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Swiss Agency for Development and Cooperation SDC

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Swiss Agency for Therapeutic Products

New partnership to accelerate access to quality health products

Despite tremendous progress in access to life-saving medicines against HIV, TB, malaria and other diseases, large parts of the population in low- and middle-income countries still do not have timely access to essential therapeutic products. Reasons for this range from high prices to inadequate procurement and supply systems, and to the geographical inaccessibility of health products and poverty of people in need. Weak national medicines evaluation and registration procedures are a neglected dimension. The Federal Department of Home Affairs and the Federal Department of Foreign Affairs have therefore joined forces to accelerate access to therapeutic products and other health interventions in resource-constrained countries by focusing on the regulatory approval process.

In January 2014 the Bill & Melinda Gates Foundation, the Swiss Federal Department of Home Affairs (FDHA) and the Federal Department of Foreign Affairs (FDFA) agreed on a Memorandum of Understanding (MoU) to improve and accelerate access to therapeutic products and other health interventions in resource-constrained countries. This is to be achieved by coordinating and leveraging resources through cooperation, in order to strengthen the regulatory systems in these countries with a view to bringing high quality, life-saving therapeutic products to patients as quickly as possible.
Work under the partnership is led by Swissmedic, the Swiss Agency for Therapeutic Products, which reports to the FDHA and is the national authority responsible for the authorisation and supervision of therapeutic products, and the Swiss Agency for Development and Cooperation (SDC), which is responsible for the implementation and overall coordination of development activities within the FDFA and is strongly committed to facilitating access to quality health services, including medicines, in low- and middle-income countries.

The overarching provisions of the MoU have been worked out in more detail to facilitate its implementation. Two project components have been developed that aim to strengthen national regulatory systems. They link to the marketing authorisation process at different stages. While the first project component supports the ongoing African Medicines Regulatory Harmonization (AMRH) Initiative with technical expertise in different fields provided by Swissmedic and the World Health Organisation (WHO), the second offers the National Medicines Regulatory Authorities (NMRAs) and the WHO a unique possibility to participate in a Swissmedic evaluation procedure for medicinal products that disproportionately affect low- and middle-income countries. The expectation is to accelerate the WHO pre-qualification listing and national evaluation and registration of a submitted product following Swissmedic's marketing authorisation.

Project component I	• Support the implementation of the African Medicines Regulatory Harmonization (AMRH) by focusing on the East African Community Medicines Registration Harmonization (EAC-MRH) Project
Project component II	• Swissmedic procedure for scientific advice and for marketing authorization for global health products (MAGHP Procedure) for medicinal products disproportionately affecting low and middle-income countries

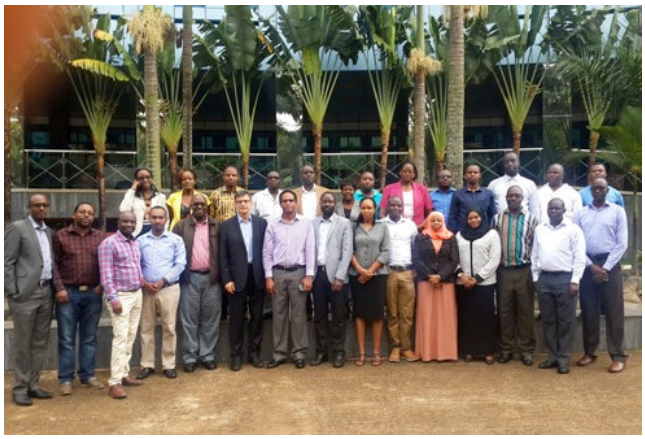
Project component I: Support the implementation of the African Medicines Regulatory Harmonization (AMRH) by focusing on the East African Community Medicines Registration Harmonization (EAC-MRH) Project

The African Medicines Regulatory Harmonization (AMRH) Programme, a collaborative effort of a consortium of partners (www.amrh.org), supports African countries in building effective regulatory networks and systems inside established Regional Economic Communities (RECs) in order to improve access to essential quality medicines. The first REC to secure funding under the AMRH Programme was the East African Community (EAC) (www.eac.int). The EAC-MRH initiative was launched in March 2012. The initiative aims to accelerate access to quality medicines for people in the EAC member states by harmonising their national medicines registration systems. Common guidelines have been developed and are in the process of being implemented in the following four subject areas:

- Medicines Evaluation and Registration (MER)
- Good Manufacturing Practice (GMP)
- Quality Management Systems (QMS)
- Information Management Systems (IMS).

Work by Swissmedic is done in close collaboration with the WHO which assumes the technical coordination and lead. Swissmedic contributes to the development of technical guidelines, their implementation and maintenance, to joint assessments and inspections as well as training programmes and other activities in the four areas listed above. The approach developed within the EAC will be used as a basis for similar programs in other RECs in sub-Saharan Africa.

1st EAC Joint Assessment MER (October 2015)



Source: http://mrh.eac.int/

Project component II: Swissmedic procedure for Scientific Advice and Marketing Authorisation for Global Health Products (SAGHP and MAGHP)

In line with the project's overall objective to improve access to therapeutic products and other health interventions in resource-constrained countries, Project component II aims to make the Swissmedic authorisation procedure and the procedure for providing scientific advice accessible to representatives of regulatory authorities in resource-constrained countries and the WHO. Those representatives from NMRAs and the WHO Pre-Qualification Programme can actively participate in the assessment or just observe the procedure. It is expected that the timelines for the WHO-PQ listing and marketing authorisation by NMRAs will be significantly reduced because they have followed the MAGHP procedure and have gained confidence in its outcome. Overall, this would lead to a faster access to those medicines for the patients in need.

Although other regions may be involved, the initial focus in a pilot phase will be on supporting regulators in the EAC. The procedure is intended to apply particularly to medicinal products for those diseases that affect the African region disproportionately. It builds on the existing procedure for marketing authorisation for medicinal products not intended for the Swiss market (so-called "export registration"), which has been available for de-cades.

Overview of draft procedure for marketing authorisation for global health products (MAGHP).

Funding

These two project components are funded under a grant agreement between the Bill & Melinda Gates Foundation and Swissmedic. SDC complements these efforts by providing funds to WHO for additional activities in East Africa and other parts of the continent.

Contact and further information

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