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Improving access to Pharmaceuticals in the African region
(Making progress on achieving the Sustainable Development Goals)

1. Introduction

The pivotal role of pharmaceuticals[(i)] is reflected in the Sustainable Development Goal (SDG) 3.8, which refers to "access to safe, effective, quality and affordable essential medicines and vaccines for all". The SDG 3.b also underscores the need to support research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries as part of efforts to reduce treatment gaps.

Universal Health Coverage (UHC), which is to be achieved in part through access to medicines, is a much-needed global outcome, as the lack of, or limited access to life-saving and health-promoting essential medicines and health technologies can lead to human suffering and the loss of life from preventable or treatable diseases. Global and regional commitments have been reaffirmed through several resolutions adopted since 2014 on Access to Essential Medicines, Regulatory System Strengthening for Medical Products, and Combatting Antimicrobial Resistance[(ii,iii,iv,v)]. All of them emphasize the need to improve access to essential, quality-assured and affordable medicines.

Unfortunately, too many people worldwide do not have access to even a limited basket of essential medicines[1]. In most African countries, some basic pharmaceutical functions such as selection of essential medicines and health products, pricing and sustainable financing, procurement and supply, quality and safety, rational use and governance issues remain weak.

i A pharmaceutical is any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient. In this document, the terms medicine and pharmaceutical are used interchangeably

ii Resolution WHA67.20, Regulatory system strengthening for medical products. In Sixty-seventh World Health Assembly, Geneva. http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R20-en.pdf. Accessed on 08 November 2016.

iii Resolution WHA67.21, Access to biotherapeutic products, including similar biotherapeutic products, and ensuring their quality, safety and efficacy. In Sixty-seventh World Health Assembly, Geneva. http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R21-en.pdf. Accessed on 08 November 2016

iv Resolution WHA67.22, Access to essential medicines. In Sixty-seventh World Health Assembly, Geneva. http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R22-en.pdf. Accessed on 08 November 2016

v Resolution WHA68.7, Global action plan on antimicrobial resistance. In Sixty- eighth World Health Assembly. http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_R7-en.pdf. Accessed on 08 November 2016

This impacts countries' capacity to adequately and timely make available and affordable essential medicines and health products and exposes many people to the damages of substandard medical products.

Rapid urbanisation, globalisation and public health emergencies of international concern are part of the African landscape that, together with the complexity of emerging health challenges the continent is facing, necessitate more innovative approaches to health service delivery[2]. In order to deliver on the SDGs, national governments need to take specific, innovative actions.

The purpose of this paper and the proposed framework is to help Health Ministries in the African Region to review and reform their pharmaceutical systems and assess and review their organisational structures and functions towards achieving their policies and strategic goals.

2. Situation analysis

2.1. Selection of essential medicines and health technologies

The WHO models of Essential Medicines Lists (EML) are valuable evidence-based tools that enable countries to identify a core set of medicines, which need to be accessible to provide quality medical care. Most countries in the African Region have national EMLs and treatment guidelines[3,4]. However, few countries are regularly revising the NEMLs whose scope remains mainly limited to medicines. For instance, with the support of the "Fonds Français Muskoka" seven (7) countries[(vi)] jointly revised their NEMLs to include live saving medicines for mothers and children[(vii)]. In most countries, the 2-year revision interval as recommended by WHO is not always followed, and the average revision period is about 5 years. Through the use of the EMLs, Zambia demonstrated an increase in availability, whereby paediatric malaria medicines became available in 88% of public health centres in pilot districts, against 51% in control districts.[5] The use of EMLs is however not systematic. A 2007 study carried out in the United Republic of Tanzania found that only 52% of health facilities surveyed procured medicines within the EML[3].

2.2. Pricing and sustainable financing

Access to medicines in the Region is hampered by insufficient funding from domestic and international sources; an example being the funding for antiretrovirals.[6] Whilst the lack of financial resources has been identified as a limitation to health commodity access, there can be a negative correlation between expenditure on health per capita and health indicators. In essence, a simple increase in financial resource allocation does not necessarily improve health outcomes.[7] Rather, it is the effective and efficient use of resources that yields results and hence should be the joint focus in funding considerations.

