Policy Briefs

NEPAD Planning and Coordinating Agency
Agence de Planification et de Coordination du NEPAD

African Medicines Regulatory Harmonisation (AMRH) Programme contribution to the African Union (AU) Pharmaceutical Manufacturing Plan for Africa (PMPA)

Brief No. PMPA/AMRH/1

African Medicines Regulatory Harmonization (AMRH) Programme

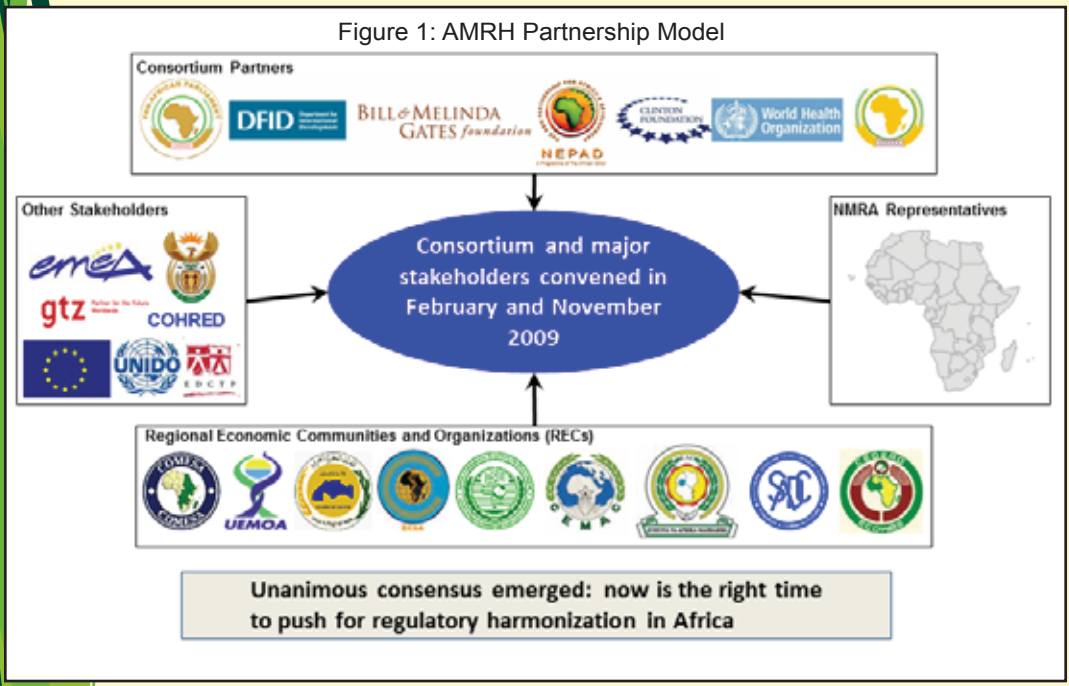
Introduction

Under the theme “Strengthening of Health Systems for Equity and Development in Africa” the African Union Conference of Health Ministers (CAMH3) in April 2007 responded to the AU Assembly decision 55 taken during the Abuja Summit in January 2005 which mandated the AU Commission to develop a Pharmaceutical Manufacturing Plan for Africa (PMPA) with the framework of the New Partnership for Africa’s Development-NEPAD (AU 2007).

The African Medicines Regulatory Harmonisation (AMRH) Programme under the guidance of a consortium of partners and stakeholders and coordinated by the NEPAD Planning and Coordinating Agency works to fulfil this mandate. The overall aim of the AMRH Programme is to support African countries to improve public health by increasing access to good quality, safe and effective medicines through harmonising medicines regulations, and expediting registration of essential medicines (AMRH 2012).

