Revision of
WHO Guideline for procedures and data requirements for approved vaccines and biotherapeutics

CASSS- CMC Europe 2026

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on behalf of drafting group

World Health Organization

Outline

- Background
- Guideline development
- Key revision/changes
- Revision process

Guidelines development

- Guidelines on procedures and data requirements of vaccines
- Guidelines on procedures and data requirements of biotherapeutic products
- ECBS review and adoption in 2014 for vaccines
- ECBS review and adoption in 2016 for BTPs
- Published in WHO TRS 993 Annex 4 in 2015 and TRS 1011 annex 3 in 2017

WHO Post-approval changes guidelines

- Norms and standards for biologicals developed through broad international scientific **consensus**
  - alignment with evolving technologies and
  - regulatory frameworks across Member States.
- Continuous updates to maintain relevance and **regulatory convergence.**
- Promote **reliance pathways** to recognize decision of reference NRA

Key revision/changes

- Consolidate two GLs as **one**
- Scope: for all biological products.
  - Cell and gene therapy products are not covered
  - Changes related to GMP are not included.
- Harmonization of terms for vaccines and BTPs
  - e.g. DS, DP instead of bulk, antigen, final bulk and final product etc.
- New terms: Established condition, Grace period, PACMP (comparability protocol), WLA
- Emphasis on **reliance** pathways, removal of animal tests, new strains
- Shorter review timelines and **more**…

Revision process

- Drafting group meetings
- Report to ECBS 2025
- First-round public consultation Dec 2025-Jan 2026
- Updated draft of guideline
- Editing
- Second-round public consultation (July-Sept 2026)
- ECBS review: Oct 2026

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- Participants of industry: IFPMA and DCVMN
- Comment providers of first-round public consultation

  Guideline temporarily available here:

  https://cdn.who.int/media/docs/default-source/biologicals/call-for-comments/guidelines.post-approval-changes.for-web-site.pdf?sfvrsn=88515e55_1

World Health Organization

Thank you

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