Funding for pharmaceuticals at country level comes from government expenditure, public and private health insurance, households and donations; the percentage contribution differing from

vi Benin, Burkina Faso, Côte d'Ivoire, Democratic Republic of Congo, Guinea, Mali and Senegal

vii Cécile Macé et Jean-Baptiste Nikiéma, La contribution du Fonds Français Muskoka à l'amélioration de l'accès aux médicaments essentiels et produits de santé prioritaires pour la mère et l'enfant (in press)

country to country. Gabon's 2013 pharmaceutical expenditure was financed 25.6% by Government, 15.4% by public health insurance, 4.7% by private health insurance, 54.2% by households and 0.06% by donations. According to Ghana's 2012 figures, government funds contributed 57%, private funds-companies and households 34% and international funds, 9%. In 2009/2010, Rwanda's health sector financing relied 60% on donors, whilst household payments contributed 18% and the public sector another 18%.[8] The 2001 Abuja Declaration urges African states to allocate at least 15% of their national budgets to the health sector. Despite the expressed commitment, only six countries[(viii)] had implemented this by 2012.[5] Nonetheless, it should be acknowledged that the average general government health expenditure increased steadily between 1995 and 2013 from 4%, to catch up with the global figure of approximately 11-12%.[9]

How populations pay for health commodities has a direct impact on access. In high-income countries, most payments for pharmaceuticals are made by the State or insurance schemes, allowing influence on pricing and benefit from economies of scale in procurement. In contrast, in low and middle-income countries, more than half and as much as up to 90% of expenditure on medicines is Out-of-Pocket (OOP).[8] It has been documented that OOP that are in excess of 20% of the Total Health Expenditure (THE) lead to significant negative financial impact.[7] This raises concerns over the 2012 WHO Afro Region figures revealing that 35 of the 47 countries in the region had OOP expenditure exceeding 20% of THE.[5] Commendably, some countries are developing and implementing alternative payment methods. Ghana has a national health insurance scheme presently covering about 43% of the population,[10] whilst the United Republic of Tanzania has a 50% cost-sharing scheme.[11] With the Renewed Partnership support, the Ethiopian Health Insurance Agency has developed a list of medicines that should be reimbursed based on the NEML.[12] Some countries like Gabon face the challenge that the reimbursement list is not comprehensive enough, resulting in many prescription medicines falling outside of the list.[8]

High prices of medicines and price variations between generic brands were noted in price and availability surveys carried out in the Region.[5] There are a number of contributing factors for this. From manufacturer to end-user there are many middlemen, a scenario that contributes to national prices being higher than global prices,[10] as do excessive mark-ups. Duties and taxes levied on medicines and raw materials[8,13] used in the manufacture of medicines also contribute to high prices. Median consumer price ratio of selected generic medicines to their equivalent international reference prices ranged from 1.7 to 6.5 for public sector and 2.3 to 13.8 for private sector.[14] In terms of national procurement, significant differences were noted to exist between the Southern Africa Development Community (SADC) country public sector procurement prices, whereby the highest price paid by one country could be more than 50 times as high as the lowest price paid by another country.[15]

viii Liberia, Rwanda, Swaziland, Zambia, Malawi and Togo

2.3. Procurement and supply

Fragile logistics and storage capacity challenges and high transport and distribution costs hinder broad access and affordability of essential medicines.[16] Shortages of essential HIV and tuberculosis medicines in most South African provinces reported in 2015 were described as a "systematic obstacle to the largest antiretroviral treatment program in the world",[17] with most of these stock-outs noted to be due to internal problems between the bulk stores and health facilities, and only a minority of the stock-outs attributed to national or international stock shortages.[18] Similar findings were made in Malawi in 2007, where on average, medicines for treating pneumonia were out of stock for six months during one year of observation, and anti-malarials were not available for periods ranging from 42 to 138 days, the main reason being insufficient deliveries from the regional medical store.[19]

