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Heroin-Assisted Treatment and the United Nations international drug control apparatus

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Key Points

- There is now a powerful evidence base for heroin-assisted treatment (HAT). In view of the present epidemic of drug-related mortality, the treatment should have a more significant role in public health policy.
- Much research concerning the impact of the international drug control regime on the implementation of harm reduction interventions by member states attributes an often 'chilling' role of the guardian of the UN drug control conventions, the International Narcotics Control Board (INCB or Board)
- Interviews with former health officials from countries that pioneered the trialling of HAT in the 1990s revealed that while some felt that the INCB sought to act as a break on the intervention, others believed that although the Board was generally hostile to new policy interventions its stance on HAT was relatively neutral.
- In recent years, the INCB has undergone a shift in tone and outlook regarding HAT, changes that took place particularly under the leadership of Werner Sipp.
- However, the UN drug control system, including the World Health Organisation, has
 in general been lukewarm at best in its support for HAT.
- The most realistic and promising appraisal of HAT came in the UN System Report of 2019, which directly backed the use of HAT.
- The INCB has clearly long been hostile to drug policy innovation and has carried this
 over into its attitudes to HAT. Yet, while the influence of the Board is complex, it is
 likely that national governments themselves are the main source of reluctance in
 making use of this intervention.

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Introduction

This working paper examines the present situation regarding Heroin-assisted treatment (HAT), in addition to the early history (in the 1990s and early 2000s) of HAT as a contemporary drug treatment intervention. It explores domestic policy contexts in several countries making use of the intervention, with particular reference to those states that pioneered it, such as Switzerland and the Netherlands. It deploys a special focus on the relationships obtaining between these countries and the institutions of the United Nations-administered international drug control regime, relationships which have been long-contested and provided the context for disputes surrounding both HAT and other innovative forms of drug policies and practices.

The paper conducts a brief global survey of HAT trials, which have provided the evidence base for the intervention, and facilities where it is practiced. It considers the key policy debates within which the intervention sits, drawing on evidence gathered from both documentary sources and interviews with former officials from countries which, in the context of HAT, dealt with the International Narcotics Control Board (INCB or Board) and the international drug control regime more broadly. The author sets out with a working hypothesis regarding the INCB, namely that it was a prominent force in blocking the progress of HAT in UN member states. This hypothesis was tested against the empirical textual evidence gathered in the course of research and will be discussed further below.

Heroin-assisted treatment

Heroin-assisted treatment involves supplying pure pharmaceutical diacetylmorphine (diamorphine, heroin) to those who are dependent on the drug but have not benefited from the standard substitution therapies utilising methadone and buprenorphine. It is currently considered most effective as a second line treatment that assists people to escape the criminal entailments of addiction to street heroin and the health hazards associated with illicit drug use, such as the sharing of needles and other injection paraphernalia that lead to the risk of infection with HIV, Hepatitis C and other viral illnesses. Doses are administered under direct supervision with medical staff in attendance, a framework that which distinguishes HAT from previous forms of heroin treatment such the classic 'British System' of 1916 to 1967³. Further treatment modalities are available, and medical and social support services at hand.

A considerable evidence base has been accumulated to underpin the treatment. The prescribing and administration of diamorphine to people dependant on heroin has expanded greatly in recent decades and has now reached the point at which the highly respected RAND Drug Policy Research Institute has been urging the Federal authorities to undertake Randomised Controlled Trials in the historically hostile territory of the United States. This position is based on a close review of the evidence carried out by RAND researchers, but it remains to be seen whether US politicians will want to take on such an apparently risky- it is perceived as electorally unpopular- mode of addiction treatment.

At first sight, there has been relatively little engagement of the UN drug control regime with heroin assisted treatment, though under the leadership of Yury Fedotov, which commenced in 2010, the United Nations Office on Drugs and Crime (UNODC) has declared its general

support for public health interventions and human rights imperatives in the field of illicit drugs, both in law enforcement measures and those providing therapeutic treatment.⁴ This new emphasis may have been generated in part by the deliberation in the UN system in the lead up to the 2016 Special Session on Drugs, in which several other UN agencies participated, including the UN Development Programme, UNAIDS and others taking the debates outside the Vienna drug control bodies and their field of understanding.⁵

The INCB, the watchdog of the UN drug control conventions that underpin the regime's legal and normative architecture, has at least softened its position somewhat, too, after spending a number of years expressing its 'concerns' about the impact of HAT, though still stopping far short of a ringing endorsement in its 2017 Report. In 1999, the INCB had rejected the validity of any conclusions drawn from the ground-breaking HAT trials in Switzerland and was supported in this rejection by the Director General of the WHO. The Board also advised other countries not to follow the Swiss approach by offering supervised heroin on prescription (for a detailed account see below).

The recent growth of HAT facilities is, however, likely to bring the UN system into enhanced engagement with the intervention, and this paper is intended to inter alia develop a dialogue with the International Drug Control regime with respect to this treatment modality.

History and the emergence of heroin assisted treatment

In the early twentieth century, maintenance-based provision of opium, morphine and heroin to illicit consumers did exist. In the United States, for example, which later became highly resistant to the medical use of heroin under any circumstances, several cities set up clinics that opioid consumers attended in order to receive doses of morphine, in an attempt to preempt the rapidly growing black-market supply of these drugs and the urban street subculture it supported. By the end of 1923, however, the facilities were closed in the face of growing pressure from the US Federal authorities, which were working toward the total prohibition of heroin.⁶

Britain was at this time the world's leading location for the medical supply of heroin and morphine to the overwhelmingly upper- and middle-class patients who had recourse to private doctors and their prescription pads.⁷ The legal provision of heroin to these dependent patients became known as the 'British System', which was carried on until the late 1960s when regulatory changes were made that meant only doctors licensed by the Home Office could prescribe the drug, and a clinic-based system was introduced. Prior to these developments, any registered medical doctor could supply heroin to dependent patients, according to their best clinical judgement. The police were unable to intervene.⁸

While the 'British System' is viewed as the forerunner of HAT, it important to understand the major differences underpinning the two modalities. Key to the British system was the prescribing of what are now known as 'take-out doses', enabling the patients to consume the drug at home and according to their individual choices. HAT is based, by contrast, on the strict medical supervision of supply, in which patients receive the drug under direct observation at a treatment facility and are rarely if ever permitted 'take-outs'.

HAT in its contemporary form emerged firstly in Switzerland in response to a public health emergency. Here, open drug scenes had formed on the street of several cities, most notably Zurich and Bern. Often located in public parks, these open drug scenes were tolerated by the police and the local authorities as a means of containing the problem, a move that was to some extent successful. However, the scenes attracted thousands of users who sourced and injected their heroin from the dealers who were, naturally enough, drawn to what became generally agreed upon as squalid and unhealthy urban spaces. They likewise attracted the attention of global mass media, causing embarrassment to the traditionally conservative Swiss authorities.

Yet the scenes were so extensive that the usual law and order-based solutions were simply impractical; neither would they meet the public health imperatives that the Swiss increasingly recognised as central to an adequate response to the problem. An alternative approach was required, and it was in this context that Switzerland developed heroin-assisted treatment. Drawing on the experience of physicians who had had previously worked with heroin prescribing, a research protocol was developed and approved by the Federal Narcotics Commission, the national health authorities and finally the Federal government. At the instigation of the INCB, which repeatedly voiced its 'concerns' over the treatment, an external panel of experts was established by the World Health Organisation (WHO) to monitor the project and to review its conclusions (see discussion below).

