World Health Organization

EXECUTIVE BOARD
139th session
Provisional agenda item 9

EB139/12
27 May 2016

Report on meetings of expert committees and study groups[1]

Report by the Secretariat

SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS

Fiftieth report of the Expert Committee on Specifications for Pharmaceutical Preparations Geneva, 12–16 October 2015[2]

1. The Expert Committee on Specifications for Pharmaceutical Preparations advises the Director-General in the area of medicines' quality assurance. It provides independent expert recommendations and guidance to ensure that medicines meet standards of quality worldwide. Its advice is developed through a broad consensus-building process and covers all areas of quality assurance of medicines, from their development to their distribution to patients.

Main recommendations

2. In the area of quality control, the Expert Committee endorsed the document on good pharmacopoeial practices, which is the outcome of three years of international meetings of world pharmacopoeias organized by WHO. In 2015, those meetings were hosted by the United States Pharmacopeial Convention and the Chinese Pharmacopoeia Commission. The draft document was circulated widely for comments by users. The aim is to converge pharmacopoeial requirements in order to reduce the duplication of efforts and thus facilitate access to medicines. In addition, the Expert Committee provided advice on the plan for the new Phase 7 of the External Quality Assurance Assessment Scheme for quality control laboratories, adopted 22 new specifications and general texts for inclusion in *The International Pharmacopoeia* and adopted nine International Chemical Reference Substances established by the European Directorate for the Quality of Medicines and Health Care, which is the custodian centre for International Chemical Reference Substances.

3. In the various areas of quality assurance, the Expert Committee adopted new guidance on good data and record management, on good trade and distribution practices for pharmaceutical starting

[1] The Regulations for Expert Advisory Panels and Committees provide that the Director-General shall submit to the Executive Board a report on meetings of expert committees containing observations on the implications of the expert committee reports and recommendations on the follow-up action to be taken.

[2] WHO Technical Report Series, No. 996, 2016.

materials, on establishing national requirements for the regulation of variations to pharmaceutical products and on the conduct of medicines' quality surveys. It also adopted a guidance text developed in collaboration with the International Pharmaceutical Federation on the provision of children-specific preparations that are not available as authorized products.

4. The Expert Committee agreed to revise the collaborative procedure for the speedy registration of medicines that have been fully assessed and prequalified by WHO's Prequalification Team and to extend it to prequalified vaccines. Acknowledging the need for a model regulatory framework for medical devices, the Expert Committee discussed possibilities in this regard.

5. The Expert Committee revised the guidance on good manufacturing practices: inspection report, which includes a model inspection report, to reflect current practices. Furthermore, it adopted the revised guidance on good manufacturing practices for biological products, following the adoption of that guidance by the Expert Committee on Biological Standardization. In the area of multisource (generic) pharmaceutical products, the Expert Committee adopted a revision of the guidance for organizations performing in vivo bioequivalence studies.

Significance for public health policies

6. In 2015, the Expert Committee celebrated its fiftieth anniversary. Representatives of national regulatory authorities emphasized the importance and value of the Expert Committee's work for WHO Member States. The written and physical standards to test medicines for their quality, together with the wide range of guidelines, good practices and regulatory guidance in the area of medicines' quality assurance, are designed to: serve all Member States (especially their national and regional regulatory authorities), international organizations and the Interagency Pharmaceutical Coordination group and other entities in the United Nations system; support regional and interregional harmonization efforts; and underpin important public health initiatives, including the prequalification and procurement of quality medicines through international organizations such as UNICEF and major international bodies such as the Global Fund to Fight AIDS, Tuberculosis and Malaria. An illustrative example is the endorsement of the model quality assurance system for procurement agencies as an interagency publication in 2015.[1]

7. The Expert Committee responds to the increasing demands and international need in the area of medicines' quality assurance and the related regulatory aspects. Much of its work is intended to increase convergence in these areas and to facilitate efficient synergies among and within the respective authorities and pharmacopoeias and to reduce duplication of efforts and therefore costs.

