



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



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Director-General: National Department of Health

To: Healthcare Stakeholders

INVITATION TO COMMENT ON THE SCOPE FRAMEWORK FOR THE REVIEW OF THE PHARMACO-ECONOMIC GUIDELINES OF 2012

1. The Pricing Committee established in terms of Section 22G of the Medicines and Related Substances Act of 1965, has commenced the review of the Pharmacoeconomic Guidelines published in 2012.
2. The Review of the Guidelines involves the publication of this Scope Framework attached, which identifies methods, principles, practices, and current research in the area of assessment of evidence for medicines and related substances.
3. Furthermore, the Scope Framework Identifies significant new developments for methods in assessment and evaluation in relevant sections of the current Pharmacoeconomic Guidelines.
4. In undertaking the review of the Pharmacoeconomic Guidelines, the Pricing Committee will consider the relevance of existing guidance documents on specific methodologies contained within guidelines published by comparable international health technology assessment agencies, regulators and internationally recognised authorities in the assessment of evidence.
5. Stakeholders should note that the Scope Framework has been undertaken to kickstart the consultation process for the Review of the Pharmacoeconomic Guidelines (2012) and that it must be considered when providing evidence and submission to be considered in the final review of the Pharmacoeconomic Guidelines.
6. The Scope should be seen as a technical paper for discussion on each issue for the revision, including identifying any issues of scientific debate and consideration of the South African and international best practices.

7. Preparation of proposals for how to address each technical issue for the revision of the Pharmacoeconomic Guidelines undertaken by relevant stakeholders should be submitted by interested stakeholders using the numbering system and topics in chronological order as appearing in the Scope Framework.
8. Consolidation of these submissions and comments will be incorporated into a Stakeholder Consultation Document and a revised Scope Framework identifying methods in the process identified and agreed upon as out-of-scope will be published as a final Scope Framework on the Website of the National Department of Health and other communication platforms.
9. The management of a public consultation process for the proposed Revision of Pharmacoeconomic Guidelines will be publicly released on various platforms of the National Department of Health and again comments will be invited on the revised version.
10. The final process will include the following steps:
 - a. Incorporate accepted consultation feedback into the draft revised Guidelines.
 - b. Present the finalised revised Guidelines for comment by all relevant stakeholders.
11. The closing date for receipt of stakeholder comments shall be 17 January 2025.
12. All comments must be emailed to sepupdates@health.gov.za and cc'd to ntobeko.mpanza@health.gov.za



DR SSS BUTHELEZI

DIRECTOR-GENERAL: HEALTH

DATE: 04/10/2024