

Accelerating regulatory approvals through the World Health Organization collaborative registration procedures

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Towards African Regulatory harmonization processes – Accelerating patient access to medicines.

The role played by properly functioning regulatory systems towards enhancing access to essential medicines for patients is crucial. This is especially the case in Africa which has seen progressive growth in the regulatory environment. At the center of this growth has been the African Medicines Regulatory Harmonization (AMRH) initiative. This initiative seeks to strengthen regulatory capacity and encourage harmonization of regulatory requirements – with the ultimate aim of expanding access to quality, safe, and effective medicines for patients in need in Africa. A lot of progress has been made during the last years, with initial focus on the East African Community, where harmonization related regulations have already been implemented. The same is now being rolled out in other regions such as West Africa and the Southern African Development Community.

Removing bottlenecks and reducing redundancies in regulatory processes that slow access to medicines for patients in need today is critical. In this sense, collaboration between the World Health Organization and relevant stakeholders, including the research-based pharmaceutical industry, on collaborative registration procedures that support fast and efficient review and approval of essential medicines in Africa is essential.

African regulatory harmonization offers many benefits to regulatory authorities, patients in Africa and industry alike – and most critically for the protection of public health.

Keywords: Accelerated registration, collaborative registration procedure, joint reviews/assessments, Africa Medicines Regulatory Harmonization (AMRH)

1. Introduction

In sub-Saharan Africa, the lack of harmonized technical requirements and capacity for medicines registration is a significant barrier that prevents access to essential medicines and health technologies. To ensure the safety and health of its citizens, each country must regulate the pharmaceutical products distributed within its borders, conducting a rigorous scientific assessment during the registration process to ensure all medicines meet critical standards of quality, safety, and efficacy. However, many National Medicines Regulatory Authorities (NMRAs) in Africa struggle to meet these important obligations, stemming from challenges including but not limited to shortages of human resources, technical capacity, and funding. The registration process for key essential medicines may be extremely lengthy, stretching

over a period of years, and regulators may not have the capacity to fully ensure acceptable standards are met [1]. As a result, essential medicines are oftentimes less available in African countries than in other markets, despite significant need, and individuals may be at risk of harm from substandard, spurious, falsely labelled, falsified, and counterfeit (SSFFC) medical products. These shortfalls cost millions of lives, and contribute to poor health outcomes and lower life-expectancy relative to other regions of the world.

Over the last decade, African regulators and the international community have come together to address this issue. Given limited resources available to local NMRAs, key opportunities exist to combine efforts through collaborative registration procedures, in which NMRAs can inform their own assessment process by drawing on 1) joint review processes conducted together with other countries in their region, and/or 2) assessments done by the World Health Organization (WHO) Prequalification of Medicines Program (PQP) and/or stringent regulatory authorities (SRAs). Recent successes in accelerating registration processes through these procedures represent an important step towards facilitating access to essential medicines and improving health. Based on this premise, this article will provide:

1. A background on the development of collaborative procedures for medicines registration
2. An overview of procedures currently in place and their applications
3. A closer look at a specific application of collaborative registration and its outcomes.

2. Background

2.1. Development of regulatory harmonization efforts & joint review processes

In the past, the approximately 50 NMRAs in Africa have worked independently to register medicines, with different agencies applying different administrative procedures and technical requirements. The diversity and opacity of these processes have significantly delayed manufacturers in bringing key medicines to local markets in an efficient and timely manner [2]. In 2008, WHO members at the 13th International Conference of the Drug Regulatory Authorities (ICDRA) requested that the WHO support harmonization approaches enabling NMRAs to use their limited resources more effectively [3]. In response, the WHO initiated a series of discussions with global partners that led to the formation of a high-level alliance between the New Partnership for Africa's Development (NEPAD) Agency, the WHO, the Bill & Melinda Gates Foundation (BMGF), the World Bank, the UK Department for International Development (DfID), and the Clinton Health Access Initiative (CHAI) [3]. This consortium established a trust fund to support a new initiative, the African Medicines Regulatory Harmonization Initiative (AMRH) [4].