8. The Expert Committee's deliberations cover the entire life cycle of medicines from their development to distribution to the patient, wherever he or she may be. The outcome is intended to protect patients and facilitate access to quality medicines.

Implications for the Organization's programmes

9. The Expert Committee responds to the needs of major public health interests as identified by other WHO programmes. Its outcomes and recommendations have broad implications for relationships within and between clusters, for links with regional offices, country offices and partnerships, and for

[1] WHO Technical Report Series, No. 986, Annexes 3 and 4, 2014.

the work of other WHO expert committees. This Expert Committee's work enables WHO to fulfil its constitutional mandate in the area of medicines' quality assurance and is of relevance for all those within WHO who are involved with medicines.

10. In particular, the Expert Committee serves WHO's Prequalification Team and its Regulatory Systems Strengthening Team. Both teams use the international guidelines, standards and specifications recommended by the Expert Committee. In return, they provide practical feedback to the Expert Committee through their direct links to those who implement its more than 80 guidelines, 700 specifications and 240 International Chemical Reference Substances.

11. On the basis of the Expert Committee's recommendations, WHO is in a position to offer technical scientific advice to all those dealing with the development, production, quality control, regulatory pathways, inspection, supply and procurement of medicines. WHO can provide tools to help ensure that quality medicines reach patients, which is one of the ways it contributes to the achievement of global health coverage.

12. The following guidelines, as contained in the Annexes to the Expert Committee's fiftieth report, were adopted and recommended for use:

- Annex 1: Good pharmacopoeial practices (new)
- Annex 2: International Pharmaceutical Federation–WHO technical guidelines: points to consider in the provision by health-care professionals of children-specific preparations that are not available as authorized products (new)
- Annex 3: Guidance on good manufacturing practices for biological products (revision), following its adoption by the Expert Committee on Biological Standardization on 16 October 2015
- Annex 4: Guidance on good manufacturing practices: inspection report, including a model report (revision)
- Annex 5: Guidance on good data and record management practices (new)
- Annex 6: Good trade and distribution practices for pharmaceutical starting materials (revision)
- Annex 7: Guidelines on the conduct of surveys of the quality of medicines (new)
- Annex 8: Collaborative procedure between WHO's Prequalification Team and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines (revision)
- Annex 9: Guidance for organizations performing in vivo bioequivalence studies (revision)
- Annex 10: WHO general guidance on variations to multisource pharmaceutical products (new).

BIOLOGICAL STANDARDIZATION

Sixty-sixth report of the Expert Committee on Biological Standardization Geneva, 12–16 October 2015[1]

13. The Expert Committee on Biological Standardization reviews developments in the field of biological substances used in human medicine, which include vaccines, biological therapeutics, blood products and related in vitro diagnostic devices. It coordinates activities leading to the adoption of recommendations for assuring the quality, safety and efficacy of such substances and the establishment of international reference materials.

Main recommendations

14. The use of international reference materials for designating the activity of biological substances used in prophylaxis or therapy, or for ensuring the reliability of quality control or diagnostic procedures, allows comparability of data worldwide. Based on the results of international collaborative laboratory studies, the Expert Committee established 17 new or replacement WHO international biological reference preparations. These are the primary calibrants against which regional or national measurement standards are benchmarked.[2]

15. The Expert Committee also adopted revised guidance on good manufacturing practices for biological products; revised recommendations to assure the quality, safety and efficacy of recombinant human papillomavirus virus-like particle vaccines; new guidelines on the stability evaluation of vaccines for use under extended controlled temperature conditions; and a new guidance document on the regulatory assessment of approved rDNA-derived biotherapeutics (biotherapeutic protein products prepared by recombinant DNA technology).

16. The Expert Committee endorsed plans for WHO to initiate a new process to conduct risk-benefit assessments of antivenoms intended for use in sub-Saharan Africa, with a view to posting on the WHO website a list of products that have a favourable risk-benefit profile.

