EXPERT SEMINAR ON THE CLASSIFICATION

OF CONTROLLED SUBSTANCES

Initiative of the Transnational Institute

Amsterdam – 10 December 2009

The Expert Seminar on the Classification of Controlled Substances, an initiative of the Transnational Institute (TNI), took place in Amsterdam, the Netherlands, on 10th December 2009. Thanks are due to Thanasis Apostolou for chairing, and to Martin Jelsma and Ernestien Jensema for their preparation and organisation of the meeting.

The seminar was held under Chatham House rule to ensure confidentiality and to allow participants a free exchange of ideas. Over 20 people attended and comprised a mixture of current and past domestic and international policy makers as well as representatives of non governmental organisations and academic institutions.

Three themes were covered over the course of the day:

- UN treaty schedules – inconsistencies and options for reform;
- National classification systems – comparing the UK and Dutch models; and,
- Conclusions - achieving more consistency and rationality.

Each theme was prefaced by introductory remarks by key participants, in order to stimulate reflection and dialogue, followed by frank discussion. This report conveys the highlights of the discussion, although no individuals are quoted, in keeping with the anonymity stipulated by the Chatham House rule. The ideas expressed were those of individuals in their capacity as experts in the field of the classification of controlled substances, and should not be interpreted as reflecting consensus among the group, or endorsement by the organisers.

Introduction

The TNI Drugs and Democracy Programme focuses on many aspects of international drug policy and in recent years the attention of the Project has been drawn to the issue of the classification of controlled substances by the following developments:

- The growing tension between the World Health Organisation ('WHO') and the International Narcotics Control Board ('INCB') following conflicting recommendations on drug scheduling and the lack of clarity in their respective mandates;
- The classification of controlled substances as an obstacle to ensuring the availability of essential medicines;
- The dismissal, at both the international and domestic level, of expert, evidence-based recommendations on drug scheduling in favour of politically expedient resolutions; and,

- The efforts of Bolivia to amend the Single Convention on Narcotic Drugs 1961 as regards coca leaf.

It therefore appeared timely to reflect upon the consistency and effectiveness of the UN treaty system as regards the classification of controlled substances especially with the approach of the fifty year anniversary of the Single Convention on Narcotic Drugs 1961 ('the 1961 Convention') and the one hundred year anniversary of the Hague Opium Convention 1912. Accordingly, the purpose of the seminar was threefold:

1) To provide an instructive grounding in the terminology and the legal and scientific issues which underlie the classification of controlled substances;

2) To bring together experts, NGO representatives, and policy makers to foster a working relationship for the future; and,

3) To develop strategies with which to approach the inconsistencies, tensions, and developments in this field.

Session 1 – UN Treaty Schedules: Inconsistencies and Options for Reform

The 1961 and 1971 Conventions both include four schedules with varying levels of controls. How did the distinction between narcotic drugs and psychotropic substances come about? What exactly are the differences of control levels between the two treaties and their lists? Several inconsistencies have been pointed out over the years, including by the WHO and INCB. For example, the inclusion of cannabis in Schedule I and IV of the 1961 Convention and of dronabinol / THC and buprenorphine under the 1971 Convention, and of coca leaf in Schedule I of the 1961 Convention, etc. Adding substances to the lists appears easier than changing overly strict classification of certain substances into a more appropriate Schedule. In recent years, tensions have arisen between WHO Expert Committee recommendations and INCB reports, for example on khat, ketamine, poppy straw and dronabinol. There may also be some conflicts around the 1988 Table of Precursors, for which the INCB has the mandate to make recommendations, while it also affects the accessibility of ephedrine on the WHO List of Essential Medicines, for example. Is there a need to clarify WHO and INCB mandates and scheduling criteria to prevent further tensions? What are the prospects of introducing more rationality in the UN classification system? With regard to consistency on plants and extracts, what seems more likely to happen: that poppy straw, khat and ephedra will eventually become scheduled, respectively under the 1961, 1971, and 1988 conventions, or that coca leaf can be 'unscheduled' from 1961? Is there a case to make for a review that includes questioning the separation between the 1961 and 1971 Conventions?

The parameters of the morning session were ambitious. Participants were aided by the preparation of exhaustive background papers by the experts in attendance which clarified technical matters in advance so as to enable a free-flowing discussion further to the introductory remarks of key participants. This summary attempts to conflate these varying contributions and to précis the technical background information so that the reader can appreciate the context of the discussion.

Historical Context

There was little dissent among participants that the Conventions reflected the cultural and economic context of their time and, particularly, the perspectives of the industrialised and colonial powers rather than the evidence base.

In the early 20th Century, the main source of drugs of 'abuse' was the diversion of substances from licit channels - the pharmaceutical industry and its distribution networks – for illicit purposes, such as recreational use or self-medication. It was this diversion, together with the traditional use of cannabis, coca, and opium, that was the target of the Single Convention on Narcotic Drugs, 1961 ('The 1961 Convention').

The preamble of the 1961 Convention makes clear that it was intended for the health and welfare of mankind and recognises in the first instance that the medical use of narcotic drugs is indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes. Only thereafter does the 1961 Convention speak about the need to prevent and combat drug abuse.

As a response to the suppression of diversion, a new illicit drug trade developed that participants agreed the 1961 Convention was not equipped to control. The new criminal justice issues which arose appeared to furnish drug policy with greater political importance than before so that diplomats began to take over the roles previously assumed by scientists; this, in part, led to the evidence gap between scheduling decisions and scientific reality apparent today not least in the artificial use of the 'psychotropic' and 'narcotic' labels.

The substances scheduled under the Convention on Psychotropic Substances, 1971 ('the 1971 Convention') were not a result of these developments. Problems with amphetamines, barbiturates and tranquilizers had already been apparent at the time of drafting the 1961 Convention but at this time it was said that national control measures were considered sufficient to deal with the problem. Also, concerns were raised about the huge burden[1] that would beset the control system by the classification of substances which in any event, were considered (unlike now) to have high therapeutic value. However, problems with these substances and with hallucinogens continued to worsen and developing countries began to seek to reset the balance of the control system, having themselves suffered the major burden of the 1961 Convention. However, the 1971 Convention was a great deal weaker than was recommended by these delegations and, indeed, than was recommended by many from the treatment, medical, and research communities of the time[2].

The weakness of the 1971 Convention was generally seen by participants to have been the result of the western industrial countries powerful lobbying on behalf of their commercial interests and also a reflection of their cultural preference for synthetic drugs based on scientific experiment over natural substances. The adage of alcohol and tobacco being the drugs of the negotiators and therefore not placed under control was recalled by participants. It was also noted that the Preamble of the 1971 Convention mentions determination to prevent and combat drug abuse in

[1] Lande, A. (1973): The International drug control system (in Drug Use in America: Problem in Perspective. Appendix: The technical papers of the second report of the Commission on Marijuana and Drug Abuse vol. III. Pp. 6 -132'

[2] The global political economy of scheduling: the international-historical context of the Controlled Substances Act. W.B. McAllister Drug and Alcohol Dependence 76 (2004) 3-8

advance of recognising that the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted.

There was a further explosion in the use and traffic of illicit drugs throughout the 1970s and 1980s, however, and this led to The United Nations Convention Against Illicit Traffic In Narcotic Drugs and Psychotropic Substances 1988 ('the 1988 Convention'). The 1988 Convention was an attempt to strengthen the drug control system with the creation of: more offences; more powers for the regulatory bodies such as the International Narcotics Control Board ('INCB'); and, a broader scope of reference – to include, in particular, precursor substances. It was noted that the 1988 Convention also inaugurated the concept of shared responsibility between consumer and producer countries by creating offences on the consumer side of the drug trade.

Critical notice was paid to the Preamble of the 1988 Convention by participants for being silent on the issue of ensuring the availability of substances for medical and scientific purposes. It was said that this concrete diminishment of the primary aim of the Conventions over the course of time has led to restricted access to essential medicines for millions of people across the world[3].

