:

- Experts suggested by the Community Pharmacy Section, the Military and Emergency Pharmacy Section, the Social and Administrative Pharmacy Section, the Hospital Pharmacy Section and the Health and Medicines Information Section
- Member organisations will be asked to nominate a representative

All members should be fluent in English as the work will be done in English but they should also ideally be fluent in at least one other language.

The project team work will be facilitated by a FIP staff member.

### Collaboration expected on this project from other stakeholders

The following potential contributors should be considered when setting up the working group:

- The World Health Organization
- International Narcotics Control Board

### Publication of the results

The final reference document will be sent out to all FIP member organisations. The pdf version will be available on the FIP website.

The article summarising the findings of the reference document will be published in the *IPJ* and therefore will be made available to all FIP individual members. If approved by the FIP Executive Committee, this article could be reproduced in another journal after its publication in the *IPJ* (so that the FIP ownership of the findings is properly preserved).

### Financing of the project

The cost of the working group will be covered by the FIP Bureau budget.

The budget for this working is set as EUR2,000, to cover the costs of:

- Meetings of the working group (online, no costs)
- Meeting during FIP congress (no costs)
- Design of the publication (up to EUR2,000)

## Possible time schedule

Description	Who	Deadline
Adoption of the terms of reference	FIP Bureau	March 2015
Appoint the chair(s) of the working group	FIP Bureau	March 2015
Appoint the members of the working group	FIP Bureau	October 2015 (Düsseldorf)
Beginning of drafting of a reference document as described under “expected final outcomes”	Working group (WG) members	October 2015
First draft to be submitted to the FIP ExCo (v1) for their feedback	WG members/FIP ExCo	January 2016
Review of the draft reference document (interim progress; v2)	FIP Bureau	March 2016
Revision of the reference document and preparation of the final version*	WG members	April 2016
Approval of the draft reference document (v3) for consultation and comments from member organisations (MOs)	FIP Bureau (via e-mail)	1 May 2016
Consultation and comments from MOs on reference document	WG members	May 2016
Final version of the reference document submitted to the FIP ExCo and Bureau for approval	FIP Bureau and FIP ExCo	June 2016
Inclusion in the Council agenda	FIP Council	July 2016 (Buenos Aires)
Presentation of the reference document to the Council (and FIP congress)	WG members	August 2016 (Buenos Aires)
Preparation of the article summarising the reference document for the <i>IPJ</i> (and possibly another journal)	WG members	September 2016
Validation of the article	FIP ExCo	October 2016
Publication of the article in the <i>IPJ</i>	WG members	December 2016
OPTIONAL: Publication of the article in another journal	WG members	March 2017

\* If time permits (and if approved by the Bureau), a draft statement may be developed in parallel with the finalisation of the reference document for approval by Bureau in March 2016 and adopted by FIP Council in August 2016.

If time does not permit, the statement will be submitted for approval by the Bureau in March 2017 and adopted by FIP Council in August 2017.

## Appendix 2

Law N° 19.172 Regulación y Control del Cannabis / Uruguay

Statement

HOME OFFICE  
 MINISTRY OF FOREIGN AFFAIRS  
 MINISTRY OF ECONOMY  
 MINISTRY OF DEFENSE  
 MINISTRY OF EDUCATION AND CULTURE  
 MINISTRY OF TRANSPORTATION AND PUBLIC WORKS  
 MINISTRY OF INDUSTRY, ENERGY AND MINING  
 MINISTRY OF LABOUR AND SOCIAL SECURITY  
 MINISTRY OF PUBLIC HEALTH  
 MINISTRY OF LIVESTOCK, AGRICULTURE AND FISHERIES  
 MINISTRY OF TOURISM AND SPORTS  
 MINISTRY OF HOUSING, TERRITORIAL ZONING AND ENVIRONMENT  
 MINISTRY OF SOCIAL WELFARE

Montevideo, 8th August 2012

Dear President of the General Assembly,

The Executive, acting in a Cabinet meeting, is honored to put before this body this Bill aiming at setting forth the regulatory provisions to control and regulate the cannabis market, to the effect of helping reduce the risks and potential dangers that those using marijuana for recreational or medicinal purposes face, when forced to obtain their supply from the illegal market and therefore find themselves denigrated, involved in criminal activities and high risk practices, also exposing themselves to contact with more toxicologically dangerous drugs, such as cocaine base paste (CBP), among others.

### 1.- Drug use and its regulations throughout history.

There is proof dating back thousands of years, of humankind's growing and using several types of drugs. When Europeans reached our continent, they found drugs, such as tobacco, among others, that were regularly used by the locals since time immemorial. And also since time immemorial have human societies tried to control and regulate its use. For millennia, different societies have devised ways to control and regulate drug use through culture and informal mechanisms of social control, with religions playing a key role in that control. On the other hand, global control through punitive policy and criminal law is relatively new, its origins dating back to the 1920s with the basic foundations of what 40 years later would become the Single Convention on Narcotic Drugs (1961).

