

## Building medical regulatory authorities in Africa

To read *Registering New Drugs: The African Context* see <http://www.dndi.org/regulatory.html>

A new report commissioned by the Drugs for Neglected Diseases Initiative (DNDi) has outlined several recommendations for African nations to bolster their capacity to register drugs for tropical diseases. *Registering New Drugs: The African Context* highlights shortcomings in the current system and advocates—among other things—the establishment of regional Centres of Regulatory Excellence in Africa and the formal inclusion of African experts in regulatory decisions on products targeting endemic African diseases.

A 2004 WHO study found that “90% of medical regulatory authorities [MRAs] in the African region...cannot guarantee the quality, efficacy, and safety of medicines”. Hence, for drug registration Africa tends to rely on stringent regulatory authorities outside the continent, such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). But this approach is problematic.

Take risk-benefit analysis, for example. The report cites a rotavirus vaccine licensed by the FDA and subsequently withdrawn on the grounds of a one in 10 000 risk of intussusception: odds that are unacceptable in the USA, but are not necessarily so in countries where rotavirus is more deadly. Or there is the case of rifapentine, a tuberculosis drug registered in the USA but unusable in Africa because its efficacy in patients

with both HIV and tuberculosis is untested. “In approving a new drug”, the report declares, “no MRA has the obligation to request clinical data that is relevant outside their own market.”

There have been attempts to bridge this gap. In 2004, the European Commission established the hitherto little-used Article 58 mechanism, which provides a rigorous scientific assessment of products aimed at non-European markets, involving WHO in the review process. The FDA’s “tentative approval” scheme is roughly similar. In 2001, WHO set up its drug prequalification programme to help facilitate access to drugs for malaria, HIV, and tuberculosis in Africa; the programme, in which African reviewers are well-represented, should be expanded to include products targeting other diseases, advises *Registering New Drugs*. Nevertheless, the report confirms that there are “currently no regulatory approaches that satisfy all the components of optimal drug registration in Africa”.

“This is a major issue for tuberculosis”, says Mel Spigelman (TB Alliance, New York, USA). He points out that lack of clarity in the prevailing system is an impediment to drug development, slowing the entry of products to the market and discouraging participation in the field. “Increasing the regulatory capacity [of African MRAs], and the transparency and knowledge base of regulatory services and guidelines will help on all these fronts”, he told *TLID*.

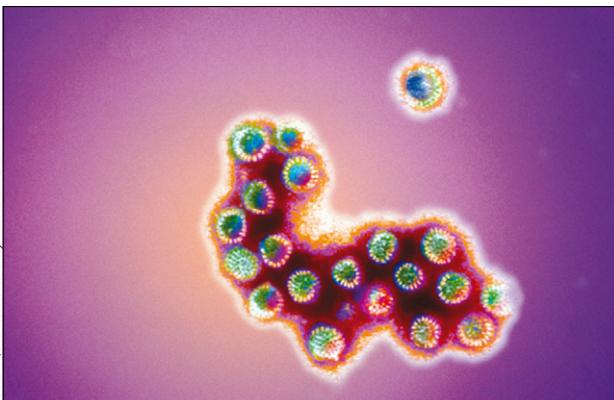
Jean-Rene Kiechel (DNDi, Geneva, Switzerland) notes that the ultimate aim is for African countries to assess product dossiers. He concedes it will be a slow process, perhaps taking 5–10 years. Two-thirds of African MRAs lack the financial resources to effectively investigate new pharmaceutical products—more than 40 are barely functional at all—national drug legislation is commonly vague or non-existent, political motivation scant, and qualified staff hard to come by.

None of which is a reason not to try, counters Spigelman. “It is naive to think that all African countries will progress uniformly, but I wouldn’t use the exception of a Somalia or a Sudan to detract from the main message of building capacity and expertise”, he said. Besides, other countries on the continent are better-placed. Kiechel believes that Tanzania will soon be able to participate fully in the assessment of new chemical entities. *Registering New Drugs* describes South Africa’s MRA as “fully functional”, and is hopeful about several other countries on the continent, including Ghana, Ethiopia, and much of the Arab north.

“It’s a matter of ensuring that the people who are going to be the recipient of a drug play as significant a role as possible in deciding whether or not to regulate the drug”, explains Robert Don (DNDi, Geneva, Switzerland), which is not to say ill-adapted regulators should be encouraged to register new drugs. “We certainly don’t want to cut any corners”, Don stressed, “particularly in terms of registering a drug which would not be acceptable to EMA or FDA.” In the short-term, he hopes for a pan-African regulator.

Kiechel feels things are starting to move in the right direction. “The possibility of having a twinned assessment of a novel product is more than just an aspiration”, he said, “it can happen in the not-too-distant future”. Spigelman added that in many cases “regulators in one country can only act after other countries have acted first: we want to move from sequential effort to parallel effort”. *Registering New Drugs* aims to spark a discussion on how best to achieve this, and the other crucial aim of harmonising regulatory processes. On the latter issue, the document is realistic about the task at hand. After all, it took Europe 40 years of “trust-building” before it established the EMA.

Talha Burki



Risks of a rotavirus vaccine must be weighed against prevalence of the infection