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NOTICE OF REQUEST FOR COMMENT: UPDATING OF HEALTH TECHNOLOGY ASSESSMENT METHODS GUIDE TO INFORM THE SELECTION OF MEDICINES TO THE NATIONAL ESSENTIAL MEDICINES LIST

The Essential Drugs Programme (EDP) within the National Department of Health is in the process of updating the existing technical methods used for the assessment and appraisal of medicines when considering selection to the National Standard Treatment Guidelines (STGs) and Essential Medicines List (EML).

The EDP coordinates the assessment of all technologies that fall within the scope of the STGs and EML (primary, second and tertiary and quaternary level of care) utilising an internal staff secretariat and Ministerial-appointed advisory committees.

The updated methods aim to strengthen the practice of health technology assessment (HTA) for medicines in South Africa by establishing formal methods for estimating budget impact and cost-effectiveness in addition to the existing evidence-based medicine methodology. In addition, the methods also aim to standardise approaches for developing evidence beyond effectiveness and efficiency to incorporate equity and other social values, creating a comprehensive HTA methodology for generation of evidence-informed decisions related to the use of medicines in South Africa. The methods do not preclude any procedural or institutional developments related to HTA under National Health Insurance reforms and will clarify and aim to strengthen the existing methodological practice in this technical area.

The first draft of the proposed methods is attached and further details relating to the HTA Methods Guide are described below. Comment is invited on the proposed methods over an extended consultation period acknowledging the complexity of HTA methods and variety of stakeholder groups that may have an interest in this field. The extended consultation period will also allow pilot use of the methods within the existing process and use by research groups and affiliated units to conduct analyses, facilitating direct feedback from applied analysis.

What is health technology assessment (HTA)?

Health Technology Assessment (HTA) is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system. The National Department of Health currently applies aspects of HTA to decision-making when adding medicines to the National Essential Medicines List, and this updated methodology will provide a more explicit and consistent terminology for the way that evidence is generated.

How was the updated methodology developed?

The development of this Guide builds on global best practice in HTA but is firmly anchored in the existing experience of the EDP programme, including the processes and methods that have been put into place in the review of the STGs and EML.

In particular, this guide builds on the following existing documentation produced by the South African Department of Health:

- Essential Drugs Program Reviewer's manual
- Methods guide for rapid reviews for COVID-19 medicine reviews
- Existing medicine reviews and economic analyses
- Guidelines for Pharmacoeconomic Submissions in South Africa

The development of the HTA Methods Guide also included a review of methods and processes of multiple HTA agencies and research organisations globally, and incorporates concepts and approaches appropriate for the South African setting. Organisations reviewed include the Health Intervention and Technology Assessment Program (HITAP) in Thailand, National Institute for Health and Care Excellence (NICE) in England and Wales, Canadian Agency for Drugs and Technologies in Health (CADTH) in Canada, Republic of the Philippines Health Technology Assessment in the Philippines, and Pharmaceutical Management Agency (PHARMAC) in New Zealand.

What does the updated methods guide contain?

The specific objectives of the HTA Methods Guide are to:

- Provide clear guidance on the methods for gathering and producing evidence on clinical efficacy, safety, effectiveness and affordability, as well as factors like equity, feasibility and cost-effectiveness.
- Ensure consistency of methods for analysis and reporting, leading to more consistent and transparent decision-making.

The HTA Methods Guide provides detailed guidance on the processes and methods to follow when prioritising topics for assessment, developing a scope for a technology assessment, assessing a medicine or group of medicines, and reporting the assessment findings. The scope of this Guide applies to medicines only in the form of an individual medicine or a class of medicines to be listed on the EML.

The EDP will coordinate the HTA workplan in a manner that takes into account the urgency of the decision, the level of uncertainty and the available resources. It will utilise a tiered approach consisting of the following two stages:

Stage 1: Technical Report

- A Technical Report will be compiled for all technology appraisals, and it is expected that in most cases the information in the Technical Report will be sufficient to inform a decision regarding the inclusion or exclusion of the medicine to the EML.
- The Technical Report will contain medicine details, a description of the review question/s, a review of the clinical evidence, pharmaceutical costs, a summary of other HTA agency decisions (if relevant), equity considerations, social value considerations, and feasibility considerations.