17. The Expert Committee also provided advice to WHO on the written standards and reference preparations under development and on the plans for submission to the Expert Committee in 2016–2017.

Significance for public health policies

18. The standardization of biologicals has risen to be high on the agenda of Member States.[3] The work of the Expert Committee is directly relevant to this agenda.

19. Undertaking the regulatory assessment needed for dealing with situations where, for various reasons, rDNA-derived biotherapeutics have been licensed with data packages that do not follow

[1] WHO Technical Report Series, No. 999, 2016.

[2] An up-to-date list of WHO international biological reference preparations is available at http://www.who.int/bloodproducts/catalogue/en/ (accessed 23 March 2016).

[3] See resolution WHA67.21 (2014) on access to biotherapeutic products, including similar biotherapeutic products, and ensuring their quality, safety and efficacy.

current international regulatory standards for these biologicals has presented a challenge for many countries. The International Conference of Drug Regulatory Authorities discussed the matter and requested WHO to assist in developing approaches for evaluating these already-licensed products according to current WHO guidelines. The document on regulatory assessment of approved rDNA-derived biotherapeutics[1] responds to that request and, although it deals primarily with rDNA-derived biotherapeutics, some aspects may also be relevant to other biotherapeutics.

20. The Expert Committee established the first WHO reference reagent for Ebola virus antibodies and the first WHO reference reagents for Ebola virus RNA for nucleic acid amplification technology-based assays.[2] These reagents were developed and evaluated in a very short period of time in order to respond to the Ebola virus disease outbreak in West Africa, which constituted a public health emergency of international concern. The reagents provide stakeholders with internationally validated calibrants with which diagnostic tests and assay results from clinical trials can be expressed in a common unitage.

Implications for the Organization's programmes

21. The revision of the guidance on good manufacturing practices for biological products reflects the developments in science and technologies for the manufacture and control of biological products, taking into account the inherent variability that is characteristic of this essential and evolving class of medicinal products. In addition, the revision addressed the application of risk-based approaches to good manufacturing practices. The updated document ensures that WHO guidance remains fit for purpose and will facilitate access to biological products. Moreover, it defines the standards applied by the Organization's prequalification programme for vaccines.

22. Vaccines may undergo degradation during long-term storage under cold chain conditions (for example, at 2–8 °C), and this degradation is typically enhanced at higher temperatures. Consequently, establishing the stability characteristics of products is a critical element of the overall evaluation by national regulatory authorities to ensure that licensed vaccines remain efficacious at the end of their shelf-life when stored under the approved conditions. In response to the stability evaluation needs identified by national regulatory authorities, WHO developed guidelines on the stability evaluation of vaccines.[3] While it is well understood that vaccine quality depends on cold chain storage, it is also recognized that immunization programmes in certain regions face substantial challenges in maintaining cold chains in the field, especially during the final stage of distribution in remote areas. The new guidelines on the stability evaluation of vaccines for use under extended controlled temperature conditions[4] are a direct response to programmatic needs and establish the short-term performance of a vaccine at temperatures above those of a typical cold chain. Stability evaluation and subsequent labelling allow for greater flexibility in vaccination campaigns by reducing the burden on health-care workers, saving the costs of refrigeration infrastructure and eliminating the need for wet ice. Furthermore, this on-label approach, approved by national regulatory authorities, prevents the administration of off-label vaccines, which is inconsistent with official guidance on best practice.

[1] WHO Technical Report Series, No. 999, Annex 3, 2016.

[2] WHO Technical Report Series, No. 999, Annex 6, 2016.

[3] WHO Technical Report Series, No. 962, Annex 3, 2011.

[4] WHO Technical Report Series, No. 999, Annex 5, 2016.

