

# Medicines development and regulation in Africa

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**Abstract:** Africa is one of the world's fastest-growing economic regions, with a rise in its pharmaceutical industry value from \$4.7 billion in 2003 to \$20.8 billion in 2013. Multinational pharmaceutical companies are becoming more active in drug production and clinical trials across Africa, and there is an increase in the number of local companies engaged in medicines development and marketing. Such expansion of the local pharmaceutical industry requires trained pharmaceutical specialists to support it. The current situation and future requirements for local medicines development, regulation, education and training needs are discussed.

**Keywords:** medicines development, medicines regulation, Africa, training, education, PharmaTrain, IFAPP, SAHPRA

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## 1. Pharmaceutical Economic Environment in Africa

According to a McKinsey Report, Africa is one of the world's fastest-growing economic regions, with a rise in its pharmaceutical industry value from \$4.7 billion in 2003 to \$20.8 billion in 2013<sup>[1]</sup>. Africa's estimated growth rates between 2013 and 2020 are in the range of 6 and 11% for prescription drugs, generics, over-the-counter (OTC) drugs and medical devices. The growth in medical care as a whole is reflected in the acquisition of 70,000 new hospital beds, 16,000 doctors and 60,000 nurses in Africa between 2005 and 2012.

Besides the well-known burden of infectious diseases (HIV/AIDS, tuberculosis, malaria and tropical diseases), non-communicable diseases (NCDs) are becoming increasingly important in Africa. NCDs accou-

nted for 28% of morbidities and 35% of mortalities in Africa in 1990, with a projected rise to 60% and 65% respectively by 2020<sup>[2]</sup>.

Africa is, however, a very diverse continent of 54 countries, each with its own economic landscape and political complexities. The top 5 pharma markets (billion US\$, IMS Health 2014 estimates), namely South Africa (4.9), Egypt (3.9), Algeria (3.5), Morocco (1.8) and Nigeria (1.2), account for about 70% of the total African market value. Within each country, there are major differences between the rich and the poor, with major cities responsible for a large part of the economic growth. Collapse in the oil price and crises such as the recent Ebola outbreak contribute to economic instability and regional differences.

As in everywhere else, pharmaceutical companies in Africa are exposed to mergers and acquisitions, joint ventures, strategic alliances, partnerships and

private-equity deals. The South African generics company Aspen Pharmacare has grown to be one of the top ten generic companies in the world. Such expansion of the local pharmaceutical industry requires trained pharmaceutical specialists to support it. The bigger multinational pharmaceutical companies are increasingly active in drug production and clinical trials across Africa. According to the McKinsey Report, more than 300 companies have drug manufacturing sites on the continent<sup>[1]</sup>.

Clinical trials across all phases have a long tradition in South Africa in particular, with an estimated annual value of about 1.3–2 billion Euro<sup>[3]</sup>. About 270 new trials start every year, and 550 trials are active in the country at any given time<sup>[4]</sup>.

## 2. Impact on Pharmaceutical Industry

In the industry, these developments have led to the establishment of medical departments within pharmaceutical companies and subsequently of contract research organisations (CROs) during the 1980s. In South Africa, physicians working in the pharmaceutical industry were organized in the South African Association of Pharmaceutical Physicians (SAAPP) which, until 2005, had 83 active members. This organization then went through a period of dormancy but is now in the process of re-activation. Meanwhile, the clinical research specialists are represented by the South African Clinical Research Association (SACRA), an active nonprofit organization that has regular consultation with the regulatory body about pertinent issues, is involved with the move towards the registration of Good Clinical Practice training providers and hosts an annual conference.

Clinical research in sub-Saharan Africa is mainly performed by international and local companies, but increasingly also by clinicians in the form of investigator-initiated trials. There is a clear need for more and better clinical research in Africa addressing the major contributors to burden of disease in this part of the world<sup>[5,6]</sup>.

Another challenge is the ever changing regulation of the pharmaceutical marketplace. In South Africa, certification with the Marketing Code Authority (MCA) established in 2014 is a requirement, and pharmaceutical professionals must comply with its code of conduct. Employees must be adequately trained. Unfortunately, other African countries do not yet have such an oversight body and hence there is minimal guid-

ance on marketing of medicines.

## 3. Medicines Regulation

Regulatory agencies in Africa are also struggling. The South African Medicines Control Council (MCC) is the most established regulatory body in Sub-Saharan Africa. Due to the increasing complexity of product submissions and the present working model which relies on external reviewers mainly from universities and research institutions, the review timelines are long and unpredictable. Delays in clinical trial submissions can also be a setback for sponsors to consider South Africa for their clinical development plans, although typically good recruitment rates may make up for lost time.

