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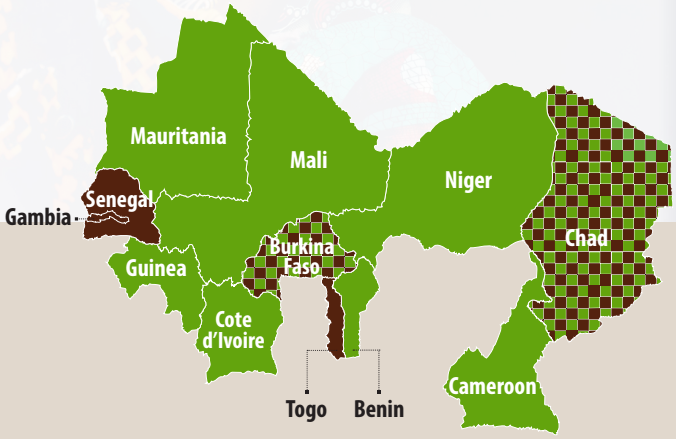
8

SWEDD SERIES: BEST PRACTICE GUIDE

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

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



SWEDD (2015–2024) SWEDD+ (2024–2028) SWEDD & SWEDD+

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The project covers countries in West and Central Africa

Ensuring the quality and safety of medicines and medical products worldwide, particularly in sub-Saharan Africa, remains a major public health challenge. According to World Health Organisation (WHO) and United States Pharmacopoeia (USP) reports on the quality of medicines, around 10 per cent of medicines available on the market in low- and middle-income countries were counterfeit or of inferior quality (Hajjou et al., 2015; Petersen et al., 2017).

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In order to address this issue and improve the efficacy and safety of medicines for the population of West Africa, in line with the existing literature (Sopein-Mann et al., 2021; National Academies of Sciences et al., 2019; Ndomondo-Sigonda et al., 2020; PAHO/WHO, undated; Ndomondo-Sigonda et al., 2017), the 15 member states of the Economic Community of West African States (ECOWAS) have established National Medical 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.

Sample: Four SWEDD project countries: Burkina Faso, Mali, Niger and Chad.

Main data sources: Key respondent answers to online questionnaires.

Collection methodology: Online questionnaires sent to participants, in accordance with the Conversation Guide, specifically adapted to the theme, with telephone follow-up if necessary.

Analysis methodology: Qualitative analysis of contextual data (participants' responses to questionnaires) by WAHO.

Date: July - November 2023.

See the annexes for more details on methodology and sampling.

As of 2014, the West African Health Organisation (WAHO) had initiated coordination between the NMRAs in the region, to establish a harmonised drug registration process. At the same time, the West African Economic and Monetary Union (WAEMU) is supporting this process for francophone countries. Using the Resolution on a harmonised common technical document as its starting point, WAHO asked the ECOWAS Assembly of Ministers of Health (AMS/ECOWAS) to grant the necessary autonomy to the NMRAs. The aim of this approach was to guarantee their independence and to ensure that high-quality, safe and effective medicines are placed on the market (WAHO & ECOWAS, undated). Coordination was intensified from 2014 to 2017 with the support of projects such as Sahel Women's Empowerment and Demographic Dividend (SWEDD) and the West Africa Medicines Regulatory Harmonization initiative (WA-MRH). During this period, nine NMQCLs in the region improved their quality management systems by adopting the Good Laboratory Practice standard, and achieved International Organisation for Standardisation (ISO) 17025:2017 accreditation. The institutions in SWEDD countries involved in this process include the National Public Health Laboratory in Côte d'Ivoire, the National Laboratory for the Quality Control of Medicines in Mali and the National Agency for Environmental, Food, Labour and Health Product Safety in Burkina Faso.[1]

This Guide documents the technical support process offered by WAHO to the NMQCL and NMRA. This technical assistance was provided in a participatory manner, with the aim of defining how to commission the NMQCLs and NMRAs in order to improve the future processes of such organisations in the countries joining the SWEDD project, and in other countries wishing to undertake similar improvements. The support process was divided into three phases: (1) design and planning of support; (2) implementation; and (3) monitoring, evaluation and sustainability.