This Convention and the policies derived thereof were, like everything else, a product of human culture, a result of that particular time, with its potentials and weaknesses and should thus be subject to critical revision, modification and improvements in the present time. For decades, it would have been unthinkable to question the Convention within the framework of International bodies, let alone consider amending or improving it. However, in different national States and regions, in particular Latin America, different steps have been taken over the past two decades in order to make the approaches to drug policies more flexible based on this legal instrument which leaves little to no room for other approaches and has proven to be ineffective, inefficient and counterproductive for the goals it wishes to achieve.

### 2.- The Failed War on Drugs

A year ago, in 2011, the Global Commission on Drug Policy ([www.globalcommissiondrugs.org](http://www.globalcommissiondrugs.org)) presented a very important report which read, in its introduction: "The global war on drugs has failed. When the United Nations Single Convention on Narcotic Drugs came into being 50 years ago, and when President Nixon launched the US government's war on drugs 40 years ago, policymakers believed that harsh law enforcement action against

those involved in drug production, distribution and use would lead to an ever-diminishing market in controlled drugs such as heroin, cocaine and cannabis, and the eventual achievement of a 'drug free world'. In practice, the global scale of illegal drug markets – largely controlled by organized crime – has grown dramatically over this period. While accurate estimates of global consumption across the entire 50-year period are not available, an analysis of the last 10 years alone shows a large and growing market." UN estimates reveal that the annual use of opiates between 1998 and 2008 had a 34,5% growth (from 12,9 to 17,35 million users), 27% for cocaine use (from 13,4 to 17 millions) and 8,5% for cannabis (from 147,4 to 160 million users). In spite of the growing evidence that current policies are nowhere near achieving their goals, the majority of national and international political agencies have tried to avoid examination and debate about possible alternatives. This lack of leadership when it comes to drug policy has motivated the creation of our Committee and guides us in our vision that this is the right time for a thorough, sensible and large-scale revision of the strategies used to respond to the drug phenomenon. The starting point for this revision is the acknowledgment that the global problem of drugs poses a series of intertwined sanitary and social challenges to be managed rather than a war to be won. Committee members have agreed to four fundamental principles that should guide strategies and policies on drug use, locally and internationally and have made eleven suggestions for specific actions." (The members of the Global Committee for Drug Policy are: Former Presidents and Prime Ministers: Fernando Henrique Cardoso (Brazil), César Gaviria (Colombia), Ernesto Zedillo (Mexico), Ruth Dreifuss (Switzerland), George Papandreou (Greece). Former international officials: Kofi Annan, former UN Secretary General (Ghana), Javier Solana, former EU High Representative for Common Foreign and Security Policy (Spain), Louise Arbour, former UN High Commissioner for Human Rights (Canada). Asma Jahangir former UN Special Rapporteur on Extrajudicial, Summary or Arbitrary Court Seizures (Pakistan), Michel Kazatchkine Executive Director for the Global Fund to fight AIDS, Tuberculosis and Malaria (France). Intellectuals: Mario Vargas Llosa (Peru), Carlos Fuentes (Mexico). Foreign Government Officials: Paul Volcker, former President of the Federal Reserve (USA), George Shultz, former Secretary of State (USA), Marion Caspers-Merk, former Secretary of State at Federal Ministry of Health (Germany), Thorvald Stoltenberg, former Minister of Foreign Affairs and UN High Commissioner for Refugees (Norway). Entrepreneurs: John Whitehead, banker, President of the World Trade Center Memorial (USA), Maria Cattai, member of the Board of Petroplus Holdings, former Secretary General of the International Chamber of Commerce (Switzerland), Richard Branson, Virgin Group and co-founder of The Elders (United Kingdom)). It should be clear that Uruguay has set an international example in its struggle against legal and illicit drug use. In the case of tobacco, the previous administration defined a clear policy, which was well received with the population and has been followed up the current administration. As a consequence, our country is presently involved in multimillionaire lawsuits from powerful tobacco company Phillip Morris. However, we are not to change our positions on the issue. It is worth noting that we shall not abandon our commitment to fighting drugs over these foregone consequences. The Executive Power shall continue to work by all possible means, to reduce and if possible, eradicate drug use, whether it be legal or illicit as we have so far as well as taking a stand against all health deleterious practices.

In this context, we begin by confirming and asserting that, unfortunately, we are witnesses to the unarguable failure of an international strategy (that we have accompanied at a local and regional level) designed not long ago and exclusively towards drugs considered illicit, which are not all drugs and which are also not the ones more widely produced. The unquestionable failure of this "War" on drugs is manifest in the following key aspects:

One: In spite of said war, and after half a century of its harsh application, drug use has grown and expanded, as have its dreadful consequences. It has grown in places where use was not new but it has also reached new places where it did not exist before. On the other hand, drug seizures achieved by such large scale operations and at such high cost pale in comparison with the large scope of the diverse drug markets. We are not, however, in this position due to the inefficiency of the repressive procedures devoted to those endeavors but to the difficult reality that we shall outline later.

Two: Humankind has wasted colossal amounts of money and countless resources including human and scientific, in the wrong waging or a wrongful war. What is more, it has been poor countries which have been wasting resources they did not even have, neglecting basic needs of their peoples and even the actual combating of crime. But besides the above, we have paid for this mistake with extremely harsh social consequences. Among them is prison overpopulation, nothing but a mass, large scale involuntary treatment, an overburdened judicial system, as well as the double standards and the perversion that will be inevitably linked to any illicit commercial activity. The consumer is unavoidably denigrated and subjected to such activity should he wish to access what he wants; this, the double standard and the anomia, does not, and will not come without a price for any society as it will also open the gates for other calamities.

