
Matters for information: report on meetings of expert committees and study groups¹

Report by the Director-General

Biological standardization

Eighty-first report of the Expert Committee on Biological Standardization, hybrid meeting,² 13–16 October 2025³

Main recommendations

1. The Committee recommended the adoption of the WHO Guidelines on the replacement or removal of animal tests for the quality control of biological products. The Committee reiterated its strong support for this milestone document and related WHO leadership initiatives in this evolving and increasingly high-profile area.
2. The Committee expressed its support for the development of future such WHO recommendations, guidelines and other guidance documents in line with currently identified global public health needs. The Committee also welcomed the Organization's recent efforts to more widely communicate the process used to prioritize the development of these vital resources.
3. The Committee recommended the preparation of 17 new or replacement WHO biological reference materials for biological products for use in manufacturing and regulatory control laboratories worldwide and endorsed the proposed development of nine future such specialized reference materials.

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 In-person attendance by Committee members and WHO Secretariat at the WHO Training Centre, Tunis, with virtual attendance of other participants.

³ WHO Technical Report Series (forthcoming 2026).

Significance for public health policies

4. The new WHO Guidelines on the replacement or removal of animal tests for the quality control of biological products will directly support the progress now being made in the development and use of non-animal in vitro methods as alternatives to animal testing, which is often highly variable and time-consuming. Such increasingly sophisticated non-animal methods can substantially reduce the time and resources needed to ensure the quality, safety and efficacy of licensed biological products. This in turn will facilitate more timely and equitable access to high-quality vaccines, biotherapeutics and other vitally needed biological products worldwide.
5. The preparation of the 17 new or replacement WHO biological reference materials recommended will similarly facilitate broader and more equitable access to biological products of assured quality, safety and efficacy. In addition, the availability of these highly specialized reference materials will support efforts to strengthen national, regional and global regulatory systems, while also underpinning the vitally important work of the Organization's prequalification programme for biological products and related in vitro devices.

Implications for the Organization's programmes

6. The Committee's support for currently identified WHO priorities in the development of WHO recommendations, guidelines and other published guidance on biological products is key to ensuring that WHO technical support for the manufacture, evaluation and regulatory approval of biological products remains relevant and up to date.
7. The Committee's recommendation to prepare 17 new or replacement WHO biological reference materials supports a core normative activity of WHO, as set out in its Constitution. In addition, the endorsement by the Committee of the proposed development of nine further priority WHO biological reference materials will facilitate their timely availability, just as the innovative new and improved biological products to which they refer come on line. The development and distribution of such reference materials thus directly support the work of the numerous programmes and initiatives within WHO and other international organizations that rely on the availability of vaccines, biotherapeutics and other biological products to address both existing and emerging global health priorities.

Evaluation of certain contaminants in food

One hundred and first report of the Joint FAO/WHO Expert Committee on Food Additives, Geneva, 15–21 October 2025⁴

Main recommendations

8. The one hundred and first report of the Joint FAO/WHO Expert Committee on Food Additives contains the Committee's evaluations of technical, toxicological and epidemiological data, including with regard to the occurrence of and dietary exposure to one food contaminant.
9. The Committee assessed the safety of certain food contaminants, specifically inorganic and organic arsenic species, and exposure to them. Arsenic is on the Committee's priority list of

⁴ WHO Technical Report Series, No. 1061 (in press).

contaminants for evaluation, which was last amended at the Eighteenth Session of the Codex Committee on Contaminants in Foods.

10. The Committee's assessments, recommendations and comments will be discussed by the Codex Committee with a view to producing recommendations for national authorities on risk-management and risk-mitigation measures to reduce human exposure.

11. WHO will publish detailed monographs in the WHO Food Additives Series containing the toxicological and related information on which the safety assessments for the compounds in question are based.⁵ FAO publishes summaries of the identity of contaminants in food.

Significance for public health policies

12. The Committee identifies and, where possible, quantifies the public health significance of exposure to chemicals in food – in this case, inorganic and organic arsenic species – through scientific risk assessments based on international consensus. When a health concern is identified, clear recommendations are issued for action by national governments or through the relevant organs of the Joint FAO/WHO Food Standards Programme.

13. The 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 Committee. This ensures that internationally traded food commodities meet strict safety standards to protect the health of consumers and ensure fair practices in food trade.

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

15. Given its complexity, and because it involves reaching an international scientific consensus on the evaluation of these compounds, the Committee's work has unique importance for and impact on global public health decisions related to food safety.

Implications for the Organization's programmes

16. The evaluation of chemicals in food by the Committee is an ongoing activity. The Committee held three meetings in the 2024–2025 biennium.⁶ Two of these meetings focused on evaluating the safety of food additives and one on contaminants in food.

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

18. 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.

⁵ Safety evaluation of certain food additives. WHO Food Additives Series, No. 92. Toxicological monographs of the one hundred and first meeting (in press).

⁶ Further information is available on the [Committee's website](#) (accessed 28 August 2025).

Drug dependence

Forty-eighth report of the Expert Committee on Drug Dependence, Geneva, 20–22 October 2025⁷

Main recommendations

19. At its forty-eighth session, the WHO Expert Committee on Drug Dependence reviewed three novel psychoactive substances: one synthetic cannabinoid and two novel synthetic opioids. None had previously undergone formal WHO review, and none are currently under international control. Following scientific assessment, the Committee recommended that the two novel synthetic opioids be placed under international control pursuant to the Single Convention on Narcotic Drugs, 1961. These opioids have no recognized therapeutic use and present a high risk of substantial harm, including fatal overdose. The Committee further recommended that the synthetic cannabinoid be placed under international control pursuant to the Convention on Psychotropic Substances, 1971.

