Project work

Regulation

Aim

To explore the principles and politics of medical products regulation and develop campaign proposals for PHM around priority issues.

Background

Africa has been working towards medicines regulatory harmonisation since 2007 when the **Africa Medicines Harmonisation Initiative** was launched (see NEPAD; also NEPAD & WHO 2009; and Annual Report 2017 and Ndomondo-Sigonda 2018).

The African Medicines Agency was established in 2018 (IP Watch 2017; Zarocostas 2018; Anon 2018; Ndomondo Sigonda et al 2018). Legal framework here.

In 2019 the WB invited expressions of interest in a consultancy for the strategy and business plan of the African Medicines Agency.

The AU has developed (is developing) a **model law on medicines regulation**. (See Infographic and Issues Brief.) The full AU Model Law is here. The Issues Brief summarises the model law as follows:

> Marketing health technologies: All medical products must be registered and have valid authorization to be marketed and promoted. Applications for this authorization will be reviewed by the NRA.
>
> Licensing: Only with a licence from the NRA may a person or company manufacture or distribute health technologies.
>
> Quality and safety of health technologies: The NRA will be responsible for monitoring and analysing adverse effects of registered health technologies and clinical trials, as well as the recall and withdrawal of substandard products. The NRA will conduct quality and safety inspections of health technologies and manufacturing facilities, and a National Quality Control Laboratory will be established for research, training and the analysis of medical products.
>
> Clinical trials: To conduct a clinical trial with human participants, the trial must be cleared by a National Ethics Committee or Institutional Review Board and authorized by the NRA.
>
> Appeals procedures: The authority overseeing the NRA (e.g. the Ministry of Health) will establish an Administrative Appeals Committee to hear cases lodged against the NRA.
>
> The Brief further advises that the model law contributes to the AU Pharmaceutical Manufacturing Plan for Africa (PMPA, see AU,WHO,UNIDO 2012 and Kurian 2019) and the 2012 Roadmap for Shared Responsibility and Global Solidarity for the AIDS, TB and malaria response in Africa (here).

The adequacy of medical products regulation in African is variable but often quite inadequate. Ndomondo-Sigonda and colleagues (2017) advise that:

> *Globally, the World Health Organization (WHO) estimates that at least 30% of NMRAs have limited capacity to perform the core regulatory functions. According to WHO, there are 54 NMRAs in Africa, but their capacity is variable with most of them incapable of performing the*

core functions expected of NMRAs. The WHO report shows that only 7% of African countries have moderately developed capacity with more than 90% having minimal or no capacity.

See also the earlier assessment of MRAs in Africa by WHO in 2010; and the report from Dansie et al (2019).

Following the adoption of WHA Resolution 67.20 on Regulatory System Strengthening, and counterpart WHO Regional Committee resolutions, the WHO has developed a Global Benchmarking Tool to assist in the evaluation of national and regional DRAs.

National medical products policy. Medical products regulation can be extremely contentious. Many stakeholders have conflicting interests in how medical products regulation works. A national medicines policy can be an important tool in managing such conflicting interests. In 2003 WHO produced a briefing paper on how to develop a national drug policy which identified three broad objectives of such a policy:

- Access: equitable availability and affordability of essential medicines, including traditional medicine;
- Quality: the quality, safety and efficacy of all medicines;
- Rational use: the promotion of therapeutically sound and cost-effective use of medicines by health professionals and consumers.

Some people might wish to add to this something about developing a viable local production industry.

(This briefing paper refers to a national *drug* policy; in modern parlance this would be described as a medical products policy so as to encompass biologicals, cell therapy, diagnostics and devices.)

Questions

What are the contentious issues in medical products regulatory regimes? Who are the stakeholders who are contending over these issues and what are their interests. How do you believe these conflicting interests would be best managed/resolved?

Review the medical products regulatory regime in your countries and regions.

How well does it serve the public? How well does it address the main contentious issues that you have identified.

Task

Develop a set of lobbying messages for your own government (or regional organisation); for the strategy and business plan of the African Medicines Agency; and for the AU regarding possible revisions of the Model Law.

Develop a set of practical proposals for the consideration of PHM circles in Africa regarding a campaign around these messages.