Three: By focusing on Offer all action on Demand has been abandoned. Very few resources, in fact, virtually none, have been allocated to fighting use by means of actions related to prevention, information and persuasion, damage recovery and overall attention of users, advertising campaigns and research. The comparison between what has spent and is currently spent in repression with what should be devoted to the aforementioned areas is one of the most evident manifestations of this failure.

And fourth, the worst consequence of all: it has given rise, as forewarned by the most basic economy manuals, to the build up of a significant “potential market”, the monopoly in law and in fact for criminal activities. A market forced to pay astronomical prices for drugs, leaving tax-free profit and accumulation generated by said prices, in the hands of ever powerful mafias. We are also clearly facing subsidized, unfair competition by legally fronted money laundering operations, against law abiding businesses. Each link in this long “chain of production” “enjoys” such benefits that, when accumulated, make it absolutely impossible and unrealistic to attempt to defeat traffickers with the always scarce resources that States have. Some consider that this “business” is one of the largest in the world, second only to oil. In any case, all calculations indicate it as one of the largest. The colossal money supply of an activity such as traffic, which end users pay in cash can only have devastating financial consequences. The close connection between drug traffic and the illegal sale of weapons, gold and diamonds, crucial for the laundering of such large sums of money have been well documented and date back to the Opium Wars and ever before that. Such concentration of power easily finds its way to corruption at any social level and activity. This has been proved, is well known and it is still haunting us. The press covers it all over the globe: politicians, judges, attorneys, military and police...even the designation of Presidents in political campaigns. At different places and times, the State is virtually replaced or rendered irrelevant; societies lacking stability and at the mercy of criminal gangs and democracy shattered. This is not mere threats, but observable facts. The cost of any attempt to avoid or prevent this once it reaches a certain degree, is bloodshed and suffering.

To sum up: the “cure” has proven to be much worse than the “disease”.

### 3.- Uruguay's Policies on Drugs in the second decade of the XX1st Century

Uruguay has built, in accordance with The National Drug Control Board (“Junta Nacional de Drogas” - JND in Spanish) a strategy for the 2011 – 2015 term, as well as its programmatic Basis which among other considerations includes:

- The framework that drug use is a complex social problem, with multiple dimensions and causes, deeply rooted in political and cultural factors in society and the community. It requires the active presence of the State as to its fundamental obligations, as well as the active and leading participation of society showing strong commitment to all areas of administration and also the incorporation of non-profit organizations and the private sector.
- Accepting responsibility in the development of public policies on drugs and the protection of individual as well as collective rights and liberties. National strategy is defined from a point of view incorporating the complexities of the issue of Drug use in the continuity and complementation of actions from different areas, following the principles of shared responsibility and joint management of risks between the State and society. Among its objectives is the creation of public policies that promote and guarantee, from the institutional mechanisms to control the State to those stemming from organized community or being implemented by the active participation of society. Considering Drug Policy as a continuum, embracing the promotion of healthy habits and values, prevention, damage reduction, treatment, rehabilitation and social reinsertion, as well as control of drug supply and prevention and repression of asset laundering.
- Acknowledging that the social complexity of the rise of drug use and illicit traffic requires incorporation in Social Welfare Policies. The social inclusion and integration approach is part of a comprehensive strategy to attain the aim of generating sustainable human development that may be fair and equitable, just as it endeavors to reduce the vulnerability and damage of social suffering by means of local policies providing help and promoting social resources for employment, educational, recreational and cultural reinsertion.
- Holding local actions by means of decentralization and localization of Drug Policy as cornerstones of policy making, in a joint effort with municipal authorities and persons active in communities, involving prevention in work environments through permanent and concerted action by employers and workers in both the public and private sphere, a socio-sanitary approach within Primary Health Care, and systematization and



institutionalization in the Educational System incorporating information and prevention on the subject of drugs with a view to educating and promoting life skills.

- Decentralization is a process inherent to shared management of policies on the drug problem. It means a leading role for municipal authorities, mayors, Provincial Drug Boards and non-profit organizations. It originates in an essential concept intending to make use of the knowledge and capacity of an organized community, of its neighbor associations, social and non-government organizations, together with local action by national and municipal agencies.

- A socio-sanitary approach shall be encouraged, from the standpoint of public health in its widest sense, to include the right to health and to health education, the prevention, early detection, care and treatment of illness and damage reduction by means of different procedures. This public health

approach is one of the pillars of the Strategy with a view to social solidarity and a bio-psychosocial concept calling for promotion, prevention and community work with participation of all local actors.

- The driving initiative of the State together with a social network of promotion and prevention measures, health assistance and care, accessible treatment and social reinsertion shall coordinate all action inherent to the problematic consumption of legal and illicit drugs with a participative and inclusive intent.

- A preventive educational approach should be incorporated in formal and non-formal educational systems, stressing that teachers, parents, students and community agents should incorporate a critical and creative, rational and emotional way of thinking in order to develop skills and values useful in life.