The movement of the drug control regime away from a health focus towards the lens of criminal justice was also a source of consternation for participants. The reasons for this development were partly, it was suggested, because it is easier to source funding for criminal justice issues, and partly because it was a natural coupling further to the creation of the huge criminal black-market when the drug trade moved from diversion of licit substances into a completely illicit chain. Nevertheless it was felt that the result has been that the important issue of health and welfare has been obscured and that the Conventions have become outdated with artificial interpretations used to apply a system made to control the diversion of licit substances to the very different problems of a free-standing illicit market.

Participants found it interesting to conduct a review of the successes and failures of the Conventions as compared against their own terms of reference. For the 1961 Convention, in terms of successes, all agreed that it could claim certain successes in the control of the diversion of drugs from licit sources (though the initial effectiveness has more recently become undermined by now widespread diversion of new pharmaceutical opioids). Success could also be claimed, it was said, in the near-elimination of the traditional use of opium in West and South Asia and –to a much lesser extent- of traditional use of cannabis in India and some other Asian countries. In terms of failures, on the other hand, the illicit trade and use of heroin, cannabis, and cocaine has become a global phenomenon, the extent of the illicit coca bush cultivation is significant, and the traditional use of coca leaf continues in South America. Likewise, the impaired availability of essential medicines controlled under the 1961 Convention (e.g. morphine and methadone) should be considered an abject disaster. A similar balance was found when the 1971 and 1988 Conventions were considered.

The decision to draft a new convention at each stage rather than extend the scope of the original was ascribed to the reticence of the developed countries to be confronted with similar controls of the 1961 Convention that had placed so much burden on the developing world The outcome is three different mechanisms of classifying substances, based on different criteria and procedures,

[3] WHO 'Impact of Impaired Access to Controlled Medications'
http://www.who.int/medicines/areas/quality_safety/Impaired_Access/en/print.html

and with different control outcomes. In the discussion on inconsistencies which followed, many participants saw the origins of the classification problems now in these historical developments.

The Nature of the Conventions

The 1961 Convention

The substances controlled under the 1961 convention are primarily natural drugs associated with the following three plants: opium poppy; coca bush; and, cannabis. Active ingredients of these plants (e.g. morphine, codeine, cocaine) are also included, as are semi-synthetic compounds (e.g. heroin), some precursors (e.g. thebaine and ecgnonine), and synthetic opioids (e.g. pethidine, methadone, fentanyl etc). The substances are divided into four schedules, which vary in the levels of control they impose.

● Schedule I contains substances considered most addictive and to cause the most severe ill effects (e.g. cocaine, methadone, opium); these substances may or may not have therapeutic potential – where they have no such potential, they will also be listed under Schedule IV. Substances under Schedule I are very strictly controlled by the 1961 Convention which limits their production, manufacture, export, import, distribution of, trade in, use, and possession exclusively to medical and scientific purposes. Control requirements also include: submission of estimates of drug requirements and statistical returns to INCB, the limitation of manufacture and importation to quotas provided by INCB; the limitation of trade, manufacture and production except by those who are licensed and subject to supervision and inspection; and, the seizure and confiscation of substances and of equipment used in offences.

● Schedule II contains substances normally used for medical purposes and presenting a low risk of addiction (e.g. codeine). The control of such substances is less strict than under Schedule I in the sense that the restrictions on trade and distribution are less onerous.

● Schedule III contains preparations of substances listed in Schedule I or II considered to present no risk of abuse / addiction and produce no ill effects and from which the drug therein is not readily recoverable. These preparations are exempted from most of the control measures placed upon the drugs they contain, thus estimates and statistics to INCB can be restricted to the quantities of drugs used in their manufacture and the restrictions on manufacturing, trade and distribution do not apply; further to these exemptions, the control regime under Schedule III can be described as extremely lenient.

● Schedule IV contains what are considered to be the most dangerous substances in that they are considered to be exceptionally addictive and to produce severe ill effects. These substances are not considered to contain any substantial therapeutic advantage. Examples are cannabis and heroin. Schedule IV substances are very strictly controlled as, in addition to the base control measures under Schedule I, the 1961 Convention also exhorts Parties to enact further domestic control measures as necessary[4]. It is the only category of drugs for which the Convention explicitly mentions the possibility for a Party to "prohibit" their production, trade, possession and use except for medical and scientific purposes, though only "if in its opinion the prevailing conditions in its country render it the most appropriate means of protecting the public health and welfare".

[4] Single Convention on Narcotic Drugs, 1961, Article 2(5)(a-b).

Whether a new substance is to be placed on any schedule is determined by 'the Similarity Principle' i.e. is it similar - in terms of its liability to abuse, production of ill effects, therapeutic potential, or recoverability - to substances already scheduled? If the World Health Organisation finds such a similarity, this information is submitted to the Commission on Narcotic Drugs ('CND') for a decision on scheduling.

The 1971 Convention

The substances (and their preparations) controlled under the 1971 Convention are generally hallucinogens, amphetamine-type stimulants, hypno-sedatives, or anxiolytics and are primarily synthetic. In clear contrast to the 1961 Convention, plants and precursors are not included. The substances are divided into four schedules, which vary in the levels of control they impose.

● Schedule I contains substances considered to: present a high risk of abuse; pose a particularly serious threat to public health; and, have very little or no therapeutic value. The degree of control is very strict and the use of such substances is prohibited except for scientific or limited medical purposes. Examples are LSD, MDMA, Mescaline, and Cathinone.

● Schedule II contains substances considered to: present a risk of abuse; pose a serious threat to public health; and, have low or moderate therapeutic value. The degree of control is lenient compared with Schedule I in the sense that a Party has discretion under Article 5 as to the extent of the limitation measures it adopts. Examples are Amphetamines and Dronabinol (*delta*-9-tetrahydrocannabinol).

● Schedule III contains substances considered to: present a risk of abuse; pose a serious threat to public health; and, have moderate or high therapeutic value. The control regime is more lenient than Schedule II; the availability of such substances for medical purposes is expressly permitted. Examples are Barbiturates and Buprenorphine.

● Schedule IV contains substances considered to: present a risk of abuse; pose a minor threat to public health; and, have a high therapeutic value. The control regime is even more lenient than in the preceding schedules and again, the availability of such substances for medical purposes is expressly permitted. Examples are Diazepam and Phenobarbital.

Whether a new substance is to be placed on any schedule requires a lengthier assessment than under the 1961 Convention. First, the World Health Organisation ('WHO') must consider whether the substance has: the capacity to produce a state of dependence and central nervous system stimulation or depression, resulting in hallucinations or disturbances in motor function or thinking or behaviour or perception or mood; or similar abuse and similar ill effects to another substance already under Schedule I, II, III, or IV. If this first aspect of the test is satisfied, then WHO must consider whether there is sufficient evidence that the substance is being or is likely to be abused so as to constitute a public health and social problem warranting the placement of the substance under international control. WHO's findings are then conveyed to CND which may take into account any other factors it considers relevant prior to its decision on scheduling.

The 1988 Convention

The substances controlled under the 1988 Convention can be split into two groups: direct precursors of psychotropic substances and their salts (Table I) – examples are ephedrine, and lysergic acid; and, reagents and solvents (and their salts) which can be used during the illicit

production process of narcotic drugs and psychotropic substances (Table II) - examples are sulphuric acid and ethyl ether. It was noted that albeit the Convention was conceived along this idea of a distinction between immediate precursors and essential chemicals, however, the decision was later taken not to formally distinguish the lists in this way and no definition is provided in the Convention[5].

The control measures to which Tables I and II are subject are very similar and include licensing of and restrictions upon manufacture, distribution, imports and exports and INCB reporting requirements. The Convention also creates offences of dealing with Table I or Table II substances in any way, knowing that they are to be used for illicit purposes[6]. Table II controls are, however, the more lenient in the sense that Parties from whose territory a Table II substance is to be exported does not have to communicate all details of the transaction to the importing country[7]. On the other hand the control provisions do not apply at all to pharmaceutical or other preparations containing substances in both Tables I and II where they are compounded in such a way that the substances are not easily used or recoverable[8]. On a separate note, Article 3 requires States to criminalise the possession, purchase, or cultivation of drugs scheduled under the 1961 and 1971 Conventions.