Role of AMRH in the PMPA

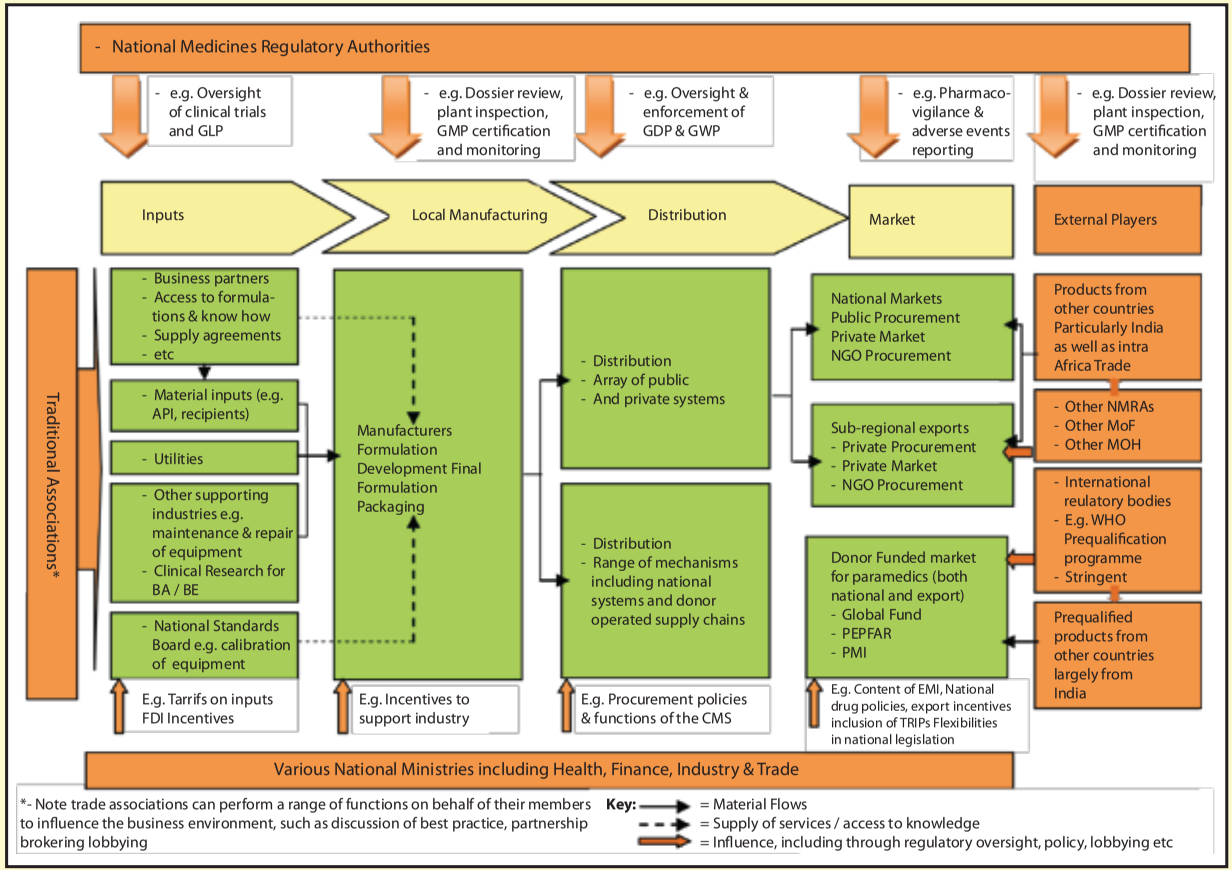
Figure 1: AMRH Partnership Model



The African Medicines Regulatory Harmonization (AMRH) Programme was created through a series of briefing meetings including the Pan African Parliament (PAP) Committees on Health, Labour and Social Affairs and Science and Technology held in 2007 and 2008; followed by the African Ministerial Conference on Science and Technology decision in 2008. In addition the NEPAD Agency and PAP held a joint meeting with Regional Economic Communities (RECs) and National Medicines Regulatory Authorities (NMRAs) in February2009 which was hosted in collaboration with the African Medicines Regulatory Harmonisation (AMRH) consortium partners. Figure 1 above depicts the collaborative partnership model that emerged from the consultation. This partnership is dynamic and is intended to be a broad-based collaborative network.