- A world of uncertainty where challenges related to the risks of the problem use of drugs are constantly encountered requires strengthening protection factors. Educational proposals shall be capable of positive discrimination in practice according to age and different problems related to the psychosocial development of students.

- The University of the Republic has an all-important role in this approach to the drug problem, incorporating the matter in the respective curricula of different disciplines and in specialization and research programs, and in this context plans for extra mural studies are significant for their contribution to the community and for coordinated action towards locally shared management of social policies on drugs.

- Our National Strategy does not agree with prohibitionist approaches and “war on drugs” concepts widespread on an international level with the consequence of causing greater harm, generating more violence and corruption, and failing in the attainment of aims sought. This prohibitionist model, with a disproportionate shift of political, cultural and budgetary weight on to reducing supply, is being questioned for ineffectiveness and inefficiency. The ruling criterion should be that punishment is to be proportionate to seriousness of offence related to drugs. An approach seeking to integrate the provisions of Conventions and current drug legislation with international instruments on Human Rights is to be advanced. It is with this intent, among others, that the legal framework in force and provisions of Conventions on the subject should be discussed.

- An approach supporting individual rights and civil liberties should be coupled with staunch advocacy of social solidarity and concern for sectors that suffer social and cultural exclusion. An approach grounded on public health and citizens living together in peace and safety, is a challenge to

social integration and means recognition of the rights of others. Promoting social welfare for the most vulnerable sectors of society implies fostering capacity for autonomy, freedom and citizen support for solidarity and self-managed care for all.

- For effective control of illicit traffic and asset laundering the essential requirements are transparency and efficiency in control agencies with the support of a forthright and precise political mandate. The fight against money laundering and the decision to act on all levels of society and against all sectors and individuals involved, no matter who they may be, is one of the main ethical and political pillars of action. The battle against organized crime is a collective task for multiple actors and agencies collaborating to attain said end, in cooperation with the Permanent National Plan of Integrated Operations against Drug Traffic and Money Laundering.

• Uruguay adheres to the principle of shared mutual responsibility equitably fulfilled, in the sense of equitable compliance with commitments and suitable response to challenges within the sphere of international cooperation, bearing in mind the diverse and complex aspects of a transnational phenomenon with due respect for the national and cultural sovereign nature of all nations. The model arbitrarily dividing countries into producers, transit and consumers, is obsolete and has only been functional within a discriminatory scheme which has proved to be deleterious and inefficient. Recognition of different situations within multilateral assessments implies sharing a challenge with multiple dimensions. Control, assessment and research in connection with different expressions of the rising drug problem mean sharing burdens and allocating costs. Stressing recognition of regional occurrences of the problem use of drugs and of differentiated circuits of local traffic that have great social impact (as in the case of smokeable cocaine) also means assessing collateral effects of generally operating control policies which have focused attention on other aspects. Policies calling for eradication of cultivation and for alternate development in our region should take into account the integral character of economic and social development in these countries, not admitting unequal burdens with regard to responsibilities and the human cost involved. Concerted action should be faced with firm determination in observance of international law and respecting civil liberties inherent to individual and collective Human Rights, including considerations regarding gender, ethnic minorities and preservation of the environment and biodiversity.

• Uruguay has defended the need to hold, in regional, continental and world forums and organizations, an open Political Debate to discuss the hegemonic paradigm with regard to Drug Policies. Such debate should question different modes of control and inspection and the principles that sustain such models, based on procedures stipulated in international legal instruments, the 1961 Single Convention on Narcotic Drugs and the 1988 United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

• The current debate is shifting towards questioning the principles behind the strategies for control and regulation of drugs at a regional and global level. This prohibitionist model, with a disproportionate shift of political, cultural and budgetary weight on to reducing supply, is being questioned for ineffectiveness and inefficiency. This approach has resulted in more harm, not only in terms of its collateral effects but also due to the fact that it is unquestionably non-compliant with the principles embodied in Human Rights instruments enshrined by the international community. The different modes of control and inspection as well as the principles that sustain such models, should be put under scrutiny, in open and thorough democratic discussion, without forbidding denunciation or prejudice of any kind. Moreover, such a debate is needed for countries to generate the checks and balances necessary for a rising problem with dangerous incidence from a geopolitical viewpoint. The forms and methods of organized crime, asset laundering schemes and cash flows, as well as the strategic position of countries with military prowess enforcing the dominant warlike approach, give rise to novel subordination situations and represent a greater menace to our vulnerable populations. In that regard, this Strategy passed by the NDCB on 29th April 2011 sets out the following as fundamental principles to guide all actions: Human Rights. Integration of Human Rights principles and instruments in drug policy. Respect of rights and civil liberties to their full extent. Equitable status. Commitment to achievement of human dignity and equitable status, incorporating equitable socio-economic status, and equitable status with respect to gender, generations, territories. Democracy. The need for an open discussion integrating all views as a democratic way of strengthening strategy on drugs. Cooperation, mutual responsibility equitably shared. Defense of multilateral agreements as a birth right of our hemisphere celebrating unity in diversity. Comprehensiveness, balance and transverse views and application of procedures. A complex inter-institutional approach, cooperation with non-profit organizations, and a broad range of vision and modes of action. Participation. Shared management of risk, joint policy-making with communities and the presence of the State, shared social responsibility. Scientific Evidence and Best Practices. Drug Policies based on information and knowledge of scientific facts, adopting duly assessed best practices.