Whether a new substance is to be placed on either Table of the 1988 Convention must begin with a finding by the INCB that the substance is frequently used in the illicit manufacture of a narcotic drug or psychotropic substance and that the volume and extent of the illicit manufacture of a narcotic drug or psychotropic substance creates serious public health or social problems so as to warrant international action. Such a finding, together with an assessment of the likely effect of adding the substance to either Table I or Table II on both licit use and manufacture, is then communicated to the CND for a decision on scheduling.

Mandates and Tensions

The 1961 Convention, Article 2, and the 1971 Convention, Article 3 mandate WHO to make recommendations to the CND that either a new substance be scheduled, or that an already scheduled substance be transferred from one Schedule to another or be deleted altogether from the Schedules. The United Nations Office on Drugs and Crime ('UNODC') is the Secretariat for CND and the agency responsible for coordinating international drug control activities.

Within WHO, the Expert Committee on Drug Dependence ('ECDD'), assumes the responsibility of formulating recommendations to CND. The ECDD works according to a 'critical review' procedure and instructs experts to consider substances according to the 'WHO Guidelines on the Evaluation of Dependence Producing Drugs for International Control' and to draft a 'critical review report' on the substance. In the Critical Review, a substance is considered by experts according to the following criteria: similarity to known substances and effects on the central nervous system; dependence potential; actual abuse and/or evidence of likelihood of abuse; and, therapeutic usefulness. The report is discussed within the ECDD and then within WHO's

[5] Commentary on the United Nations Conventions Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988, United Nations, New York 1998 at 36.6
[6] United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988, Article 3(a)(iv) and Article 3(c)(ii).
[7] United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988, Article 12(10)
[8] United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988, Article 12(14)

governing body, and recommendations are thereafter made to CND as to whether a substance should be controlled internationally, and if yes, under which Schedule.

Also, under both the 1961 and 1971 Conventions, a State Party may notify the Secretary General that it has information which may require an amendment to any of the Schedules. Where this occurs, the Secretary General will forward the notification to WHO to follow the process described above.

The 1961 Convention does not require that CND accept the recommendations of WHO, but the decision must be notified to the Economic and Social Council ('ECOSOC') which has the power to confirm, alter, or reverse it. However, neither CND nor ECOSOC, may make a decision which has not been the subject of a recommendation by WHO following the required procedure.

Under the 1971 Convention, CND must accept the communication from WHO on medical and scientific matters as determinative[9] but CND may also bear in mind 'economic, social, legal, administrative and other factors it may consider relevant'[10] and so reject a recommendation where it thinks fit.

It was suggested that WHO could be more forthright with recommendations and critical reviews of difficult topics and noted that controversial issues are often shied away from by this organ or not followed up – the example of the non-availability of the original and full report on the classification of coca in either the WHO archives or online was made. On the other hand, it was expressed, that if WHO were to assume such a role, criticisms that it was acting *ultra vires* could be levied, albeit wrongly. It would be better, it was said, for a Party to submit a sensitive issue for critical review by WHO – this would be less confrontational and would enable a clear division between the scientific assessment and the political evaluation; it was suggested that such an approach would be less likely to meet resistance once it reached CND.

INCB describes its mandate as 'the independent and quasi-judicial monitoring body for the implementation of the United Nations international drug control conventions.'[11] However, the role of INCB is restricted under the 1961 and 1971 Conventions to endeavours which 'limit the cultivation, production, manufacture and use of drugs to an adequate amount required for medical and scientific purposes, to ensure their availability for such purposes and to prevent illicit cultivation, production, and manufacture of, and illicit trafficking in and use of, drugs'[12]. These functions are to be achieved through administration of the estimate system, communicating with Governments, and the preparation of annual reports. INCB is not mandated under these Conventions to make scheduling recommendations but dissenting views on ECDD scheduling recommendations have been clearly implied in various INCB reports, notably as regards to khat[13] - examples were also given by participants of ketamine, poppy straw, oripavine, and dronabinol.

On the other hand, under the 1988 Convention, it is INCB and State Parties which are mandated to recommend that a substance be scheduled. This process begins by the recommendation, and the information upon which it is based, being conveyed by INCB to the Secretary General who,

[9] Convention on Psychotropic Substances 1971, Article 2(5)
[10] Ibib
[11] http://www.incb.org/incb/mandate.html
[12] Single Convention on Narcotic Drugs 1961, Article 9(4)
[13] See 34th Report ECDD, Geneva 2006 at 2.2.4 as compared with the discussion on khat as a substance not under international control in the INCB Report for 2008 at 338 – 339 and elsewhere in the report.

in turn, submits it to CND. The recommendations of INCB must be considered determinative as to scientific matters however, CND may reject the recommendation[14].

It was noted that 1988 Convention function of INCB is the cause of tension with WHO because the scheduling of substances under this Convention can have such a deleterious impact on WHO's essential medicines programme. The extent to which either organ should focus or work on the issue of access to essential medicines is also a cause of separate tension between them as both seek to claim this mandate for their own or exclude it from the other, even though there is a formal collaboration between the two in the WHO Access to Controlled Medications Programme.

All the organs discussed, it was said, are problematically possessive of their mandates to the extent that where new evidence comes to light from an external source it will not exist for the UN system. The example of the Beckley Foundation Global Cannabis Commission Report was made; the report was commended by participants but because it was not tabled by an official organ, its findings were not formally recognised or enacted. It was suggested, however, that such information could be put before the regime if a country were to endorse the report and send it to WHO to initiate a critical review.

Ultimately, whether a scheduling decision is initiated by WHO, INCB, or a particular State Party, the decision is made by CND, which comprises 53 UN Member States, elected by ECOSOC, but which holds discussion with all UN Member States. In this forum, which is peopled by diplomats rather than scientists, many participants felt that political, moral and philosophical considerations were prioritised over the scientific. This issue was discussed in greater detail in the afternoon session of the seminar, but certainly many participants expressed a feeling that there was political deadlock in CND whereby it is difficult to raise any debate at all in the hope of moving towards a more rational classification. An example was given of the issue of methadone and buprenorphine for drug dependence treatment – an essential HIV prevention measure which continues to be unavailable in many countries – but on which CND has been markedly silent.

A further example was given of cannabis which is subject to the strictest level of control possible being under Schedule IV of 1961 Convention; it is not possible to schedule it more strictly. Participants note that whether or not this scheduling was a true reflection of the evidence in 1961, it is an outdated position now in terms of the current body of evidence as to the addictive qualities of cannabis, its harmful effects and its therapeutic potential. Many experts felt that none of the mandated bodies would articulate these developments, however, let alone consider a lesser scheduling of cannabis because of the political and moral resistance with which they would be confronted at CND and the example was made of the 2009 attempt in the opposite direction of the CND to control cannabis seeds.

Scheduling Criteria

This Similarity Principle was considered a relatively straightforward test. It was said that a competent scientist can easily look at the chemical structure of two substances and their effects and say whether or not they are similar. The Similarity Principle was considered to function very smoothly, allowing for the practically automatic scheduling of the analogues of natural and synthetic narcotic drugs as they are developed and sourced by the illicit market. Further,

[14] United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988

Schedules II and III of the 1961 Convention, which allow for substances to be exempt from the most strict level of control if there is therapeutic utility or if the harmful substance is not easily recoverable, were considered to be very helpful and pragmatic mechanisms.

