



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Reference No:

Enquiries:

Ms K Jamaloodien

Office No:

S0501

Extension:

8130

Date:

20 September 2024

THE DIRECTOR-GENERAL

SUBJECT: TO REQUEST THE DIRECTOR-GENERAL OF HEALTH TO APPROVE THE DEVIATION FROM NORMAL PROCUREMENT PROCESSES; AND SIGN THE MEMORANDUM OF AGREEMENT WITH THE SOUTH AFRICAN MEDICAL RESEARCH COUNCIL FOR THE DEVELOPMENT AND IMPLEMENTATION OF A FRAMEWORK FOR FORMALISING HEALTH TECHNOLOGY ASSESSMENT IN SOUTH AFRICA

PURPOSE

1. To request the Director-General: Health to:
 - Approve the deviation from normal procurement processes; and
 - Sign the Memorandum of Agreement (MOA) with the South African Medical Research Council (SA MRC) for the development and implementation of a framework for formalising Health Technology Assessment (HTA) in South Africa, establishing HTA capacity and enabling the evolution of the medicine selection structure.

SUMMARY

2. The Essential Drugs Programme (EDP) was established under the National Drug Policy (1996) to ensure that affordable, good quality essential medicines are always available, in adequate amounts, in appropriate dosage forms, and to all South African citizens. Healthcare demands are continually growing in the resource-limited environment in which the South African public health sector operates.
3. HTA was allocated an amount of R16 616 000.00 at the beginning of the financial year 2024/25 (see Annexure A). The National Department of Health's (NDoH's) HTA activities to date have been focused on the development of the HTA strategic framework for formalising HTA processes in support of National Health Insurance (NHI) and the strengthening of HTA processes in the selection of essential medicines.
4. With the framework now in place, the EDP intends to collaborate with the SA MRC to implement this framework, establishing HTA capacity and enabling the evolution of the medicine selection structure in place for the use of HTA to support recommendations for an addition or change to the health technologies associated with health benefits.

5. It is recommended that the Director-General of Health approves the deviation from normal procurement processes; and signs the MOA with the SA MRC for the development and implementation of a framework for formalising HTA, establishing HTA capacity and enabling the evolution of the medicine selection structures.

STRATEGIC FOCUS OF THE SUBMISSION (APP AND STRATEGIC PLAN)

6. To promote HTA by providing an accountable mechanism to support decision-making relating to the funding, cost and use of health interventions, technologies and services in South Africa funded under NHI. This will be performed by building on and strengthening existing processes to provide information on the best use of HTA to optimise health outcomes, access, and equity and to promote fiscally responsible allocation of resources within available funding.

DISCUSSION

7. The EDP was established under the National Drug Policy (1996) to ensure that affordable, good quality essential medicines are always available, in adequate amounts, in appropriate dosage forms, and to all South African citizens. Healthcare demands are continually growing in the resource-limited environment in which the South African public health sector operates.
8. As South Africa moves towards strategic purchasing under NHI, the need for a reliable and trusted process for evaluating all components of the health system will grow. It is envisaged that the HTA model will evolve, in an iterative manner, the process of piloting health technology evaluations on priority interventions. This will lead to a fundamental embedded and compulsory component of the evaluation and adoption of all new health technologies nationally.
9. HTA was allocated an amount of R16 616 000.00 at the beginning of the financial year 2024/25 (see Annexure A). The SA MRC is a National Public Entity as contemplated in Schedule 3A of the Public Finance Management Act 1 of 1999 and a statutory science council established in terms of Section 2 of the Medical Research Council Act 58 of 1991. The SA MRC has a mandate to improve the health of the country's population, through research, development and technology transfer, so that people can enjoy a better quality of life and a strategic objective to help strengthen the health systems of the country.
10. The Health Systems Research Unit of the SA MRC conducts research to contribute to national, regional and international evidence-informed health and social policy decision-making and health systems with the aim of contributing to Universal Health Coverage and Primary Health Care.
11. The NDoH's HTA activities to date have been focused on the development of the HTA strategic framework for formalising HTA processes in support of NHI and the strengthening of HTA processes in the selection of essential medicines. With the framework now in place, the EDP intends to collaborate with the SA MRC to implement this framework, establishing HTA capacity and enabling the evolution of the medicine selection structure in place to the use of HTA to support recommendations for an addition or change to the health technologies associated with health benefits.

