Main outcomes of the meeting of the WHO Expert Committee on Biological Standardization held from 20 to 24 April 2026

The 82nd meeting of the WHO Expert Committee on Biological Standardization (ECBS) was held from 20 to 24 April 2026 as a virtual meeting. The ECBS discussed a broad range of issues in relation to the quality, safety and efficacy of biological products used in medicine. Prior to the main meeting, an open information-sharing session was held on Monday 20 April 2026 that included representatives of non-state actors, intergovernmental organizations and other entities. ECBS members, regulatory authority representatives and subject matter experts from governmental organizations then participated in the main meeting from Monday 20 April to Thursday 23 April 2026. All ECBS decisions and recommendations regarding the establishment of new and replacement WHO measurement standards, as well as the adoption of one WHO Recommendations document, were made during a closed session held on Friday 24 April 2026 attended only by ECBS members and the WHO secretariat. At the end of the closed session, the ECBS provided its feedback and recommendations to WHO. A full meeting report will be published in the WHO Technical Report Series later in the year.

The main meeting outcomes included the ECBS recommendation to adopt the following WHO document:

- **WHO Recommendations for the preparation, characterization, establishment and use of WHO international biological reference standards**

A core function of WHO, enshrined in its Constitution, is to develop, establish and promote the use of international standards that form the basis of the regulation of vaccines, biotherapeutics, in vitro diagnostics and other vitally needed biological products. First published in 1978, and last revised in 2004, this latest revision of a pivotal WHO document has been updated to reflect the significant technological advances that have taken place in this field in recent years. Such advances, together with the emergence of an increasingly complex range of biological products and procedures, have led to new challenges in international biological standardization efforts. In addition to the strengthened core guidance set out, including new guidance on the optimal use of such standards, the document also provides more-detailed information on key issues such as ensuring the homogeneity and, where relevant, commutability of the standards. New guidance is also provided on the procedures to be followed to expedite the availability of crucially needed WHO international biological reference standards during public health emergencies. A series of appendices then provides guidance on the information required to establish WHO international biological reference standards, the nomenclature conventions to be applied in their naming and the information to be provided to end users.

As shown in Table 1, the ECBS also recommended the establishment of nine new and three replacement WHO international biological reference standards. The ECBS also endorsed nine proposed projects to establish future such reference standards.

Table 1. WHO international biological reference standards established on the recommendation of the ECBS in April 2026

Material	Unitage	Status
Blood products and related substances		
Unfractionated heparin for molecular weight calibration	Table of values provided in the accompanying instructions for use (IFU)	First WHO International Standard
Blood coagulation factor VIII and von Willebrand factor (plasma)	FVIII:C 0.69 IU/ampoule FVIII:Ag 1.05 IU/ampoule VWF:Ag 0.99 IU/ampoule VWF:RCo 0.82 IU/ampoule VWF:CB 1.03 IU/ampoule VWF:pp 1.01 IU/ampoule VWF:GPIbR 0.85 IU/ampoule VWF:GPIbM 0.85 IU/ampoule	Seventh WHO International Standard
High-throughput sequencing technologies		
Whole genome high-throughput sequencing of oral poliomyelitis vaccines	Type 1 OPV • background/system-suitability control • high-threshold control Type 3 OPV • background/system-suitability control • high-threshold control No unitages assigned	WHO international reference reagents
Vaccines and related substances		
Antibodies to hepatitis A virus	20 IU/ampoule	Third WHO International Standard
Pertussis vaccine (whole cell)	60 IU/ampoule	Fifth WHO International Standard
Antibodies to Crimean-Congo haemorrhagic fever virus for neutralization assays	25 IU/ampoule	First WHO International Standard
Antibodies to Crimean-Congo haemorrhagic fever virus for binding assays	250 IU/ampoule anti-glycoprotein IgG 250 IU/ampoule anti-nucleoprotein IgG	First WHO International Standard
Sabin inactivated poliomyelitis vaccine for in vivo potency assay	• NIBSC code 17/130 • NIBSC code 17/160 No unitages assigned	WHO international reference reagents

Key issues in international public health of direct relevance to the discussions and recommendations made by the ECBS at the current meeting include:

1. The recommended establishment of the two WHO international biological reference standards for antibodies to Crimean-Congo haemorrhagic fever virus directly supports

ongoing efforts by WHO and collaborating entities to proactively prepare for emerging diseases with the potential to cause pandemics or other public health emergencies. Severe and often fatal, Crimean-Congo haemorrhagic fever virus is a WHO priority pathogen for which there are currently no vaccines or treatments available. The establishment of these standards will therefore facilitate the development and evaluation of much needed vaccines and other biological products in this area.

2. Most regions of the world are now considered to be free of polio, with health services now increasingly switching to the use of safer inactivated poliovirus vaccines based on Sabin poliovirus strains (sIPV) for routine immunization programmes. The recommendation of the ECBS to establish the four WHO international reference reagents for sIPV for use in high-throughput sequencing technologies shown in Table 1 will directly support the use of these extremely sensitive technologies in sequencing vaccine strain genomes in minute detail. As such technologies are considered to be far superior to the historically used animal-based neurovirulence testing of poliomyelitis vaccine safety, their broader use will lead to greatly improved approaches to the quality control of such vaccines. In addition, the establishment of these standards aligns with, and directly supports, the increasing efforts now being made to eliminate the use of animal testing whenever possible and scientifically justified, as set out in detail in the recently published WHO Guidelines on the replacement or removal of animal tests for the quality control of biological products, recommended for adoption by the ECBS in October 2025.

3. Establishing appropriate criteria for blood donor selection is critical in ensuring the safety and quality of blood and blood products given to recipients, as well as the safety of donors themselves. The ECBS was updated on the revision of the 2012 WHO Blood donor selection guidelines on assessing donor suitability for blood donation. Following recent advances in transfusion-transmissible infection testing, in particular the widespread adoption of nucleic acid-based testing and resulting significant impact on blood donation risk assessment, WHO had been requested by stakeholders to provide updated guidance on specific donor deferral criteria. While recognizing the crucial importance of this ongoing revision process, the ECBS agreed that it went beyond the scope of its responsibilities for norms and standards used in the regulation of biological products. The Committee therefore proposed that alternative options be explored for reviewing and developing the document using other expert groups with relevant experience and remits, such as the WHO Advisory Group on Blood Regulation, Availability and Safety. In addition, the ECBS recognized that gaps currently exist in the scientific evidence base on donor selection criteria, with a potentially resulting need for frequent updates. Given these considerations, and the considerable size of the document, the ECBS advised that it might be more appropriately published as standalone WHO guidance rather than as WHO Guidelines in the WHO Technical Report Series.

The next meeting of the ECBS is scheduled for 12–16 October 2026.