It was noted, on the other hand, that the Similarity Principle excludes many addictive substances which are capable of producing ill effects to such an extent that it is unnecessary limiting. Although this problem could have been dealt with by having a separate special mechanism to introduce new types of substance, this did not occur and the 1971 Convention was drawn up instead. The underlying issue was identified by some participants as the fact that the international control system has never articulated definitively what it is about a substance that requires it to be controlled. It was noted that many addictive and / or harmful substances have escaped control and many non-addictive and non-harmful substances have been controlled and that the determinative characteristic has often appeared to be whether or not a substance was capable of producing pleasure. It was expressed by some that they considered this the reason for the availability of methadone rather than heroin. The example of co-proxamol was given. This substance, a moderately strong analgesic was banned on the ground of overdose death by the UK Committee on Safety of Medicines but paracetamol, responsible for even more overdose deaths was not. Commentators suggested that the only difference was that co-proxamol is an opioid. The control system it was also suggested, is subjectively weighted in favour of the rich and on grounds of availability. The example of the Japanese Puffer Fish was given; the fish contains tetrodotoxin a fatal poison with no known antidote yet the fish is prepared for consumption as a delicacy in Japan which is highly dangerous to eat. The only reason it is not banned, it was suggested, was because the substance is so expensive that very few people can afford to eat it. If was argued that if Japanese Puffer Fish were cheap (like cannabis, coca leaves) it would probably have been banned.

Few were optimistic that the international drug control regime would grapple with the subjective and moral aspects to its classification regime in any near future. The other problem ascribed to the Similarity Principle was its perpetuation of the premise that the original Convention classifications were correct whereas many felt, certainly with regards to cannabis and coca leaf, that this was an incorrect premise.

In some ways, therefore, the extra requirements for evidence under the 1971 Convention were very welcome to participants, some of whom felt that the assessment criteria and schedules could benefit from either greater nuance. It was said, for example, that a truly scientific approach would require the scheduling of morphine injections for instance with slow-release morphine tablets available through pharmacies. Other participants, however, decried the delay (and expense) caused by even the 1971 Convention assessment process; it was said that the delay in scheduling decisions leads to the propagation of new drugs of abuse. It was also noted that the delay at the international level is then compounded by delay at the national level where the domestic classification procedure which is triggered can take up to one year to effect in some countries[15]. The issue of opportunity cost was also discussed, it was suggested that the resources expended by WHO under the 1971 scheduling mechanisms could better be spent on ensuring the availability of essential medicines. At this juncture it was brought to the attention of participants that the ECDD has been profoundly affected by the global financial downturn and is beggared by funding difficulties such that the issue of opportunity cost may be moot.

[15] Legal Responses to New Psychoactive Substances in Europe, EMCDDA, February 2009, Table 1 at page 18

It was suggested therefore that in specific cases it might be better to schedule a substance preventatively than wait for the abuse to materialise. Because of the potential impact of the availability of a substance for licit medical and scientific purposes, it was retorted that a necessary safeguard to such an innovation would be some kind of preliminary assessment to ensure that there really was no therapeutic value in the substance.

Participants heard the story of the 2000-2006 attempts to modernise the WHO guidelines by producing a supplement which was rejected by various state parties concerned about the impact the guidelines would have upon the availability of buprenorphine for drug dependence treatment. A second modernising attempt, which sprouted in a working group in 2007, is ongoing; it was finally brought up to the executive board of WHO last summer but the delegates required further time to consider it and also requested an internet consultation and further consultation with the INCB and so up to date guidelines remain outstanding. The draft guidelines' list of criteria was published online until recently but for reasons which are unclear it has now been taken down from the web and was no longer available at the time of the seminar[16]. All in all, the delay and political deadlock together have led to a situation where some expert commentators expressed that there is such a discrepancy between the scheduling in the conventions and current scientific knowledge that the conventions are, or should be, obsolete.

It was suggested, however, that the delays caused could be harnessed as an opportunity to monitor the *legal high* market, many of the substances in which are similar to those that are under control. Domestic governments could place these legal highs under a regulatory model with an appropriate education campaign, and monitor the success in terms of harm-prevention of such a model without being in breach of their Convention obligations until such time as they became scheduled at the international level. This would enable more data on the effectiveness of different control models to be accrued which could go on to power either amendments to the existing conventions or redrafting if the evidence were supportive.

On the other hand, some State Parties or regional bodies pre-empt the international scheduling decisions and control substances either on the basis of different criteria (many participants had noted that States often choose their measures of domestic control on the basis of law-enforcement or health objectives rather than scientific classifications) - or before there is sufficient evidence to justify the control; this is, in itself, a cause of tension and inconsistencies.

The example of 1-benxylpiperazine ('BZP') was given. Despite BZP being outside of the UN control regime and still currently in the process of critical review by the ECDD, following a risk assessment of BZP by a Special Session of the Extended Scientific Committee of the European Monitoring Centre for Drugs and Drug Addiction ('EMCDDA') which revealed 'a lack of conclusive scientific evidence on the overall risks of BZP'[17] a Decision of the Council of the European Union[18] required that Member States of the EU place this substance under domestic control. Such a preventative step would not be accommodated in the Convention scheduling decisions.

The example of ketamine was also given as a case-study in which the various tensions between the mandated organs are particularly visible. Ketamine is listed as an essential medicine by

[16] It has since then been made available again: EB125/6, *Guidance on the WHO review of psychoactive substances for international control: proposed revision, Report by the Secretariat*, 12 May 2009. http://apps.who.int/gb/ebwha/pdf_files/EB125/B125_6-en.pdf
[17] Council Decision 2008/206/JHA of 3rd March 2008 at (8)
[18] Ibid

WHO[19] as it is a particularly important medicine in resource limited settings where it enables surgery when conventional anaesthesia is otherwise unavailable. Ketamine was subject to critical review by the ECDD in 2006 which held that its propensity to cause dependence in humans was 'very limited' whereas on the contrary, in terms of therapeutic usefulness, it was 'widely used'[20]. The ECDD did not therefore recommend scheduling. Nevertheless, participants noted how INCB often speaks of 'the abuse of, and trafficking in, ketamine'[21] and that in the course of the ECDD meeting, the CND adopted a resolution calling upon Member States to control ketamine at the domestic level[22] and many states are said to have taken this course of action. INCB has further urged 'all governments to provide to it and to WHO all available information on the abuse of ketamine in their countries'[23]. The ECDD was therefore asked to look again, immediately, at the issue of the ketamine and present an updated version of the critical review to their next meeting. It was noted that WHO was criticised for not taking into account future developments in ketamine use and abuse, but this criticism was answered by the fact that 'future developments' do not form part of their mandated criteria when considering a substance and nor would such a criteria be workable.

The result of the further ECDD review is awaited; the concern is that scheduling (considered unnecessary by WHO experts) would restrict access to the substance for the many millions of people across the world that require it for licit therapeutic purposes. Some in the seminar felt that the ECDD position was incorrect, and that the increasing levels of seizures and ketamine abuse alone justified its control. These participants reflected that this situation was a clear demonstration of the failure of the Convention scheduling process not least because it undermined the first principle of international drug control that 'effective measures against abuse of narcotic drugs require co-ordinated and universal action'[24]. Others in the seminar disagreed, citing the importance of ketamine for medical purposes and reflecting that the ECDD had reached the correct decision especially as international control should be a last resort where national measures are insufficient. At least all agreed that these inconsistencies and tensions called for a close review of the system.