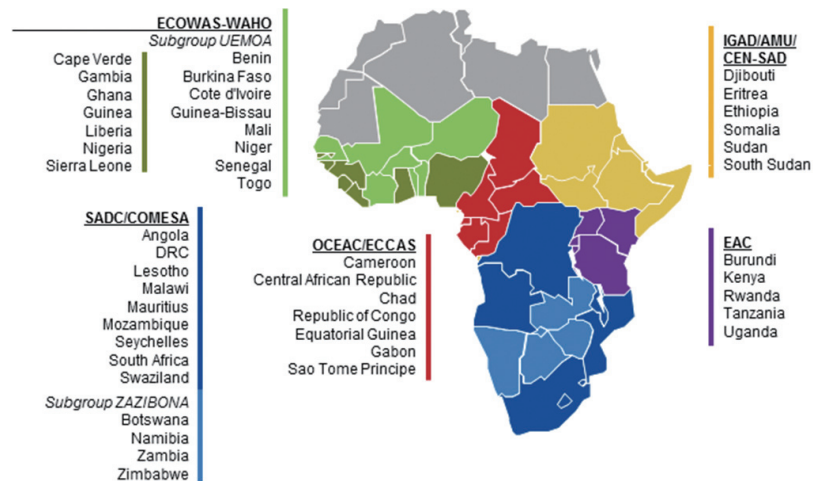


Fig. 1. AMRH Regions. Source: NEPAD Agency.

The goal of the AMRH consortium is to achieve a harmonized medicines registration process in countries belonging to the Regional Economic Communities (RECs), based on common documents, processes, and shared information systems. AMRH is coordinated by NEPAD and implemented with support from partner organizations, particularly the WHO as the primary technical partner. Working with RECs and individual countries, the WHO provides technical assistance in the development and implementation of harmonized approaches for the registration of medicines, supporting overall capacity building, training, and joint activities [3].

Since its establishment, five RECs have begun engagement with AMRH, each at different stages of the harmonization process (see Fig. 1). The East African Community (EAC) was the first region to officially begin harmonization through AMRH in 2012 and has made significant advances to date. In West Africa, the Economic Community of West African States – West African Health Organization (ECOWAS-WAHO) launched AMRH in February 2015, followed by the Southern African Development Community/ Common Market for Eastern and Southern Africa (SADC/COMESA) in July of that same year. Initial progress has also been made in Central Africa, where the Organization for the Coordination and Control of Endemic Diseases in Central Africa (OCEAC) will hold its first joint assessment in 2016 and its first joint Good Manufacturing Practices (GMP) inspection by year's end, and in North-eastern Africa, where the Intergovernmental Authority on Development (IGAD) is preparing a proposal for participation in AMRH [5]. To date, joint review processes for medicines registration have been successfully implemented in the EAC region and in the ZaZiBoNa sub-region, comprising Botswana, Namibia, Zambia, and Zimbabwe.

2.2. Development of collaborative procedures with WHO PQP and SRAs

In addition to collaborating with other regulatory agencies in the region, NMRAs in sub-Saharan Africa have begun drawing on the work of international bodies, such as SRAs or the WHO PQP. In 2010, a WHO assessment of medicines regulatory systems in 26 sub-Saharan African countries found that few NMRAs effectively leveraged WHO PQP to improve registration processes. In response, the WHO developed guidelines for a Collaborative Registration Procedure (CRP) for WHO-prequalified products, designed to accelerate registration through improved information sharing between the WHO PQP and local NMRAs [1]. Subsequently, the WHO, with the support of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), developed similar guidelines for collaborative registration, drawing on assessments conducted by SRAs.