[1] The Burkina Faso laboratory has not yet obtained accreditation, but as result of its participation in the SWEDD project it has established a system that meets the requirements of ISO 17025: 2017. The laboratory has just applied for accreditation and is preparing to welcome the accreditation team in February 2024.

The laboratory accreditation process

The accreditation process for ISO certification of an NMQCL or NMRA for international certification is determined based on the facility's current level.

- For laboratories, regional standards include WHO pre-qualification, ISO 17025:2017 and ISO 9001:2015.
- For NMRAs, the benchmark is to achieve at least WHO level three maturity using the WHO Global Benchmarking Tool (WHO-GBT) and then move on to level four.
- The internationally recognised ISO standards established as objectives for NMQCLs and NMRAs are as follows:
  - » ISO-9001-2015 https://www.iso.org/standard/62085.html for quality management; and
  - » ISO 17025:2017 (ISO/IEC 9001, 2021) https://www.iso.org/standard/66912.html for the competence of the laboratory.
- There are also specific procedures governing the WHO maturity level, starting with a self-evaluation by the NMRA, followed by a WHO visit. In the event of non-compliance, a second visit is scheduled to resolve the problems detected.


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PHASE 1

SUPPORT DESIGN AND PLANNING

In 2014, at regional level, WAHO and WAEMU convened the directors of the NMQCLs and NMRAs of the 15 ECOWAS Member States. The aim was to ensure regional harmonisation, integration and collaboration, by pooling resources and developing a common approach to achieving common goals. These regional meetings led to further national-level collaboration and relationships, such as peer-to-peer mentoring.

From 2016 to 2019, with the support of the SWEDD project, WAHO organised annual meetings of NMQCL directors to encourage discussion and make recommendations for institutional capacity-building. A representative of the Mali NMRA explained: "*The decision to request SWEDD project support to build the capacity of the Department of Pharmacy and Medicines (DPM) was taken by the Ministry of Health and Social Development via the DPM, to address the shortcomings identified, particularly those relating to the quality of the services offered and governance.*" These include absence of pharmaceutical governance guidelines, lack of a national pharmaceutical procurement strategy, lack of quality assurance guidelines, lack of working procedures, inadequate human resources, lack of mobile logistics and the problems of storing products in Community Health Centres (McKinsey, undated).

WAHO and SWEDD project regional support for the NMRAs and NMQCLs

Support for the NMRAs: For a number of years, WAHO, with the support of the ECOWAS Commission and technical and financial partners[a], has supported the NMRAs in building their capacity to operate optimally and meet certain international standards in Good Regulatory Practice (GRP), Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), among others. In 2018, seven expert working groups were created, including a representative from seven ECOWAS countries, selected following an evaluation.[b] The engagement of the NMRAs and the 7 working groups resulted in a harmonised common technical document and technical documents to support the regional joint drug approval process were developed and deployed, to enable interested manufacturers to undergo a regional evaluation through one of the Medical Product Dossier Evaluation and Registration Working Groups (MPDER-WG).

Support for the NMQCLs: Under the SWEDD project, support was provided to NMQCLs to guide them towards accreditation and the supply of high-quality, affordable reference substances from the USP-USA. A WAHO evaluation of the NMQCLs in 2011 classified them in three categories (A, B and C) based on their level of development and performance. The most common challenges identified within these categories were the following: (a) lack of maintenance and calibration of laboratory equipment; (b) limited or non-existent supply of reference substances; (c) poor quality of documentation; and (d) poor training of technical staff. To remedy these problems, existing laboratory equipment was analysed and mapped with the aim of organising the maintenance of national laboratory equipment, while building the capacity of laboratory staff to perform the maintenance.

[a] Partners included WAEMU, the African Union Development Agency - New Partnership for Africa's Development (AUDA-NEPAD), the African Medicines Regulatory Harmonisation (AMRH), the Global Medicines Regulatory Harmonisation (GMRH), the Bill and Melinda Gates Foundation (BMGF), the WHO, Swissmedic and the USP.

[b] The other eight ECOWAS member states, as well as Mauritania and Chad (non-ECOWAS member states), acted as observers. Mauritania and Chad were included because they are among the countries participating in the SWEDD project.