EVALUATION OF CERTAIN FOOD ADDITIVES AND CONTAMINANTS

Eightieth report of the Joint FAO/WHO Expert Committee on Food Additives Rome, 16–25 June 2015[1]

Main recommendations

23. The report contains the Expert Committee's evaluations of technical, toxicological and dietary exposure data for seven food additives (benzoates; lipase from *Fusarium heterosporum* expressed in *Ogataea polymorpha*; magnesium stearate; maltotetraohydrolase from *Pseudomonas stutzeri* expressed in *Bacillus licheniformis*; mixed β-glucanase, cellulase and xylanase from *Rasamsonia emersonii*; mixed β-glucanase and xylanase from *Disporotrichum dimorphosporum*; and polyvinyl alcohol (PVA) – polyethylene glycol (PEG) graft copolymer) and two groups of contaminants (non-dioxin-like polychlorinated biphenyls and pyrrolizidine alkaloids).

24. Specifications for the following food additives were revised or withdrawn: advantame; annatto extracts (solvent-extracted bixin and solvent-extracted norbixin); food additives containing aluminium and/or silicon (aluminium silicate; calcium aluminium silicate; calcium silicate; silicon dioxide, amorphous; and sodium aluminium silicate); and glycerol ester of gum rosin.

25. The report presents general considerations and guidance, in particular on improvements in the assessment of the potential allergenicity of enzymes and on the application of systematic review methodology to the work of the Expert Committee.

26. The assessments, recommendations and comments by the Expert Committee will be discussed by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Food, in order to provide recommendations to national authorities on the safe use of these food additives and on addressing health concerns regarding the contaminants, and to identify and recommend appropriate risk management and risk-mitigation measures to reduce human exposure, where necessary.

27. WHO has published detailed monographs in the WHO Food Additives Series of the toxicological and other related information upon which the safety assessments of the compounds were based.[2] FAO publishes summaries of the identity and purity of food additives.

[1] WHO Technical Report Series, No. 995, 2016.

[2] Safety evaluation of certain food additives and contaminants. WHO Food Additives Series, No. 71, 2015. Toxicological monographs of the eightieth meeting. For further information on the WHO Food Additives Series see http://www.who.int/foodsafety/publications/monographs/en/, accessed 26 April 2016.

EVALUATION OF CERTAIN VETERINARY DRUG RESIDUES IN FOOD

Eighty-first report of the Joint FAO/WHO Expert Committee on Food Additives Rome, 17–26 November 2015[1]

Main recommendations

28. The Expert Committee assessed the safety of residues of five veterinary drugs when used for food-producing animals and in accordance with good veterinary practices and responded to specific concerns raised by the Codex Committee on Residues of Veterinary Drugs in Foods regarding one coccidiostat. Acceptable daily intake values for these drugs were established and maximum residue limits that are compatible with human health were recommended for specified animal species and tissues.

29. The report also presents general considerations and guidance, in particular on improved risk assessment methodologies relating to acute health effects and improved exposure assessments, and on the establishment of maximum residue limits for fish species.

30. The assessments, recommendations and comments provided by the Expert Committee will be discussed by the Codex Committee on Residues of Veterinary Drugs in Food and will result in the identification of appropriate risk management and risk-mitigation measures to reduce human exposure where necessary, and in recommendations to national authorities for the safe use of these veterinary drugs in food producing animals.

31. WHO will publish detailed monographs of the toxicological and other related information upon which the safety assessments of the compounds were made.[2] FAO publishes detailed residue monographs.

Significance for public health policies[3]

32. The Expert Committee identifies and, if possible, quantifies the public health significance of exposure to chemicals in food – in these cases, food additives and contaminants, and residues of veterinary drugs – through scientific risk assessment based on international consensus. When a health concern is identified, clear recommendations are issued for action by national governments or through the FAO/WHO Food Standards Programme (the Codex Alimentarius Commission and its subsidiary bodies).

33. All Member States face the problem of assessing potential risks of chemicals in food; however, only a few scientific institutions systematically assess, on a national or regional basis, all relevant toxicological, epidemiological and related data. It is therefore important that the reports of the Expert Committee provide Member States with valid information on both the general aspects of risk assessment and the specific evaluations of the veterinary drugs, food additives and food contaminants

[1] WHO Technical Report Series, No. 997, 2016.