The initial outcome of the Swiss response was the 'PROVE' study, involving approximately 1,000 participants, conducted at 18 treatment centres between 1994 and 1996.

Heroin-assisted treatment: practice and evidence

As discussed briefly in the introduction, heroin-assisted treatment entails the medically supervised provision of heroin, either injected or smoked, in the treatment of opioid dependence. It is viewed amongst medical practitioners as a second-line treatment intervention, to be deployed in cases where individuals and their medical advisors have found methadone or buprenorphine, the most commonly used pharmaceutical adjuncts, to be ineffective. It is widely understood, that is, as a mode of opioid substitution therapy that may be appropriate for the most hard-to-reach and intractable heroin consumers. This understanding was incorporated into the Swiss structure, and subsequently into the HAT research and practice in other countries that adopted or trialled the treatment. According to figures provided by Ambros Uchtenhagen in 2017, 10 HAT is provided by 58 clinics in 8 countries, though reaching only 1 per cent of people undergoing agonist maintenance in these countries. It has been estimated that some 5 to 10 per cent of those in substitution treatment do not make progress with methadone or buprenorphine. 11 This means that there remains a considerable shortfall in the numbers of treatment slots available. Of states providing the treatment, the Netherlands and Switzerland are the only ones with HAT facilities in double figures, these being 18 and 23 respectively. 12

In practical terms, the intervention involves people who use heroin attending twice or three times daily at a treatment facility at which doctors, nurses and other clinical staff are present to supervise and, if necessary, assist in the act of injecting. Usually, the supply of diamorphine

is augmented by further health and social services, assistance with housing and employment issues, and so on. In certain trials, therapies utilising other substitution medications were compared with HAT, for example, the UK's Randomised Injectable Opioid Therapy Treatment (RIOTT) offered injectable methadone as well as optimised oral methadone treatment, the latter involving high dose methadone supplemented by intensive social and health services provision to parallel client groups as the control measure.

Following the WHO critique of the methodology of the PROVE research, randomised controlled trials (RCTs) of HAT, conceived as the 'gold standard' of evidence production within forms of knowledge claiming the status of 'science' and the only form of evidence taken seriously by government policy-makers and international drug control institutions, have been carried out in the following locations: Canada, Germany, the Netherlands, Spain, Switzerland (the PROVE study included a small element of RCT undertaken in Geneva) Belgium and the United Kingdom (UK) (see table 1). All these trials shared similar core objectives, including identifying the impact of the intervention on illicit heroin use and associated criminal involvement, on physical and psychological health status, social functioning, retention in treatment, and an investigation of the treatment's cost-effectiveness. Generally positive outcomes were reported across these measures, demonstrating a greater success with diamorphine than with the control measure of optimised oral methadone, or with injectable methadone where this was offered.

Roseanna Smart, reviewing the evidence for the RAND Institute in 2018, noted that some 47,000 opioid overdoses had occurred in the US in 2017.¹³ In the light of this alarming figure, the author advocated the adoption in the US of two sets of measures that have been trialled in Europe and elsewhere: HAT and Supervised Consumption Sites (SCS). The RAND review is, following the trial protocols, focused on the effectiveness of HAT as a second line treatment option. Reviewing 10 RCTs that examined the question, it concludes that, 'the strongest and most consistent effects across studies are shown for reducing illicit heroin use and improving treatment retention. These are important findings given the current harms people who use heroin face from exposure to fentanyl and other synthetic opioids in many illicit markets.' ¹⁴

The review also found injectable diamorphine to be more cost effective than oral methadone, largely owing to the reduction in criminal justice costs associated with the clients in the heroin group. These factors led the RAND authors to recommend the conducting of RCTs in the US in order to investigate the impact of HAT.

Table 1: HAT Randomised Controlled Trials

Country .	<u>Intervention</u>	Control	<u>Duration</u>	Main paper
Netherlands 1998-2001	Injectable heroin &oral methadone, Inhalable heroin & oral methadone	Oral methadone	12 months	Van den Brink et al, 2003
Spain (PEPSA) 2001-2004	Injectable heroin & oral methadone	Oral methadone	9 months	March et al, 2006
Germany 2002-2004	Injectable heroin 7 oral methadone	Oral methadone	12 months	Haasen et al, 2007
Canada NAOMI 2005-2008	Injectable heroin & oral methadone, Injectable hydromorphone & oral methadone	Oral methadone	12 months	Oviedo-Joekes, E., Brissette, S., Marsh, D., et al, 2009
United Kingdom RIOTT 2005-2008	Injectable heroin & oral methadone, Injectable methadone & oral methadone	Optimized oral methadone	6 months	Strang et al, 2010
Belgium TADAM 2011-2013	Injectable or inhalable heroin and oral methadone	Oral methadone	12 months	Demerat et al, 2014

The beginnings of the HAT debate: The international drug control regime and policy innovation in Switzerland

In February 1994, the INCB dispatched a mission to Switzerland. The Board's Annual Report for that year, drawing attention to what it regarded as the general laxity of several countries' drug control apparata, including Switzerland, noted:

Missions of the Board have met with the Governments of Austria, Belgium and Switzerland to remind them of their longstanding promises to accede to the 1971 Convention. The failure of those major manufacturing and exporting countries to control international trade in many psychotropic substances has had a negative impact on the effectiveness of the international drug control system. The Board hopes that those States will act expeditiously to close a serious gap in the control of international trade in psychotropic substances. ¹⁵

Though the preceding paragraph is not specific to HAT, it indicates the wider tensions existing between the Board and these countries, which formed part of the context in which Switzerland was operating in its attempts at policy innovation. Later, the Report stated that governments should review their overall legislative basis for controlling drugs and chemicals. It had 'come to the attention' of the Board that commercial companies previously known to have involved themselves in the diversion of psychotropic drugs were also implicated the diversion of precursors. It concluded the paragraph with the specific observation that '(t)his problem has been identified in Switzerland'.¹⁶

The Annual Report went on to add that '(t)he failure of the Government to accede to the 1971 Convention and to control international trade in substances in Schedules III and IV of that Convention has been repeatedly emphasized by the Board in its reports. Swiss territory continues to be used to divert psychotropic substances from international trade.' ¹⁷

As noted above, attention is drawn to these remarks in order to provide some context for the ensuing discussion on the Swiss plans to trial heroin assisted treatment. It is clear that relations between the Federal authorities in Switzerland and representatives of the INCB were at times tense prior to the opening of discussions.