3. Joint registration procedures

3.1. EAC joint assessment

EAC member countries Kenya, Tanzania, Uganda, Rwanda, and Burundi were the first to initiate substantial harmonization efforts under the AMRH initiative in 2009. To facilitate collaborative registration processes amongst member countries, the region quickly developed the following tools:

1. An agreed common technical document for registration of medicines
2. A quality management system implemented in each of the EAC Partner States' NMRAs
3. A platform for information sharing on dossier assessments
4. A framework for mutual recognition of regulatory decisions made by the NMRAs of other EAC Partner States

With these key elements in place, EAC countries developed a joint assessment procedure and, with WHO support, launched an initial pilot in 2011 of two pharmaceutical products. The joint assessment procedure was designed to focus on high-priority medicines, including medicines from the essential medicines lists of member countries and medicines considered lifesaving commodities by the UN Commission on Life Saving Medicines for Women and Children, among other criteria [6]. In submitting a product for consideration, the manufacturer must consent to information-sharing of dossier assessment results among member countries. Once an application is made, a team of assessors from EAC Partner States jointly conducts an assessment, during which external expertise could be sought from other NMRAs, WHO PQP, and academic institutions under confidentiality agreements [6].

Over the course of several pilots, the procedure resulted in a number of successful joint assessments, initially for generic products: a first pilot in 2010–2011

led to two recommendations for licensing of generic products, and a second joint assessment in 2013–2014 resulted in 5 recommendations for licensing of generic products. Subsequently, in April 2014, the EAC joint assessment procedure was endorsed by EAC Ministers of Health. Following that decision, EAC conducted its first successful joint assessments of innovative biotherapeutic products, with a joint EAC/Swissmedic/WHO Clinical Review in October 2015 of Avastin[®] (*bevacizumab*) 100 mg and 400 mg and Herceptin[®] (*trastuzumab*) 150 mg and 440 mg, resulting in their recommendation for licensing in the EAC [7]. (*For more information on the EAC harmonization and registration process, see additional article on EAC harmonization.*)

3.2. ZaZiBoNa worksharing scheme

In 2014, NMRAs in Zambia, Zimbabwe, Botswana, and Namibia (collectively known as ZaZiBoNa) jointly took the initiative to collaborate on medicines registration with support from WHO PQP and the Southern African Regional Program on Access to Medicines and Diagnostics (SARPAM). Other countries such as Malawi, Mozambique, the Democratic Republic of Congo, Tanzania, South Africa, Swaziland, and Lesotho started to participate at a later stage in the process as observers. The process is considered as part of a regional regulatory harmonization effort, aimed at accomplishing five objectives: reducing regulatory workload; accelerating the registration process; strengthening intra-regional partnerships for regulatory collaboration; testing a collaborative registration process that could be scaled to other regions; and providing a regional platform for trainings and collaboration in other regulatory fields [7].

The ZaZiBoNa collaborative procedure consists of a work-sharing process for assessing registration applications incorporating SADC and WHO standards. For a product to be considered, it must be submitted for approval in at least two countries in the group, with special consideration given to medicines that address high-priority therapeutic areas as identified by SADC and the UN Commission on Life-saving Commodities for Women and Children, such as maternal, newborn and child health [8]. Manufacturers must also consent to share information amongst ZaZiBoNa regulators as part of the registration process. Once the process is initiated, the regional group appoints one country to lead the assessment of a given product, known as the “rapporteur”. The rapporteur compiles a draft assessment report that is discussed at a quarterly face to face meeting with all ZaZiBoNa health authorities. Jointly, they come up with questions to the applicant, subsequently relaying and assessing responses. Finally, the rapporteur finalizes a suggested Consolidated Assessment Report (CAR) for the group, whereby each NMRA makes its own decision on the final approval of the considered product [9]. Overall, the process was designed to achieve registration within a total time of 11 months [8].