The situation analysis and feasibility study for the SADC Pooled Procurement of Essential Medicines and Medical Supplies[15] indicated that almost all Member States had various programs for strengthening Procurement and Supply Management systems and Quality Assurance systems, most of them supported by Development Partners. Ethiopia has developed a master plan for pharmaceutical logistics that involves on-going reforms to computerise supply chain management and the dispensing of medicines in the public sector. Rwanda is strengthening medicine access through the construction of modern warehouses, and the launch of an electronic logistic management system.[8]

Africa imports approximately 70% of its pharmaceuticals, with some countries relying solely on imported medicines to cover their needs.[20] This degree of import dependence puts Africa at risk. In the interest of promoting sustainable supply, the local production of health commodities is being explored, with the Pharmaceutical Manufacturing Plan for Africa (PMPA) being the overarching continental policy instrument for this strategy. The PMPA business plan, endorsed by African Union (AU) Member States in January 2012, focuses on sustainable local production of quality-assured health commodities as a long-term solution to health commodity security.[21] Further commitments to making local production a reality are apparent in the regional manufacturing strategies that are aligned to the PMPA, such as the East African Community (EAC) Regional Pharmaceutical Manufacturing Plan of Action, which was endorsed in 2012 to run for a 5-year period.

In 2012, an estimated 38 African countries had pharmaceutical manufacturing entities.[21] The total number of manufacturing sites in Africa is less than 1000, with more than 500 of these located in South Africa, Nigeria, Algeria, Morocco, Egypt, Ghana and Kenya. The rest of the countries combined contribute to less than 400 manufacturers. Almost all this manufacturing capacity produces generic medicines[22], the product portfolio consisting of older-generation medicines that are not well-aligned with emergent treatment needs and market demand.

The majority of local pharmaceutical manufacturers on the continent meet the Good Manufacturing Practice regulatory standards of their own national authorities. These standards are not necessarily recognised by developed country markets or supply procurement

programmes operated by multilateral agencies resulting in limitations to the market available for manufacturers on the content. This limits the potential scale of production, the development of production efficiencies, and operating more profitably based on export sales.[23] In order to improve manufacturing standards, manufacturers in some countries are upgrading their facilities.

WHO has worked with manufacturers in Ghana and Kenya to improve capacities for the manufacture and prequalification of paediatric antimalarial medicines.[24] Five manufacturers in Kenya, South Africa, Uganda, Zimbabwe and Senegal have attained WHO Prequalification standard, the Senegalese facility being a vaccine manufacturing facility.[5] An additional capacity that is required is that for the testing of generic formulations to demonstrate bioavailability/bioequivalence. Currently, only South Africa has Phase I clinical trial units that meet WHO Pre-qualification standards. As a result, there are efforts to establish such units in Ghana, Ethiopia, Kenya and Zimbabwe. The African Institute of Biomedical Science and Technology (AiBST) Clinical Trial and Bioanalytical Laboratory at Wilkins Hospital, Harare is aiming at WHO Pre-qualification and ISO 15189 certification by February 2017.[25]

Access to essential medicines is threatened by WTO TRIPS and TRIPS-plus provisions, in that India, which has been largely instrumental in providing Africa with good quality, affordable generic medicines, will no longer be able to manufacture products that have valid patents. Given that in November 2015, the WTO TRIPS Council recognised that patent protection of pharmaceuticals in some Least Developed Countries (LDCs) would negatively and adversely affect securing access to affordable medicines, and so extended the transition period for LDC compliance with respect to pharmaceuticals, Africa's 34 LDCs have special dispensation until 2033.[26] This window of opportunity allows Africa to actively promote the local production of specific products regardless of their patent status in the interest of public health.

2.4. Quality and safety of health products

Medicine regulation is the vital link between access and quality. Less effective, poor quality and counterfeit products waste resources and cost countless lives.[27] Even so, the regulatory systems in most African countries still require strengthening[28] and the risk posed by substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products is very real in the African Region, which is currently leading in reporting to the WHO rapid alert system.[29] Although the evidence of SSFFCs is disturbing, the reports are also evidence of reinforced regulatory capacity and the presence of surveillance and monitoring systems in Africa to curb SSFFC proliferation.