Another a major reason given by the INCB for its mission was linked to its concerns over the prospect of heroin prescription in the country. It summed up the situation thus:

The situation in some big European cities, such as Zurich, illustrates the consequences of almost unrestricted availability of drugs of abuse. The many years of tolerating the sale and use of such drugs at certain places in the city of Zurich resulted in abusers, as well as traffickers, being attracted from many parts of Switzerland and from other countries, to a situation that the authorities could control only with difficulty. An attitude of non-intervention led to increasing drug abuse and illicit trafficking. ¹⁸

The Swiss population and its government were, in fact, acutely aware of the problems associated with drug use in the country, a situation that provoked debates in which the electorate was profoundly involved. Citizens had become accustomed to seeing addicts in the areas where drug use was prevalent, and their ill-health and chaotic lifestyles were painfully evident. This helped to turn the debate within the nation toward one within which drugs scenes were viewed primarily as involving a series of problems related to health. Moreover,

the institutional context of Swiss governance contributed to this view, since public health was part of the home affairs ministry, and no conflict arose between those departments of the Federal government representing, respectively, the imperatives of health and of control. The electorate was, moreover, an educated and engaged group, and it became increasingly clear that a major shift was occurring in Switzerland in relation to drug control policy.¹⁹

This was a shift specifically toward health and pragmatism, following the broad lines of the government's own vision, rather than the liberalisation of drug use and drug policy in general. The Swiss position became clear in two initiatives on which the electorate voted in relation to drug policy, the first in 1997 calling for a highly restrictive set of policies which would go so far as to preclude the use of Opioid Substitution Therapy (OST), the second approximately one year later calling for the legalisation of all presently illegal drugs. In the event, both extremes of the policy spectrum were rejected by the Swiss electorate, which moved closer to the pragmatic middle-ground espoused by its governing class.²⁰

The Board, nonetheless, maintained its hostility toward HAT, and went on to comment that the planned distribution of heroin to 'a broad circle of addicts' – something that did not in fact feature in Swiss plans – while ignoring the drug's long-term effects on the individuals concerned, as well as on the wider society, was a 'risky undertaking'.²¹

The INCB's 1994 mission reviewed the Swiss PROVE trial, under the auspices of which, from January of that year, a limited number of heroin users had received injectable heroin and oral methadone (the latter for overnight maintenance, during which time the clinics were closed). The Board was informed that the authorities planned to transfer the trial clients to smokable heroin after 6 months. It stated that a total of '700 patients will be integrated into the overall research project: 250 patients to be treated with heroin and 450 patients to be treated with either morphine or methadone. Since most of the addicts are also taking cocaine, plans are being made to provide them with cocaine in smokable form'.²²

The Federal authorities assured the INCB that the results of the trial would be thoroughly investigated prior to any further expansion in heroin prescribing, and the government was not contemplating any general legalisation of nonmedical drug consumption. Nonetheless, the Board concluded that:

In the present situation, the Board recommends that the Swiss Government should invite WHO to take part in the consideration of the medical and scientific aspects of the ongoing Swiss clinical trials aimed at evaluating the efficacy of distributing heroin to addicts on a prescription basis. In addition, the Board urges the Commission on Narcotic Drugs to consider all of the consequences of the possible extension or even general application of this method, including its impact on the drug control policy of other countries. ²³

The Swiss government cooperated willingly with this request from the Board. An External Panel of assessors was convened by the WHO, and its eventual findings were critical of the methodological structure of the PROVE trials. It concluded that '(t)he final study design was a prospective outcome study that was intended to measure the impact of the intervention but could not determine the efficacy of one intervention compared to other interventions.' Despite this, the Panel in broad terms agreed with the Swiss conclusions, stating that:

(1) it is medically feasible to provide an intravenous heroin treatment programme under highly controlled conditions where the prescribed drug is injected on site, in a manner that is safe, clinically responsible and acceptable to the community; (2) participants reported improvements in health and social functioning and a decrease in criminal behaviour and in reported use of illicit heroin.²⁴

The WHO's Expert Committee on Drug Dependence (ECDD) further considered the early development of HAT at its 30th Meeting in 1998. It judged that the treatment had been 'a subject of extensive controversy', and that claims had been made for its efficacy 'without good evidence'. Referring to 'a large clinical study now in progress in Switzerland', the Expert Committee concluded:

However, because this study is neither randomized nor double-blind, but a controlled observational study, it will not provide robust data on comparative effectiveness or cost-effectiveness. Further trials and studies are reported to be planned in the Netherlands. There is a need for rigorous experimental design in the execution of these projects if the controversial issues they raise are to be empirically addressed.'26

Quoting the Director General of WHO's findings on the PROVE study to the effect that the work was an 'observational study without the possibility of making reliable unbiased comparisons between treatment options', ECDD argued that it did not provide clear evidence for the benefits of heroin treatment over other substitution agents.²⁷ Moreover, the study demonstrated 'no causal link...between prescription of heroin and improvements in health or social status.'

The INCB elaborated its conclusions regarding the Swiss heroin trials in the following terms:

Mindful of its international responsibility as guardian of the global drug-control Conventions, and attentive to the last-cited conclusion of the WHO, the International Narcotics Control Board perceives, in the light of this study, no reason to alter its previously expressed concerns over the heroin project and policy of heroin prescription, which has not been based on scientific and medical results. It therefore does not encourage other countries to follow this course of action. ²⁸

The Board was thus highly critical of the government response to the Swiss open drug scenes, which it viewed as mere tolerance of drug use, of the country's apparent reluctance to ratify the Convention on Psychotropics Substances of 1971, and of the willingness of Switzerland to contemplate heroin prescription as a public health response, however tightly supervised.

It is noteworthy that the INCB's 1994 Annual Report discusses the Swiss PROVE project alongside the topics of harm reduction and the legalisation of nonmedical drug consumption – all aspects of the family of 'controversial' policy measures. As often pronounced by the Board, it was noted that 'harm reduction programmes should not be more harmful than the harm that they are intended to prevent'.²⁹ Clearly, the body consequently implied that HAT would be more harmful than street heroin use and all that it so often entails in terms of ill-health and human misery. None of the subsequent evidence has supported these views. Nonetheless, the INCB went on to defend its position by reference to some curious rhetorical strategies, referring to opinion polls carried out and

...published by the Plan Nacional Sobre Drogas of Spain which shows that only 4 per cent of the people of that country above the age of 18 support legalization, while over 60 per cent plainly

favour penalization of the non - medical use drugs and over 30 per cent are even against the use of substitutive (methadone) treatment for heroin addicts. In the opinion of the Board, the results of the poll in Spain are much more in conformity with the attitude of society in many other European countries than are the subjective views of some individuals or groups published in the mass media, which may, by presenting simplistic approaches, misdirect public opinion. ³⁰

It is not within the mandate of the INCB to base its policies on treatment upon speculative notions of the potentially uneducated opinions of the population at large in Spain or any other country, but to identity their place within the international drug control treaties, and to liaise with the WHO on their scientific basis.

In 2002, in response to the Board's inquiries regarding the legality or otherwise of various harm reduction measures and to the Board's repeatedly expressed alarm, the Legal Affairs Section of the then-UN Drug Control Programme examined the admissibility of these innovative approaches under the international drug control conventions. Essentially, the Legal Affairs Section came to the opinion that, as treatment was not defined by the terms of the Conventions, substitution treatment with non-orthodox opioid agonists was not in contravention to their provisions. The legal experts compared the use of opium to maintain opium-users in Pakistan, and concluded that 'what was said at the seventy-fourth session of medical use in respect of the provision of opium to opium addicts (E/INCB/2002/W.2/SS.2, paragraphs 97 and 98) would apply mutatis mutandis to the dispensation of opium to opium addicts or heroin to heroin addicts as substitution/maintenance treatment in a harm reduction strategy...' ³¹ The Conventions, therefore, were deemed to contain sufficient flexibility for HAT to be practiced perfectly legally – though the Board had, presumably, been hoping for a different outcome when soliciting the opinion of the Legal Affairs Section.

