Understanding the role of Regional Centres of Regulatory Excellence in strengthening medicines regulation in Africa

INTRODUCTION

The medical products regulation and harmonisation agenda in Africa is largely motivated by a need to increase access to essential health technologies and bolster continental innovation. An adequate health care workforce and medicines regulatory science expertise are essential factors in contributing to the realisation of this need, as well as in evaluating the efficacy, safety, quality, and performance of medical products. However, human and institutional capacity and regulatory standards and practices continue to lag behind in Africa. In addition, an inadequate and sometimes lack of health care workforce, incoherent ad hoc training of a regulatory workforce, weak infrastructure, and unsustainable health care financing mechanisms have exacerbated the situation. As a result, many African countries still face challenges related to the delivery of quality health care.

In 2014, as a response to the noted deficits, the African Medicines Regulatory Harmonisation Programme coordinated by the New Partnership for Africa's Development (NEPAD) Agency, the technical arm of the African Union (AU), successfully led efforts to initiate the designation of Regional Centres of Regulatory Excellence (RCOREs) across the African continent.[1] The main aim of the designated RCOREs is to support a regulatory workforce that enhances human and institutional capacity and contributes to improved health care delivery, regulatory standards, and practices in Africa. RCOREs use multiple approaches focusing on the following important interventions:

(1) Provision of academic and technical training in regulatory science applicable to different regulatory functions and managerial aspects.

(2) Skills enhancement through hands-on training, twinning, and exchange.

(3) Practical training through placement in the pharmaceutical industry.

(4) Execution of operational research to pilot-test innovations and interventions to inform best practices for scale-up to other National Medicines Regulatory Authorities.

These interventions are meant to leverage ongoing efforts to harmonise policies and regulatory frameworks in Africa and strengthen regulatory capacity. RCOREs contribute to and feed in to the Science, Technology and Innovation Strategy for Africa (STISA) 2024 through enhancing technical and professional competence in the area of health. STISA is a key AU pillar in science, technology, innovation, and human capacity development.[2]

An outline of how an institution(s) can attain designation status

A SUMMARY OF THE EXPECTED ROLES OF RCOREs IN AFRICA

An RCORE is an institution or partnership of institutions with specific regulatory science expertise and proven capacity and capabilities in training and/or delivery of services in at least one of the categories of regulatory and managerial functions identified (see the diagram).[3]

[1] The 11 RCOREs were designated for a period of four years. Their performance will be evaluated, and based on the outcome of the evaluation, designation may be renewed. The NEPAD Agency will in due course publish a second Expression of Interest for designation of other interested institutions.

[2] STISA replaces the previous African Science and Technology Consolidated Plan of Action and was adopted by the AU heads of state and government in 2014.

[3] RCORES Guide 2014.

There are currently eleven (11) designated RCOREs operating across the African continent in a total of eight (8) regulatory functions as represented above

These institutions may include, but are not limited to, those involved in medicines regulation, academia, scientific and research institutions, centres of information dissemination, and pharmacovigilance centres. Currently, there are a total of 11 RCOREs spread across the African continent specialised in eight regulatory functions as illustrated in the diagram.

Some of the activities an RCORE is expected to play include training and capacity-building in the field and category of expertise and designation, engage in information dissemination, ensure implementation of regional and national programme activities in support of medicine products regulation and harmonisation, and organise events (i.e. conferences, meetings, workshops), as well as undertake a coordination role of joint assessment and inspection activities.

RCOREs have a pivotal role to play in medicines regulatory capacity development in Africa and shall contribute towards enhancing the potential of AU member states in achieving a sufficient number of qualified, experienced pharmaceutical and other professionals working in the pharmaceutical sector. In turn, this will help improve the assessment of the safety, efficacy, quality, and performance of medical products and improve quality assurance and control of medicines and medical devices. An adequate and trained health care workforce will not only help increase access to essential health technologies, but also reduce the prevalence of spurious, substandard, falsely labelled, falsified, and counterfeit medical products in Africa through improving the licensing of the manufacture, import, export, distribution, promotion, and advertising of medicines according to internationally accepted standards. RCOREs also focus on building medicines regulatory science expertise in Africa, which is essential in ensuring effective medicines regulation on the continent. They are trendsetters who occupy a critical role in developing competence of experts in emerging areas of medical products regulation in Africa.