20. In addition, the Committee reviewed coca leaf, following formal notification by a Party to the 1961 Convention regarding its scheduling status. The scientific assessment process began in 2023 upon receipt of the notification and concluded with recommendations being submitted to the Secretary-General of the United Nations. The Committee determined that traditional use of coca leaf does not appear to pose a serious public health risk. However, because coca leaf can be readily processed into coca paste and cocaine, it meets the criteria for retention in Schedule I of the 1961 Convention.

Significance for public health policies

21. The new psychoactive substances recommended for international control by the Committee have no therapeutic use and have contributed to substantial numbers of deaths by overdose, in addition to other significant harm to public health. Placing them under international control will restrict their availability for use and oblige Member States to implement national controls for these substances to protect public health.

22. The Organization's mandate to assess psychoactive substances and make recommendations to the United Nations Commission on Narcotic Drugs ensures that a science-driven methodology informs the international control of psychoactive substances. Its public health mandate under the international drug control conventions ensures that psychoactive substances that cause harm to public health are appropriately regulated, and that excessive drug control measures are not placed on substances that have recognized therapeutic use.

Implications for the Organization's programmes

23. Novel synthetic drugs, particularly synthetic opioids, are falsely sold as medicines and may pose threats to the health of individuals. The Organization's work to tackle the problem of substandard and falsified medical products, including the WHO Global Surveillance and Monitoring System, should facilitate detection of these dangerous substances and falsified medicines. The

⁷ WHO Technical Report Series (forthcoming in 2026).

WHO–UNODC Stop Overdose Safely (S-O-S) initiative is also critical in reducing overdose deaths and promoting the use of medications like naloxone.

24. Substances under international control must remain available for legitimate medical and scientific purposes. While evidence remains limited, the Committee noted potential therapeutic applications of coca leaf and acknowledged its cultural and therapeutic importance for Indigenous Peoples and certain communities. The WHO Secretariat will therefore continue internal collaboration to strengthen the scientific evidence base for coca leaf in traditional medical contexts, including and alongside engagement with the Global traditional medicine strategy 2025–2034 and the Global Plan of Action on the Health of Indigenous Peoples.

Specifications for pharmaceutical preparations

Fifty-ninth report of the Expert Committee on Specifications for Pharmaceutical Preparations, hybrid meeting,⁸ 20–24 October 2025

Main recommendations

25. The Committee recommended the adoption of 15 new and revised specifications and general texts for inclusion in The International Pharmacopoeia and three International Chemical Reference Substances. The Committee advised continuing the External Quality Assurance Assessment Scheme for quality control laboratories, including the post-assessment assistance programme.

26. The Committee recommended the adoption of the following guidelines and guidance texts:

- (a) WHO points to consider in continuous manufacturing of pharmaceutical products;
- (b) International Atomic Energy Agency/WHO guidelines on good practices for quality control of in-house radiopharmaceutical preparations;
- (c) Procedure for prequalification of pharmaceutical products;
- (d) WHO listing of quality control laboratories: procedure for assessing the acceptability, in principle, of quality control laboratories for use by United Nations agencies;
- (e) WHO/United Nations Population Fund specifications for personal lubricants;
- (f) Development of paediatric medicines: points to consider in formulation;
- (g) Good regulatory practices for market surveillance and control of medical products;
- (h) Regulatory considerations for the life cycle of medicinal oxygen; and
- (i) WHO Biowaiver List: proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms.

⁸ In-person attendance by Committee members and WHO Secretariat at the WHO Training Centre, Tunis, with virtual attendance of other participants.

Significance for public health policies

27. The Committee provides a wide spectrum of written and reference standards to enable medicines to be tested for quality during their life cycle. It also recommends regulatory guidelines of importance to multisource medicines designed to be used globally, including in low-income settings. The outcome is intended to protect patients and facilitate access to good-quality medicines. These quality standards and guidelines are designed to serve all Member States, in particular their national and regional regulatory authorities, as well as entities of the United Nations system and regional and interregional harmonization efforts, and to underpin important public health initiatives, including the prequalification and procurement of good-quality medicines through major international bodies, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, and international organizations such as UNICEF.

Implications for the Organization's programmes

28. The outcome and recommendations of this Committee have broad relationships and links within and across regional offices, country offices and partnerships and with other WHO expert committees. In particular, the Committee serves the WHO Secretariat teams dealing with the prequalification of medicines and strengthening of regulatory systems by ensuring the availability of the Organization's international guidelines, standards and specifications. The Committee provides norms and standards to determine the quality of medicines globally and thus assists WHO in fulfilling its normative role.

Action by the Executive Board

29. The Executive Board is invited to take note of the report and of the Expert Committees' recommendations, recognizing them as part of WHO's normative function to set and maintain globally applicable standards and regulatory guidance for medicines and biological products, to be used by Member States and the Secretariat in their implementation and regulatory strengthening activities. It is also invited to consider the questions set out below:

- What actions should be taken across the Organization to support WHO's mandate to ensure that psychoactive substances with therapeutic use are safely available while protecting against harms to public health arising from their non-medical use?
- In the light of the current resource constraints within WHO, what efficiency measures should the Organization consider while maintaining the scientific input essential for the Codex General Subject Committees to fulfil their mandates?
