World Health Organization

# DRAFT DISCUSSION DOCUMENT FOR COMMENTS

# WHO REGULATORY GUIDANCE AND RELATED TEXTS: REVISIONS/NEW TEXTS FOR DISCUSSION

Please submit your comments through **the specific word template for this document** [Table for comments-qas23.940] or online platform, PleaseReview™ (https://who.pleasereview.net/Main/Default.aspx?action=loaddocument&reviewid=210). If not registered or included in our mailing list, kindly submit your request with your full name, email address and organization/affiliation to nsp@who.int.

For any technical questions, please contact **Dr Steve Estevão Cordeiro**, Technical Officer, Norms and Standards for Pharmaceuticals, Technical Standards and Specifications (estevaos@who.int), with a copy to **Ms Bezawit Kibret** (Kibretb@who.int, nsp@who.int).

Comments should be submitted through the online platform on or by **6 October 2023** Please note that only comments received by this deadline will be considered for the preparation of this document.

Our working documents are sent out electronically and uploaded into PleaseReview™. The working documents are also placed on the WHO Medicines website (https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/pharmaceuticals/working-documents-public-consultation) under the "Working documents in public consultation".

If you wish to receive all our draft guidelines during the course of the year, please send your full name, organization / affiliation, and email address to jonessi@who.int, nsp@who.int and your name will be added to our electronic mailing list and review platform.

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DRAFT DISCUSSION DOCUMENT QAS/23.940:

# WHO regulatory guidance and related texts: revisions/new texts for discussion

| Description of activity | Date |
|---|---|
| Preparation of the first draft discussion document | August 2023 |
| Mailing of working document to the Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations (EAP) inviting comments and posting of the working document on the WHO website for public consultation. | 28 August - 6 October 2023 |
| Discussion of the document at the Joint Meeting on Regulatory Guidance for Multisource Products | 22 – 23 September 2023 |
| Presentation to the Fifty-seventh meeting of the ECSPP | 9 – 13 October 2023 |
| Any other follow-up action as required | |

# WHO regulatory guidance and related texts: revisions/new texts for discussion

## Contents

# 1. Introduction & scope

The World Health Organization (WHO) is committed to providing high-quality, evidence-based guidelines for pharmaceuticals to ensure that medicines are of good quality, safe, and effective. The completed and updated list of WHO norms and standards for medicines, quality assurance (QA) and regulatory guidance texts adopted by the Expert Committee and published in the WHO Technical Report Series (TRS) is published as Annex 1 in TRS 1044, 2022 *(1)*.

QA guidelines are the recognized WHO technical standards to support the whole life cycle of medical products, from development to production, marketing authorization and distribution, up to the post-marketing phase.

QA guidelines and guidance texts must be updated to reflect the constant technical progress in pharmaceutical development, production, regulatory science, and quality control. WHO is soliciting stakeholder feedback in line with WHO procedures for adequate consultation as described in the procedure for developing WHO medicines QA guidelines *(2)*. The discussion document aims to solicit feedback on which WHO guidelines for pharmaceuticals should be reviewed or updated and new topics to develop guidelines or guidance to address gaps in the existing WHO QA guidelines and related texts.

A short list below reflects guidelines over seven years old or for which significant changes in the field necessitate a review or update. The feedback can cover any aspect, including the relevance of the guidelines to current needs, the accuracy and up-to-dateness of the guidelines, the most important topics that the guidelines should cover, the most important gaps in the existing guidelines, or if other current guidelines supersede the guideline, therefore, should be withdrawn. Additional feedback for review or updates of guidelines adopted by the Expert Committee not included in the shortlist but published in the TRS is welcomed. Recommendations for developing new guidelines or guidance based on current needs are also welcomed.

Guidelines related to good manufacturing practices and inspection are out of scope as these will be covered in a separate request for feedback for the WHO GMP Compendium.

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89 # 2. Shortlist of guidelines or guidance for stakeholder feedback

| Title | Annex | TRS | Year | Weblink |
|---|---|---|---|---|
| Basic tests for drugs | N/A | N/A | 1998 | https://www.who.int/publications/m/item/basic-tests-for-drugs-pharmaceutical-substances-medicinal-plant-materials-and-dosage-forms |
| Guidelines on packaging for pharmaceutical products | Annex 9 | 902 | 2002 | https://www.who.int/publications/m/item/annex-9-trs-902 |
| WHO pharmaceutical starting materials certification scheme (SMACS): guidelines on implementation | Annex 3 | 917 | 2003 | https://www.who.int/publications/m/item/annex-3-trs-917 |
| WHO guidelines for sampling of pharmaceutical products and related materials | Annex 4 | 929 | 2005 | https://www.who.int/publications/m/item/annex-4-trs-929 |
| Guidelines for registration of fixed-dose combination medicinal products | Annex 5 | 929 | 2005 | https://www.who.int/publications/m/item/annex-5-trs-929 |
| Guidelines on active pharmaceutical ingredient master file procedure | Annex 4 | 948 | 2008 | https://www.who.int/publications/m/item/annex-4-trs-948 |
| Guidelines for the preparation of a contract research organization master file | Annex 7 | 957 | 2010 | https://www.who.int/publications/m/item/trs-957-annex-7 |
| Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services | Annex 8 | 961 | 2011 | https://www.who.int/publications/m/item/annex-8-trs-961 |
| Pharmaceutical development of multisource (generic) finished pharmaceutical products – points to consider | Annex 3 | 970 | 2012 | https://www.who.int/publications/m/item/pharmaceutical-development-of-multisource-(generic) |
| Development of paediatric medicines: points to consider in formulation | Annex 5 | 970 | 2012 | https://www.who.int/publications/m/item/trs970-annex-5-development-of-paediatric-medicines-points-to-consider-in-formulation |

| Title | Annex | TRS | Year | Weblink |
|---|---|---|---|---|
| Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part | Annex 6 | 986 | 2014 | https://www.who.int/publications/m/item/annex-6-trs-986 |
| Guidance for organizations performing in vivo bioequivalence studies | Annex 9 | 996 | 2016 | https://www.who.int/publications/m/item/annex-9-trs-966 |
| WHO general guidance on variations to multisource pharmaceutical products | Annex 10 | 996 | 2016 | https://www.who.int/publications/m/item/trs966-annex10 |

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# References

1. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Annex 1: Guidelines and guidance texts adopted by the Expert Committee on Specifications for Pharmaceutical Preparations. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-sixth report. Geneva: World Health Organization; 2022:69 - 86 (WHO Technical Report Series, No., 1044; https://apps.who.int/iris/rest/bitstreams/1486295/retrieve, accessed 25 August 2023).
2. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Annex 1: Procedure for the development of World Health Organization medicines quality assurance guidelines. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-third report. Geneva: World Health Organization; 2019:87 - 91 (WHO Technical Report Series, No., 1019; https://apps.who.int/iris/rest/bitstreams/1217390/retrieve, accessed 25 August 2023).