The ZaZiBoNa registration procedure has yielded substantial success; to date, about 125 generic products have been assessed [10], including anti-infectives, anti-hypertensives, and anti-diabetics [11] as well as one innovative medical product,

Novartis' Coartem[®] (*artemether-lumefantrine*) 80/480 mg [12]. In the process, ZaZiBoNa member countries have continued to build regulatory capacity through regional trainings and to strengthen harmonization by coming to common agreements on critical areas such as data requirements, format, and interpretation methods [11].

3.3. Joint registration procedures: Next steps

Moving forward, the successful regional joint registration processes developed among EAC and ZaZiBoNa countries could be considered models to implement in other regional groupings or potentially for the African Medicines Agency (AMA), in order to effectively combine resources, share workload, and facilitate medicines registration. The WHO and other institutions are currently looking to build on this process and support regional harmonization and joint assessment processes in other regions of sub-Saharan Africa as well as around the world, particularly among the Association of Southeast Asian Nations (ASEAN) member states [13].

4. Collaborative registration procedures (CRP)

4.1. WHO CRP

The WHO CRP was the first CRP to be developed, and was designed to leverage the work of the WHO PQP to support participating NMRAs. The WHO CRP seeks to facilitate and accelerate national regulatory approvals by confidentially sharing specific data on the results of the dossier assessment by the WHO PQP with a NMRA reviewing the same dossier for registration. Participation in the CRP is voluntary for manufacturers and NMRAs, and does not interfere with national decision-making processes and regulatory fees already in place. To engage in the process, interested NMRAs must agree to confidentiality, commit to following the principles of the process, and attempt to make a decision on the registration of a product within a target timeline of 90 days. Subsequently, the manufacturer provides the NMRA with the same product and registration dossier that was approved by the WHO PQP, and WHO PQP confidentially shares the outcomes of its assessments and inspections to support the local NMRA as it makes its decision [14].

Since its initiation in 2012, the WHO CRP has been implemented with substantial success. So far, 28 NMRAs have participated, successfully registering over 110 products – with an additional 85 products in the pipeline – as of March 2016 [15]. Many of these products address key health priorities for sub-Saharan Africa, including [15]:

- 50 products registered for HIV/AIDS
- 22 products registered for tuberculosis
- 20 products registered for malaria
- 17 products registered for reproductive health

- 1 product registered for a neglected tropical disease

The WHO CRP has also reduced registration timelines significantly. Over half of all WHO CRP registrations have been successfully completed within the target timeline of three months, with nearly three-quarters in less than four months [15], and median registration time has fallen considerably as the program has matured [7].

4.2. SRA CRP

Following its experience implementing a collaborative registration procedure for WHO-prequalified products, in 2014, the WHO began developing and piloting a similar procedure to draw on the assessment and inspection outcomes from SRAs with the support of the IFPMA [16]. Through the SRA CRP, the manufacturer agrees to share detailed assessment and inspection outcomes from a consenting SRA with the support of the NMRA(s). Consequently, for a product to be considered via the SRA CRP process, pharmaceutical companies and the SRA must consent to information exchange with the NMRA(s) to which a product has been submitted for regulatory approval; similarly, NMRAs must agree to protect sensitive data and ensure its confidentiality. With these preconditions in place, the NMRA is able to draw on data belonging to the SRA in considering a product for approval. The SRA CRP has been piloted for the first time together with the European Medicines Agency (EMA) and Janssen, the Pharmaceutical Companies of Johnson & Johnson, for the pediatric formulation of the antiretroviral INTELENCE™ (*etravirine*) 25 mg oral tablet [17]. Currently, there are four additional drugs being piloted in collaboration with EMA and the Medicines and Healthcare Products Regulatory Agency (MHRA) of the United Kingdom as the participating SRAs.