[2] See WHO Food Additives Series at http://www.who.int/foodsafety/publications/monographs/en/, accessed 26 April 2016.

[3] This section is relevant to both the eightieth and the eighty-first reports of the Joint FAO/WHO Expert Committee on Food Additives.

mentioned. The Expert Committee's work, in its complexity and in reaching an international consensus on the evaluation of these compounds, is unique in its importance for and impact on global public health decisions related to food safety.

34. The Expert Committee's recommendations are used by the Codex Alimentarius Commission in the development of international food safety standards and other guidance and recommendations. Such standards are science-based and are established only for substances that have been evaluated by the Expert Committee. This ensures that food commodities that are traded internationally meet strict safety standards, to protect the health of the consumer and ensure fair practices in food trade.

35. The advice provided by the Expert Committee is also considered by Member States directly when national or regional food safety standards are being established.

Implications for the Organization's programmes[1]

36. The evaluation of chemicals in food by the Expert Committee is an ongoing activity. Three meetings of the Expert Committee were held in 2014–2015: one in June 2014 and the two mentioned in the present report in 2015.

37. WHO is a partner in the Joint FAO/WHO Food Standards Programme, whose principal organ is the Codex Alimentarius Commission. In its capacity to assure the sound scientific basis for international standards and recommendations on food additives and contaminants in food, the work of the Expert Committee is crucial to the work of the Codex Alimentarius Commission.

38. The Committee's evaluations are also used by Heads of WHO offices in countries, territories and areas and by regional offices when advice is provided to Member States on food safety issues.

EXPERT COMMITTEE ON DRUG DEPENDENCE

Thirty-seventh report of the Expert Committee on Drug Dependence Geneva, 16–20 November 2015[2]

39. The Expert Committee on Drug Dependence was composed of 13 experts from the six WHO regions. Meeting participants also included advisers to the Secretariat and observers from UNODC and the International Narcotics Control Board. Nine substances were assessed and recommendations for placing seven psychoactive substances under international control were conveyed to the Commission on Narcotic Drugs, which made the final decision on scheduling in March 2016.

[1] This section is relevant to both the eightieth and the eighty-first reports of the Joint FAO/WHO Expert Committee on Food Additives.

[2] WHO Technical Report Series, No. 998.

Main recommendations

40. The Expert Committee recommended that the substances listed below be placed under international control:

(a) in Schedule I and Schedule IV of the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol :

- acetylfentanyl, chemical name *N*-phenyl-*N*-[1-(2-phenylethyl)-4-piperidinyl]acetamide

(b) in Schedule I of the 1961 Convention:

- MT-45, chemical name 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine

(c) in Schedule I of the Convention on Psychotropic Substances, 1971:

- *para*-methoxymethylamphetamine (PMMA), chemical name 1-(4-methoxyphenyl)-*N*-methylpropan-2-amine

(d) in Schedule II of the 1971 Convention:

- α-pyrrolidinovalerophenone (α-PVP), chemical name 1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one

- *para*-Methyl-4-methylaminorex (4,4'-DMAR), chemical name 4-methyl-5-(4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine

- methoxetamine (MXE), chemical name 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexanone

(e) in Schedule IV of the 1971 Convention:

- phenazepam, chemical name 7-bromo-5-(2-chlorophenyl)-1,3-dihydro-2*H*-1,4-benzodiazepin-2-one.

41. **The Expert Committee recommended that the following substance not be placed under international control**:

- 4-fluoroamphetamine (4-FA), chemical name 1-(4-fluorophenyl)propan-2-amine.

Owing to the current insufficiency of data regarding dependence, abuse and risks to public health (including risks to the individual), the Expert Committee recommended that 4-FA not be placed under international control at this time, but be kept under surveillance.

42. **For psychoactive substances for which pre-reviews[1] were carried out, the Expert Committee recommended that a critical review[2] is warranted for**:

- etizolam, chemical name 4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine.

