

Section Guidance for Part 6 Scientific Discussion of a WHO Public Assessment Report (WHOPAR)

SCIENTIFIC DISCUSSION

The purpose of the Scientific Discussion (Part 6) of a WHO Public Assessment Report (WHOPAR) is to provide an account of the assessment performed by WHO, as well as a summary of the safety and efficacy of the prequalified product.

The summary of product safety and efficacy should provide information (current at the time of compilation of the WHOPAR), on the product's safety and efficacy, in support of the information provided in the Patient Information Leaflet and Summary of Product Characteristics. It should be 2–4 pages long (or more, as appropriate, in the case of a multisource product for which no innovator or comparator/reference product is available). It should not contain promotional statements and should be written in easily-understandable English.

The summary should provide an integrated evaluation of the product and not just a summation of the product information for the individual actives contained in e.g. fixed-dose combinations. Similarly, for such products, the rationale for use of the product should be described in terms of the combination. Further guidance is provided in the WHO Guidelines for Registration of Fixed-dose Combination Medicinal products (Technical Report Series, No. 929, Annex 5, 2005).

The outline for the Scientific Discussion should follow the format described below:

1. Introduction
2. Assessment of quality (provided by WHO)
3. Assessment of bioequivalence (provided by WHO)
4. Summary of product safety and efficacy
 - Introduction
 - i. Background
 - ii. Product design
 - iii. Unique product characteristics
 - iv. Approved indication(s)
 - Clinical pharmacology
 - i. Pharmacodynamics
 - ii. Pharmacokinetics
 - Drug interactions, related side-effects and contraindications
 - Clinical efficacy
 - i. Controlled studies
 - ii. Observational studies
 - iii. Supportive studies
 - iv. Clinical studies in special population
 1. Kidney dysfunction
 2. Liver dysfunction
 3. Paediatric population
(additional subpopulations may be applicable, e.g. for antiretrovirals: antiretroviral-naïve and -experienced patients)
 - Clinical Safety
 - i. Patient exposure
 - ii. Serious adverse events/deaths
 - iii. Adverse events
5. Benefit : risk assessment and overall conclusion

Copies of documents referenced (e.g. literature references) in the summary of product safety and efficacy should be provided.