The PMPA proposes that the promotion of industrial development and the safeguarding and protection of public health are not mutually exclusive priorities and that the production of quality medicines and the development of an internationally GMP compliant industry in Africa are possible, desirable and eminently feasible (AU 2012). Limited capacity has resulted in countries being unable to enforce proper drug regulations, putting at risk the health of millions from improper drug use, all this happening in the backdrop of mounting complexities from killer diseases such as malaria, tuberculosis and HIV/AIDS (Kalua et al 2009). A regional example of complementarity of public health policy and industrial development is illustrated by the East African Community Regional Pharmaceutical Manufacturing Plan of Action (RPMPoA) whose declared objective is the development of a regional roadmap to guide the East African Community (EAC) towards evolving an efficient and effective regional pharmaceutical manufacturing industry that can supply national, regional and international markets with efficacious and quality medicines (EAC 2012).

Figure 2: Schematic representation of the small molecule "Pharmaceutical Manufacturing System"



Source: PMPA Business Plan

Figure 2 below depicts the myriad of factors and stakeholders that impact on the PharmaceuticalManufacturing System. The role of the NMRAs and a functioning medicines regulatory system cannot be overemphasized.

The national medicines regulatory system shown in Figure 2 provides an anchor through which critical quality-related parameters of a pharmaceutical manufacturing system will be processed thus contributing to access to medicines for patients and other users.

NMRAs will have considerable impact on the pharmaceutical manufacturing value chain and activities such as oversight of clinical trials and Good Laboratory Practice (GLP), dossier review, plant inspection, Good Manufacturing Practice (GMP) certification and monitoring; oversight and enforcement of Good Distribution Practices (GDP) and Good Wholesaling Practices (GWP). Pharmacovigilance and adverse events reporting system will come under the purview of the medicines regulatory system.

Dr. Ibrahim Assane Mayaki
The Chief Executive Officer of the NEPAD Planning and Coordinating Agency (NPCA)

"Essential medicines save lives and improve health when they are available, affordable, of assured quality and used rationally"

Speaking on the occasion of the inaugural launch of the implementation of the East African Community Medicines Regulatory Harmonisation project in Arusha - Tanzania, March 31, 2012.

Figure 3: Illustration of challenges across the manufacturing value chain

Source: PMPA Business Plan

Figure 3 illustrates the many challenges encountered in the pharmaceutical manufacturing value chain as envisaged in the PMPA Business Plan. A key challenge identified is the weak regulatory framework, poor quality and counterfeit medicines, conflicting policies, capacity and skills shortages and lack of partnerships and linkages.

Regional Networks for Implementation of AMRH

In 2011, NEPAD Agency and the African Union Commission (AUC) undertook to propose with subsequent endorsement by the 5th Session of the Conference of Health Ministers (CAMH-5) the regional networks for implementation of the AMRH initiative. In 2012 about 85% of sub-Saharan African countries were already covered by harmonization projects or project proposals.

Figure 4: Status of AMRH implementation in RECs.

Roughly 85% of Sub-Saharan Africa covered by proposals already completed or in process.

REC progress

• REC	• Status	• Comments
• EAC	• MRH Project Proposal finalised 2011	• Project launched 30th March 2012
• ECCAS/OCEAC	• Under consultation	
• WAHO/UEMOA	• Finalized for AMRH Partners consultation	
• SADC		
• North/North East Africa	• Under consultation	

Completed or in-process RECs	Countries covered	Total members *	% pop covered
EAC & ECCAS/OCEAC	12 (20%)	11	17%
EAC, ECCAS/OCEAC, ECOWAS	26 (46%)	26	45%
EAC, ECCAS/OCEAC, ECOWAS, SADC	41 (74%)	41	72%

AMRH in the global context of pharmaceutical reforms

For the PMPA to succeed efforts need to be expended to ensure that there is policy coherence for both industrial development and health development. Policy coherence need also to transcend across other sectors such as trade and tax regimes. There is thus need for public health concerns to take centre-stage in a policy framework for local production of medical products (WHO 2011). The AMRH Programme advocates for legislative and regulatory reforms in the pharmaceutical sector in order to standardise the tools used in medicines regulation. The harmonisation process will lead to increased access to medicines for those in need and an expansion of the regional markets for pharmaceutical manufacturers and intermediaries.