One of the key recommendations of the 2017 Annual Meeting of Directors of the National Medicines Quality Control Laboratories was to develop five-year national strategic business plans to set the direction for NMQCLs and NMRAs. All the respondents interviewed for this Guide stressed the importance of drawing up strategic, operational and annual plans and roadmaps. These documents should highlight priority activities, institutionalise the quarterly evaluation of plan implementation, and develop a clear reference framework for related activities.

A key respondent from Chad reported that there is a 2017-2020 strategic plan, "*...the Supply Chain Transformation Plan, developed in 2018 and revised in 2022 is the most used by NMRA.*" A similar plan also exists in Mali, according to the respondents. According to the National Health Laboratory (NHL) and Mali's DPM, key stakeholders participated in the meetings at which the strategic plans

were developed, including "*NHL staff, technical departments of the Ministry of Health and Social Development, financial and technical partners, led by experts funded by the U.S. Agency for International Development's Drug Quality Promotion Fund Plus programme (PQM+/USAID).*"


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Key lessons learned from design and planning

LESSON 1: Engaging the highest level authorities, such as the Ministry of Health, is an essential starting point in the process of developing and planning the standardisation of medicines and medical products.

Institutions such as the NMRAs, the equivalent of Food and Drug Authorities in other countries, as well as independent NMQCLs, can only be created with engagement at the highest levels, particularly when backed by legislation, as was the case in the ECOWAS region.

LESSON 2: The development of strategic and business plans is of crucial importance.

Not only to identify and define objectives, but also as a tool to highlight other needs such as a clear commitment from national senior leaders, strategic partnerships, collaboration and leveraging efforts.

LESSON 3: Leveraging the leadership and support of regional institutions, such as WAHO and WAEMU, is crucial for supporting NMRAs and NMQCLs in meeting the standards and procedures.

For example, WAHO organised regional meetings that resulted, among other outcomes, in the recommendation to develop a strategic plan and a five-year business plan for the NMQCLs and NMRAs. The objectives defined in the five-year strategic plans of the NMQCLs and NMRAs were high-level and could not be achieved by each country in isolation.

PHASE 2 IMPLEMENTATION

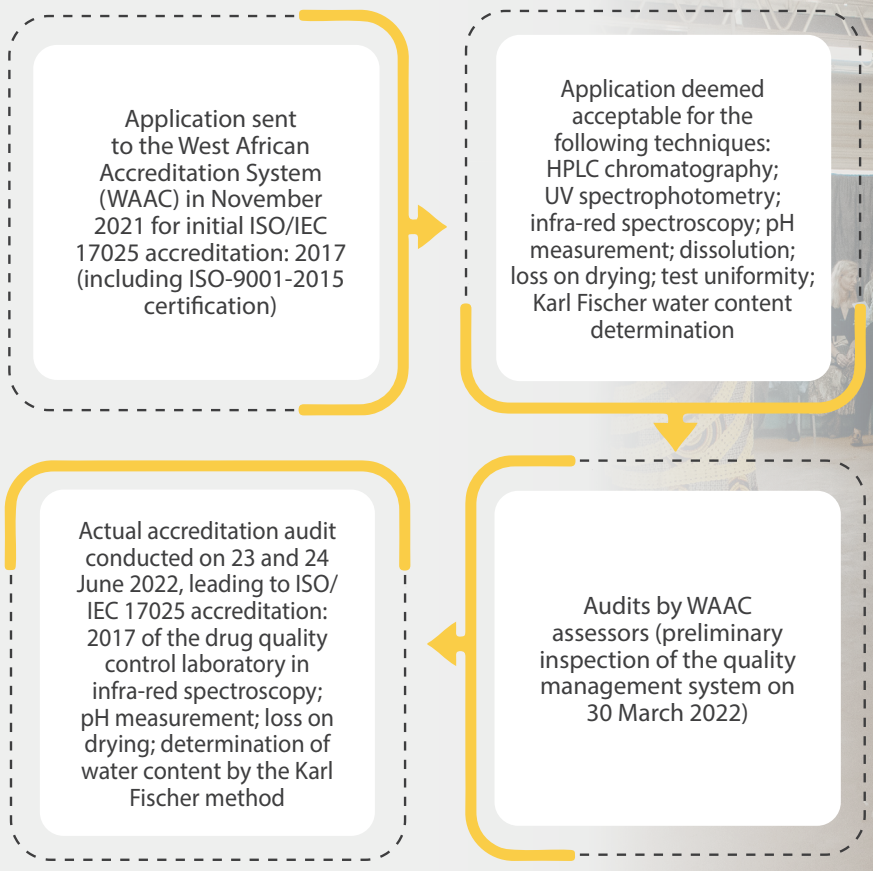
Implementation focused on improving the quality and technical capacity of participating NMQCLs and NMRAs, including preparation and applications aimed at achieving international standards. As noted by Mali's DPM, the areas requiring technical support included: (i) development of a national plan for effective pharmaceutical governance; (ii) supply of IT equipment and materials for the storage of health products; (iii) monthly updating of stock inventories; (iv) last-mile distribution of medicines and other health products; (v) ongoing training of key implementation actors; and (vi) development and validation of a manual of implementation and continuous improvement procedures.