When the Swiss government began the process of amending its federal legislation to permit the use of heroin in treatment, following a nationwide referendum in September 1997 that voted in favour of the move, the INCB remarked that although:

...the amendment recommends some limitations on the medical prescription of heroin, regarding both the number and types of persons to be treated, the Board reiterates its previously expressed concerns about the programme. The Board notes with regret that the WHO evaluation of the programme, requested by the Government of Switzerland at the suggestion of the Board, was not available before the decree was promulgated.³²

The INCB and the Netherlands

The INCB's relationship with the government of the Netherlands was another beset by tensions over drug policies, which went back long before the advent of HAT. The Board's Annual Report for 1974, for example, observed that

...the Netherlands authorities have adopted a liberal attitude towards cannabis. There can be little doubt that the ease of access to supplies of cannabis draws consumers to the Netherlands. This movement is extending to other dangerous substances as well, such as heroin and LSD.

The Netherlands authorities are not alone in their concern about the situation, which is causing alarm in several neighbouring countries. While it is confident that the authorities will do all that is necessary, the Board has decided to keep the problem under permanent observation.³³

This category of 'permanent observation' to which the Netherlands was to be made subject is apparently an informal one, as it is not mentioned in the international drug control conventions. Nonetheless, the Board has indeed carried it out, with regular interventions from itself and the UN drug control regime more broadly criticising the Dutch 'coffee-shop' system and the legal separation of 'soft' and 'hard' drugs that underpins it, and, like Switzerland, the slow pace of the country's accession to the 1971 Convention, among other factors elaborated in the Board's 1995 Annual Report. For instance,

...the Board expresses its continued concern at the persistence of certain practices, only slightly altered, which call into question the Government of the Netherlands' fidelity to its treaty obligations. This includes continuing the failed policy of "separation of markets", tolerating the continued cultivation of *nederwiet* provided that it is of lower THC content, permitting the operation of so-called coffee shops, many of which have fallen under the control of criminal elements, and continuing to stockpile narcotic drugs for nonmedical purposes. The Board will continue to observe closely the progress made by the Government of the Netherlands in fulfilling its treaty obligations.³⁴

These passages are quoted here in order, again as in the case of Switzerland, to illustrate the difficult relationship obtaining between the Board and the Netherlands, in this case stretching over decades. In its 1997 Report, the INCB 'regretted' that, prior to the evaluation of the Swiss PROVE trials, 'pressure groups and some politicians are already promoting the expansion of such programmes in Switzerland and their proliferation in other countries'. It went on to state that:

The Government of the Netherlands has already submitted to the Board estimates for heroin to be used in conducting a similar project. The Board expressed the same reservations about that project as it had expressed about the Swiss project and firmly believes that no further experiments should be undertaken until the Swiss project has undergone full and independent evaluation.³⁵

It is evident that both of these innovative States experienced reiterated criticism from the INCB over their attempts at flexible and pragmatic innovation in terms of drug policy, despite the long-term failure of the orthodox methods endorsed by the international drug control regime. 'The INCB was against *everything* we did', said one high ranking Dutch ex-official. 'It was against any policy that tended toward innovation...[and]...any practical solution to the country's drug problems.' The interviewee also explained that the Board was at that time dominated by several conservative policy figures. Within this context, 'The entire Dutch policy edifice was criticised', he said; 'needle exchange, pill-testing, the coffee shops, all harm reduction measures, HAT – everything was bad.' The evidence on which the Board's approach was supposed to be based consisted of statistics gathered by UNODC, specifically those from the *World Drug Report*.

Interviews conducted with former Dutch Department of Health officials reveal that the INCB was approached submissively by the government during the early part of the 1990s. Soon afterwards, however, this stance was to change; a strong and outspoken figure occupied a senior role in the Netherlands' Health Department and he was 'afraid of no-one. Rather, the INCB was afraid of *him*'.³⁶

According to another interviewee, the Dutch government varied by department in its relations with the Board, with the Justice and International Affairs Ministries tending to subservience toward the Board and the Health Ministry conducting a much more conflicted relationship.³⁷ As such, health officials were said not to take the Board very seriously, except on the diplomatic surface level; the available UN data was of poor quality, sourced from the World Drug Report which at this point featured numerous gaps owing to the failure of countries to respond to the Annual Reports Questionnaires sent out by UNODC. According to our Dutch interviewees, these data enabled the Board to 'say whatever it liked'. Gradually, one ex-official explained, the INCB lost its former authority; this was partly because of the Board's reliance on suspect World Drug Report data, and partly because of its 'eternal criticism' of innovative Dutch policies. 'There was never a positive word from the Board concerning our measures', even though harm reduction policies that largely originated in the Netherlands spread throughout Europe and beyond. Both Dutch and Swiss officials liaising with the INCB on HAT projects expressed their disappointment that the INCB repeatedly found nothing of worth in these countries' policies, and the only opinions the Board expressed were critical ones. This was despite a generally worsening set of drug problems upon which the orthodox responses had had little or no positive impact.

The senior Dutch health official most critical of the INCB reported that the final straw with the Board came when it approached the Dutch government to try and ban a TV programme, translated into English as 'Inject and Swallow', a progressive drug and sex educational show broadcast in the Netherlands and aimed at the Dutch youth market.³⁸ A popular and effective TV intervention that engaged young people and their drug cultures, the Board's objection to the programme was regarded with some outrage by the Dutch government and this interjection represented the end of whatever respect the Board still enjoyed. As one former official from the health ministry explained, 'That was it for me'.³⁹

Another Dutch ex-official believed that, while the INCB had been hostile to practically all the other innovative Dutch policies, it was actually largely fair in its treatment of the HAT trials, probably because these were clearly within the terms of the international drug control conventions. 40 Most of the Dutch officials who were interviewed, however, remarked on the hostility of the INCB toward both the HAT trials and the country's entire spectrum of drug policies. Many government officials of countries that experimented with heroin prescription, especially the pioneers such as Switzerland and the Netherlands, expressed their disappointment with the Board's continued animosity toward innovation in drug policy, despite the fact that illicit drug consumption was expanding, and the traditional interventions were having little or no impact in reducing social consequences such as crime and ill-health. The lack of encouragement for harm reduction policies or the reform of the 'war on drugs' style of approach given prominence by the INCB provoked deep-seated dissatisfaction amongst these countries, whose policies were among the only effective means of reducing drug- and policy-related harms then in existence.

Notwithstanding the INCB's hostility toward innovation, the HAT genie was well and truly out of the bottle, with the Swiss trials – regardless of their alleged methodological weaknesses – inspiring much interest in other countries in Europe and beyond. Despite the INCB's

disapproval, the trials proved to be a turning point and a catalyst for the expansion of heroin assisted treatment, beginning with the series of RCTs as itemised above. It is arguable that this is a result of the generally low esteem in which the INCB is held by governments of member-states, though this does vary widely. Those governments adopting similar principles to the Board- a conservative, strongly held commitment to the status quo of international drug control- naturally quote the INCB's discourse with approval. Any understanding of the Board's role in the adoption or otherwise of an intervention such as HAT must, therefore, be nuanced toward the complexity of social and governmental context.

