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Meeting Report

Informal consultation on WHO Recommendations for the preparation, characterization, establishment and use of WHO international biological reference preparations

Virtual meeting

22-24 September 2025

World Health Organization

Overview

In response to requests from the field, WHO initiated the revision of Annex 2 of WHO Technical Report Series No. 932 to update the Recommendations on the preparation, characterization, establishment and use of international biological reference preparations (IBRP), reflecting scientific and regulatory advances since the previous revision in 2004. Following expert drafting group work and a first round of public consultation, a fourth draft of the revised Recommendations was developed. To further refine the document and obtain feedback from stakeholders, WHO convened a virtual informal consultation on 22–24 September 2025 with representatives from regulatory authorities, manufacturers, pharmacopoeias, standard-setting bodies and other stakeholders. Participants exchanged perspectives on the use of WHO IBRP, reviewed the draft document and discussed key issues requiring clarification, including terminology, principles of biological standardization, metrological aspects, commutability, and lifecycle considerations for IBRP, as well as the responsibilities of users, including manufacturers. Consensus was reached on a number of amendments to strengthen clarity, alignment with international practice and practical applicability. The outcomes of this meeting have informed further improvement of the revised Recommendations, towards final submission to the WHO Expert Committee on Biological Standardization.

Session I: Opening of the meeting

The meeting was opened by Dr Ivana Knezevic (WHO), who delivered the welcoming remarks. Dr Paul Stickings (Medicines and Healthcare products Regulatory Agency) served as chair, and Dr Micha Nübling (consultant) acted as rapporteur. Dr Tiequn Zhou (WHO) informed participants that the assessment of the WHO Declarations of Interest had identified no potential conflicts of interest. She then introduced the background, objectives and expected outcomes of the meeting. WHO has played a key role for more than 70 years in establishing the international biological reference preparations (IBRP) to standardize vaccines and other biological substances, and in developing WHO written standards (such as guidelines and recommendations) to ensure the quality, safety and efficacy of biological products. WHO provides biological reference preparations to scientific communities, manufacturers of biological products, and national control laboratories around the world, which serve as reference sources of defined biological activity expressed in an internationally agreed unit. These preparations form the basis for a uniform system of reporting, enabling physicians, scientists, regulatory authorities, and manufacturers to communicate using a common language when designating the activity or potency of biological preparations used in prophylaxis or therapy. They also support the reliability of in vitro biological diagnostic procedures used for disease diagnosis and treatment monitoring. The WHO biological reference materials are established following a standardized development procedure, as described in the WHO Recommendations for the Preparation, Characterization and Establishment of International and Other Biological Reference Standards (revised 2004), published as Annex 2 of the WHO Technical Report Series (TRS) No. 932 [1] (hereinafter referred to as the “Recommendations”).

The use of IBRP has played a critical role in ensuring the quality of biological products over the past decades; however, the concepts, types, uses and other aspects of these preparations have continued to expand and evolve with technological advances in the manufacture and

testing of biological products. Important issues and questions have been raised from stakeholders on various occasions regarding the rationale, selection, development, distribution and use of reference preparations, for example: global harmonization of terminology, response to public health emergencies, commutability, stability testing, assignment of unitage to different assays, continuity of units, appropriate uses of IBRP, and potential impacts following replacement of IBRP.

WHO has been requested to revise the current Recommendations [1] to provide harmonized, up-to-date information to guide the development and use of IBRP, particularly International Standards (IS). In 2024, WHO initiated the revision of Annex 2 of the WHO TRS No. 932, including engagement of experts to review existing relevant documents and information, identify key issues, and conduct informal discussions with WHO Collaborating Centers and custodian laboratories. A drafting group, composed of experts from WHO custodian laboratories and WHO Collaborating Centers, was convened by WHO and worked intensively on the revision of the document through physical and virtual meeting(s). A series of drafts were prepared by the drafting group; the previous Draft 3 of the revision underwent public consultation during May to June 2025, during which 150 comments were received from 19 stakeholders. These comments were reviewed and addressed by the drafting group in the current Draft 4, which was circulated to meeting participants at the beginning of September 2025 and formed the basis for discussion at this informal consultation meeting during 22 to 24 September (13:30- 17:00 CEST each day).

