National medicine regulatory authorities in Africa: key to access to safe and effective medical products

Inadequate access to quality and affordable medical products in Africa has been a major public health challenge for decades in a majority of the 55 African states.

This is partly due to the weakness of **National Medicine Regulatory Authorities** (NMRAs) - or, in countries without an NMRA, of the Directorate of Pharmacy in the Ministry of Health.

Indeed, the NMRA is the official agency in each country in charge of medicines and health products. This responsibility includes 5 key functions:

- marketing authorization of a medicine,

- pharmacovigilance,

- surveillance of the drug market,

- quality control,

- clinical trial monitoring.

In other words, an NMRA deals with:

- all activities before the first marketing authorization of a medicine or health product,

- all activities after the first marketing authorization of a medicinal product or health product,

- all inspections and control activities.

All African countries, except for the Sahrawi Arab Democratic Republic, have an NMRA or at least an administrative unit performing some or all the functions of an NMRA. According to WHO, 7% of these NMRAs have low capacity and 90% have minimal capacity. Only Ghana and Tanzania have a so-called 'maturity' level of 3 on a scale of 4. About 40 out of 46 NMRAs analyzed have legislation on medicines but only 15% of these NDRAs have a legal mandate to

perform the 5 essential regulatory functions.

The weakness of NMRAs in Africa is linked to:

- Weak or absent policy and regulatory systems,

- Lack of sufficient numbers of competent regulatory professionals,

- underfunding,

- sometimes arising from corruption,

- ineffective or lack of regional collaboration between NMRAs.

In response to national regulatory challenges in Africa, several regional harmonisation efforts were introduced by the **African Medicines Regulatory Harmonisation Initiative** (**AMRH**) in 2009.

Initially the aim of the AMRH was:

- to assist African countries to establish an effective drug registration system through regional harmonization and capacity building.

- and to improve the fragmented regulatory system for product registration in Africa by moving from a country-centric approach to a streamlined, regional collaborative approach.

AEFJN reported on this in the ECHOS of 26 March 2018 to which we refer the reader.

In 2016, the **AU Model Law on the Regulation of Medical Products** was adopted by the AU; the purpose of this law is to establish an effective and efficient system of regulation and control of medical products and to ensure that these products meet the required standards of safety, efficacy and quality. The AMRH Initiative has been tasked with putting this law into practice, which has broadened its mission. Ultimately, it is proposed that the AMRH initiative will form the basis for the establishment of the **African Medicines Agency** (**AMA**).

Unfortunately, the implementation targets of the AU Model Law have not been fully met and the AMA Treaty has not yet been ratified by the minimum number of countries required for its establishment. Despite these challenges, the AU Model Law and the AMA promise to address gaps and inconsistencies in national regulatory legislation and ensure effective drug regulation by galvanising technical support, regulatory expertise and resources at the continental level.

On 25/11/2020, the European Commission communicated to the European Parliament, the European Council, the Economic and Social Committee and the Committee of the Regions a 29-page document entitled **Pharmaceutical Strategy for Europe**!

Page 26 of the document states:

"*Global markets are a key source of growth, including for SMEs. This includes ensuring a level playing field and a regulatory environment conducive to innovation and competitiveness. In bilateral relations with other countries, the Commission will promote EU interests, including reciprocal access to public procurement markets in third countries, but will also identify areas of common strategic interest. In particular, Africa is an important partner with which to explore cooperation on innovation, production and technology transfer...*".

So, Africa is seen as an important partner and the EU wants to explore cooperation with it.

This is a respectful language and commendable intentions.

Nevertheless, one may regret:

- the lack of emphasis on Africa in the Strategy, even though Africa is described as an 'important partner' and that the health of African populations has consequences for the health of European populations. Instead, Africa is seen in the Strategy as a potential trading partner.

- the lack of commitment to act at WTO level in favour of a relaxation of the extremely strict patent policy (**TRIPS** or **Trade Related Aspects of Intellectual Property Rights**) in order to facilitate technology transfer and to allow, in the medium or long term, the manufacture of vaccines and medicines of public interest to supply regional markets.

AEFJN calls on the European Parliament, in addition to the measures foreseen in the European Pharmaceutical Strategy for Africa, to commit to:

- provide more resources to support African NDRAs in order to strengthen their capacities in the sense of the AMRH Initiative and to promote the development of the AMA.

- defend a position at WTO level that would allow it to deal with public health emergencies, including the use of a temporary waiver of Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in the case of the COVID19 pandemic, as requested by India and South Africa.

More on this in a future article.

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