SWEDD
AUTONOMISATION DES FEMMES ET DIVIDENDE DÉMOGRAPHIQUE AU SAHEL
SAHEL WOMEN'S EMPOWERMENT AND DEMOGRAPHIC DIVIDEND

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SWEDD SERIES: OPERATIONAL BRIEF

TECHNICAL SUPPORT FOR NATIONAL MEDICINES QUALITY CONTROL LABORATORIES (NMQCL) AND NATIONAL MEDICINES REGULATORY AUTHORITIES (NMRA)

The research informing this brief was led by the West African Health Organization (WAHO) and is based on the SWEDD project. The information will guide the implementation of SWEDD+

This operational brief is part of a series that retrospectively documents the process of implementing the interventions of the Sahel Women's Empowerment and Demographic Dividend (SWEDD) project. It describes good practice, challenges and lessons learned in the provision of technical support to regulatory systems that play a key role in ensuring the quality, safety and efficacy of medical products. It is based on a literature review and the responses to questionnaires submitted to key respondents in Burkina Faso, Mali, Niger and Chad between July and November 2023. The experiences described in this brief and the guide of the same name serve to inform the implementation of NMQCLs and NMRAs in SWEDD+ countries, and other projects in other countries of the global South, particularly in West and Central Africa.

Technical support for NMQCLs and NMRAs helps these institutions to improve the quality of Reproductive, Maternal, Newborn, Child and Nutritional Health (SRMNIN) products. This technical support was implemented in three phases.

Technical support phases for the NMQCLs and NMRAs

Phase 1: Design and planning

- The development of annual and five-year strategic business plans at national level to define the direction of NMQCLs and NMRAs.
- Commitment at the highest level (such as the Ministry of Health) and from regional technical bodies (such as WAHO).

Phase 2: Implementation

- Assessment of the country's quality management systems (QMS).
- Building maintenance and technical capacities and improving materials.
- Rigorous selection of competent, internationally-renowned experts as resources for on-site staff training.
- Support for international accreditation (WHO, ISO).

Phase 3: Monitoring and evaluation

- The monitoring and evaluation strategies and tools used include: laboratory equipment inventories, materials inventories, internal and external audits, quarterly, half-yearly and annual activity reports, mission reports, and Annual Action Plan evaluations.

The need for NMQCLs and NMRAs

In order to improve the efficacy and safety of medicines for the population of West Africa, in accordance with existing documentation, the 15 ECOWAS Member States have established national medicines quality control laboratories (NMQCL). These laboratories are either autonomous or part of the National Medicines Regulatory Authorities (NMRAs). The governments of ECOWAS member states established these institutions by means of decrees and laws as early as 1993, and several of them have been created since 2000. Over the course of the World Bank's financial support for the SWEDD project and the technical support of WAHO, at least nine NMQCLs in the region have improved their quality systems through the use of the Good Laboratory Practice (GLP) standard and have obtained ISO 17025:2017 certification.

Sources: Sopein-Mann et al, 2021; PAHO/WHO, n.d.

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Main operational challenges influencing the improvement of quality and operation of NMQCLs and NMRAs	Lack of information and access to appropriate technical and material resources.
	Lack of highly-qualified personnel and maintenance companies.
	Logistical problems such as irregular electricity supply and inadequate laboratory construction.
	Inefficient and slow administrative and bureaucratic procedures leading to delays.
	Erratic organization of tests required for accreditation.
Measures suggested by countries to meet some of the challenges and ensure the sustainability of quality improvements	Maintenance of laboratory equipment through a three-year preventive and corrective maintenance plan, particularly for highly technical equipment.
	Updating of documentation and ongoing training.
	The increase in examination fees, which are still fairly low.
	Maintaining a skilled workforce through a system of incentives.
	Participation in international calls for tenders for tests.

SUMMARY OF KEY LESSONS

Phase 1: Design and planning	1	The commitment of the highest level authorities, such as the Ministry of Health, is an essential starting point in the process of developing and planning the standardization of medicines and medical products.
	2	The development of strategic and business plans is of crucial importance.
	3	Leveraging the leadership and support of regional institutions, such as WAHO and WAEMU, is crucial for supporting NMRAs and NMQCLs to comply with standards and procedures.
Phase 2: National implementation of content	4	The involvement, commitment and leadership of the highest national authorities in the Ministries of Health, the NMRA, the NMQCLs and the SWEDD Project Management Units (PMUs) are crucial from the planning phase through to the implementation of capacity-building.
	5	Committing to internationally accepted standards as targets for NMRAs and NMQCLs, and understanding and following the procedures required to meet these standards, requires sustained political commitment and a significant allocation of human and financial resources.
	6	Innovative and collaborative strategies can help countries overcome these challenges.
	7	Sustainability of achievements is possible, but it requires constant vigilance in priority areas.
Phase 3: Monitoring and evaluation	8	It is important to carry out monitoring and evaluation not only at national level but also at regional level.

Sources: PAHO/WHO. n.d. About the Quality and Regulation of Medicines and Health Technologies Project. Pan American Health Organization and World Health Organization. Retrieved October 15, 2023; Sopein-Mann, O., Ekeocha, Z., Byrn, S. R., & Clase, K. L. 2021. Medicines Regulation in West Africa: Current State and Opportunities (1st ed.). Purdue University. https://doi.org/10.5703/1288284317443.

This brief is based on a guide that describes in detail the process of designing and planning, implementing and monitoring-evaluating technical support for National Medicines Quality Control Laboratories (NMQCL) and National Medicines Regulatory Authorities (NMRA). It was developed by the West African Health Organization (WAHO) with the technical support of UNFPA and the World Bank.

For more information on the documentation of the processes involved in this intervention and on the SWEDD project, visit the SWEDD project's virtual resource platform: https://sweddknowledge.org/