12. The Health Systems Research Unit of the SA MRC has already been providing technical support and training to the EDP related to the review of the national Standard Treatment Guidelines and Essential Medicines List. The rigorous HTA process applied in the selection of essential medicines is the foundation for the establishment of formalising HTA processes in the context of NHI.
13. An MOA has been prepared between the NDoH and the SA MRC to enable collaboration going forward, with the intention to utilise R11 606 583.00 of the earmarked funds for HTA services (see Annexure B). The SA MRC has also developed a workplan outlining the activities that will be delivered during the period of the MOA as well as a summary of the reporting requirements to the NDoH (see Annexures C and D). The MOA has been assessed and approved by the NDoH's Directorate: Legal Services (see Annexure E).
14. This has built upon a previous Memorandum of Understanding (expired February 2024), signed by the Director-General: Health on 2 February 2021, between the NDoH, SA MRC and University of Stellenbosch to enable collaboration on evidence-based medicine reviews to inform the selection of medicines and other health products.
15. National Treasury's Public Finance Management Act, 1999 (Act No. 1 of 1999) Supply Chain Management (PFMA SCM) Instruction No. 03 of 2021/2022 in section 4 allows for the procurement of goods and services by other means, provided that the reasons for deviating from inviting bids must be recorded and approved by the Accounting Officer. Furthermore, section 4.6 requires the NDoH to report the procurement to National Treasury and the Auditor-General of South Africa in a format determined by National Treasury (see Annexure F).
16. Single source procurement is required, as contracting for these services with a different service provider poses a risk to the health system for the following reasons:
 - The Health Systems Research Unit and Cochrane South Africa are units of the SA MRC that have firmly established HTA methodological processes and the necessary technical expertise for the conducting and delivering of evidence syntheses for all health technologies in South Africa. The Health Systems Research Unit and Cochrane South Africa are already collaborating on local and international research, evidence and methods projects (refer to Annexure C) required for evidence-informed decision making. The NDoH could leverage off these existing projects, and particularly the South African Grading of Recommendations Assessment, Development and Evaluation (GRADE) network.
 - The SA MRC is a co-founder of the South African (GRADE) Network which network aims to advance the use of GRADE for evidence-informed decision making for policy and practice in South Africa.
 - In terms of the application of HTA processes in the review of the EML, implementing a new system with a different service provider may threaten the stability of the medicine selection process. Establishing further support from the SA MRC would allow for continuity in existing service provision. In addition, this will allow a seamless transition for the expansion of HTA processes to other health technologies.

SUBJECT: TO REQUEST THE DIRECTOR-GENERAL OF HEALTH TO APPROVE THE DEVIATION FROM NORMAL PROCUREMENT PROCESSES AND SIGN THE MEMORANDUM OF AGREEMENT WITH THE SOUTH AFRICAN MEDICAL RESEARCH COUNCIL FOR THE DEVELOPMENT AND IMPLEMENTATION OF A FRAMEWORK FOR FORMALISING HEALTH TECHNOLOGY ASSESSMENT IN SOUTH AFRICA

- Collaborating with the SA MRC would be a natural continuation of previous EML work and enhanced reliability of the services due to the exceptional ability of the SA MRC. The unique partnership has enabled holistic service provision beyond that of any one other stakeholder, due to the SA MRC's existing intellectual property and expertise, as well as a history of high-quality outputs and valuable capacity building of the EDP and contributing stakeholders.
- Onboarding a new service provider on the processes and framework used by the EDP would negate the investment previously made and take up valuable time of the EDP members. Collaborating with the SA MRC will result in economic and time savings to the NDoH.

17. Hence, it is recommended that the Director-General of Health grants approval to deviate from normal procurement processes; and signs this MOA, with the intention to utilise R11 606 583.00 of the earmarked funds for HTA services through the SA MRC.