Invited participants in the meeting included representatives from manufacturers, national regulatory authorities, pharmacopoeias, standard-setting bodies, and international alliances, societies, and expert groups involved in standards and standardization activities. The objectives of this meeting were: to exchange perspectives from stakeholders on the subject including the role and use of WHO IBRP; to review Draft 4 of the Recommendations for the preparation, characterization, establishment and use of WHO IBRP; and to discuss key issues from the first round of public consultation to identify gaps and propose improvements. The expected outcomes were that consensus would be reached on the content of the proposed Recommendations and that improvements would be proposed towards finalizing the document for submission to ECBS for consideration/adoption at its meeting in April 2026.

In the capacity of the Secretary of the Expert Committee on Biological Standardization (ECBS), Dr Knezevic gave an update on the recent and future WHO activities in the area of biologicals. Biological standardization is one of the core activities defined in WHO constitution [2]. The work is accomplished through WHO biological programme, WHO Collaborating Centers, and the WHO ECBS. This work also involves close collaboration with international scientific and professional communities, regional and national regulatory authorities, manufacturers, and expert laboratories worldwide. Updates on organizational changes at WHO were presented. In the context of the development and implementation of WHO written and measurement standards, Dr Knezevic emphasized the importance of the Recommendations for biological reference preparations as a master document for measurement standards established by the WHO ECBS. It is expected that the revised document will facilitate future development and use of WHO standards for biologicals.

Session II: Perspectives from regulators, manufacturers and other stakeholders on the role and use of WHO international standards

Dr Mihaela Buda (European Directorate for the Quality of Medicines and HealthCare, EDQM) presented a brief introduction to the European Pharmacopoeia and highlighted key aspects related to the establishment and role of the Ph. Eur. Reference Standards. She focused on the EDQM's work in the field of WHO IS for antibiotics and provided an update on the EDQM's Biological Standardization Programme, with focus on projects related to the establishment of Ph. Eur. Biological Reference Preparations (BRP). Regarding the topic of this meeting Dr Buda emphasized the point that WHO IBRP may be used for many purposes (e.g. assay development/validation, calibration and monitoring stability of secondary standards) and according to the current Recommendations are to be provided free of charge to national control labs and intergovernmental organizations. The need for aligned practices across custodian laboratories was identified. She also mentioned that the approach outlined for the assignment of WHO IBRP in SI units required additional clarity.

Dr Yukari Nakagawa (Pharmaceutical and Medical Device Regulatory Science Society of Japan) reported on the Japanese Pharmacopoeia and the development of reference standards in different fields, including biologics. Where possible, these are calibrated against the relevant WHO IS.

Dr Brunda Ganneru (Developing Countries Vaccine Manufacturers Network) summarized challenges with availability and use of WHO reference preparations in low and middle income countries. There was a call to increase international collaboration to reduce several gaps in the field of biological standardization, e.g. rapid provision of primary standards for emerging pathogens or availability of secondary standards.

Dr Dean Smith (International Alliance for Biological Standardization) summarized the experience with quality control of vaccines based on different secondary (in house) reference preparations calibrated against different WHO IS preparations, which had led to inconsistent potency estimates for batches of a given product. As a consequence, manufactures of biologicals should be encouraged to implement a reference management programme to maintain the consistency and quality of their product over its shelf-life and throughout the product life-cycle.

Dr Liesbet Deprez (European Commission, Joint Research Center) discussed different ISO standards in the context of different sections of the draft TRS 932 revision, e. g. ISO17511 being applicable for SI units assigned to international conventional calibrators or ISO15194 being applicable for requirements and documentation of international conventional calibrators.

Session III: Review draft Recommendations and discuss key issues from public consultation

Following a round of self-introductions by the drafting group members, Dr Nübling presented the history of the Recommendations and provided an overview of the current draft document, highlighting the main changes introduced by the drafting group following the first public consultation.

The WHO Recommendations for biological reference preparations were first published in 1978, followed by several previous revisions, with the last revision published in 2004 as Annex 2 of TRS 932 [1]. Draft 4 of the revised Recommendations provides guidance on the development, evaluation, establishment, distribution, use and life-cycle of IBRP, which may be useful for WHO custodian laboratories, institutions involved in biological standardization, manufacturers of biologicals and other users of IBRP.