5. Case study of SRA CRP Pilot

5.1. INTELENCE™ 25 mg oral tablet (Janssen, the Pharmaceutical Companies of Johnson & Johnson)

5.1.1. Background

At the end of 2014, IFPMA sent an expression of interest to all of its member companies to propose drug candidates for the first WHO-facilitated SRA CRP pilot; the pediatric antiretroviral, INTELENCE™ (*etravirine*) 25 mg oral tablet, manufactured by Janssen, the Pharmaceutical Companies of Johnson & Johnson, was selected. The pilot aimed to accelerate dossier review through the use of the SRA Common Technical Document (CTD) adapted for collaborative procedures and GMP inspection waivers, as SRA inspection reports were available for reference. Additionally, dossier reviews were conducted in parallel to other processes (i.e., mandatory sample lab analysis) rather than sequentially, contributing to overall efficiency.

The pilot began in March of 2015 in 11 African countries, with submissions in two waves (see Fig. 2):



Fig. 2. SRA CRP participating countries by wave.

- WAVE 1: Botswana, Democratic Republic of Congo, Namibia, Zambia, and Zimbabwe
- WAVE 2: Burkina Faso, Cameroon, Côte d'Ivoire, Kenya, Tanzania, and Uganda
- OBSERVERS: Rwanda, Burundi

5.1.2. Dossier contents

The contents of the adapted SRA dossier included modules 1, 2, and 3, annexes (including commitments and data sharing authorizations), and a limited number of samples. Module 1 consisted (among other documents) of the Quality Information Summary (QIS-SRA template, available on the WHO PQP website) as well as full EMA assessment and inspection reports. This format of the dossier – the content of which is aligned with initial submission dossiers for the EMA – was well accepted by the NMRAs, though some countries requested additional documentation (e.g., a local application form); most accepted the provision of this additional documentation during the review and not at initial submission.

5.1.3. Review process

In March 2015, WHO facilitated initial face-to-face meetings with NMRAs from ZaZiBoNa and the Democratic Republic of Congo; in May 2015, similar meetings occurred with NMRAs from the countries of the EAC and French West Africa. Prior to the meetings, a rapporteur country was assigned for each wave and was tasked with an initial review of the dossier. The rapporteur countries were also responsible for facilitating mutual understanding during the NMRA meetings and honing in on common issues deserving attention. Following the initial meetings, the WHO acted as a facilitator, providing Janssen with questions submitted by the NMRAs. Some NMRAs sent deficiency letters, with one providing some additional country-specific requirements. In order to save time, Janssen submitted responses to all NMRAs independent of whether they sent a deficiency letter or not. Afterwards, Wave 1 and Wave 2 countries met again with the WHO to discuss the responses submitted by Janssen.

5.1.4. Approvals

On 4 June 2015, INTELENCE™ 25 mg oral tablet received its first approval in a pilot country within the target window of 90 days from initial submission. As of the date of publication of this article, a total of nine approvals (including both Wave 1 and Wave 2 countries) have occurred within one year of submission, with two additional outlier countries for which registrations are still pending. In one case, the registration certificate was not issued immediately after the positive opinion, creating a delay in completing the registration process. In the other outlier country, GMP inspection was not waived despite the availability of an EMA inspection report. Overall, the median approval timeline across the nine countries was seven months – a significant reduction from the 20-month median timeline cited in a recent BMGF study as a basis for comparison [18]. The result of the pilot has been positive, demonstrating that accelerated registration procedures in Africa involving SRAs are possible, though shorter timelines will likely be targeted in future pilots.