Recognition of the weaknesses in medicine regulatory systems prompted action. Between 2005 and 2015, Member states with National Medicines Regulatory Authorities (NMRAs) in place increased from 40 (87%) to 45 (96%) and 16 (34%) of these are autonomous or semi-autonomous. Thirty-four (72%) countries have quality control laboratories in place at different stages of development.[30] Responding to the weak regulatory systems, the African Medicines Regulatory Harmonisation (AMRH) programme, seeks to coordinate medicine regulation across

the continent through harmonised requirements for the regional groupings, adoption of normative tools, offering faster, predictable and transparent processes that are better aligned to public health needs. The African Vaccine Regulatory Forum (AVAREF) was established by WHO as a platform for strengthening regulatory capacity for clinical trials and harmonization of regulatory practices through joint reviews.

The EAC was the first REC to launch its harmonisation project in March 2012; and following suit, the Economic Community of West African States (ECOWAS) and the SADC have developed platforms to facilitate harmonisation. Within these initiatives, the national medicines regulatory authorities have embarked on joint reviews and inspections for product applications. Additionally, in October 2014, NEPAD designated 10 institutions as Regional Centres of Regulatory Excellence to support regulatory capacity development in Africa. Strengthening of regulatory systems ensures that patient safety is not subordinate to access. The diversity in capacity amongst EAC Member States necessitated a regional Quality Assurance system,[31] something that will need to be a strong consideration for the Region.

2.5. Availability of essential medicines and health technologies: lessons learnt from MDGs

Childhood vaccination coverage, family planning needs, antiretroviral therapy coverage, and median availability of selected generic medicines have been used as MDG indicators offering insight into progress towards access within the Region. Aiming for the 90% target by 2015, measles-containing vaccine immunization coverage amongst 1-year olds for the Region was at 73% in 2014 (range: 22-99%). Commendably, 14 individual countries had already surpassed the 90% target at that stage. The overall percentage of unmet need for family planning between 2007 and 2013 was well above the targeted 0%, ranging from 6% to 38% for the Region, indicating a high failure to meet family planning needs. Between 2007 and 2013, median percentage of availability of selected medicines in a sample of health facilities ranged from 21.2% to 88.8% for the public sector and from 22.2 % to 81.3 % for the private sector. By 2014, the regional total for antiretroviral coverage among people with advanced HIV infection had dropped to 35.31% from 44.0% in 2007, falling far below the MDG target set at 80% by 2015. The drop is a cause for concern, as HIV/AIDS ranks as the number one cause of death in the African Region, responsible for 121.9 deaths per 100, 000 people. None of the countries attained the universal access target of 80%, however, eleven countries had coverage rates of more than 50%, Rwanda attaining the highest at 68%.[9] UNAIDS data indicates that in Sub-Saharan Africa (SAA), 10.7 million (41%) people living with HIV had antiretroviral therapy in 2014 leaving 59% of those living with HIV in SSA without access to ARVs.[32] The assessment of coverage shows that some countries have effectively increased access yet too many gaps still remain.

For the particular case of antivenoms, in addition to non-availability of adequate amounts of quality and effective products on the world market for treating snakebite by African poisonous snakes, high price is also an issue. According to an analysis covering the period 2007-2011, the wholesale cost of antivenom for sub-Saharan Africa ranged from US$18 to US$200 per vial[33] The cost per effective treatment using recommended doses was US$55 to US$640, with an

average cost of US$124 [on average 6 vials per treatment but ranging from 1 to 12 vials]. These costs are well beyond the capacity of rural communities and even urban dwellers in most of sub-Saharan Africa.