The technical support process involved a range of key actors, including: (i) the highest national authorities, for advocacy, approval, inclusion, and increase of national budget lines for the laboratories; (ii) the Project Management Units (PMUs) of the SWEDD countries, for planning, implementation, financial and budgetary management, and monitoring and evaluation; (iii) the laboratory staff responsible for day-to-day analytical activities; and (iv) the international and regional organisations that provided technical and financial assistance. Other specific key actors may vary from country to country.

The international community has recommended that laboratories and NMRAs in the region engage in the development of good regulatory practice, good laboratory practice standards, and accreditation by international standards such as WHO pre-qualification and ISO, among others. These objectives had not been achieved by national laboratories in francophone West African countries in 2014, particularly with regard to good laboratory practice standards, WHO pre-qualification, and achieving ISO 9001-2015 / ISO 17025:2017.

In order to achieve these objectives, WAHO carried out an evaluation of the countries' quality management systems (QMS). Following this evaluation, accreditation roadmaps were presented to each country. So far, two countries in the SWEDD project have obtained ISO 17025:2017 accreditation - the National Public Health Laboratory in Côte d'Ivoire and the National Laboratory for the Quality Control of Medicines in Mali. Meanwhile, Burkina Faso is on track to obtain accreditation in February 2024.[2] Figure 1 illustrates Mali's accreditation process.

Figure 1: The accreditation process: the example of Mali



Respondents stressed the importance of certain key processes in quality control and accreditation. These include: (i) rigorous selection of competent and internationally renowned experts as resource persons, based on needs and in close collaboration with the NMQCL authorities and staff; (ii) on-site training of staff by selected international experts; and (iii) ongoing coaching of staff throughout the process on laboratory aspects such as use of equipment, analytical methods, management of the quality management system, etc.

All respondents mentioned a number of implementation challenges. Two of the institutions reported delays in obtaining no-objection notices. Niger's National Public Health and Expertise Laboratory (LANSPEX) has stated that "*...at donor level, the activities scheduled in the Annual Work and Budget Programmes should not be hampered by implementation difficulties due to the lack of feedback on no-objection notices.*" Chad's NMQCL representative also highlighted a communication gap between SWEDD and WAHO. Other challenges are detailed in table 1 below.

Measures suggested by countries to meet some of the challenges and ensure the sustainability of quality improvements include: (i) maintaining laboratory equipment by means of a three-year preventive and corrective maintenance plan, particularly for highly technical equipment; (ii) updating documentation and providing ongoing training; (iii) increasing examination fees, which are still fairly low; (iv) maintaining qualified staff through a system of incentives; and (v) taking part in international invitations for tenders for tests.

[2] Six other NMQCLs in non-SWEDD countries in the region have also achieved ISO 17025:2017 certification: the Food and Drug Authority in Ghana; four NAFDAC laboratories in Nigeria, and INLAB in Cape Verde.

Table 1: Main operational challenges influencing the improvement of quality and general operation according to the respondents

Lack of information and access to sufficient technical and material resources:

- Laboratories' limited knowledge of the scope of the accreditation body;
- Lack of recognised official pharmacopoeias;
- Challenges relating to the availability of reference substances for pharmacopoeias: these are expensive and are generally only affordable if they are obtained under agreements with organisations such as the USP/USA.