Stage 2: Additional Analysis

- Some medicine topics will require different or more complex analytical assessment of clinical and economic data than that provided in the Technical Report.
- Figure 1 summarises some of the considerations when determining the appropriate Stage 2 analysis for a technology appraisal. The different types of additional analysis are described in more detail below, classified as clinical, economic, and bespoke analysis.

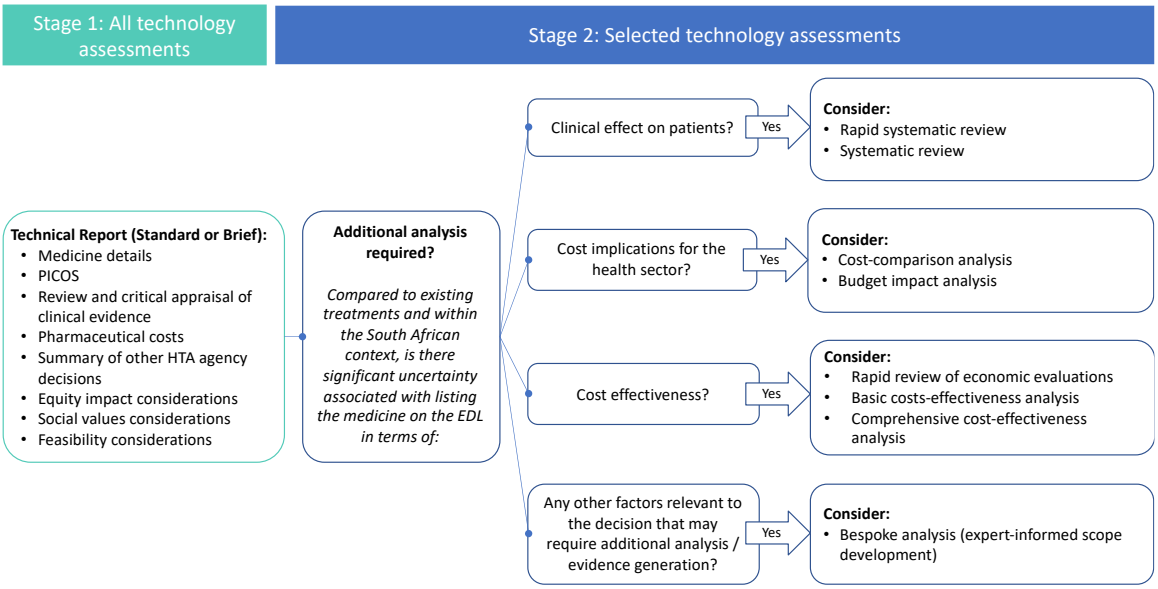

Figure 1. Determining analysis required for a technology assessment

The HTA Methods Guide can be used by anyone involved in preparing the technology assessment, including staff of the EDP, Expert Review Committee (ERC) members, members of the National Essential Medicines Committee (NEMLC), National Department of Health (NDoH) partner organisations, provincial Pharmaceutical and Therapeutics Committee (PTC) members, pharmaceutical or medical device companies, and Contracted Expert Reviewers (CER) or academic units.

What information is sought in this consultation?

We invite comments and feedback on the updated methods guide from interested individuals and institutions. We are interested in hearing your thoughts about the following:

- Are the methods specifications appropriate in the South African context?
- Are the methods specifications feasible in the South African context?
- Is the structure of the HTA Methods Guide appropriate?
- Is the language and approach in the HTA Methods Guide clear and understandable?
- Are there any major gaps in the methods that may be useful for the assessment of medicines in South Africa?
- Are there any factual inaccuracies that should be corrected?
- Specific feedback on the sections in the HTA Methods Guide

How can I submit a consultation response?

Please use the consultation form (Annexure 1) to provide your comments.

Consultation responses and requests for further information should be emailed to Dr Janine Jugathpal @ Janine.Jugathpal@health.gov.za by 04 October 2021.

Kind regards

DR S.S.S BUTHELEZI
DIRECTOR-GENERAL: HEALTH
DATE: 28.06.2021