2.6. Scientifically sound and effective use of essential medicines

Putting in place policies, strategies, and standards for production, procurement and distribution must culminate in the rational use of the medicines. The overuse, underuse or misuse of medicines results in wastage of scarce resources. The Nairobi Conference on Rational Use of Drugs held in 1985 formulated a recommendation that National Medicines Policies should be defined in each country. Training curricula on rational medicine use (RMU) for health workers from as far back as the 1980s is also an indication that RMU represents a challenge.[34] In May 2007, the WHO resolution WHA60.16 was passed, whereby the World Health Assembly requested the Director-General to strengthen WHO's leadership in promoting RMU. Currently, various initiatives to improve RMU are ongoing in the Region, with relative successes, for example, RMU has improved in Ethiopia through support of Drugs and Therapeutic Committees at hospital level.[12]

There is also evidence of active monitoring of RMU in the Region. The 2013 Zimbabwe National Medicines Survey reports on RMU. With respect to polypharmacy 66.7% of the surveyed facilities were prescribing on average between two and three medicines, while 23.1% facilities were prescribing between one and two medicines. Nine point four percent of the remaining facilities were prescribing at most one medicine whilst 0.9% more than three medicines. In terms of generic prescribing, on average 66.2 % of prescriptions surveyed were prescribed using full generic names as required by the national policy, and in terms of antibiotic use, almost half of the prescriptions evaluated (40.9%) were antibiotics. The median and average percentage of patients receiving one or more antibiotics at the health facilities was 41.3% and 40.7% respectively translating to an increase since the previous survey in 2011. Other elements also reported on were use of injections, patient knowledge, discrepancy, labeling quality, and adherence to STGs.[35]

2.7. Governance and countries' leadership

The pharmaceutical industry is complex representing varying interests[7,13], and with a global value estimated at nearly 880 billion in 2013, it is a target for unethical practices.[24] Pharmaceutical assessments in the Region have found poor transparency and weak governance of medicines.[5]

A standardised WHO assessment tool that looks at the six essential functions of registration, control of promotion, inspection of facilities, selection, procurement and distribution of essential medicines can be used in the assessment of transparency to improve good governance in public pharmaceutical sectors. The 2008 Malawi assessment showed that the sector suffers from extreme vulnerability to corruption, with promotion of medicines, selection of medicines for the EML and procurement being the areas of greatest concern.[36] Similarly, the 2012 Kenya assessment showed moderate vulnerability, however with inspection and market

control as well as selection of medicines for the EML having high vulnerability[37]. In the case of the 2007 assessment of Zambia, registration, inspection, procurement and distribution were marginally vulnerable, while promotion and selection were moderately vulnerable to corruption. The absence of declaration of conflict of interest was the major concern noted.[38] These examples indicate gaps that could become worse if not addressed.

Evidence of the existence of national good governance frameworks is lacking. Such frameworks can be developed using WHO's Good Governance for Medicines (GGM) programme 3 phrase approach: Phase I - conducting a national assessment of transparency and potential vulnerability to corruption, which these 3 countries have done; phase II - development of a national GGM programme through a nationwide consultation process and Phase III - implementation and promotion of the programme.

Across the continent there is widespread appreciation of the need to develop and implement national medicines policies and plans to improve access to essential medicines. All countries of the Region have both national health policies and national health strategic plans in place, with the process of revision being at varying stages. 2015 WHO data confirmed the existence of revised national health policies and strategies in 39 countries, covering varying periods, with Burundi, Kenya, Niger, Seychelles and South Sudan having policies up to 2025.[9] Whilst some countries in the Region, such as Botswana, Gabon, Ghana and Rwanda, can be commended as they are already implementing strategies to improve access[5], there must be acknowledgement that all policies and strategies currently in place were developed before the advent of the SDGs.

At country level, the control of medicines, their production, trade and use largely falls under the Ministries of Health through acts of parliament. Many of the public health acts on the continent and those for medicine regulation were drafted in the colonial era and are in need of review and revision to incorporate such concepts as the right to health, and provisions for adequate control. Recognition of legislative gaps has led to RECs in Africa developing Regional Plans of Action to guide their Member States in the implementation of the AU Model Law on medical products registration and harmonisation.[39] Relative homogeneity in some aspects, as was the case with procurement legislation and institutional frameworks in the EAC Member States facilitated progress in pooled procurement.[31]

Though the health ministries have primary responsibility, multiple actors inclduing public and non-state providers, private for-profit and private not-for-profit actors, the communities themselves and players outside the health sector characterise the nature of health systems in the African Region[7,13]. Notwithstanding, the existence of legislation and guidelines for health products management, spelling out the mandates and roles of all stakeholders is not universal.