The current draft of the Recommendations is presented in the following sections, followed by appendices:

- (a) Introduction, (b) Purpose and Scope, and (c) Terminology, summarize the background and intention of the document and provide definitions for terms used;
- (d) General Considerations address the scientific basis of biological standardization and the principles applied to IBRP;
- (e) Part A describes the procedures followed by WHO and the laboratories involved in development, production, characterization and distribution of IBRP;
- (f) Part B provides considerations on the use of IBRP;
- (g-i) Appendixes 1, 2 and 3 describe: (g) the information to be provided to WHO for the establishment of IBRP; (h) the outline and content of Instruction for Use for WHO IBRP; and (i) detailed information on nomenclature used for WHO IBRP.

Major changes introduced during the ongoing revision process were summarized. These changes span all parts of the document and reflect a range of aspects, from the concept of biological standardization to updates of technical and procedural requirements. Comments received during the public consultation, together with the corresponding responses of the drafting group, were highlighted in the version of the document (Draft 4) circulated prior to the meeting.

Meeting participants were invited to provide comments during the review of Draft 4, with particular focus on the highlighted amendments proposed by the drafting group in response to comments received through the public consultation.

The key issues addressed during the review of Draft 4 are summarized below:

Purpose and Scope

It was agreed to make the following additions and clarifications:

a) to add a statement indicating that product manufacturers should establish and maintain their own reference standard programmes in order to assure the consistency and quality of their product over its shelf-life and throughout the product life-cycle. Accordingly, the following sentence was added: “The recommendations also include guidance for users of these preparations as one part of a manufacturer’s overall strategy to ensure product quality and consistency”;

b) to note that the term “digital data standards”, intended to describe data sets used as references for bioinformatic approaches, may be potentially misleading, and to supplement it with the wording “in the form of reference data sets”.

Terminology

Consensus was reached on the following:

a) not to include the IBRP categories IS, IRR and IRP into the definitions section, as the different IBRP categories are explained in the "General Considerations" under "(2) Categories".
b) to use the terms "bioassay" and "immunoassay" consistently, in place of "biological assay" or "immunological assay", in order to align with nomenclature used in TRS documents;

c) to include a definition for "binding assay".

General Considerations

The following proposals for amendments were agreed:

a) to add, in Section 3. Principles of international biological reference preparations, a statement emphasizing the need for users to independently assess continuity of the IU following replacement of an IS, using their own analytical procedures and products, in order to identify any unintended changes attributable to the replacement IS rather than to product consistency;
b) to rephrase Section 4.2. SI units to improve clarity;

c) to note the limitation that digital PCR, when cited as a reference measurement procedure, is suitable only for synthetic DNA, as reflected under the "like-versus-like" principle for nucleic acid amplification technologies in Section 3. Principles of international biological reference preparations;

d) to note, in Section 4.5 Metrological aspects, the exception that a small number of WHO IS do not include a statement of measurement uncertainty despite having SI units assigned;
e) to add an explanation for assay selectivity in Section 6, Commutability.

Part A. Recommendations for the preparation, characterization and establishment of international biological reference preparations

The following proposals for amendments were agreed:

a) to include examples of situations where there is a change of status from IRR to IS in Section A.1.4. Endorsement and establishment of IBRP (as already described in General Considerations, 2.2. International Reference Reagent);
b) to add ISO standard 15194 in Section A.3.1. Quality management system, as additional example since this standard covers not only certified reference materials but also WHO conventional calibrators;
c) to supplement in Section A.5,1. Containers, the described glass type recommended for IBRP ampoules by adding "as minimum" (in order to comply with requirements of the USP);
d) to clarify in Section A.5.5. Labelling, that labels of IBRP (candidates) should contain both the term "WHO" and the year of the ECBS recommendation for establishment;
e) to add in Section A.9. Final report for submission to WHO, that the report should contain a statement about geographical representation of collaborative study participants and how participants were selected;
f) to include in Section A.8.8.3. Commutability conclusions, the reference to the collaborative study report to direct users to the most appropriate information regarding commutability of the

standard;
g) to add in Section A.10.2. Distribution of IBRP, the following statement:"IBRP may be distributed free of charge to national control laboratories and/or international or regional standardization bodies for their intended purpose i.e. calibration of secondary standards."
This statement is intended to provide additional flexibility for custodian laboratories in managing the "free-of-charge" supply of IBRP to relevant organizations.