18. Please find included in the submission:

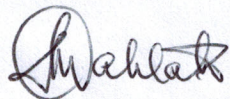
- Annexure A: HTA budget allocation to the NHI Branch;
- Annexure B: MOA between the NDoH and the SA MRC for signature by the Director-General of Health (two copies for signature);
- Annexure C: Workplan outlining HTA activities to be delivered by the SA MRC;
- Annexure D: Summary of reporting requirements from the SA MRC to the NDoH;
- Annexure E: Letter of approval of the MOA from the National Department of Health's Directorate: Legal Services;
- Annexure F: National Treasury's PFMA SCM Instruction No. 03 of 2021/2022; and
- Annexure G: SA MRC sole supplier letter.

RELEVANCE TO THE NATIONAL DEVELOPMENT PLAN

19. The vision for HTA in South Africa is anchored in the ideals of Universal Health Coverage. The measure of whether HTA is successful or not is the extent to which it contributes to healthcare outcomes.

CORPORATE SERVICES IMPLICATIONS

20. The MOA has been reviewed by the NDoH Directorate: Legal Services (see Annexure E for the letter of approval of the MOA).



DR MP MAHLATI
ACTING HEAD: CORPORATE SERVICES
DATE: 25/9/2024

FINANCIAL AND SUPPLY CHAIN MANAGEMENT IMPLICATIONS

21. The current HTA budget is R16 616 000.00 as per the table below (see Annexure A):
22. A total amount of R11 606 583.00 is set aside to cover the expenditure.
23. With reference to section 8 of the MOA (refer to Annexure B), the NDoH shall make payments to the SAMRC monthly based on the value of the services rendered and work done.

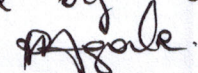
Fund: HEALTH TECHNOLOGY ASSESSMENT

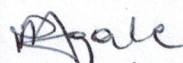
Objective: HEALTH TECHNOLOGY ASSESS

Responsibility: HEALTH FINANCING & NHI

Original Budget	Available Budget
R16 616 000.00	R16 616 000.00
Expected Expenditure	
South African Medical Research Council	R11 606 583.00


MR PP MAMOGALE
CHIEF FINANCIAL OFFICER
DATE: 11/10/2024

Invoices be paid based on value of work done and confirmation of service rendered by the end user. 

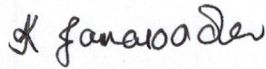
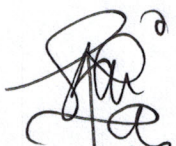
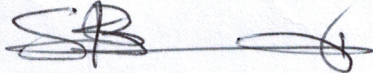
Paragraph 8.1 of the SIA is supported which indicates that SAMRC will be paid based on the value of the service rendered and work done.

28/10/2024

SUBJECT: TO REQUEST THE DIRECTOR-GENERAL OF HEALTH TO APPROVE THE DEVIATION FROM NORMAL PROCUREMENT PROCESSES AND SIGN THE MEMORANDUM OF AGREEMENT WITH THE SOUTH AFRICAN MEDICAL RESEARCH COUNCIL FOR THE DEVELOPMENT AND IMPLEMENTATION OF A FRAMEWORK FOR FORMALISING HEALTH TECHNOLOGY ASSESSMENT IN SOUTH AFRICA

RECOMMENDATION

23. It is recommended that the Director-General of Health:

- Approves the deviation from normal procurement processes; and
- Signs the MOA with the SA MRC for the development and implementation of a framework for formalising HTA in South Africa, establishing HTA capacity and enabling the evolution of the medicine selection structures, through the single source selection in accordance with National Treasury's PFMA SCM Instruction No. 03 of 2021/2022.

CHIEF DIRECTOR: MS K JAMALOODIEN CHIEF DIRECTORATE: SECTOR-WIDE PROCUREMENT  DATE: 20/9/2024 Recommended/Not recommended	DEPUTY DIRECTOR-GENERAL: PROF N CRISP BRANCH: NATIONAL HEALTH INSURANCE  M. NKOS DATE: 23/09/2024 Recommended/Not recommended
DIRECTOR-GENERAL: DR SSS BUTHELEZI  DATE: 04/11/2024 Approved/Not approved/amended	