3. Main challenges

Inappropriate procurement, chronic shortages, irrational use of medicines, inappropriate staff mix and deployment, coupled with a lack of performance incentives, are not uncommon

associations with health product management in Africa.[7] Legal provisions for most essential aspects of medicine control exist, but many of these provisions were, and in some countries, still remain difficult to implement as they are not adequately supported by strong regulatory systems: fragmentation of responsibilities and gaps in terms of undefined grey areas are documented in baseline studies. For instance, low numbers of pharmaceutical personnel in the SADC region and the implication on management of pharmaceuticals was evident.[13]

Various tools to measure different dimensions of access are available. Notably though, there is lack of a comprehensive, universal baseline on access to medicines for the Region. Landmark assessments such as the WHO 2009 Baseline assessment of the pharmaceutical situation in SADC countries[13] and the WHO 2010 Assessment of medicines regulatory systems in Sub-Saharan African countries[40] have not been repeated. Databases maintained at country level have differing approaches to the collection of information. It is therefore not possible to conclusively quantify the gap to achieving universal access. Lack of information to power decisions is a critical challenge.

4. Opportunities for improvement

Member States, WHO African Region, partners and other stakeholders continue to demonstrate commitment towards achieving UHC. Member State political will and commitment is evident through the Regional Committee resolutions passed in respect to access to medicines (AFR/RC38/R19, on local production of essential drugs in the Region; AFR/RC49/R5, regarding a situation and trend analysis on essential drugs in the Region; and AFR/RC54/R5, on improving access to care and treatment for HIV/AIDS). Political will and commitment must be supported by the implementation of required policies and operational reforms. Pursuant to the passing of the resolutions, funds were mobilised, and implementation of essential medicine programmes as highlighted earlier started.[41] The same commitment can achieve UHC.

Collaboration initiatives have yielded results, expressly in the areas of regulatory harmonization and pooled procurement. The African Region can take advantage of the commonalities between Member States to set goals and coordinate activities to further the UHC agenda.

5. Priorities for action

With the aim to achieve universal access to essential medicines and health products, four priority areas emerge:

a) Taking stock: at national level, there is need to critically look at where we are, what we have achieved and where we want to go, whilst being realistic about what we can achieve.
b) National health policies and strategies must align to SDGs.
c) Existing frameworks must be leveraged.
d) Information-based decision making must take priority

6. Action points

The following recommendations are made in respect of action at national and regional level:

- Surveys or assessments must be conducted at country level to guide country-specific action plans.
- Development of an overarching tool that caters to continuous and comprehensive monitoring of all aspects of access to essential medicines and also allows benchmarking.
- Review and revision of policies and strategies to line up with SDGs, is required together with setting of achievable goals.
- Development of legal and institutional frameworks that spell out roles and responsibilities for the multiple players.
- Formulate access strategies, paying particular attention to emergencies and disasters, as well as neglected diseases.
- Translate proposed funding models into policies and further, into legislation to ensure affordability and sustainability.
- Commitments made must be revisited and implementation challenges identified and eliminated.
- Countries must fit themselves into existing support and action programmes, e.g. regulatory harmonisation; pooled procurement, SSFFC programme participation. Sincere, active collaboration must be prioritised.
- Resources should be channelled to those strategies that have already yielded results. Best practice should be identified and replicated, albeit with modifications.
- Reliable, continuous generation of information that speaks to availability, cost, and logistics must be supported. eHealth and mHealth can largely contribute and the strategies proposed in the relevant paper must be amalgamated with these action points.
- The conduct of research to provide evidence must be supported in order to enhance dissemination of best practice.
- Innovative approaches of improving access must be explored. The approaches may be novel in the proposed setting, yet tried and tested elsewhere.
- Monitoring and evaluation mechanisms specific to access need to be put in place.

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