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 reagents. It coordinates activities leading to the adoption of guidelines and recommendations for assuring the quality, safety and efficacy of such substances and the establishment of international standards and other reference materials.

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.

Main recommendations

Based on the results of international collaborative laboratory studies, the Expert Committee established 25 new or replacement WHO international biological reference preparations (WHO TRS 1011, annex 6). These are the primary standards intended for use as calibrants against which secondary standards (for example, regional or national measurement standards) are benchmarked. Measurement standards of particular importance for regulatory evaluation of vaccines include but are not limited to 1st International Standards (ISs) for monovalent (type 1, 2 and 3), bivalent (type 1+3) oral poliovirus vaccines, 2nd IS for pertussis toxin, 1st IS for Vi polysaccharide of Vi polysaccharide of S. typhi, 1st IS for Anti-Typhoid capsular Vi polysaccharide IgG (Human), 1st IS for antiserum to Respiratory Syncytial Virus, 1st IS for EBOV antibodies and 1st International Reference Panel for EBOV antibodies. An up-to-date list of WHO international biological reference preparations is available at http://www.who.int/bloodproducts/catalogue/en/ (accessed 26 March 2018).

The Expert Committee also adopted new guidance documents on:

- the quality, safety and efficacy of Ebola vaccines
- procedures and data requirements for changes to approved biotherapeutic products
- rapid diagnostic tests for HIV infection for professional use and/or self-testing

The Expert Committee recommended that WHO urgently establish a small working group of experts to further consider the most appropriate approach and time to develop WHO guidelines for cell therapies and prepare a progress report on this rapidly developing global biologicals field for the Committee’s meeting later in 2018. It was also agreed that any WHO standardization activities should include stem cells.

The Expert Committee also provided advice to the Director-General on the written standards and reference preparations under development and on the plans for submission to the Expert Committee in 2018–2020.
New written standard of particular interest for Strategic Advisory Group of Experts (SAGE) on immunization is recently developed document entitled “Guidelines on the quality, safety and efficacy of Ebola vaccines” (WHO TRS 1011, annex 2). It was prepared in response to the request of the Expert Committee at its sixty-fifth meeting in October 2014 when it recognized the importance of providing guiding principles for evaluation of these vaccines. Development of this document started during the Ebola virus disease outbreak in 2014-2015 and it was reviewed by the Expert Committee at its sixty-seventh meeting in October 2016. The Expert Committee noted progress in its elaboration but requested further revision to address the potential use of multivalent Ebola vaccines and innovative clinical trial designs. The latest version of the guidelines, adopted by the Expert Committee at its sixty-eighth meeting, includes this new information and also takes note of the fact that the development of Ebola vaccines had been the subject of discussions by the SAGE on immunization. It is expected that the new written standard for Ebola vaccines will serve as a tool for regulatory preparedness in Member States for future public health emergencies. The adopted text not only provides comprehensive guidance on regulatory expectations for quality, safety and efficacy for full licensure, but also considers which aspects might be accelerated and data sets required during a public health emergency so as to allow rapid vaccine introduction.

Next ECBS meeting is going to take place from 29th October to 2nd November 2018.