The Netherlands, the INCB, and ongoing tensions

The Netherlands was the locus of two further Randomised Controlled Trials. Taking note of the methodological criticisms made about their Swiss predecessor, the Dutch exercised great care in the scientific planning and elaboration of the trials. Beginning in 1998, one involved injectable diamorphine and the other an inhalable form for heroin smokers. Each trial contained a control group utilising methadone. The successful outcome of HAT in both trials led the Dutch government in 2004 to incorporate the two forms of heroin into its regular treatment arrangements as second line treatments for patients who had not responded well to more orthodox modes of opioid agonist therapy.

As will be clear from the foregoing contextual discussion, this was not, however, before further difficulties with the INCB:

In the Netherlands, a randomized clinical study was begun to compare the relative effectiveness of the use of medically co-prescribed heroin and oral methadone and the use of oral methadone alone in chronic, treatment refractory heroin addicts. In general, the Board remains concerned over the possible proliferation of heroin experiments and the adoption of social policies, including the prescription of heroin before projects have undergone full and independent evaluation. The Board also remains concerned over the effect that the experiments may have on global efforts to deal with the drug problem. ⁴¹

The Board's 1998 Report was preceded by a mission to the Netherlands, with the Dutch HAT trial high on the list of topics for discussion, and it was in regular touch with the Dutch authorities in the subsequent years. It was on the INCB mission that the 'strong figure' in the Health Ministry, mentioned above, gave an outspoken rebuttal of its position on HAT, defending the Dutch views in unequivocal terms when the government met the Board's representatives. 42

It is worth noting that within the Netherlands itself the HAT trials were highly controversial, though the general public appeared largely in favour. Within the coalition government in power between 1994 and 2002, the Health Minister, Mrs. Borst-Eiler, was the driving force behind the development of heroin assisted treatment. As observed by one of our interviewees, 'HAT occurred in politically highly sensitive and turbulent surroundings'. Even with the governing coalition, it was controversial; this reluctance and resistance only faded as a consequence of the meticulous approach of the HAT trial policy and subsequent reporting and debate within parliament. The HAT process required confirmation and approval at every step of the way. 44

In May 2002, the general election in the Netherlands brought about a radical change in government, with a largely right-wing coalition elected. The HAT process underwent a critical

step at this stage, initially being rejected by the incoming government in an emergency vote, which was reversed following large demonstration by one of the coalition partners, 'Liveable Rotterdam', who agenda included elements normally considered to lie on the progressive dimension of politics. Overall, the Netherlands has however been one of those countries that embraced the use of diamorphine in its treatment system, with HAT now provided in 17 outlets in 16 cities, and a total of 668 treatment slots currently available.⁴⁵

The Board's position has itself shifted somewhat since the debates of the early 2000s, with our interviewees from several countries citing the May 2015 to May 2017 Presidency of the German Werner Sipp as representing something of a turning point in the conduct of the INCB, and a significant shift in the approach of the Board and in its relationships with UN Member States.

The 2017 Annual Report stated that:

Some Governments have been conducting trials with prescription heroin maintenance programmes for patients not receiving other forms of treatment, although that is not a first-line treatment. Research indicates that prescription heroin maintenance treatment may help heroin-dependent individuals to remain in treatment, limit their use of street drugs and reduce illegal activities. 46

The Report nonetheless follows up this statement with a reservation:

However, owing to the risk of adverse effects and a number of operational factors, this treatment has not been recommended by WHO or other United Nations agencies.⁴⁷

The Netherlands earlier defended its heroin prescription programme at the 2007 CND, disputing the INCB's characterisation that the Dutch government provided free heroin to hard core addicts, and noting that its heroin co-prescription programme supplied heroin as a medicine, in combination with methadone, according to strict criteria, and had achieved significant improvements in patients' health.⁴⁸

Nonetheless, the INCB's views appear arguably to have changed relatively little in practical terms since its declaration in 1999, in the wake of the ECDD's methodological critique of the PROVE trials, that:

The INCB, for its part, will continue to be guided in this matter by the relevant resolutions of the World Health Assembly of 1953 and of the United Nations Commission on Narcotic Drugs, which in 1995 recalled its previous resolutions of 1978 and 1987, in which it had strongly urged Governments to prohibit the use of heroin on human beings.⁴⁹

The Board's position here was undoubtedly influenced by cultural and historical factors, mediated by the powerful influence of the United States, which has since the early 20th century been implacably opposed to the use of heroin. The US had attempted in the 1920s to impose its domestic prohibition on the manufacture of this drug on the then administrator of the international drug control regime, the League of Nations, stopping production in all countries. The move was not a success but illustrates the existence of a set of attitudes that later became highly influential in the regime. ⁵⁰

General opposition to HAT and the use of heroin

According to Uchtenhagen, a set of related anxieties and concerns underlie the opposition to HAT. He lists them as follows: the idea that patients will demand ever greater dosages of heroin; the attenuation of the will to abstinence and recovery; an increase in ill health and overdose deaths; diversion of supplies into the illicit economy; sending out the 'wrong message' on drug use, and finally the waste of human and financial resources. In practice, however, an examination of the evidence shows that these fears have not been realised: dosages have tended to decrease rather than increase across the trials, significant numbers of clients have achieved or moved toward abstinence, morbidity has been reduced, mortality rates improved for both HAT and oral methadone engagement, while strict supervision has prevented diversion of prescribed diamorphine. Criminal justice involvement has been significantly reduced amongst HAT patients as compared to those receiving oral methadone. Fears of a negative impact of HAT centres on the surrounding community, while reported often prior to trials, have generally been assuaged by the failure of the anticipated large numbers of street addicts to materialise, and a reduction in crime, street nuisance and drugrelated litter. Smart noted the community level outcomes of the trials were not tested in RCTs, ⁵¹ but it is surely stretching the positivist epistemological and methodological model underlying these studies to imagine that a comparable urban area identical to those in which the trials took place could be identified that replicated them in every way except for the presence of a HAT facility. Qualitative data are best suited to answering such questions, and for the present these have indicated the absence of negative community impacts.

Influence of HAT trials on domestic drug policies

Many of the countries that conducted trials with heroin assisted treatment have gone on to establish the therapy as a part of the regular treatment apparatus, albeit as a second-line treatment. Germany, for instance, modified its drugs legislation in 2009 to permit the prescribing of heroin. The pilot study for the HAT trials in Germany was at first resisted by the INCB but was legal within the terms of the international drug control conventions, and the country's Federal government was therefore able to move ahead with the project.⁵²

HAT was regarded as a very important project in Germany. The goals were integrated into the country's broader drug control strategy within Federal and State structures, and sought to prevent or minimise drug use, facilitate access to counselling, support and treatment for a broad range of drug users and their 'significant others', and to reduce or at least maintain the levels of adverse health and social impacts.

The results of Germany's heroin-assisted treatment of opiate dependence pilot have been scientifically evaluated. ⁵³ The findings were to be incorporated into the dependence treatment provided to heroin dependent persons who failed in substitution or drug free treatment (that is, patients who used psychoactive substances besides their substitution medication for a certain period of time). A clinical study was conducted in seven German cities. 1,032 patients were included at the study centres from 2003 - 2006. One study group was provided with diamorphine and the other group with methadone. The groups were randomised. Both groups also received psycho-social support, such as psycho-education or case management. The retention rate of heroin-assisted treatment was 67 % after 12 months,

slightly lower than in the studies from Switzerland and The Netherlands. Only 39% of the methadone group completed their treatment. This was mainly due to the fact that one third of the randomised patients of the control group attended for treatment. It should be noted, however, that at the 12-month examination, 39 % of the dropouts of the heroin group and 44 % of the dropouts of the methadone group were still in maintenance treatment outside the study or in alternative addiction treatment.