Based on the evidence available regarding dependence, abuse and risks to public health, the Expert Committee recommended that a critical review of etizolam is warranted for a future meeting. The Expert Committee noted deficiencies in information and suggested several potential sources that could be helpful in the preparation of the critical review, including reports on road traffic injuries, seizure data, user forums and pharmacovigilance data.

Update on cannabis

43. In its resolution 52/5 (2009), the Commission on Narcotic Drugs stated that it looked forward to "an updated report on cannabis by the Expert Committee, subject to the availability of extrabudgetary resources". In its report for 2014, the International Narcotics Control Board reiterated "its invitation to WHO to evaluate the potential medical utility of cannabis and the extent to which cannabis poses a risk to human health." Accordingly, WHO commissioned an update report on cannabis and cannabis resin.[3]

44. An update on the scientific literature on cannabis was presented and reviewed during the meeting, covering pharmacology, toxicology and the claimed therapeutic applications. The Expert Committee then deliberated on the content of the material presented. The Expert Committee requested that the Secretariat begin collecting data with a view to carrying out a pre-review of cannabis, cannabis resin and extracts and tinctures of cannabis at a future meeting. Furthermore, it specifically requested that the Secretariat place emphasis on any therapeutic advantages that these substances may have, relative to other existing therapeutics.

Update on ketamine

45. Updates on ketamine were presented, in which the levels and consequences of its abuse and new potential medical applications were identified. Levels of ketamine abuse appeared to be declining in many countries worldwide. Potential new therapeutic uses were identified, including for depression and refractory status epilepticus. The use of ketamine for treating depression is under evaluation in Phase III clinical studies.

46. Ketamine is widely used as an anaesthetic agent in human and veterinary medicine globally. Ketamine is the anaesthetic agent of choice in low-income countries and in emergency situations where there are shortages of trained medical personnel and anaesthesia machines and inconsistent sources of electricity.

[1] **Pre-review**: An initial review to determine whether a critical review is warranted ("the purpose of the pre-review is to determine whether current information justifies an Expert Committee critical review").

[2] **Critical review:** A review to make decisions on scheduling or a change in scheduling ("is to consider whether the Expert Committee should advise the Director-General to recommend the scheduling of, or amending of the scheduling status of, a substance").

[3] For more information, see http://www.who.int/medicines/access/controlled-substances/ecdd/en/ (accessed 6 May 2016).

47. Following its deliberations, the Expert Committee unanimously agreed that it found nothing in the updates, nor in the information that was disclosed during its deliberations, that would give it reason to recommend a new pre-review or critical review of ketamine with a view potentially to changing its standing recommendation of 2014 that ketamine should not be placed under international control.

Other matters

48. The Expert Committee agreed to establish an informal working group to discuss the terminology used in its reviews and the guidance on the WHO review of psychoactive substances for international control. The working group will also explore efficient mechanisms for the prioritization and assessment of new psychoactive substances by the Expert Committee.

Significance for public health policies

49. The substances that were recommended for scheduling by the Expert Committee at its thirty-seventh meeting were considered to present risks in terms of abuse, dependence and public health.

50. One substance that is liable to similar abuse and productive of similar ill-effects as the substances in Schedule I and that is particularly liable to abuse and to produce ill-effects, with such liability not being offset by substantial therapeutic advantages not possessed by substances other than drugs in Schedule IV of the 1961 Convention, has been placed in Schedule I and Schedule IV of that Convention.

51. One substance that is liable to similar abuse and productive of similar ill-effects as the substances in Schedule I has been placed in Schedule I of the 1961 Convention.

52. One substance that presents especially serious public health risks has been placed in Schedule I of the 1971 Convention, and three substances that present substantial public health risks have been placed in Schedule II of that Convention.

53. One substance, which liability to abuse constitutes a substantial risk to public health and which has moderate to great therapeutic usefulness, has been placed in Schedule IV of the 1971 Convention.