Lack of highly-qualified personnel and companies required for maintenance:

- Lack of highly qualified human resources at national level for certain tasks such as preventive maintenance and qualification of purchased state-of-the-art equipment;
- Limited local availability of qualified equipment maintenance companies.

Logistical problems:

- Inadequate laboratory equipment;
- Inadequate laboratory construction (e.g. lack of fume cabinets);
- Irregular supply of electricity during power cuts, even when the laboratory is prepared to bear high fuel costs for the generators.

Inefficient and slow administrative and bureaucratic procedures leading to delays:

- Procurement procedures sometimes differ between government and donors;
- Slow approval of contracts by the Public Procurement Department;
- Lengthy procurement process when recruiting essential staff.

Erratic organisation of tests required for accreditation.

- Lack of trained staff to carry out aptitude and inter-comparison tests;
- Irregular proficiency tests and inter-comparison tests on certain methods in accreditation processes.

A useful process established in the region is the creation, by the NMRA directors, of their own forum dedicated to West Africa, under the name of the Forum of West African NMRA Directors (FOWAHN). The countries use this forum to share updates, discuss challenges, put forward solutions and support each other. For example, NMRAs at WHO maturity level 3 (see box on accreditation processes), such as those in Ghana and Nigeria, provide technical support to NMRAs at WHO maturity level 1 or 2, such as those in Côte d'Ivoire, Sierra Leone and the Gambia. This example illustrates the value of strategic partnerships, between the countries themselves and, by leveraging the efforts of sister organisations, in building the capacity of NMRAs and NMQCLs.

The NMQCLs recognised that the achievements are sustainable; however, as Chad and Mali pointed out, further efforts would be needed to ensure this sustainability. Chad mentioned the importance of "*...maintaining equipment, updating documentation and ongoing training.*" Mali pointed to a number of issues requiring attention, such as "*increasing test fees, which are still relatively low; maintaining qualified staff through a system of incentives; participating in international tenders for tests; and implementing a three-year preventive and corrective maintenance plan for highly technical equipment.*"

Best practice actions were also noted, specifically:

- The empowerment of the technical directorates as implementation organisations within the NMRA;
- The formal designation of key contacts and/or a project management unit (SWEDD-PMU);
- The participation of the project country's monitoring and evaluation manager in meetings to validate the NMQCL's annual activity reports;
- Mali and Chad's choice of distribution models for last-mile transportation of medicines, adapted to reach hard-to-reach health centres, particularly because of distance (as in the case of Chad, where some health centres are located more than 200 km from a main centre and are served by impassable roads);
- The engagement of the Directorate General for Pharmacy, Medicines and Laboratories;
- On-site staff training provided by international experts;
- Expert support for staff throughout the process, including the use of equipment, analysis methods, quality system management and the drafting of standards documents;
- The establishment of an NMQCL and identification of its needs through independent external audits and the planning of activities;
- Building material, technical and human capacities.

Key implementation lessons learned

LESSON 4: The involvement, engagement 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.

These stakeholders played different roles to ensure that the capacity-building of the NMRAs and NMQCLs ran smoothly and was in line with identified needs. Officials of the Ministries of Health advocated for an adequate budget allocation for these institutions, while laboratory managers focused on networking, learning from counterpart organisations, and awareness-raising about their needs and their importance for public health among key ministerial decision-makers. Regional institutions provided technical, financial and advocacy support at regional level. Taken together, these efforts helped to build the necessary capacity.

LESSON 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 engagement and a significant allocation of human and financial resources.

Numerous stages are required between the initial submission of applications and obtaining the reference certifications/accreditations.[3] Thus, political engagement at the highest level is essential, while the effective implementation of each stage requires time, financial resources and the active participation of several entities.

LESSON 6: Innovative and collaborative strategies can help countries overcome these challenges.

This includes using on-site training for laboratory staff (particularly during the COVID-19 pandemic), fostering autonomy, building capacity in drug quality control, adopting a more collaborative approach, and leveraging the efforts of other departments in national Ministries of Health, as well as other domestic and foreign institutions.