On the main conclusion of this study, the lead investigator stated that:

'Heroin-assisted treatment proves to be decidedly successful in the treatment of the most severely dependent heroin users.' ⁵⁴

The group of "treatment-failed" heroin dependents was successfully recruited. Their health improved substantially according to various measures: their street heroin consumption decreased considerably and there was no increase in their cocaine consumption. After 12 months, heroin-assisted treatment showed significantly better results with respect to improvement in health and the reduction of illicit drug use than methadone treatment. The effects are largely independent of the target group, psychosocial intervention forms and study centre.

The study also demonstrated that diamorphine treatment can be safely and effectively implemented. No study-related death occurred. The mortality rate was equal in both groups, with all death cases due to previous illnesses. But higher safety risk in the heroin group (because of injection of the substance) calls for treatment in special out-patient clinics and does not allow a policy for heroin as a 'take home' medication. Heroin-assisted treatment is significantly more effective than methadone maintenance treatment for this specific group of long-term drug users with respect to improvement in health and decreased of illicit drug use. As an important additional value, heroin prescription led to a considerable reduction of drug related crimes.

In May 2009 the German Parliament passed an amendment to the Narcotic Law which permitted, under certain strictly regulated conditions, the prescribing of diamorphine to clients who were not benefitting from treatment with methadone or buprenorphine. The implementation phase into the treatment system is well underway, with some 300-400 patients are currently in heroin-assisted treatment.

In Spain and Canada, according to Uchtenhagen, ⁵⁵ only those patients who formerly took part in trials are allowed the prescribed substance; the approach has not, consequently, been integrated into the regular drug treatment systems of those countries. Indeed, in Spain, researchers complained of a tangled and hostile relationship between science and politics. ⁵⁶ They say that the Spanish Drug Agency omitted the Swiss clinical experience with oral Immediate Release (IR) heroin when it requested the Catalan Oral Heroin Study Group to refrain from conducting a randomised controlled trial comparing this form of the drug with sustained release morphine and methadone. These authors also point to the blocking by the Ministry of the Interior of a well-designed trial that was to have been run in 2004-5 within a prison in the Basque region. This Ministry is responsible for overseeing prisons in Spain, and

such events point to the political hostility that exists toward HAT, despite its proven effectiveness as a second-line treatment for people who use heroin.

Developments in HAT treatments in Norway and other countries

In contrast, certain countries have judged the evidence base for HAT generated by the Swiss study and the subsequent RCTs to be sufficient to proceed to the opening of HAT facilities without the need to conduct their own trials. Denmark, for example, has moved straight to the use of HAT without establishing its own trial, concluding that the country was socially and culturally similar enough to Germany, the Netherlands and Switzerland for existing trial findings to be transnational in application. The country has set up five HAT facilities since 2010, when the first opened in Copenhagen. The country has set up five HAT facilities since 2010, when the first opened in Copenhagen. Luxembourg, likewise, opened its first HAT clinic in 2017, and Norway announced at the 62nd Commission on Narcotic Drugs (CND) held in Vienna in 2019 that it intended to establish experimental HAT facilities, opening in 2020, with the experiences and knowledge gained being used to decide on whether the intervention will be extended into the permanent drug treatment system.

The Norwegian move is regarded by many as something of a surprise. Despite its well-deserved reputation as a progressive state in which health and human rights are embedded, Norway's drug policy stance has historically tended toward the oppressive. A period of debate in the early 21st century resulted in the government considering the introduction of HAT. However, it rejected the move. In the (undated) words of the Europe Against Drugs pressure group:

a new Norwegian white paper on alcohol, drugs and doping says no to heroin assisted treatment (HAT) in Norway. The Government bases its rejection of heroin distribution on consultations with experts and interest groups as well as on the advice of two expert commissions that have evaluated the evidence for the efficiency and cost effectiveness of heroin assisted treatment. The current evidence base is weak, the intended target group for HAT is excluded in international studies and effects are only marginally better than other substitution treatments, states the white paper. ⁵⁸

However, in October 2016, the Conservative government's Health Minister announced a major change in the direction of the country's drug policies, stating that the 48 million Kroner collected from fines for drug possession was 'detrimental and meaningless'. Instead, Norway would follow the general terms of the Portuguese drug strategy, transferring drug use responses from the Criminal Justice system to the Health sector. HAT was to be an element of this new Norwegian approach.

In the UK, despite the success of the trial, the three RIOTT clinics in London, Brighton and Darlington were forced to close in 2016 when the government withdrew funding from the HAT project. It is worth noting that in its December 2016 report, *Reducing Opioid-Related Deaths in the UK*, the Advisory Council on the Misuse of Drugs noted that 'Central government funding should be provided to support HAT for patients for whom other forms of Opioid Substitution Treatment have not been effective.' ⁵⁹ In this spirit, in October 2019, a new HAT pilot facility opened its doors in Middlesbrough. ⁶⁰ Lack of central funding meant that this is not only supported as an effective intervention, but also funded by the local Police and Crime Commissioner (PCC). If deemed to be successful following independent evaluation, the

PCC plans to use funding from the Proceeds of Crime Act to extend it for a second year and across all four Boroughs of Cleveland, of which Middlesbrough is a part.⁶¹ The clinic currently has places for an initial 15 clients, drawn from those whose lives are most involved with the cycle of crime and imprisonment, buying and using street heroin and living and dying on the streets of the town.

In an astute comment summing up the benefits of HAT, the PCC observed that:

By removing street heroin from the equation you remove the need to commit crime to fund addiction and the impact this has on local residents and businesses, you remove the health risks of street heroin and the associated drugs litter and you remove the drain on public services including health and police. In addition, you halt the flow of funding to drugs gangs. ⁶²

A second HAT facility is shortly to open in Glasgow, a city which faces record levels of overdose and a new wave of HIV infections associated with its sizeable illicit heroin market. ⁶³ Discussions are also taking place elsewhere within the UK, including Durham and the West Midlands, usually – as was the case in Middlesbrough – driven by the local PCC. Despite the manifold benefits, including savings across health and criminal justice sectors over time, the relatively high cost per client ensures that funding remains a perennial consideration and oftentimes barrier. ⁶⁴

Concluding remarks: Heroin assisted treatment and the future direction of UN travel

Although the INCB has clearly long been hostile to drug policy innovation, and this has carried over into its attitudes to HAT, it is likely that national governments are the main source of reluctance to make use of this intervention. This is the case even in the context of the present epidemics of opioid-related overdose, morbidity and mortality. A combination of the financially expensive nature of the treatment and a historical and cultural anxiety surrounding diamorphine is likely to motivate those governments hostile to HAT. They will doubtless deploy the INCB's rhetoric when convenient, but the Board is unlikely to constitute the fundamental block on making use of this treatment. It may, however, be influential at the level of the international control apparatus.

In the 2012 revision of the 2009 *Technical Guide for Countries to set Targets for Universal Access to HIV Prevention, Treatment and Care for Injecting drug users,* produced by WHO, UNODC and UNAIDS, the use of agonists other than methadone receives a mention. The Guide observes that diamorphine, slow-release morphine and opium tincture are used in a small number of countries and may be used in maintenance treatment. However, they receive little discussion. ⁶⁵ Since then, however, the WHO has been surprisingly reticent in its support for the rolling out of HAT, a life-saving treatment with significant potential to alleviate the present epidemic of morbidity and mortality associated with street heroin and related opioids such as fentanyl.