5.1.5. Lessons learned and considerations for future pilots

1. **Communication and collaboration between NMRAs:** The review process served as a positive experience for all, especially the less-experienced NMRAs, which stood to benefit from engaging with more experienced NMRAs. Moreover, the face-to-face meetings led to increased dialogue between regulators – for example, about different practices used by each country in dossier review (e.g., the number of samples required). Throughout the process, the WHO served as a vital link between the NMRAs and Janssen, facilitating trust, providing guidance at every step, and enabling a faster flow of administrative tasks. During reviews, the WHO guided discussions among NMRAs to reach a common opinion and provided much sought-after technical input.
2. **Benefits and limitations of using the same dossier for all countries:** From the perspective of the manufacturer, the reviewers were thorough, giving adequate time to respond, and a significant amount of time and resources were

saved because the same dossier was submitted to all countries and a consolidated list of questions was received from all NMRAs. However, it was also apparent that the SRA reports did not reflect some of the on-the-ground realities in some of the pilot countries. In the future, it may be helpful for these reports to include additional information relevant to the African context (e.g., stability data meaningful to resource-limited settings). It might also be useful to consider the inclusion of a bridging report in the submission dossier (i.e., a summary prepared by the manufacturer) to ensure that necessary locally-relevant details are provided to the NMRA.

3. **Suggestions for overall process improvement:** Several suggestions for future pilots emerged from an analysis of this case study. First, it would be advisable for any variation already approved by the SRA and annexes of the assessment reports to be added to the dossier at initial submission to avoid the need to provide this information during the review period. Moreover, there is a clear need to establish a direct line of communication between the applicant and a focal person at the NMRA to facilitate faster follow-up and information sharing during the process. Importantly, to ensure approvals are granted within the outlined timeframe, strict deadlines for phases of evaluation and the provision of responses should be set at the outset and a clear face-to-face meeting calendar established with the NMRAs.

6. Additional SRA CRP pilots

Following the success of the SRA CRP pilot for Janssen's INTELENCE™ 25 mg oral tablet, the regulatory harmonization community has begun to leverage available resources and expertise to apply the SRA CRP beyond the individual country level and adapt it to harmonized joint review processes at the regional level.

At the end of 2015, the IFPMA sent an expression of interest to all of its member companies to propose drug candidates for a second WHO facilitated SRA CRP pilot. As high-priority new therapies addressing important disease areas, PREZISTA™ (*darunavir*) 400 mg oral tablet and PREZISTA™ 100 mg/ml oral suspension – both Janssen antiretrovirals – as well as SIRTURO™ (*bedaquiline*) 100 mg oral tablet, the company's anti-TB medicine, were selected as candidates, among others. Both products have been submitted as part of the EAC and ZaZiBoNa joint assessment processes, “fast-tracked” with SRA CRP support.

Submissions for PREZISTA™ 400 mg oral tablet and 100 mg/ml oral suspension began in November 2015 for joint assessment by ZaZiBoNa countries. The first submissions for the SIRTURO™ 100 mg tablet began in February 2016 and are being considered jointly by EAC countries as well as Ghana, Nigeria, Cameroon and Ethiopia [19]. Reviews are ongoing.

7. Conclusion

As demonstrated by successful pilots, including that of Janssen's INTELENCE[®] 25 mg oral tablet, the potential benefits of collaborative registration procedures are significant and include reducing the time and costs of regulatory approvals for NMRAs and manufacturers alike. Most importantly, these streamlined procedures can positively influence health outcomes, enabling quicker access to quality medicines for patients in need. Moving forward, regional joint assessment processes have the potential to increase efficiencies in regulatory processes by empowering NMRAs to combine resources and share workload.

The strengthening of these mechanisms in the EAC and ZaZiBoNa regions, as well as potential expansion to other economic communities, represents an important opportunity to build collective local regulatory capacity. Similarly, collaborative registration provides a mechanism to leverage the expertise of SRAs and the WHO PQP program to fast-track registration. Used together, these procedures enable local NMRAs to draw on both regional communities and international support to access to much-needed innovative pharmaceutical products.

Acknowledgements

The author would like to thank Dr. Milan Smid of the World Health Organization and the Janssen HIV access and Compound Development Teams for their support throughout the course of the SRA collaborative registration procedure pilot. The author also thanks Anna Moccia-Field, Maura Reilly and Samantha Young of Rabin Martin for their assistance with the preparation of the manuscript.

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