In November 2015, the South African parliament passed a bill to phase out the Medicines Control Council and create the South African Health Products Regulatory Agency (SAHPRA). The agency should be set up by 2016 and promises to streamline the process. It will fall outside the mandate of the South African National Department of Health and in-house staff will do much of the work. However, a critical mass of trained internal and external reviewers will still be needed to carry out its mandate.

For low- and middle-income countries, WHO promotes the establishment of regional multinational joint regulatory organizations to reduce the delays in uptake of new medicines, vaccines and medical innovations<sup>[7]</sup>.

## 4. Teaching and Training of Competencies in Medicines Development and Regulation

The increasing need for experts and accredited specialists in pharmaceutical companies, clinical trial groups and regulatory agencies across Africa needs to be addressed with urgency.

In the medical affairs departments for example, pharmaceutical companies across Africa have to hire personnel without necessary professional exposure and competencies for their roles. Thus, there is a reliance on “on the job training”. As the pharmaceutical landscape evolves, the role of the pharmaceutical specialist in translational medicine has become ever more important. Principles of evidence-based medicine are being applied more regularly in patient management, requiring a pharmaceutical specialist who understands the science of medicine development and is able to communicate this into clinical practice. Thus, with

limited training in pharmaceutical medicine in Africa, “on the job training” will not be adequate to provide all necessary competencies.

Whereas Pharmaceutical Medicine is not a specialty in any of the African countries, Clinical Pharmacology has been recognized in South Africa as a full medical specialty since 2009<sup>[8]</sup>. In 2011, the UK Faculty of Pharmaceutical Medicine exported its Diploma in Pharmaceutical Medicine examination to South Africa as a pilot project. Unfortunately, this initiative has subsequently been abandoned due to the lack of medically qualified candidates prepared to take this examination.

Regulatory science and medicines development are not taught at undergraduate level in Africa. However, several South African universities have developed bachelor and/or master courses in regulatory science, drug development, pharmacoeconomics, pharmacovigilance and pharmaceutical affairs. In 2010 a fully accredited 2-year diploma program in medicines development was started at Stellenbosch University following the PharmaTrain syllabus and standards. As the first non-European training course, this program is accredited as a Center of Excellence by the PharmaTrain Federation. Non-academic training programs and workshops in medicines development and drug regulation are for example offered by the Fundisa African Academy of Medicines Development<sup>[9]</sup> which presented the first Clinical Investigator Certificate (CLIC) course according to the PharmaTrain syllabus in 2015.

The South African Health Products Regulatory Agency (SAHPRA) will require a new model of staff training, combining capacity building through a blended e-learning platform, including mentoring, workplace assignments and specific courses in cooperation with the universities and other training providers. Recommendations for the training of regulatory experts in South Africa were provided by the EU-funded Ecorys Health Consortium. Currently, the Institute for Regulatory Science (IRS) is being established in the National Department of Health to coordinate training of agency staff, clinical trial specialists and industry employees in South Africa.

Ongoing initiatives for capacity building in medicines development and regulatory sciences in emerging African countries were discussed at the 4<sup>th</sup> African Regulatory Conference held in Dakar, Senegal in April 2015. Progress has been made in the development of pharmacovigilance in Africa, and some Afri-

can countries have become members of the WHO Programme for International Drug Monitoring. In 2010, WHO designated the University of Ghana Medical School as a WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance.

An initiative with no borders is The Global Health Network, which provides a website forum for clinical investigators and their teams to address technical competence, and knowledge-sharing<sup>[10]</sup>. This offers open access, peer-reviewed e-learning products, tools and templates, articles, discussion forums and a professional membership scheme that supports career development in clinical trials. Since its start in 2010 by Oxford University, this website has become widely popular, with more than 230,000 visits recorded to date.

Following a workshop at the 17<sup>th</sup> World Congress of Basic and Clinical Pharmacology (WCP2014) in Cape Town<sup>[11]</sup>, PharmaTrain Federation and the International Federation of Associations of Pharmaceutical Physicians & Pharmaceutical Medicine (IFAPP) jointly established a Working Group on Education of Medicines Development in Low and Middle Income Countries. Zimbabwe, Ghana and Ethiopia were selected as initial African pilot countries in which to consider expanding the IFAPP-PharmaTrain remit to these regions.

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