The most recent and likely the most promising UN statement on the use of HAT in the treatment of addiction came from the UN system coordination Task Team on the Implementation of the UN System Common Position on drug-related matters, which was set up by the Chief Executives Board of the United Nations, a high-level body that oversees

strategic decisions, represents 31 UN agencies and is chaired by the Secretary General. In addition to its unequivocal advocacy of a public health and human rights-based agenda, the Task Team's Report, entitled *What we have learned over the last ten years: A summary of knowledge acquired and produced by the UN system on drug-related matters* addressed the issue of HAT directly, stating that:

Heroin-assisted treatment refers to the prescription of synthetic, injectable or smokable heroin to a minority of people with opioid dependence who do not respond to treatment with one of the established medications used in long-acting agonist maintenance therapy, such as methadone or buprenorphine. For this small group of patients, heroin-assisted treatment has been found effective in improving their social and health situation. It has also been shown to be cost-effective, as it reduces costs of arrests, trials, incarceration and health interventions. In this approach, patients are provided with a form of pharmaceutical-grade heroin (injection) solution. ⁶⁶

This is a factual account of the treatment, without the INCB's oft-reiterated 'concerns' over its deployment. In the context of the broader report, it is viewed as one of the important new tools made available by the lessons that the UN has learned in recent times, with a forward by the UN Secretary General Mr Antonio Guterres, former Portuguese President. The review of HAT and its presence in such an eminent UN report is encouraging, as the growing evidence base for this treatment should outweigh the cultural anxieties and prejudices that cluster around it. In the light of the massive increase in opioid overdose mortality during recent years, the introduction of HAT may well be one of the measures that could save significant numbers of lives if its provision is expanded. And the UN international drug control agencies should play a key and urgent leadership role in this context.

As has been conclusively demonstrated above, the INCB has in the past at least attempted to act as a blockage in the path of innovative strategies for the treatment of some of the most intractably problematic forms of illicit drug consumption. Possibly, the shifts brought about in the Board's approach since the Presidency of Werner Sipp will be maintained and expanded upon, and Board will assume a new role of encouraging new and promising policies and interventions. ⁶⁷ It is also to be hoped that the interpellation of the System Coordination Task Team may contribute to a thaw in the chilling effect that the INCB and other elements in the drug control regime have had on the development and roll-out of HAT, despite the impressive evidence base it has now accumulated. Finally, the WHO in particular can, and arguably should, play an important role in these efforts, particularly in view of the capacity of heroin assisted treatment to limit the epidemic of overdose which is presently casting its shadow across several areas of the planet.

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¹ In addition to Diane Steber Buechli (see notes,4, 17 and others), other semi-structured telephone interviews were conducted with Mr Bob Keizer, Mr A. Vloemans, both former officials at the Ministry of Health, Netherlands, and one further ex-Dutch health official who preferred to remain anonymous. An interview by email was also conducted with Mr Ingo Michels of the German Health ministry. Interviews were conducted in May and June 2020.

- ¹⁰ Ambros Uchtenhagen (2017) The role and function of heroin assisted treatment at the treatment system Level Zurich Open Repository and Archive, University of Zurich, p.7 https://doi.org/10.5167/uzh-133002
- ¹¹ John Strang et al (2010) Supervised injectable heroin or injectable methadone versus optimised oral methadone as treatment for chronic heroin addicts in England after persistent failure in orthodox treatment (RIOTT): a randomised trial. *Lancet*, Volume 375, Issue 9729, P1885-1895, May 29, 2010.
- ¹² Ambros Uchtenhagen (2017)
- ¹³ Roseanna Smart (2018) *Evidence on the Effectiveness of Heroin-Assisted Treatment*. RAND Corporation: RAND Health Care and RAND Social and Economic Well-Being

https://www.rand.org/content/dam/rand/pubs/working_papers/WR1200/WR1263/RAND_WR1263.pdf ¹⁴ lbid. P.vi.

https://www.incb.org/incb/en/publications/annual-reports/annual-report-1991-2000.html

- ¹⁶ Ibid. Para 112.
- ¹⁷ Ibid. para 322.
- ¹⁸ Ibid. para 283.

²⁰ Ibid. Interviewee noted: 'In September 1997, the majority of 71% of the Swiss voters rejected an initiative calling for a strict, abstinence-orientated drug policy and prohibiting, in particular, medical prescription of narcotics. One year later, in November 1998, another initiative, proposing the opposite, namely the legalisation of illicit drugs under state monopoly, was rejected, too, with a majority of 73%. The Swiss population has in both cases followed the recommendation of government and parliament and decided against extreme solutions – at the same time showing its continuous support for the government's pragmatic fourfold approach, which includes law enforcement, prevention, treatment and harm reduction.'

These two initiatives are available, respectively, at: https://www.bk.admin.ch/ch/d/pore/vi/vis252t.html#
And: https://www.bk.admin.ch/ch/d/pore/vi/vis252t.html

² See, for example, the argument put forward in David R. Bewley-Taylor, *International Drug Control: Consensus Fractured*, Cambridge University Press, 2012, pp. 72-5 and 239-40.

³ The precise end-date of the classical British System is a matter of some debate amongst historians and other commentators. The date given here refers to the underpinning legal regime, though some suers continued to receive supplies after this. See H.B. Spear, edited by Joy Mott (2002) *Heroin addiction care and control: The British System 1916-1984*. London: Drugscope.

⁴ Since writing, the UNODC has undergone a change of leadership, and is now directed by Ms Ghada Fathi Waly, of Egyptian birth.

⁵ This point emerged form discussions with Ms Diane Steber Buechli, Swiss Federal Office of Public Health, Division of International Affairs, International Drug Policy. May 2020.

⁶ David Musto (1999) *The American Disease: Origins of Narcotic Control, Third Edition*. Oxford University Press, Oxford.

⁷ Christopher Hallam (2018) *White Drug Cultures and Regulation in London, 1916-1960.* London: Palgrave Macmillan.

⁸ H.B. Spear, edited by Joy Mott (2002) *Heroin addiction care and control: The British System 1916-1984.* London: Drugscope.

⁹ Transform Drug Policy Foundation (undated) Heroin-assisted treatment in Switzerland. https://transformdrugs.org/heroin-assisted-treatment-in-switzerland-successfully-regulating-the-supply-and-use-of-a-high-risk-injectable-drug/

¹⁵ INCB Annual Report for 1994 (1995). Para 66.

¹⁹ Interview with Diane Steber Buechli, Swiss Federal Office of Public Health, Division of International Affairs, International Drug Policy. 26 May 2020.

²¹INCB Annual Report for 1994 (1995) para 283.

²² Ibid. para 324.

²³ Ibid. para 327.

^{22.} Robert Ali et al. (1999) *Report of the External Panel on the Evaluation of the Swiss Scientific Studies of Medically Prescribed Narcotics to Drug Addicts.* Geneva: WHO.

