Strategies for assessing chemically similar substances with similar properties

Agenda item 3.3

Expert Committee on Drug Dependence
Thirty-sixth Meeting
Geneva, 16-20 June 2014
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Under the Single Convention on Narcotic Drugs 1961 as amended by the 1972 protocol (referred to as 1961 Convention hereafter) and the Convention on Psychotropic Substances of 1971, WHO is responsible for the medical, scientific and public health evaluation of psychoactive substances. This mandate is supported by the Expert Committee on Drug Dependence (ECDD), which provides advice to the Director General, WHO. The evaluations are carried out according to the guidance provided in the WHO executive Board approved WHO Guidance on review of psychoactive substances for international control (2010). Article 3 of the 1961 Convention and article 3 of 1971 primarily describe the role of WHO in relation to changes in scope of control of substances.

The WHO review procedure, grounded in considerations of public health and with an evidence-based approach, utilizes the best available relevant information. Consistent with the requirements of the 1961 and 1971 Conventions, WHO develops scheduling recommendations guided by the provisions in the Conventions regarding the changes in the scope of control of substances and also taking into account the preambles of the Conventions, the need to reduce the risk to public health, including the risk of abuse and ensuring medical availability, and the relevant resolutions of its governing bodies. The Conventions are legal instruments; the WHO review procedure is applied in a manner consistent with the letter and the spirit of the Conventions.

26 substances are being assessed at the 36th meeting of the ECDD of which 25 are provisionally identified as critical reviews. Several of these are synthetic new psychoactive substances (NPS). There are currently close to 350 such substances identified by international monitoring systems. These belong to different chemical groups and there are many within each group. Currently available data indicate that of these only a few substances take root as substances of abuse. Of concern for WHO evaluation is the paucity of evidence for many, that is required to recommend international control. Data paucity is evident especially for the assessment of dependence potential, abuse liability and both individual and public health harm from these substances. There are very limited systematic studies and most available information are from case reports. The data situation is unlikely to improve in the immediate future. Many factors are responsible for this, including lack of laboratory capacity in many countries to identify these substances especially in the health care sector. Data related to criminal activities are also poor. Added to this is the current scenario where multiple substances are used (poly substance use) by individual user, making it difficult to assess harm due to individual substance.

However, there is evidence to show at least some of these substances cause significant harm. Also, many of these have no legitimate medical use and limited scientific and research use. There is increasing international concern over the proliferation and uncontrolled use of these substances in different parts of the world.
It is in this situation that NPS is being evaluated by ECDD. Possibility of scheduling groups of substances were considered. Conventions require scheduling of substances. This is understandable since it is difficult to list a chemical structure and implement this as an international law, especially considering the differing capacities in different parts of the world. WHO secretariat has short listed a few substances for evaluation from the hundreds on the market. The criteria used for this pre selection were data from UNODC and EMCDDA through their Early Warning systems that indicated misuse in some parts of the world and data from some toxicology labs where serious harm (deaths) where these substances were identified at least in some cases during the past 2-3yrs. A few frequently misused substances, were then selected to represent different chemical groups. Critical review reports were commissioned for each of these substances and these reports peer reviewed. Data paucity is apparent in some reports.

The 36th ECDD will consider whether all substances identified have sufficient data to make scheduling recommendations. It will also discuss how convention criteria can be applied in the data poor situation to come to a decision on scheduling. This is the first time scheduling of NPS is being discussed by ECDD and so the decisions made by the Committee will have to be followed up from an implementation point of view and impact on public health. Going forward, changes may need to be made based on these experiences to the pre selection process and scheduling considerations.

Ultimate aim of the Conventions is to protect and promote public health. The scheduling considerations for all substances especially NPS have to be evaluated from this perspective.