54. Etizolam and phenazepam, which are substances with a medical use, were pre-reviewed.

55. Etizolam has pharmacological effects similar to those of the model benzodiazepine, diazepam, which is in Schedule IV of the 1971 Convention. Based on the evidence available regarding dependence, abuse and risks to public health, the Expert Committee recommended that a critical review of etizolam is warranted for a future meeting. Phenazepam belongs to the 1,4-benzodiazepines, the same family to which diazepam, oxazepam and temazepam belong, and it has a structural resemblance to diazepam, which is in Schedule IV of the 1971 Convention. Phenazepam has been in clinical use since 1978, primarily in the Russian Federation, to treat epilepsy, insomnia and alcohol withdrawal syndrome, for the short-term treatment of anxiety disorders (panic attacks), and as premedication prior to surgery, as it enhances the effects of anaesthetics while reducing anxiety.

56. The Expert Committee undertook a pre-review of phenazepam and considered that the information provided in the pre-review report was sufficient and indicated that dependence and harm caused by phenazepam was of such magnitude that proceeding directly into critical review within the meeting was warranted. All procedural requirements for a critical review, including two peer reviews, were fulfilled. Phenazepam has been shown to have effects similar to diazepam, which is in Schedule

IV of the 1971 Convention. The Expert Committee considered that the degree of risk to public health and society associated with the abuse of phenazepam has a smaller but still significant risk to public health compared to the substances in Schedules I–III. The Expert Committee considered that the evidence of its abuse warranted its placement under international control. It further recommended that phenazepam be placed in Schedule IV of the 1971 Convention.

Implications for the Organization's programmes

57. A Note Verbale from the Director-General of WHO to the United Nations Secretary-General conveyed the recommendations of the Expert Committee on the scheduling of seven substances, and these recommendations were submitted to the Commission on Narcotic Drugs for further decision.

58. In March 2016, at its fifty-ninth session, the Commission on Narcotic Drugs decided to include all the substances in the Schedules of the relevant Conventions,[1] in accordance with WHO's recommendations.

59. A list of the 11 substances that the Expert Committee has recommended be kept under surveillance is published on the WHO website.[2] These substances will be considered as a part of the prioritization process for the thirty-eighth meeting of the Expert Committee.

60. Owing to the high number of new psychoactive substances recently identified, work continues on defining relevant criteria for the prioritization of new psychoactive substances for assessment by the Expert Committee. This will ensure that the Expert Committee reviews priority substances for which sufficient robust data are available.

61. The third WHO–UNODC Expert Consultation on New Psychoactive Substances took place on 3–4 May 2016, with the aim of reviewing criteria for prioritizing new psychoactive substances to be assessed by the Expert Committee. The Expert Consultation sought to explore practical ways of prioritizing international action on the most prevalent, persistent and harmful new psychoactive substances and included: a review of current mechanisms for collecting data on new psychoactive substances, including data on harm to public health, and discussions on ways to improve those mechanisms; consideration of the mechanisms available for sharing information and of ways to strengthen coordination at the national, regional and international levels; and discussions on existing and future tools for enhancing surveillance of the most prevalent, persistent and harmful new psychoactive substances.

[1] See the relevant decisions of the Commission on Narcotic Drugs: decision 59/1, decision 59/3, decision 59/4, decision 59/5, decision 59/6, and decision 59/7. For more information, see the Report on the fifty-ninth session of the United Nations Commission on Narcotic Drugs, at: https://www.unodc.org/documents/commissions/CND/CND_Sessions/CND_59/E2016_28_Advance_unedited_19042016.pdf (accessed 6 May 2016).

[2] http://www.who.int/medicines/access/controlled-substances/Substances_under_surveillance.pdf?ua=1, accessed 28 April 2016.

62. Preparations are in place for the thirty-eighth meeting of the Expert Committee, which will take place during the course of 2016. A thorough prioritization process, with support and data from UNODC, the International Narcotics Control Board, the European Monitoring Centre for Drugs and Drug Addiction and Member States, will be carried out and will inform the reviews to be carried out by the Expert Committee.

ACTION BY THE EXECUTIVE BOARD

63. The Board is invited to note the report.

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