#### 4.- Background.

In the 70s, the Netherlands launched a pioneering experience, based on a pragmatic approach to make a distinction between the markets of what were then known as “hard drugs” (heroin, LSD, cocaine, etc.) and “soft drugs” (marijuana, hashish). The main features of the Dutch System were set out by the Baan Commission and are based on a down to earth, pragmatic approach to drug policy-making, founded on the need to reduce risks and potential harm to marijuana users who, by having to obtain their supply in the illicit market, were frequently engaged in practices involving greater medical, psycho-social and legal dangers, as well as exposed to other drugs. Thanks to this down to earth, pragmatic approach, the Dutch government set clear priorities when it comes to drug policy, based on the differential risks that the different substances pose for individuals



and the community. The preservation of life, social cohesion among citizens, promotion of individual and public health and respect for Human Rights are the cornerstones of the strategy that the Netherlands has adopted and has been applying for over thirty years now. Moreover, it is worth noting that several states and territories in Australia (Australian Capital Territory, South Australia and Northern Territory) have decriminalized the possession of cannabis for personal use, as well as cultivation for own use, implementing a punitive system of civil sanctions instead of criminal offences. Along these same lines, cannabis social clubs have been established in several Spanish provinces in the past few years. They take into account different models for regulation, in terms of production, distribution and use of marijuana. In these organizations, apart from the controlled production and distribution of marijuana, medical and legal assistance to members is provided, and informative and educational events are carried out in order to improve risk management for users.

Furthermore, from 1998 to date, seventeen U.S. States have been developing various systems for the regulation of production, marketing and use of medicinal marijuana under medical prescription.

At a national level, it is essential to note and appreciate the work carried out by the House of Representative's Commission on Addiction, which, after an exhaustive, rigorous and inclusive study of all the different approaches, concluded with a series of recommendations regarding public policy on drugs -and specifically on marijuana - clearly stressing the urgent need to ensure proper access to marijuana in order to reduce toxicological, psychological, social and legal risks derived from the illegality of the substance. Prohibitionist policies have not only proved inefficient at individual and social risk reduction in the use of the different psychoactive substances, but have also caused exponentially greater health, social, legal and economic damage, giving rise to multimillion illicit operations and systemic violence at levels previously unheard of. Uruguay has not been oblivious to the consequences of the implementation of international and national policies based on a prohibitionist paradigm, which, far from discouraging consumption and improving access to health care, have generated a growing rise in traffic and violence, as well as market growth, accompanied by an increasing precocity in terms of the age at which drug use begins. There are recent indicators that criminal activities such as revenge and contract killings are beginning to take place in the country, increasingly affecting the most marginalized and underprivileged social sectors. In our country, marijuana has long been the most consumed illicit substance, with significant legitimacy within Uruguayan society. This substance, which has a mild to moderate capacity to generate physical and psychological dependence, is clearly different, in terms of its risks, from another group of drugs with a much higher toxicological and addictive potential. Among those, we have CBP, alcohol, tobacco and psychotropic drugs. Whereas most of marijuana users in Uruguay are occasional consumers without major health consequences from their use, it is important to note that they are frequently exposed to psychological, legal and social risks stemming from the necessity to illegally obtain this drug. It is mostly the unification of the illegal markets what unnecessarily exposes users to the possible use of other more toxicologically dangerous drugs, as well as to situations of violence associated to criminal activities typical of illegal markets. These risks are to be minimized as an alternative in order to promote care for users and maintain social cohesion among citizens. To sum up, current local policies have proved inefficient in terms of reducing individual and social sanitary harm associated to marijuana use, generating a significant criminalization and exclusion of users via the selective application of the Law, and keeping problem users away from real access to the network of specialized care.

## 5. Main Objectives of the Initiative

The present Bill becomes a useful instrument to provide solutions to the situations outlined above and specifically for: The separation of the marijuana market from the other drugs in order to significantly reduce the amount of individuals joining the markets of more toxicologically dangerous substances, such as CBP or cocaine;

The normalization and social inclusion of marijuana use, to avoid stigmatization of users or their criminal convictions, and instead create the conditions for working with said users and society at large, in programs and educational campaigns aiming at providing factual and reliable information on the matter, empowering them to make informed, responsible decisions and to anticipate and manage the risks of using this substance in an efficient manner;

Undertaking (funded by taxes levied on legal marketing of cannabis, among other aspects) the development and diversification of the national system of assistance to problem users of drugs, so as to provide ready response in the different situations of problem use of drugs that users may face;

Conducting a full-fledged attack on illicit drug trafficking, depriving a business that, according to primary estimates, amounts to 30 or 40 million dollars per year and which implies a potential source of corruption and social violence.

The Executive Power greets this Body with its utmost consideration.