Part B. Use of WHO international biological reference preparations

The following proposals for amendments were agreed:

a) to revise the statement in Section B.1. General considerations for the use of WHO international biological reference preparations, concerning actions following the establishment of a replacement standard as follows: "When a replacement IS becomes available, the need for, and timing of, recalibration of existing secondary standards and/or assays should be determined on a case-by-case basis, giving consideration to the purposes of the testing performed. Laboratories who retain a local stock of the previous IS may decide to continue to use that preparation (for example to continue monitoring the stability of a local reference preparation where limits have been established based on the previous IS) subject to local regulatory and QMS requirements. However, when a new secondary standard needs to be established, or the initial validation data for an IVD need to be (re-)determined, this should be done using the replacement IS unless otherwise scientifically justified and authorized."

b) to include the following statement in Section B.1. General considerations for the use of WHO international biological reference preparations, concerning potential use of IBRP for purposes other than those intended: "WHO IBRP, or any part thereof, including derivatives (whether modified or not) must not be incorporated into any commercial product. "

Appendix 1. Detailed information to be provided to WHO for establishment of WHO international biological reference preparations

The following proposals for amendments were agreed:

a) to include, in the Biological Standardization (BS) report, a new section as follows: " Authors and Summary. The authors and their affiliations should be listed, the project leader and contact details should be included, key points of the standardization project should be summarized, followed by the proposal to ECBS";

b) to include, in the BS report, under Section 6. Collaborative study, details of the participants involved (for example, whether they are academic, industry, public health labs etc.) together with an explanation for the geographical representation of study participants.

In addition, the WHO editor, Dr Tony Waddell, presented a proposal to use the term "WHO BRP" in place of "IBRP" as the umbrella term for biological reference preparations. Under this proposal, the existing categories of IBRP and their respective names would remain unchanged. The rationale was that a three-letter abbreviation is preferable and that the international nature of reference preparations established and provided by WHO is implicit. The proposal prompted discussion among meeting participants and within the drafting group, with some expressing

concern about the potential for confusion with the term 'Ph. Eur. BRP', particularly if the qualifier "WHO" in front of BRP were omitted. It was agreed that this topic should be further discussed with the ECBS.

Session IV: Plan forward towards improving and finalizing the document

The meeting outcomes were summarized and next steps were outlined. The next step will be the preparation of a revised version of the Recommendations (Draft 5), taking into consideration the outcomes of this meeting, for presentation to and discussion by the ECBS at its meeting in October 2025. Feedback from the ECBS will be reflected in a subsequent version, which will then undergo WHO editorial review prior to a further round of public consultation planned for January- February 2026. Following consideration of comments received during public consultation by the drafting group, proposed changes and key issues will be presented to the ECBS together with the Recommendations for discussion, amendment and possible adoption at its meeting in April 2026.

References

[1] Recommendations for the preparation, characterization and establishment of international and other biological reference standards. *In:* WHO Expert Committee on Biological Standardization: fifty-fifth report. Geneva: World Health Organization; 2004. Annex 2. *(WHO Technical Report Series, No. 932).* Available at: https://www.who.int/publications/i/item/9241209321.

[2] United Nations. *Constitution of the World Health Organization.* New York; 1946. Available at: https://treaties.un.org/doc/Treaties/1948/04/19480407%2010-51%20PM/Ch_IX_01p.pdf.

Authors

Dr Micha Nübling (Consultant, Germany), Dr Paul Stickings (MHRA, United Kingdom) and Dr Tiequn. Zhou* (WHO, Switzerland), on behalf of the meeting participants (see Appendix 2).

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Appendix 1. Meeting agenda

DAY 1, Monday, 22 September 2025

Session I.	**Opening of the meeting**	
13:30-13:40	Welcoming Remarks	*I. Knezevic*
13:40-13:55	Statement on WHO assessment of Declaration of Interest Background, objectives and expected outcomes of the meeting	*T. Zhou*
13:55-14:15	Update on WHO biological standardization activities	*I. Knezevic*

Session II.	**Perspectives from regulators, manufacturers and other stakeholders on the role and use of WHO international standards**	
14:15- 15:30	Presentations from stakeholders: (10-15 min/per presentation)	
	• European Directorate for the Quality of Medicines & HealthCare	*M. Buda*
	• Japanese Pharmacopoeia	*Y. Nakagawa*
	• Developing Countries Vaccine Manufacturers Network	*B. Ganneru*
	• International Alliance of Biological Standardization	*D. Smith*
	• Joint Research Centre, European Commission	*L. Deprez*

15:30- 15:40 Break (10')