In an effort to enhance capacity and increase the regulatory workforce on the African continent, RCOREs are expected to participate in and implement the African Medicines Regulatory Professionals Fellowship Programme. The main goal of the African Medicines Regulatory Professionals Fellowship Programme is to nurture and develop technical and managerial competences to ensure effective medicines regulation in Africa. The fellowship initiative will also help develop leadership and talent in the field of regulatory science. AU member states, cooperating partners, and the private sector from within Africa and the world are at liberty

to provide financial support towards the fellowship programmes in the areas of regulatory functions of RCOREs that are of interest to them or to which they wish to contribute.

The harmonisation of training manuals is a key step towards building standardised regulatory capacity in Africa. RCOREs are strategically positioned to take a lead in current efforts to develop and apply harmonised curricula in their areas of designation and specialisation. Hence, RCOREs are critical in developing, harmonising, and standardising regulatory curricula that is essential in key areas, as has been demonstrated by RCOREs in clinical trials, medicines evaluation, and pharmacovigilance. This will also contribute towards improved processes in inspection and surveillance of manufacturers, importers, wholesalers, and dispensers of medicines.

TWOFOLD APPROACH TO ACHIEVING HIGH QUALITY IN HEALTH CARE DELIVERY IN AFRICA

It is imperative to tap in to the health care workforce in Africa and the diaspora, as these have a critical role to play in the delivery of quality health care in Africa. It is particularly for this reason that the pool of regulatory experts was established by the NEPAD Agency as a resource for consultations and expert advice on health-related matters on the continent. The simultaneous approach of targeting RCOREs and the pool of regulatory experts, institutions, and individuals is a strategic one to consolidate efforts to strengthen pharmaceutical-sector development and the medical products regulation and harmonisation agenda in Africa on both fronts.

AU member states are therefore encouraged to develop deliberate policies and strategies that can guarantee effective use of their nationals living in the diaspora to improve delivery of quality health care at the local level. In addition, the conditions of service for the health care workforce must be prioritised to reduce brain-drain and attract those already working in the diaspora to return back home. Mechanisms must be put in place to ensure sustained funding of both the health institutions and academic institutions (i.e., RCOREs that offer health-related training).

Another critical area is that of capacity and human development. RCOREs develop two yearly work plans and budgets in areas of regulatory capacity in the field they have been designated. While the NEPAD Agency provides advocacy and assistance in sourcing for funds to implement the work plans, AU member states and cooperating partners are called upon to be more proactive by financially supporting RCORE activities in the regulatory functions the countries have identified to be the most lacking in their respective territories. This is the only way that Africa can mitigate some of the consequences that result from an inadequate health care workforce. Countries can work closely with RCOREs to provide specialised training in areas that are weak and/or lacking.

RCOREs are also essential in developing standardised regulatory training manuals of international standards. AU member states, the private sector, and organisations can tap in to this pool of knowledge to improve the technical and professional knowledge in the health care workforce through supporting research and development (R&D). This approach will not only increase the number but also enhance the quality of graduates in education for health care services in Africa. In addition, local funding for RCOREs to conduct R&D will help bring about a balance in the current status where funding for R&D is dominated by international partners in Africa. AU member states are urged to begin by mobilising local resources to support RCOREs and make sure that these are used prudently and engage international partners where necessary.

Above all, the onus is on the AU member states to provide support towards sponsoring the African Medicines Regulatory Professionals Fellowship Programme under RCOREs and ensuring its sustainability. This will contribute towards building ownership in the health workforce, and the AU member states will be able to channel education resources to specific medicines regulatory challenges that are most profound and lacking in the continent. AU member states can set their own conditions and improve not only the academic excellence in the health care workforce, but also target individuals already in practice for training and retraining to boost their knowledge. RCOREs make it possible to strengthen and develop collaboration on health care education development in Africa based on South-South collaboration and common experiences.

RCOREs have therefore been established to support AU member states in improving healthcare delivery and training of the health workforce. The success and sustainability of RCOREs rely on the support of the AU member states and collaborating partners.

Note

This policy brief is the third in a series of policy briefs developed as a result of a joint effort between the NEPAD Agency and PATH. Learn more by accessing the websites of the two organisations at www.nepad.org and www.path.org, respectively.