José Mujica

President of the Republic

## References

- 1 FIP Statement of Policy on the Role of the Pharmacist in Promoting a Future Free of Tobacco (2003, Sydney), Accessible at [http://www.fip.org/uploads/database\\_file.php?id=172&table\\_id=](http://www.fip.org/uploads/database_file.php?id=172&table_id=).
- 2 WHO/FIP Joint Declaration on the Role of the Pharmacist in the Fight Against the HIV-AIDS Pandemic (1997, Vancouver). Accessible at [http://www.fip.org/uploads/database\\_file.php?id=245&table\\_id=](http://www.fip.org/uploads/database_file.php?id=245&table_id=).
- 3 FIP/WSMI Joint Statement on Responsible Self-Medication (1998, The Hague). Accessible at [http://www.fip.org/uploads/database\\_file.php?id=241&table\\_id=](http://www.fip.org/uploads/database_file.php?id=241&table_id=).
- 4 The Ottawa Charter for Health Promotion. First International Conference on Health Promotion, Ottawa, 21 November 1986. Accessible at <http://www.who.int/healthpromotion/conferences/previous/ottawa/en/>.
- 5 What is Harm Reduction? A position statement from the International Harm Reduction Association (September 2009). Accessible at [https://www.hri.global/files/2010/05/31/IHRA\\_HRStatement.pdf](https://www.hri.global/files/2010/05/31/IHRA_HRStatement.pdf).
- 6 Harm Reduction Coalition. Principles of Harm Reduction. Accessible at <http://harmreduction.org/about-us/principles-of-harm-reduction/>.
- 7 Tommasello AC. Substance abuse and pharmacy practice: what the community pharmacist needs to know about drug abuse and dependence. *Harm Reduction Journal* 2004; 1: 3.
- 8 Roberts K, Hunter C. A comprehensive system of pharmaceutical care for drug misusers. *Harm Reduction Journal* 2004; 1: 6.
- 9 Stevens A. Drug policy, harm and human rights: a rationalist approach. *International Journal of Drug Policy* 2011; 22: 233–238.
- 10 United Nations Office on Drugs and Crime. World Drug Report 2015. Accessible at [https://www.unodc.org/documents/wdr2015/World\\_Drug\\_Report\\_2015.pdf](https://www.unodc.org/documents/wdr2015/World_Drug_Report_2015.pdf).
- 11 European Monitoring Centre for Drugs and Drug Addiction. Drug-related infectious diseases in Europe Update from the EMCDDA expert network. EMCDDA 2015.
- 12 Watson T, Hughes C. Pharmacists and harm reduction: a review of current practices and attitudes. *Canadian Pharmacy Journal* 2012; 145(3): 124–127.
- 13 Matheson C, Anthony GB, Bond C, Rossi MK. Assessing and prioritizing the preferences of injecting drug users in needle and syringe exchange service development. *Journal of Public Health* 2008; 30(2): 133–138.
- 14 Lawrie T, Matheson C, Bond C, Roberts K. Pharmacy customers' views and experiences of using pharmacies which provide needle exchange services in Aberdeen and Glasgow, Scotland. *International Journal of Drug Policy* 2003; 14: 445–447.
- 15 Sheridan J, Henderson C, Greenhill N, Smith A. Pharmacy-based needle exchange in New Zealand: a review of services. *Harm Reduction Journal* 2005; 2: 10.
- 16 Stopka TJ, Geraghty EM, Azari R, Gold EB, deRimer K. Is crime associated with over-the-counter pharmacy syringe sales? Findings from Los Angeles, California. *International Journal of Drug Policy* 2014; 25: 244–250.
- 17 Siddique SS, Armenta RF, Evans JL, Yu M, Cuevas-Mota J, Page K, Davidson P, Gerfein RS. Effect of legal status of pharmacy syringe sales on syringe purchases by persons who inject drugs in San Francisco and San Diego, CA. *International Journal of Drug Policy* 2015; 26: 1150–1157.
- 18 Costenbader EC, Zule WA, Coomes CC. Racial differences in acquisition of syringes from pharmacies under conditions of legal but restricted sales. *International Journal of Drug Policy* 2010; 21: 425–428.
- 19 Lutnick A, Case P, Kral AH. Injection drug users' perspectives on placing HIV prevention and other clinical services in pharmacy settings. *Journal of Urban Health* 2012; 89(2): 354–364.
- 20 Oramasionwu CU, Johnson TL, Zule WA, Carda-Auten J, Golin CE. Using pharmacies in a structural intervention to distribute low dead space syringes to reduce HIOV and HCV transmission in people who inject drugs. *American Journal of Public Health* 2015; 105(6): 1066–1071.
- 21 Torre C, Lucas R, Barros H. Syringe exchange in community pharmacies – the Portuguese experience. *International Journal of Drug Policy* 2010; 21(6): 514–517.
- 22 Myers BJ. Primary health care for people who inject drugs in low and middle income countries. *International Journal of Drug Policy* 2012; 23: 103–110.
- 23 Parry CDH, Petersen P, Carney T, Needle R. Opportunities for enhancing and integrating HIV and drug services for drug using vulnerable populations in South Africa. *International Journal of Drug Policy* 2010; 21: 289–295.
- 24 Sarang A, Rhodes T, Platt L. Access to syringes in three Russian cities: implications for syringe distribution and coverage. *International Journal of Drug Policy* 2008; 19S: S25–S36.
- 25 Pollini RA, Rosen PC, Robles B, Brouwer KC, Macalino GE, Lozada R. Not sold here: limited access to legally available syringes and pharmacies in Tijuana, Mexico. *Harm Reduction Journal* 2011; 8: 13.
- 26 Qian H-Z, Schumacher JE, Chen HT, Ruan Y-H. Injection drug use and HIV/AIDS in China: review of current situation, prevention and policy implications. *Harm Reduction Journal* 2006; 3: 4.
- 27 Yang Y, Latkin C, Luan R, Yang C. Reality and feasibility for pharmacy-delivered services for PWID in Xichang, China: comparisons between pharmacy staff and PWID. *International Journal of Drug Policy* 2015; <http://dx.doi.org/10.1016/j.drugpo.2015.05.015>
- 28 Scott RA, Burnett SJ. Supervised administration of methadone by pharmacists. *BMJ* 1994; 308: 1438.