LESSON 7: Sustainability of achievements is possible, but it requires constant vigilance in priority areas.

This mainly includes regular maintenance of laboratory equipment, qualified staff maintained on site and motivated by appropriate incentives, as well as the provision of ongoing training, among other things.

[3]More specifically: ISO-9001-2015 / ISO 17025:2017. These steps are described on the websites of the successful organisations (such as the WHO pages dedicated to the WHO Global *Benchmarking Tools*, undated).

PHASE 3

MONITORING AND EVALUATION

Monitoring and evaluation (M&E) activities were carried out at regional and national levels. At regional level, WAHO oversees the M&E of technical support, either alone or in collaboration with partners. At national level, M&E is carried out by the SWEDD-PMU, the NMRAs, the NMQCLs and the Ministries of Health.

Regional level

M&E at regional level is aligned with WAHO M&E for other projects that it supports in the region. Every year, the WAHO M&E team visits ECOWAS member states (plus Chad and Mauritania under the SWEDD project). The visits include presentation of the results of the monitoring and evaluation of all the projects it supports, including support for the NMRAs and NMQCLs.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Following a pre-established M&E schedule, WAHO sends visit notification letters to the countries concerned, specifying the scheduled dates and times. After protocol meetings with the ministries, the laboratories are inspected to evaluate the implementation of activities, the methods used, the justification or evidence of implementation, as well as challenges encountered and any immediate solutions. These visits are also an opportunity for the regional WAHO team to request additional information or clarification from the SWEDD-PMU or WAHO management. The reports of the annual M&E exercise, together with the accompanying recommendations, are generally shared at the meetings of the WAHO Programme Committee, the ECOWAS arbitration body for the activities planned by various institutions for the following year.

One of the challenges generally encountered in the M&E process is the lack of synchronisation of monitoring visits in countries, which do not provide simultaneous justification for the activities carried out by all stakeholders. Nevertheless, each monitoring and evaluation visit helps to resolve these difficulties, thus ensuring that the countries take ownership of the programmes and the results of the projects.

> *The monitoring and evaluation process enabled adaptation of interventions, document management and the rigorous monitoring of acquisitions.*
>
> **LANSPEX Niger**

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According to NMQCL and NMRA respondents, laboratory monitoring takes place on a quarterly or half-yearly basis, under the auspices of the Ministries of Health or the NMRAs. For example, the Burkina Faso NMRA specified that "*monitoring is conducted by the Research and International Cooperation Department for technical aspects and the Finance Administration Department for financial aspects*." The monitoring and evaluation strategies and tools used include laboratory equipment inventories, inventories of materials, internal and external audits, quarterly, half-yearly and annual activity reports, mission reports, annual action plan evaluations, implementation monitoring and reports of regional meetings on the implementation status of the NMQCLs' annual action plans. Using these tools during these exercises enables each stakeholder to learn about the achievements, challenges and solutions, and to discuss them.

Respondents mentioned a few specific aspects of monitoring and evaluation that they found particularly useful. These include the appointment of key contacts or the SWEDD-PMU, which facilitated more effective monitoring and better leveraging of project activities. They also stressed the importance of the participation of those responsible for monitoring and evaluation in the annual validation meetings, discussion of the progress status of the project's activities, and the recruitment of an external evaluator whose results provide the benchmark for the technical support to be provided.

LESSON 8: It is important to carry out monitoring and evaluation not only at national level but also at regional level.

National and regional level monitoring and evaluation assignments conducted by the same entity improved communication between stakeholders at all levels, empowered countries and increased their ownership of the process. When asked about lessons learned from the monitoring and evaluation, Burkina Faso's regulartory agency (ANSSEAT) confirmed that "the monitoring conducted by the [SWEDD countries'] management unit, and by the regional coordination, complement one another."

SUMMARY OF KEY LESSONS

Phase 1: Design and planning	1	Engaging the highest level authorities, such as the Ministry of Health, is an essential starting point in the process of developing and planning the standardisation 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 in meeting the 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 engagement 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.