PMPA and Public Health

The policy coherence alluded to above will be critical when a broader framework that supports development of a viable local pharmaceutical industry that is competitive, reliable, innovative, productive and responsible – on the one hand; and promotes health through access to safe, quality, efficacious and affordable medicines on the other hand is considered. Ensuring access to medical products is a complex undertaking requiring governments, through their relevant policies, to balance the availability of quality assured medical products (supply side) with meeting priority public health needs with products that are acceptable and affordable (demand side) (WHO 2011).

The AMRH Programme activities and PMPA Business Plan are implemented within an increasingly complex and interdependent social, economic and political environment. WHO (2011) further argues that in order to ensure a strong linkage between what is produced locally and what improves access, a comprehensive and system-wide approach is needed. This has to bring coherence between industrial, trade and health policies. From a public health perspective, support for local production should have the explicit intention of improving access to medical products.

Thus in the context of public health, AMRH plays a critical role in the prevention and cure of some potentially damaging failures of the pharmaceutical value chain.

The oversight role of regulatory agencies needs to be strengthened if the benefits of local production and improved access to quality and safe medicines is to be realised. UNAIDS (2012) has advocated that regulatory strengthening and harmonisation and local production must be developed in parallel. In an issue brief focusing on the West African Region and in particular on antiretroviral drug demand and supply in ECOWAS countries, UNAIDS (2012) argues that benefits of harmonising medicines registration and regulations within the ECOWAS region are well recognised, and that the region is making notable strides. These efforts will be critical to supporting local production, as a means of ensuring quality as well as facilitating cross-border trade of locally-produced medicines.

Industrial policy options

The requirements and responsibilities imposed on most African countries arising from membership in such organisations as the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO) has placed considerable pressure for such countries to review their legislative provisions in line with these trade agreements. Apart from responding to these international trade obligations, developing countries have a responsibility to safeguard and protect public health by ensuring access to essential medicines such as antiretroviral (ARV) drugs. However many developing country regulatory systems have not been able to respond effectively (Hill and Johnson 2004).

The problems include: lack of effective legislation to allow use of TRIPs flexibilities such as compulsory licensing; lack of adequate quality manufacturing capacity; lack of adequate regulatory science capacity to assess generic products that potentially meet the need for essential drugs; lack of adequate human resources; and inadequate funding for drug regulatory activities.

It should be noted that certain countries such as Brazil and India have achieved significant synergy of attaining public health goals of access to quality affordable medicines and economic development spurred by local pharmaceutical industry. The most pragmatic solution to address these problems will include a regional approach and coordination of activities in the pharmaceutical sector. Promoting regional pharmaceutical manufacturing capacity will ensure better access, enable economic feasibility, promote quality standards and increase possibilities for compliance with international trade agreements. Regional cooperation to deal with TRIPS flexibilities may need to be considered more broadly in an integrated fashion with the region's other economic and development agenda. Medicines regulatory harmonisation will help regional cooperation on many related fronts including TRIPS flexibilities for better medicines access.

Conclusion

This policy brief makes a case for African Union (AU) member countries to participate in RECs led medicines regulatory harmonisation initiatives where such initiatives have taken root. Where consultations and discussions are ongoing, member countries are encouraged to participate much more actively. The realisation of the vision of the AMRH Programme of improving public health by increasing access to safe and effective medicines of good quality for the treatment of priority diseases should be seen as the outcome of pursuing shared goals of industrial and health policies for local production. In support of the AMRH Programme vision, the AUC PMPA Business Plan recommends that given the inherent capacity challenges faced by all regulators generally and severe resource constraints in many African countries, there is need to maximise synergies under the AMRH work and to invest in the regulatory functions critical for public health protection and a market place that is fair and competitive.

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CONTACT FOR FURTHER DETAILS:

Mrs. Margareth Ndomondo-Sigonda
NEPAD Agency Pharmaceutical Coordinator

African Medicines Regulatory Harmonisation Programme
NEPAD Science and Technology Innovations Hub (NSTIH)

NEPAD Planning and Coordinating Agency (NPCA)
P.O Box 1234
Halfway House 1685
Midrand - Johannesburg
South Africa

Email: mnsigonda@nepadst.org
Tel: +27 12 841 2980
+27 11 256 3600
Fax: +27 12 841 4414

www.amrh.org
www.nepad.org
www.au.int