- <sup>29</sup> Luger L, Bathia N, Alcorn R, Power R. Involvement of community pharmacists in the care of drug misusers: pharmacy-based supervision of methadone consumption. *International Journal of Drug Policy* 2000; 11: 227–234.
- <sup>30</sup> Sheridan J, Strang J, Barber N, Glanz A. Role of community pharmacies in relation to HIV prevention and drug misuse: findings from the 1995 national survey in England and Wales. *BMJ* 1996; 313: 272–274.
- <sup>31</sup> Matheson C, Bond CM, Tinelli M. Community pharmacy harm reduction services for drug misusers: national service delivery and professional attitude development over a decade in Scotland. *Journal of Public Health* 2007; 29(4): 350–357.
- <sup>32</sup> Matheson C, Thiruvothiyur M, Robertson H, Bond C. Community pharmacy services for people with drug problems over two decades in Scotland: Implications for future development. *International Journal of Drug Policy* 2016; 27: 105–112.
- <sup>33</sup> Gidman W, Coomber R. Contested space in the pharmacy: public attitudes to pharmacy harm reduction services in the West of Scotland. *Research in Social and Administrative Pharmacy* 2014; 10: 576–587.
- <sup>34</sup> Irwin A, Laing C, Mearns K. Dealing with aggressive methadone patients in community pharmacy: a critical incident study. *Research in Social and Administrative Pharmacy* 2012; 8: 542–551.
- <sup>35</sup> Chaar BB, Hanrahan JR, Day C. Provision of opioid substitution services in Australian pharmacies. *Australasian Medical Journal*. 2011; 4(4): 210–216.
- <sup>36</sup> Lea T, Sheridan J, Winstock A. Consumer satisfaction with opioid treatment services at community pharmacies in Australia. *Pharmacy World and Science* 2008; 30: 940–946.
- <sup>37</sup> Prevention and control of infectious diseases among people who inject drugs. ECDC and EMCDDA Guidance. 2011.
- <sup>38</sup> Winstock AR, Lea T, Sheridan J. Prevalence of diversion and injection of methadone and buprenorphine among clients receiving opioid treatment at community pharmacies in New South Wales, Australia. *International Journal of Drug Policy* 2008; 19: 450–458.
- <sup>39</sup> Uosukainen H, Bell JS, Laitinen K, Tacke U, Ilomäki J, Turunen JHO. First insights into community pharmacy based buprenorphine-naloxone dispensing in Finland. *International Journal of Drug Policy* 2014; 24: 492–497.
- <sup>40</sup> Uosukainen H, Turunen JHO, Ilomäki J, Bell JS. Community pharmacy services for drug misusers: attitudes and practices of Finnish pharmacists. *International Journal of Drug Policy* 2014; 25: 1139–1142.
- <sup>41</sup> Green TC, Dauria EF, Bratberg J, Davis CS, Walley AY. Orienting patients to greater opioid safety: models of community pharmacy-based naloxone. *Harm Reduction Journal* 2015; 6: 12–25.
- <sup>42</sup> Kan M, Gall JA, Latypov A, Gray R, Bakpayev M, Alisheva D, Rakhmatova K, Sadieva AS. Effective use of naloxone among people who inject drugs in Kyrgyzstan and Tajikistan using pharmacy- and community-based distribution approaches. *International Journal of Drug Policy* 2016; 25: 1221–1226.
- <sup>43</sup> Ministry of Health, British Columbia. A Guideline for the Clinical Management of Opioid Use Disorder. June 2017. Accessible at [http://www2.gov.bc.ca/assets/gov/health/practitioner-pro/bc-guidelines/bc\\_oud\\_guidelines.pdf](http://www2.gov.bc.ca/assets/gov/health/practitioner-pro/bc-guidelines/bc_oud_guidelines.pdf).
- <sup>44</sup> Small D, Druryer E, and Editorial for Harm Reduction Journal. Policy makers ignoring science and scientists ignoring policy: the medical ethical challenges of heroin treatment. *Harm Reduction Journal* 2006; 3: 16.
- <sup>45</sup> Schechter MT. Drug users should be able to get heroin from the health system. *BMJ* 2015; 350: h1753.
- <sup>46</sup> Grinspoon L. Medical marijuana in a time of prohibition. *International Journal of Drug Policy* 1999; 10: 145–156.
- <sup>47</sup> Bostwick JM. Blurred boundaries: the therapeutics and politics of medical marijuana. *Mayo Clinic Proceedings* 2012; 87(2): 172–186.
- <sup>48</sup> Cerdá M, Wall M, Kyes KM, Galea S, Hasin D. Medical marijuana laws in 50 states: investigating the relationship between state legalization of medical marijuana and marijuana use, abuse and dependence. *Drug and Alcohol Dependence* 2012; 120(1–3): 22–27.
- <sup>49</sup> Hall W. US policy responses to calls for the medical use of cannabis. *Yale Journal of Biology and Medicine* 2015; 88: 257–264.
- <sup>50</sup> Lutge EE, Gray A, Siegfried N. The medical use of cannabis for reducing morbidity and mortality in patients with HIV/AIDS. *Cochrane Database of Systematic Reviews* 2013, Issue 4. Art. No.: CD005175. DOI: 10.1002/14651858.CD005175.pub3.
- <sup>51</sup> Whiting PF, Wolff RF, Deshpande S, Di Nisio M, Duffy S, Hernandez AV, Keurentjes JC, Lang S, Misso K, Ryder S, Schmidkofer S, Westwood M, Kleijnen J. Cannabinoids for medical use: a systematic review and meta-analysis. *JAMA* 2015; 313(24): 2456–2473.
- <sup>52</sup> Farrell M, Buchbinder R, Hall W. Should doctors prescribe cannabinoids? *BMJ* 2014; 348: g2737.
- <sup>53</sup> Murnion B. Medicinal cannabis. *Australian Prescriber* 2015; 38: 212–215.
- <sup>54</sup> Pardo B. Cannabis policy reforms in the Americas: a comparative analysis of Colorado, Washington, and Uruguay. *International Journal of Drug Policy* 2014; 25: 727–735.
- <sup>55</sup> Lucas P. It can't hurt to ask: a patient-centered quality of service assessment of Health Canada's medical cannabis policy and program. *Harm Reduction Journal* 2012; 9: 2.
- <sup>56</sup> Lucas PG. Regulating compassion: an overview of Canada's federal medical cannabis policy and practice. *Harm Reduction Journal* 2008; 5: 5.
- <sup>57</sup> Canadian Pharmacists Association. Submission to the Task Force on Marijuana Legalization and Regulation. 29 August 2016.