In contrast to the above phenomenon, in many countries the scheduling decisions of the UN are slavishly incorporated, albeit many participants express concern, that domestic incorporation was often insensitive to the nuances of the international scheduling. Particularly, it appeared to participants that Schedule IV of the 1961 Convention and Schedule I of the 1971 Convention are interpreted in most countries as absolute prohibition whereas, in fact, so-scheduled substances should still be made available for medical and scientific purposes. Examples of such incorrect and absolute prohibition by various States were given in relation to Pentazocine, Phenobarbytol, and particularly ephedrine. Ephedrine is rated an essential medicine by WHO in the field of obstetrics, however the impaired access to this substance caused by its controlled status under the 1988 Convention is (together with the lack of access to ergometrine) according to WHO, responsible for some 250,000 maternal deaths annually[25]. The reason for such prohibition, it was said, ranges from lack of infrastructure or resources with which to comply with the Convention obligations otherwise (East Timor was given as an example), reticence on behalf of doctors to

[19] Essential Medicines WHO Model List 16th Edition (March 2009)
[20] WHO Expert Committee 34th Report at 2.2.3, http://whqlibdoc.who.int/trs/WHO_TRS_942_eng.pdf
[21] INCB Report 2007, pg. 31
[22] CND Resolution 49/6 at E/2006/28 E/CN.7/2006/10
[23] INCB Report 2007, pg. 31
[24] Preamble to the 1961 Convention
[25] WHO Impact of Impaired Access to Controlled Medications
http://www.who.int/medicines/areas/quality_safety/Impaired_Access/en/print.html

prescribe controlled medicines because of the mire of regulations and penalties surrounding mistakes in this area (USA), and in most cases, a simple lack of awareness about the options. The result in all cases was said to be the same; unnecessary suffering. It was commented that a change in either perception or substance is required to render the Conventions regulatory rather than prohibitive but the prospect of such a development was not anticipated to be likely.

Scheduling Distinctions – Scientific Inconsistencies and Tensions of Control

As earlier discussed, although the 1961 Convention is generally reserved for plant based drugs, the 1971 Convention generally reserved for synthetic drugs, and the 1988 Convention reserved for Precursors, Reagents and Solvents, there are, nevertheless, substances scheduled under each Convention which would fit more naturally and more appropriately on another. Some examples were given by participants:

● Thebaine (an opiate precursor) and ecgonine (cocaine precursor), both under the 1961 Convention would, as precursors, fit more naturally on the 1988 Convention.

● Mescaline and psilocybine, both under the 1971 Convention ostensibly reserved for synthetic drugs, would, being natural compounds (albeit usually represented in the market by synthetic compounds), fit more easily in the 1961 Convention.

● Pentazocine and buprenorphine, both under the control of the 1971 Convention, would, being synthetic and semi-synthetic opioids, fit more naturally with the other synthetic opioids under the 1961 Convention such as pethidine, methadone, fentanyl etc.

● The principal ingredient of khat – cathinone – is scheduled under the 1971 Convention, whereas khat is not itself scheduled. It was not suggested that khat should be scheduled in fact, not least, it was said, because its consumption is so widespread in some countries that outlawing it would be more difficult to implement than, say, alcohol prohibition in Europe.

● The inclusion of cannabis as a narcotic drug on both Schedules I and IV of the 1961 Convention and of THC as a psychotropic substance under 1971 Convention is contradictory.

● A discussion was had about the proper scientific meaning of a 'narcotic drug' and some participants advised that this should refer to a substance which leads to the development of a narcotic state (i.e. morphine, heroin, pethidine). However, many substances under the Schedules of the 1961 Convention on Narcotic drugs are, in fact stimulants (i.e. cocaine), hallucinogens (i.e. cannabis), and precursors (i.e. thebaine) and should not, therefore, be placed within this Convention if its title has any significance.

● Likewise, a discussion was had about the proper scientific meaning of 'psychotropic substance' and some participants advised that this should refer to drugs which have an effect on the functioning of the central nervous system. However, all the narcotic drugs in the 1961 Convention, with the exception of the precursors would fall within this definition. Basically the term 'psychotropic' was invented to create an artificial category of drugs to justify a separate convention. It lacks a solid scientific definition.

The case of buprenorphine highlighted the tensions between the control mechanisms most acutely. Buprenorphine, under schedule III of the 1971 Convention, was recommended for critical review by WHO in 2000 at the request of the INCB because the Board was concerned

that there had been significant diversion of the drug into illicit markets and that illicit use of the substance had increased dangerously. Accordingly INCB considered that benefit would accrue from a more stringent scheduling and, also it was felt that buprenorphine belonged with the other substances under the 1961 Convention. During the meeting of the ECDD it was found that buprenorphine met both the requirements for scheduling in the 1961 and 1971 Conventions. However, there was no guidance on how to choose between Schedules in such a situation. Ultimately, the ECDD recommended that buprenorphine remain in its original schedule under the 1971 Convention due to the concern that a transfer from the 1971 Convention to the 1961 Convention would, as a consequence, give rise to rescheduling at the national level, which would in turn have the unintended effect of restricting access to drugs used to treat drug dependence'[26].

A further example was given in relation to ephedrine. It was commented that it would be logical to transfer ephedrine from the 1988 Convention to the 1971 Convention because of its similarity to the amphetamine-type stimulants on the Schedules of the 1971 Convention and the need for its accessibility as an essential medicine. However ephedrine is also the most important precursor of methamphetamine and such a transfer with the Conventions if they were left otherwise un-amended would mean the discontinuation of the control of ephedrine as a precursor and would facilitate the illicit production of 'ice' in Asia.

This discussion closed with concern that the scheduling of controlled substances at the UN level was so rife with tensions and inconsistencies that it has almost reached the point, if it has not already, where the system is unworkable, obsolete, and counter-productive.

Interim Reflections

Whether it should be for scientists, diplomats, or politicians to make scheduling decisions was passionately debated by participants. On the one hand it was felt that although all scheduling decisions should be informed by the best available scientific analysis, making a recommendation or decision on scheduling is properly a political and philosophical decision and not for scientists to make. It was emphasised that there is a need for scientists to accept this and bravely state when they are unable to reach a definitive conclusion on a particular substance. The importance of a separation of roles between the scientists and the political decision makers was stressed in order that a decision could be considered 'clean' i.e. transparent and accountable. On the other hand it was argued that it is better for scientists to make the scheduling recommendations because at least scientists are in a position to comprehend exactly what about a substance is unknown and in any event, the political decisions are often miscast as if they were evidence-based with the true rational of the decision obscured; such decisions cannot be said to be clean.

It was felt that there is a real need to clarify the WHO and INCB mandates as well as the scheduling criteria if there is to be any hope of moving away from the inconsistencies and tensions discussed. From the discussions it was clear that some could certainly also make a cogent case for a review of the control system that would include questioning the separation between the 1961 and 1971 Conventions. Without such clarification the prospect of introducing more rationality in the UN system would, it was felt by many, be nominal.

How to introduce such clarity? Some participants called for a complete refresh of the control system with a new omnibus convention containing reformed and updated aims, drug control mechanisms and instruments which evaluated substances from a starting point of therapeutic

[26] Buprenorphine (final decision) 34th ECDD-2006/6.2 at V

potential. These participants felt that within the current framework the discrepancies between scheduling and current scientific knowledge is insurmountable unless the parameters were completely changed. Others felt that this was unrealistic taking into account that simple scheduling decisions remain untouched for years and these participants felt the stage has not yet been reached where the control system can or should be replaced by an entirely new Convention.

However, if nothing were to change in terms of procedure or substance, it did seem more likely to the group that poppy straw, khat, and ephedra would eventually become scheduled than that coca leaf could become unscheduled. Participants drew attention to the way in which additions had constantly been made of substances into the various Schedules so that the scope of the control regime was gradually increased without debate. Accordingly, some participants noted their concern that even if some change were initiated, it is likely, in light of the history of the drug control system, to result in change in a conservative direction. Similar concerns were raised about the domino effect of opening up the drug Conventions, in particular whether other countries would use this as an excuse to re-open the human rights treaties which a number in the group considered to be more important. Such concerns followed any discussion about moving towards regulation – it was suggested that the WHO Framework Convention on Tobacco Control 2003 could provide a template for such a change.

Employment of the convention mechanisms to reschedule substances did not cause the same level of concern; resistance yes, but no domino effect could be foreseen if the legal procedure available under the 1961 Convention[27], for example, were to be adopted by a State Party to refer the issue of a substance scheduling to WHO for a critical review. It was felt that the political considerations of CND would still provide an obstacle but at least a debate could be forced and the issues reviewed.