ANNEX 1: Methodology and sampling

I. The documentation exercise and data collection process

1 Among the beneficiary countries, Burkina Faso, Chad, Mali and Niger were chosen for interviews; these countries are the most advanced in their quality certification by bodies such as ISO or WHO, which means they have the most informative processes to document.

2 Due to process-related delays and the awarding of contracts for the external interviewers responsible for documenting the NMRA and NMQCL processes, such interviewers were not recruited. As a result, WAHO SWEDD-PMU staff conducted the exercise themselves after obtaining appropriate approval from the World Bank which was managing process documentation. WAHO SWEDD-PMU staff adapted the training materials and the Conversation Guide for laboratories and regulatory authorities. WAHO established a team to review the existing documents and draft the guide, which summarises the key points from the outline and plan provided.

3 It is important to note that WAHO has offered technical assistance aimed at improving the quality of laboratories and regulatory authorities. WAHO also collected and analysed data as part of this technical support process documentation exercise.

II. Data sources

The information was gathered using the Conversation Guide adapted by WAHO and distributed to the four SWEDD project countries specifically targeted for this documentation and to the relevant regional actors. These informants do not represent a systematic sample, "but, rather, a convenience sample of those with experience in the theme of this Guide across these four countries" that make it possible to leverage existing SWEDD capacity.

III. Sampling

The sample surveyed varies between NMRAs and NMQCLs and across countries. Annexes 2a and 2b provide the sample for each country, separately for the NMRA and the NMQCL.

IV. Data collection methodology

Potential respondents were identified by contacting the SWEDD-PMU focal points for process documentation. These key contacts in the four countries provided a list of potential respondents who were contacted directly by WAHO for a scoping meeting. The Conversation Guide, which includes a set of questions, was then sent to each person by email, with a follow-up telephone call if necessary. Respondents from each country also sent their answers to WAHO by e-mail. The quotes provided are taken from these written responses sent to WAHO, rather than from interviews (as is the case for the other Guides in this Best Practice Series).

V. Analysis methodology

The WAHO team conducted a manual analysis of the key respondents' answers to the questions put to them in order to draft this Guide. An overview summary was developed by WAHO to provide a basis for the Guide. The Guide was then drafted, first in English and then in French, with the support of the World Bank and UNFPA-RTS process documentation team.

ANNEX 2 (a): Key informants interviewed - NMQCL

Key informants	Country
1 ANSSEAT representative	**Burkina Faso**
1 national project coordinator, 1 project manager, 1 project M&E expert, 1 general manager, 1 deputy general manager and 1 LCQM manager from the National Health Laboratory	**Mali**
1 general manager, 1 head of the administrative and financial department, 1 head of the training, research and quality assurance department, 1 head of the technical-administrative department and 1 head of the LANSPEX training and research section	**Niger**
1 NMQCL director, 1 manager of SWEDD project component 2	**Chad**

ANNEX 2 (b): Key informants interviewed - NMRA

Key informants	Country
1 general manager, 1 certification manager and the head of the NMRA research department	**Burkina Faso**
1 director, 1 deputy director of pharmacy and medicines, 1 head of the quality assurance and medicines economics division at the DPM, and the SWEDD advisor on behalf of the DPM	**Mali**
1 director, 1 deputy director, the DPM Health/SWEDD programme officer	**Chad**

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This Guide is one of a series that retrospectively documents the process of implementing the interventions of the SWEDD project, and documents good practices, challenges and lessons learned. The "Sahel Women's Empowerment and Demographic Dividend" (SWEDD) project was launched in November 2015 with financial support from the World Bank, and technical support from the United Nations Population Fund (UNFPA) and the West African Health Organisation (WAHO). SWEDD aims to accelerate the demographic transition, trigger the demographic dividend and reduce gender inequalities in the Sahel. The motivation for this series is the fact that SWEDD has become a strategic framework for political decision-makers, opinion leaders (traditional and religious chiefs, and other community leaders), and the community to work together on issues considered sensitive in the region. This is why it was considered important to share the processes through which the project was developed. This includes descriptions of experiences, lessons learned and recommendations. This evidence could be used to enrich interventions in SWEDD+ and other initiatives on gender equality and the empowerment of adolescent girls and young women.

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/.