Session III.	**Review draft Recommendations and discuss key issues from public consultation**	
15:40	Self introduction of Drafting Group Members	*Drafting Group*
	Overview of key issues addressed in the revision of TRS 932, Annex 2, and key issues raised from 1st round public consultation	*M. Nübling*
	Review document: Introduction; Purpose and scope	*Participants*
17:00	Conclusion and Closure of Day 1	

DAY 2, Tuesday, 23 September 2025

Session III.	**Review draft Recommendations and discuss key issues from public consultation** *(Continue)*	
13:30	Terminology General considerations Part A. Recommendations for the preparation, characterization and establishment of WHO IBRP	

15:30 - 15:40 Break (10')

15:40	Review continue
17:00	Conclusion and Closure of Day 2

DAY 3, Wednesday, 24 September 2025

Session III. Review draft Recommendations and discuss key issues from public consultation *(Continue)*

13:30 Part B. Use of WHO international biological reference preparations
Appendix 1, 2, 3

15:30 - 15:40 Break (10')

Session IV. Plan forward towards improving and finalizing the document

15:40	Review continue: Part B and Appendices	
16:30	Next steps towards improving and finalizing the document	*T. Zhou*
	Any other issues related to the subject document	*All participants*
	Recap of the meeting discussions	*Rapporteur/Chair*
17:00	Close of meeting	*Chair, WHO*

Appendix 2. List of meeting participants

DRAFTING GROUP

Dr Mihaela Buda, Head of Section, Biological Standardization Programme, European Pharmacopoeia Department, European Directorate for the Quality of Medicines & HealthCare, Council of Europe, France; Dr Qunying Mao, Researcher, Hepatitis and Enterovirus Vaccines, National Institutes for Food and Drug Control, P.R. China; Dr Paul Matejtschuk, Head of Formulation Science, Medicines and Healthcare products Regulatory Agency, United Kingdom; Ms Clare Morris, Head of Market Analysis, Manufacturing and Logistics, Medicines and Healthcare products Regulatory Agency, United Kingdom; Dr Micha Nübling, Consultant, Germany; Dr Gerrit Praefcke, Head, Section of Product Testing Haematology, Cell and Gene Therapy, Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, Germany; Mr Peter Rigsby, Head of Biostatistics, Science & Research Group, Medicines and Healthcare products Regulatory Agency, United Kingdom; Dr Paul Stickings, Head of Vaccine Reference Materials, Medicines and Healthcare products Regulatory Agency, United Kingdom; Dr Tong Wu, Manager, Vaccine Quality Division 3, Biologic and Radiopharmaceutical Drugs Directorate, Health Canada, Canada.

PARTICIPANTS

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Ms Vinca L. Medica, Head of Quality Control Division, PT Biofarma, Indonesia; Dr Brunda Ganneru, Head, Developmental Quality Control Department, Bharat Biotech, India; Dr Sreenivasulu B. Reddy, Associate Vice President, Quality Control and Analytical R&D, GCBC Vaccines Pvt. Ltd., India.

INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS AND ASSOCIATIONS (IFPMA)

Dr Kavita Aiyer, Head of Biologics/Vaccine and Senior Director, Regulatory Affairs CMC – Innovative Medicines, Teva Pharmaceutical Industries, USA.

REPRESENTATIVES FROM OTHER ENTITIES

Dr Dean Smith, Representative, International Alliance of Biological Standardization, Board Member of IABS and Chair of the IABS–North America Affiliate / Advisor to the Director and Senior Evaluator, Vaccine Quality Division 1, Centre for Vaccines, Clinical Trials and Biostatistics, Health Canada, Canada; Dr Liesbet Deprez, Representative of Joint Research Centre, European Commission, Scientific / Technical Project Officer, European Commission – Joint Research Centre, Directorate F – Health and Food, Reference Materials Unit, Belgium; Dr Craig Thelwell, Representative of International Society on Thrombosis and Haemostasis, Head of Therapeutic Reference Materials, Standards Lifecycle, Science & Research Group, Medicines and Healthcare products Regulatory Agency, United Kingdom; Dr Yukari Nakagawa, Representative of Pharmaceutical and Medical Device Regulatory Science Society of Japan, Center Director, Pharmaceutical Reference Standards Center, Pharmaceutical and Medical Device Regulatory Science Society of Japan, Japan.

WHO SECRETARIAT

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