It was noted that there is, after all, a precedent for re-scheduling a substance between Schedules, so it is achievable. The precedent is Dronabinol which was originally included with 'Tetrahydrocannabinols, all isomers' in Schedule I of the 1971 Convention but was transferred with delta-9-tetrahydrocannabinol (delta 9 THC) and its stereochemical variants to Schedule II in 1991; this meant that medical preparations including this compound were subject to fewer restrictions than before and more easily available to patients – specifically the drug Marinol. This rescheduling marked a huge contradiction because the substance comprises the active ingredient of cannabis and cannabis resin yet these substances remain completely prohibited under the Conventions. It was expressed by participants that the cause of this re-scheduling was a persuasive lobbying campaign by the pharmaceutical industry and this was given as a further example of the strength of politics and the pharmaceutical industry as against the weakness, in political terms, of the developing countries.

Some reforms were, all agreed however, both necessary and also unlikely to have the negative knock-on effect of the suggestions previously discussed. These reforms would be: to disaggregate drug control and criminal justice; to transfer the mandate for drug control to WHO; to re-emphasise the 'health and welfare' aim of the regime; and to prioritise the issue of access to essential medicines.

The need to work with new and different partners to ensure prospects of success was discussed. For example, it was noted that matters are much more likely to progress if a donor country is behind a proposal; in particular, it was felt that the USA very much runs UNODC through its

[27] Single Convention on Narcotic Drugs, 1961 Article 3(1)

earmarked donations. Likewise, blocks of countries were noted to be much more powerful in the pushing through of reform but against this suggestion participants were reminded of the exceptional difficulty of finding a consensus on the harm reduction issue by European States going into the High Level Meeting of the 2009 CND not to mention the limited outcome.

It was noted that little could be achieved if the law-enforcement community were not supportive of the suggested reforms and the work of the International Drug Policy Consortium on finding a new role for law enforcement in this regard was noted and welcomed. Similarly, it was suggested that those lobbying for change might seek the support of the powerful pharmaceutical and manufacturing industries albeit these may not be natural allies. It was also felt that it might be well to encourage INCB to seek to balance some of the tensions in the conventions as they did so attempt in their 1994 document 'Effectiveness of the International Drug Control Treaties'[28]. Albeit CND merely agreed that Governments should study the issues raised in this report and since that time there has been silence, it was felt that there was an opportunity presented in this suggestion.

The group looked forward to the afternoon session with the optimistic reflection that an opening had arisen with a recent change of personnel at UNODC which organisation is trying to improve its drug reports and depoliticise its publications.

Session 2 – National Classification Systems: Comparing the UK and Dutch Models

Much debate is currently going on about the classification of drugs in the UK and The Netherlands. In both countries, recent recommendations of the mandated scientific expert committees have been rejected. Also, in both countries there has been an exercise to elaborate a ranking of drugs according to their relative harmfulness which triggered questions about the rationality of current classification and the distinction between 'licit' and 'illicit' drugs. In The Netherlands the distinction between 'hard' and 'soft' drugs is under reconsideration. To what extent can national scheduling systems diverge from the UN system? What is the situation in other European countries? What lessons can be learned about the apparent tension between scientific evidence and policy making?

<u>The United Kingdom</u>

As regards the classification of drugs, the United Kingdom system is ostensibly evidence-respectful. The domestic legislative framework for the classification of drugs, the Misuse of Drugs Act 1971 ('MDA') determines the availability of drugs for medical and scientific purposes and the punishment of their illicit use and supply. The MDA requires that the government consult with an Advisory Council on the Misuse of Drugs ('ACMD'). Where a substance is referred for control by either the EU or the UN, these recommendations are always followed, and the domestic classification system is only concerned with the level of restrictions and punishment for non-adherence. On the other hand, the domestic classification system will also consider and, if it finds appropriate, control substances which are not scheduled at the international level.

Substances are controlled under one of three classes – A, B, and C – with A containing the substances considered most harmful and C containing substances considered to be the least harmful – failure to adhere to the restrictions placed on these substances invokes the criminal

[28] http://www.incb.org/pdf/e/ar/incb_report_1994_1.pdf

law. There are also separate regulations as to whether substances are to be made available on prescription or through pharmacies which are determined and enforced by the Medicines and Healthcare Products Regulatory Agency ('MHRA') but this fell outside the scope of the expert seminar.

The ACMD is a statutory, non-executive, non-departmental public body made up of experts appointed by the Home Secretary. By law, the ACMD must include representatives from the practice of medicine, dentistry, veterinary medicine, pharmacy, the pharmaceutical industry, other chemistry, and people with a wide and recent experience of social problems connected with the misuse of drugs.

It is the ACMD's duty to keep under review the situation in the UK with respect to drugs which are being or appear likely to be misused and of which the misuse is having or is capable of having harmful effects sufficient to constitute a social problem and to give advice on measures which ought to be taken for preventing the misuse of such drugs or dealing with social problems connected with their misuse. Whether such harmful effects or social problems exist sufficiently to require the control of a substance, the ACMD determines by reference to a 9 point risk assessment matrix which considers: acute, chronic, and intravenous harm; intensity of pleasure; psychological dependence; physical dependence; intoxication; other social harms; and health care costs.

As a rule[29], the Government had traditionally followed the advice of the ACMD until 2008 when its recommendation that Cannabis be placed within category C – the least harmful category – was rejected. Then, in February 2009, the Government rejected the ACMD's recommendation that ecstasy be downgraded from the most harmful category – Class A – to the lesser category, Class B. The Government also rejected the ACMD's recommendation that a national scheme be created for the purpose of testing MDMA with a view to providing harm reduction advice and developing monitoring data.

The Government was legally entitled to reject the ACMD recommendations; the statutory framework only requires conscientious consultation by the Government with the ACMD on classification decisions, not that ACMD recommendations be followed. The Government relied on the precautionary principle as justification for the rejection of the cannabis recommendation[30] and offset the matter by enshrining law enforcement guidance which meant that cannabis - exceptionally amongst all substances (even those in a lower class) - could be dealt with almost administratively by way of street cautions. The ecstasy decision was justified as follows, 'It is our view that the system should be based on evidence, but it should also be based on the considered view of those responsible for policy making, and should take into consideration the impact that changes in classification are likely to have on the use of, and harms caused by drugs and the impact that that has on the criminal justice system. That is why it will remain the case that our advisers will advise us, and we will decide.'[31]

[29] There was an exception to this rule in 1978 but this was due to the ACMD having been unable to form a consensus as to what advice to give the Government.

[30] House of Commons Hansard Debates for 7th May 2008 at Column 705 per the Home Secretary, Jacqui Smith 'my decision takes into account issues such as public perception and the needs and consequences for policing priorities. There is a compelling case for us to act now rather than risk the future health of young people. Where there is a clear and serious problem, but doubt about the potential harm that will be caused, we must err on the side of caution and protect the public. I make no apology for that. I am not prepared to wait and see'

[31] House of Commons Hansard Debates for 9th February 2009 at Column 1094

There was very little public outcry, however, until October 2009 when Professor Nutt, the chairman of the ACMD was asked by the Government to resign his position for having given a speech which stated that alcohol and tobacco were more harmful than cannabis and ecstasy and which compared the dangers of ecstasy to the dangers of horse-riding. Professor Nutt's divisive speech merely repeated the findings of a study which he had made in 2007[32] and which had been widely reported at the time. The professor was asked to resign because the Home Secretary he felt that his speech had 'damaged efforts to give the public clear messages about the dangers of drugs'[33]. This decision was supported by both the Prime Minister and the Leader of the Opposition, both of whom endorsed the precautionary principle.

The public attention then turned to the issue of science versus politics and the newspapers were supportive of Professor Nutt with a groundswell of public support for his position; at the time of writing this report over 30,000 people have joined a face-book group named 'Support Professor David Nutt; we want an evidence based drug policy'. Likewise, so many other ACMD members supported Professor Nutt and resigned in solidarity with him - because, according to one member 'no self respecting scientist could serve'[34] on the Council - that, for a period, the ACMD was inquorate and unable to function.