²⁵ WHO Expert Committee on Drug Dependence (1998) *Report of the30th Meeting, 1998.* Geneva: WHO https://www.who.int/medicines/areas/quality_safety/reports/en/

²⁷ Director General of the WHO, quoted in INCB Press Release

²⁸ UN Information Service, UNIS/NAR/663, 19th May 1999. 'Concerns Over Heroin Use for Addicts Remain After Swiss Project Evaluated, INCB Says'

https://www.incb.org/documents/Publications/PressRelease/PR1999/press release 190599.pdf

- ²⁹ INCB Annual Report 1994. Para 284.
- ³⁰ Ibid. Para 286.
- ³¹ E/INCB/2002/W.13/SS.5, 30 September 2002 Prepared by the Legal Affairs Section of UN Drug Control Programme 'Flexibility of Treaty Provision as regards Harm Reduction Approaches (Decision 74/10)'.
- ³² INCB Annual Report 1998, Para 436.
- ³³ INCB Annual Report 1974 Paras. 102-103.
- ³⁴ INCB Annual Report 1995 Para 350.
- ³⁵ INCB Annual Report 1997. Para 367.
- ³⁶ Bob Keizer, interview June 2020.
- ³⁷ A. Vloemans, interviewed June 2020.
- ³⁸ The precise Dutch title is 'spuiten en slikken'. 'Inject and Swallow' was the best translation into English that the informant could devise. It was a youth-focussed sex and drugs information TV programme, with the term 'inject' carrying the signification of both injection by needle and ejaculation, thus representing in a creative, hip way the topics of the show. Thanks to Bob Keizer.
- ³⁹ Bob Keizer, interviewed June 2020.
- ⁴⁰ A. A. Vloemans, interviewed June 2020.
- ⁴¹ INCB Annual Report 1998. Para 435.
- ⁴² Bob Keizer, interviewed in June 2020 and in subsequent email clarifications.
- ⁴³ A. Vloemans, interviewed in June 2020 and in subsequent email discussions.
- ⁴⁴ A. Vloemans, in email discussion July 2021.
- ⁴⁵ European Monitoring Centre on Drugs and Drug Addiction (2019) Netherlands Country Report 2019. http://www.emcdda.europa.eu/system/files/publications/11347/netherlands-cdr-2019.pdf
- ⁴⁶ INCB Annual Report 2017. Para 34 (h).
- ⁴⁷ Ibid.
- ⁴⁸ International Drug Policy Consortium (2007) Proceedings Report on the Commission on Narcotic Drugs
- ⁴⁹ UN Information Service, UNIS/NAR/663, 19th May 1999. 'Concerns Over Heroin Use for Addicts Remain After Swiss Project Evaluated, INCB Says'.

https://www.incb.org/documents/Publications/PressRelease/PR1999/press_release_190599.pdf

- ⁵⁰ David R. Bewley Taylor (1997) *The United States and International Drug Control, 1909-1997*. London: Continuum
- ⁵¹ Roseanna Smart (2018) *Evidence on the Effectiveness of Heroin-Assisted Treatment*. RAND Corporation: RAND Health Care and RAND Social and Economic Well-Being

https://www.rand.org/content/dam/rand/pubs/working_papers/WR1200/WR1263/RAND_WR1263.pdf ⁵² Interview with Ingo Michels, 8th June 2020.

⁵³ Haasen C., Verthein U., Degkwitz P., Berger J., Krausz M. & Naber D. (2007) Heroin-assisted treatment for opioid dependence. Randomised controlled trial. *British Journal of Psychiatry* 191: 55-62.

See also: http://www.heroinstudie.de/Summ German H-Study.pdf

And see also: Verthein U., Bonorden-Kleij K., Degkwitz P., Dilg C., Köhler W.K., Passie T., Soyka M., Tanger S., Vogel M. & Haasen C. (2008). Long-term effects of heroin-assisted treatment in Germany. *Addiction* 103: 960-966.

- ⁵⁴ Haasen, C., Verthein, U., Eiroa-Orosa, F.J., Schafer, I., Reimer, J., 2010. Is heroin-assisted treatment effective for patients with no previous maintenance treatment? Results from a German randomised controlled trial. *European addiction research* 16(3), 124-130. See also, S., Vogel M. & Haasen C. (2008). Long-term effects of heroin-assisted treatment in Germany. Addiction 103: 960-966.
- ⁵⁵ Ambros Uchtenhagen (2017) *The role and function of heroin assisted treatment at the treatment system Level* Zurich Open Repository and Archive, University of Zurich, https://doi.org/10.5167/uzh-133002
- ⁵⁶ Joan Trujols & Ioseba Iraurgi (2009) Political challenges in randomized controlled trials of heroin-assisted treatment for severe heroin addiction: a Spanish experience. *Clinical Trials*, Volume: 6 Issue: 6, page(s): 658-659. https://doi.org/10.1177%2F1740774509351179

²⁶ Ibid, p.23.

- ⁵⁸ http://www.eurad.net/en/Norwegian+Government+says+no+to+heroin+assisted+treatment.9UFRrUYo.ips
- ⁵⁹ Advisory Council on the Misuse of Drugs, *'Reducing Opioid-Related Deaths in the UK'* (2016) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/576560/ACMD-Drug-Related-Deaths-Report-161212.pdf
- ⁶⁰ Police and Crime Commissioner for Cleveland https://www.cleveland.pcc.police.uk/News-and-events/Heroin-Assisted-Treatment.aspx
- ⁶¹ https://www.cleveland.pcc.police.uk/News-and-Events/News-Archive/2019/New-approach-to-tackling-drug-addiction-in-Middlesbrough-unveiled.aspx
- 62 https://www.cleveland.pcc.police.uk/News-and-Events/News-Archive/2019/New-approach-to-tackling-drug-addiction-in-Middlesbrough-unveiled.aspx
- ⁶³ https://www.nhsggc.org.uk/about-us/media-centre/news/2018/01/update-on-proposed-heroin-assisted-treatment/
- ⁶⁴ For an interesting discussion see, Transform Drug Policy Foundation, *Hitting Heroin and Crack Markets:* Funding Heroin Assisted Treatment Through Additional POCA Money, (Undated)
- ⁶⁵ WHO, UNODC and UNAIDS Technical Guide for countries to set targets for universal access HIV prevention, treatment and care for injecting drug users- 2012 Revision (2012).
- ⁶⁶ UN system coordination Task Team on the Implementation of the UN System Common Position on drugrelated matters (2019) What we have learned over the last ten years: A summary of knowledge acquired and produced by the UN system on drug-related matters.
- https://www.unodc.org/documents/commissions/CND/2019/Contributions/UN Entities/What we have lear ned over the last ten years 14 March 2019 w signature.pdf
- ⁶⁷ Werner Sipp headed up the International Narcotics Control Board between May 2015 and May 2017, having joined the INCB in 2012. He had previously worked for the German Health Ministry and was highly influential in the shift of the Board's discourse and policies in the early decades of the 21st century. He also played an important role in Germany, driving the changes to the Narcotic law that permitted the setting up of drug consumption rooms.

⁵⁷ Karen Duke (2016) Exchanging expertise and constructing boundaries: the development of a transnational knowledge network around heroin-assisted treatment. *International Journal of Drug Policy*, 31. pp. 56-63. http://eprints.mdx.ac.uk/18590/



"Nothing is more timely than the establishment and operation of an observatory to provide analysis and to allow policy reforms to be based on evidence: evidence of failures and evidence of successes"

Ruth Dreifuss, former President of the Swiss Confederation & Chair of the Global Commission on Drug Policy

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