LAYING SOLID FOUNDATIONS

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The Importance of Governance Tools to Underpin a Medicine Master Data System

South Africa has a unique HIV and tuberculosis (TB) burden. It is at the center of the global AIDS epidemic and has one of the highest burdens of TB in the world. An efficient and effective health supply chain that improves medicine availability is critical to addressing that disease burden. South Africa's unique disease burden shapes the country's national health priorities, health system design, and health funding structures. Limited funds must be allocated according to an evidence-based approach to provide the best quality health care to all South Africans. Strengthening of medicine selection and rational medicine use provides an accountable mechanism to support decision making related to the funding, cost, and use of medicines and health technologies in the country.

The National Department of Health (NDoH)'s Affordable Medicine Directorate (AMD)[1], through the relevant governance bodies, is responsible for supporting the selection of essential medicines for patients nationally, as well as making sure these medicines are accessible and available when and where they are required. Some of the key challenges faced by the department in recent years include the use of stand-alone electronic medicine management systems with a lack of integration or interfacing of these systems. This situation makes managing processes and reporting on the medicine supply chain difficult because of different naming conventions of products. There was also a lack of agreement on policy principles relating to medicine master data. In addition, as is the case worldwide, limited funds need to be allocated according to an evidence-based approach to provide the best quality health care to all.

Through the support of the United States Agency for International Development (USAID)-funded Global Health Supply Chain Program – Technical Assistance (GHSC-TA), the AMD developed governance documents to inform a Medicine Master Data System (MMDS). The system provides a set of master data for use in stock management, dispensing, and reporting systems. This includes formularies which provide information about the medicines available in a

[1] AMD is responsible for developing systems to ensure access to essential pharmaceutical commodities. It includes the Essential Drugs Program responsible for selection and rational use of medicine, the National Contracting Unit responsible for establishing centrally administered contracts, the Contract Management Unit responsible for post-award contract management and performance monitoring, and the Licensing Unit responsible for the administration of certain licenses and permits.

province, district, and health establishment and are managed by the relevant Pharmaceutical and Therapeutics Committees (PTCs).

Governance documents were developed to define the principles on which rational selection, management, and use of medicines should take place, as well as to inform the basis on which medicine management systems should be built. Initial scoping documents were developed and circulated to key internal and external stakeholders to help ensure that the guidelines address stakeholder needs, and thus support effective implementation.

Through this process, three key documents were developed - the National Formulary Guideline, the Medicine Master Data Policy, and the National PTC Guideline. The PTC policy had already been developed to provide standards for the establishment of a non-statutory, multidisciplinary, advisory committee, PTCs.

To encourage stakeholder participation, drafts of the documents were developed following literature review, brainstorming, and alignment with existing policies and international best practice. Once drafts had been prepared, rigorous stakeholder consultation took place, involving invitations for comment, presentations, and one-on-one feedback sessions. Governance documents were then refined and signed off by the relevant level within the NDoH.

Firstly, the **National Formulary Guideline** was developed to define the concept of a formulary; give guidance on the development, management, and use of formularies at all levels of care; and emphasize the importance of formularies as the basis for the procurement and management of medicine to support medicine availability and rational use.

The **Medicine Master Data Policy** was then developed to define the concept of medicine master data in the context of the public sector and provide guidance on its development, management, and use. Lastly, the **National PTC Guideline** was developed to give guidance and corresponding tools for use by PTCs, as well as an outcomes-based approach for good governance and rational selection and medicine use. It also standardizes functions, roles, and objectives for all PTCs at different levels based on generic terms of refence.

The process is far from over, and ongoing gap analysis ensures that the policies continue to be refined to ensure that they address existing challenges in real time.

Documenting and gaining agreement on the policy principles was a fundamental input to successful design, development, and introduction of the MMDS. Stakeholder consultation ensured that practical implications and considerations are considered, enhancing the acceptability and effectiveness of policy interventions.

These interventions will enable the integration of medicine selection, contracting and contract management, supply chain, and use, as well as easier analysis, alignment, and visibility of formularies. In addition, the supply chain will be informed through medicine-use evaluations, with more efficient procurement and increased medicine availability.

Electronic systems based on strong governance are key drivers of improved access to medicines. Governance tools including polices and guidelines, with implementation through electronic systems, enable the right dose of the right medicine to be given to the right patient at the right time, and promote sustained improvement in clinical outcomes.