Nevertheless, cannabis and ecstasy have remained classified and a new ACMD chairman has now been appointed; the ACMD work plan continues with a review of mephedrone and related cathinones underway. There has been some progress in the sense that the Home Secretary has entered into a joint statement with the remaining members of the ACMD about the importance of working together with them and promising not to prejudge their advice[35].

In terms of the future of the science versus politics debate in the UK, a Home Office review of the ACMD is yet to report and Professor Nutt has instituted an Independent Council On Drug Harms. This Council is intended to mirror the functions of the ACMD without being beholden to political whim and will be comprised only of scientists; the council will use a new risk assessment matrix of 18 criteria against substances and will be prepared to say that a substance is not sufficiently harmful to be controlled at all, even if it is scheduled at the UN level. On the other hand, there will be no legal requirement that the Government conscientiously consult with this Council as it must, by law, with the ACMD. Nevertheless, the decisions and evidence base for the decisions will be in the public domain and it is hoped by its proponents that by engaging the interest and viewpoint of the public the new Council could become an agent for change.

The Netherlands

The domestic legislative framework for the classification of substances in the Netherlands is the Opium Act. Substances are separated substances into two groups: Schedule I - for 'hard drugs' that pose a high risk to health e.g. rohypnol; and, Schedule II - for 'soft drugs' that pose a low risk to health e.g. cannabis and codeine.

[32] Development of a Rational Scale to Assess the Harm of Drugs of Potential Misuse. Nutt et al. The Lancet Vol 369 March 24, 2007
[33] Home Secretary Alan Johnson quoted in 'Drugs Adviser Sacked Over LSD Claims' The Independent 20th October 2009
[34] Les King quoted in 'Scientists Quit Government Drugs Body Over David Nutt Sacking' The Times 2nd November 2009
[35] http://drugs.homeoffice.gov.uk/Joint_Statement_-_ACMD__HSec.pdf

The Netherlands has demonstrated that it is possible to create new control models outside the UN schedules - the most notable of which is represented by the coffee shops – and that the resultant difficulties such as diplomatic pressure in international fora are not necessarily insurmountable.

The system in the Netherlands revolves around two organisations: the Committee for Assessment and Monitoring of New Drugs ('CAM'); and, The National Institute for Public Health and the Environment in the Netherlands ('RIVM').

CAM is appointed by the Ministry of Health and comprises experts selected on merit from amongst various disciplines including the field of policing, medicine, and law. CAM's role is to assess the harms and risks associated with different substances; it does not make recommendations about classification but only conveys its assessment to RIVM. CAM meets twice per year and deliberates as one group until there is consensus on an issue – it uses a harm index of 16 parameters and reviews the classification of medicinal products every 4 years.

The secretariat of the CAM is delegated to the RIVM (National Institute for Public Health and the Environment). The CAM secretariat organises, on request of the Minister of Health (VWS), the assessment procedure carried out by the CAM. The secretariat drafts the basic scientific document used in the assessment and summarizes the results of the drug assessment meeting of the experts of the CAM panel into a final report that contains recommendations, including on classification, for the Government to consider. Scientists affiliated to the RIVM are governmental officers funded by the state, but should be considered as independent scientists.

The Dutch Government considers RIVM's report and a decision on classification is taken by the Minister of Health together with the Minister of Justice – the Minister of Health will lead the decision. If the substance is already classified and the decision is merely that the substance should go from one list to another (as occurred recently with GHB) then parliamentary consent is not required albeit parliament will always have the ability to register dissent and ask questions. For substances which are to be newly classified, the Minister's decision requires the consent of Parliament.

RIVM recently undertook a risk assessment concerning the harmful effects of 17 drugs plus tobacco and alcohol. These 19 items were ranked according to their degree of harm by a panel of 19 scientific experts on the basis of three criteria: acute toxicity and chronic toxicity; potential for dependency; and, social harm at individual and population levels. The conclusion was that alcohol, tobacco, heroin, and crack-cocaine scored highly in terms of harm in the assessment whilst, for example LSD, magic mushrooms, and khat scored low in terms of harm. The Government of the Netherlands did not amend its drug policy to reflect these findings however, it has initiated a review of the classification system previously described.

As part of this review, the Dutch Government has expressed concern that the current system is not able to make rapid adjustments as drug issues and user groups change, new drugs are introduced, and the nature of drug-related crime develops. The Government has stated that it intends to review its traditional drug policy principles – realism, evidence-base, and proportionality - and move instead towards 'a more integrated, comprehensive approach, aimed at preventing, controlling and reducing crime, drug-related nuisance, harm to health and social harm, particularly among young people'[36]

[36] Letter to the President of the House of Representatives of the States General, Ab Klink et al, 11th September 2009 at 2.1

Once formulated, the new drug policy principles and objectives will be applied in light of the RIVM risk assessment report and particular attention given to whether to the utility of the current soft drug and hard drug schedules. To conflate the schedules would eliminate the distinction in criminal law between Schedule I and Schedule II drugs. On the other hand, consideration is being given to whether 3 or 4 Schedules with varying levels of control would be more appropriate. In particular it has been suggested that a third list which contains tobacco, cannabis, alcohol and khat might be a constructive grouping as it would allow depenalisation of the use of these substances whilst signalling that they are not a consumer product and that they are not risk-free. The key of the Dutch Government is to enable the system to respond rapidly to new trends in society, promote policy coherence, and suffer as little red tape as possible – a committee of experts is therefore being asked to look into the issue of the harm index and the required amendments to the Opium Act and a Ministerial Team is being established to affect complimentary change in the administrative structure.

The Bigger Picture

The question was posed in the seminar to what extent can national scheduling systems diverge from the UN system and the answer was clear from discussions throughout the day – divergence is limited only by the will, resources, or understanding of a particular State. Even arguable breaches of the Convention, such as the coffee shop system in the Netherlands, have not caused an insurmountable fallout. Although the 1961 Convention allows the use of Cannabis for research purposes and clinical trials (assuming that supply of medical cannabis in the Netherlands could be so described, which the INCB denies) it is fair to say that such research cannot go on indefinitely. Indeed participants heard how, every year, the INCB communicates to the Netherlands that there has been a breach of the convention and that the situation needs to be changed. The situation does not change and another letter is received the following year.

On the other hand, the irony is that many States fail to adhere to the Conventions because of their slavish attempts to adhere utterly – hence the situation previously discussed with ephedrine, Pentazocine, and Phenobarbytol.

However, it was clear that each set of expert scientific groups that had been considered - in the UK, the Netherlands, and at the international level - used a different harm index which took account of different variables and so the significance of these inconsistencies in implementation was mitigated a great deal. Discussing the ideal harm-index, it became apparent that at least within the confines of the seminar's expert participants, identifying a harm-assessment on which all could agree was an insurmountable task. Some major areas of dispute were as follows:

● How and whether to include social variables as harms i.e. the impact of: a criminal record; imprisonment; relationship breakdown; injury; crime; acquisitive crime; environmental damage; family adversity; economic cost; and, community damage.

● How and whether to factor in the harms created by prohibition including the fact that certain drugs phenomena would never have happened but for prohibition – it was said that crack would not have developed were it not for the fact that cocaine became such an expensive street product.

● How and whether to factor in economic costs and health costs i.e. health care, policing, and loss of economic activity due to absenteeism as compared to economic benefits such as the many

jobs created in policing and medicine etc which depend on the classification of controlled substances; it was suggested that factoring this employment aspect might be impossible.

● How to reflect the different harms attributable to the supply and demand sides e.g. it was said that on the one hand cannabis is relatively low risk for health, but then the supply side engages hardened criminals which engenders significant social costs.

● How and whether to factor in the benefits of various substances – not just their licit therapeutic potential where appropriate, but also the perceived therapeutic potential ascribed by many users who are self-medicating or using recreationally and also the community and identity enriching aspects of traditional uses.