- <sup>58</sup> Grinspoon L. On the pharmaceuticalization of marijuana. *International Journal of Drug Policy* 2001; 12: 377–383.
- <sup>59</sup> Michels II. Report on the initiative to separate the market for ‘soft’ and ‘hard’ drugs in Germany. *International Journal of Drug Policy* 1999; 10: 305–309.
- <sup>60</sup> Kalke J, Raschke P. Cannabis in pharmacies: a proposal from Germany on how to separate the drug markets. *International Journal of Drug Policy* 1999; 10: 309–311.
- <sup>61</sup> Barry RA, Hilamo H, Glantz SA. Waiting for the opportune moment: the tobacco industry and marijuana legalization. *Milbank Quarterly* 2014; 92(2): 207–242.
- <sup>62</sup> Stein DJ, for the Executive Committee of the Central Drug Authority. Position statement on cannabis. *South African Medical Journal* 2016; 106(6): 569–570.
- <sup>63</sup> Scott K. Comment on the Central Drug Authority’s position statement on cannabis. *South African Medical Journal* 2016; 106(6): 545–546.
- <sup>64</sup> Mr MGR Oriani-Ambrosini (IFP). Medical Innovation Bill (PMB1-2014). Accessible at <http://pmg-assets.s3-website-eu-west-1.amazonaws.com/pmb1-2014.pdf>
- <sup>65</sup> Medicines Control Council. Medicines Control Council clarifies access to Cannabis for the treatment of medical conditions. 25 November 2016. Accessible at: [http://www.mccza.com/documents/5933cac110.14\\_Media\\_Release\\_Cannabis\\_Nov16\\_v1.pdf](http://www.mccza.com/documents/5933cac110.14_Media_Release_Cannabis_Nov16_v1.pdf).
- <sup>66</sup> CEFAR. PTS - Farmácias Indicadores preliminares Ano de 2015 . Relatório. Lisboa, Janeiro 2016.
- <sup>67</sup> CEMBE. Avaliação Económica do Programa de Troca de Seringas nas Farmácias. Lisboa. 2016
- <sup>68</sup> Estudo de Avaliação Programa Troca de Seringas. EXIGO. 2015.
- <sup>69</sup> Borges M, Gouveia M, Fiorentino F, Jesus G, Cary M, Guerreiro JP, Costa S, Vaz Carneiro, A. Avaliação económica do programa de troca de seringas nas farmácias iniciado em 2015. Poster presented at: The Scientific Symposium of the 12th Pharmacy Congress, April 2016; Lisbon.
- <sup>70</sup> Jacinto I., Madeira A., Santos C., Goulao J., Pádua J. Methadone Maintenance Treatment Programme in Portuguese Community Pharmacies. 2014. *Journal of Health Science* 3. 2015; 85-94. Accessible at: <http://www.davidpublisher.com/Public/uploads/Contribute/55c9c3b201295.pdf>

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