● How to factor in things which are variable as opposed to things which are constant e.g. the social harms caused by a drug will be influenced by conditions in the particular country, whether the physiological harms of the drug will not.

● How and whether to factor in the variation in harms that are attributed to different kinds of use of a particular substance,

It was suggested that there should be a threshold of harmfulness before control can even be considered and that perhaps as alcohol and tobacco are legal, anything less harmful than these substances should be legal also.

It was queried whether it was helpful to have a vast harm index and some argued that the fewer the criteria, the more directly a relative judgment can be made. It was said that unless the assessors were truly independent of government, there would always be at least tacit pressure to formulate a particular recommendation. It was also said with the social, health, and other non-physiological harms, these assessments would often include value judgments that would skew the objectivity of the assessment. It was agreed that there has to be a move away from subjective measures and towards objective measures and that risk assessments should be regularly reviewed and updated.

Some participants pointed out that for the international mechanisms this discussion was somewhat pie in the sky because what criteria they can take into account is determined by the Conventions which restrict them only to medical and scientific issues and which do not, therefore allow representatives from other disciplines such as policing or law, to participate.

In terms of effecting any of these ideal harm-indexes, it was felt amongst the group in the main that the prospects of improving procedures of assessment were more positive than the prospects of changing structures.

<u>What Lessons can be learned about the apparent tension between scientific evidence and policy making</u>

The contentions around what is a representative and objective harm index suggests that many would be unhappy with the classification of substances even if these classifications were undertaken in accordance with the recommendations of the appropriate scientific committees. This realisation blunts the significance of the certain agreement among participants that consequent to the political, moral and philosophical considerations which in fact drive classification decisions, these decisions have a very tenuous relationship to the evidence.

Session 3: Conclusions: Achieving more Consistency and Rationality

What could be an agenda to move forward on these issues, at UN level and national levels, in the coming years?

Two potential agendas with which to move forward on the issue of the classification of controlled substances presented themselves to participants: 1) movement within the UN treaty system, and; 2) movement outside of the treaty system.

Within the UN Treaty System

It was considered imperative for the Conventions to be adapted to current scientific knowledge but to achieve this, State Parties would have to take ownership of the system, submitting information to the Secretary General to be sent on to WHO for a critical review to be undertaken of any substance under the 1961 or 1971 Conventions (for example cannabis) or to INCB for any substances under the 1988 Convention. It was felt that this would be a constructive, simple, and non-confrontational way to resolve some of the disputes that have become entrenched, for example, the issue of cannabis and particularly medicinal cannabis.

In the same way it was felt the Conventions could and should be adapted to greater utility. State Parties could seek to amend the Conventions by using the mechanisms contained within them to harmonise the scheduling criteria and processes of the conventions; on the other hand, it was felt by many that this option would require much greater conviction and effort on behalf of the State Party who proposed it and may have less traction taking into account the current political framework.

It was suggested that WHO, INCB, NGOs and others could seek to educate State Parties about the differences of meaning in the Schedules to the Convention and the opportunities contained within them to exempt substances from control and make substances available for licit scientific and medical uses. To actualise this education, it was felt that donors should be encouraged to facilitate the necessary capacity building in the requisite State Parties. The participants did not see any good reason why this suggestion could not be progressed.

INCB could and should be exploited to greater effect. It was noted that INCB had already undertaken good work on flagging scientific inconsistencies within the Conventions and measures for reform and it was felt that this work should be encouraged and used as a springboard to address the incoherence of the system. INCB certainly has the mandate, the position of respect and the voice with which to make this happen and many agreed that further work by and with this body in this field would be very constructive.

In a similar way, all parties could better highlight the issue of the availability of essential medicines which issue could be understood better and prioritised without requiring any change to the Conventions. It was felt progress in this area could be solidified if donor countries could be persuaded to earmark their contributions to support of the essential medicines programme.

The group also talked animatedly about terminating the Conventions and redrafting the classification and control system afresh, perhaps using as a model the WHO Framework Convention on Tobacco Control 2003 or (at the domestic level) the New Zealand ‘Class D’ regulation framework whereby there is the potential facility to place milder substances onto a 4th schedule whereby they could be bought by adults from special outlets. This was considered to be

the most interesting way forward and technical feasible; one would follow the Vienna Convention on the Law of Treaties 1969 which regulates the making of new treaties, the process could be facilitated by WHO, and on ratification the old Conventions would be put aside. The prospects of success of this option would depend very much, it was felt, on how many State Parties or UN Bodies were supportive, but without intense work or garnering such support, it was agreed that a new omnibus treaty was not perhaps a realistic aim in the current political environment.

Outside the UN Treaty System

Looking at the response of the INCB and the international community more generally to the experiments of particular State Parties outside the ambit of the Conventions (for example the experiments with cannabis supply in the Netherlands and the USA), it was felt that the difficulties experienced by these Parties as a result were not insurmountable and that this was a path that other States could follow if they wanted to reflect more respectfully their own domestic concerns and risk assessments. On the other hand, it was accepted that this was not perhaps an option for less affluent State Parties who are more dependent on donor countries.

It was suggested that Interested Parties could work with new and powerful partners, such as the pharmaceutical industry and donor countries, to affect or safeguard changes they wish to see rather than seek to persuade CND, WHO, or INCB on a particular issue.

The classification of drugs has a profound impact on the lives and well-being of individuals across the world and where the classification is incorrect, people suffer unnecessarily. Participants therefore felt that this is an issue that deserves greater public awareness and greater engagement with citizenry and that where such public awareness is in place (as in the United Kingdom) it should be galvanised in order to work towards a new democratic answer to this difficult situation. It was felt that if change was to occur it would ferment at national level and would not be realised from the top Vienna Level down. As diplomats receive their instructions from the capital, participants considered that lobbying should take place in the domestic context. It was noted that courage at the political level is certainly required, but many felt that politicians will advance if their constituency is supportive and that likewise, legal opinions follow political will. The need to engage public awareness on this issue further was therefore considered paramount.

New arguments could be harnessed to this end such as arguments about the footprint of drug policy both in environmental terms and otherwise. It was said that activists should look to other policy arenas for inspiration. It was noted that in the United Kingdom, the population appeared to be moved more by the destabilising impact of climate change on migration and conflict issues, than its impact upon the environment and, likewise, ineffective drug policies cause destabilisation, civil unrest, and migration also; the example of West Africa was given.

The Seminar ended on an optimistic note with the example of Bolivia's application to amend the status of the coca leaf on the 1961 Convention which, in itself, marks a break in the political deadlock earlier discussed and hopefully a move towards more States taking ownership of the treaty system. It is not yet known of course what the outcome of this application will be, but should the amendment be rejected, Bolivia would still have the option of withdrawing from the Convention and re-adhere with a reservation. What the consequences of such an action would be at the international level were debated: some felt they would not be grave and that the fall-out would be mitigated by the continuation of the Human Rights Obligations which would ensure

continued availability of essential medicines; others felt sure there would be huge conflict. Either way, it was agreed that such an action would create a new phase in international drug control and, as it will take only one State Party to affect such momentous change, the expert seminar ended on the bidding, 'he who dares wins'.

Conclusion

Time restrictions meant that the seminar could not explore the considerable variation of drug law offences and outcomes across Europe in detail, nor the scope of opportunities for decriminalisation and non-penalisation under the Conventions nor the potential templates presented by the WHO Framework Convention on Tobacco Control 2003 and the New Zealand models. Nevertheless, the panoply of control options was evident and it was felt that these were areas to which it would be instructive to return to in future seminars.

In conclusion, the Expert Seminar afforded a useful mechanism for knowledge exchange and networking and it is hoped that the new partnerships created will allow the openings noted in this area of work to be explored further and opportunities to make progress realised. It was suggested that the next Expert Seminar on this issue should be held in Vienna to facilitate the engagement of INCB and UNODC.

Genevieve Horwood, Rapporteur
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