South African Health Products
Regulatory Authority
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COMMUNICATION TO INDUSTRY

SAHPRA INVOLVEMENT IN THE SWISSMEDIC MARKETING AUTHORISATION FOR GLOBAL HEALTH PRODUCTS (MAGHP) PROCEDURE

The Marketing Authorisation for Global Health Products (hereinafter referred to as MAGHP) procedure is a Swissmedic project in the area of regulatory systems strengthening. The aim of the MAGHP project by Swissmedic is to increase the efficiency of the regulatory review and registration process by focusing stakeholders on value-added activities, and to strengthen the regulatory authorities' ability to protect their citizens' health (capacity building).

Although participation of other regions may be considered, the focus is on supporting regulators in the sub-Saharan region of Africa with the goal of accelerating access to medicinal products – mainly, but not exclusively, for those diseases that disproportionately affect the region. In the context of the MAGHP procedure, this is achieved by involving the National Regulatory Authorities (NRAs) of the countries concerned in the review procedure. Thus, SAHPRA may be nominated by the applicant to be a participating NRA in the regulatory review and registration process wherein products are submitted for registration to Swissmedic and the applicant intends to also register the product in South Africa.

The NRAs involved in the MAGHP will benefit from being part of the Swissmedic evaluation procedure in that participating in this procedure will accelerate the review process from the NRA. Furthermore, this participation will enable them to acquire knowledge about the product, gain confidence in the scientific evaluation at Swissmedic and, at the same time, provide their own inputs and comments on the evaluation. Therefore, the expectation is that the authorisation procedure can be shortened for the NRAs because a) knowledge about the product has already been acquired ("well-informed" reliance), b) access to the Swissmedic assessment and inspection reports is granted and c) confidence in the scientific process at Swissmedic has been gained.

The MAGHP procedure builds on the existing authorisation processes at Swissmedic. In case of an approval, the procedure results in a marketing authorisation for Switzerland. Therefore, those criteria that are applicable to the assessment and significant for decision-making purposes refer to the medical situation and regulatory requirements in Switzerland.

Nevertheless, the inputs and comments received from participating NRAs are taken into consideration and are included in the exchange with the applicant. These inputs may address country-specific issues, such as special requirements regarding stability data (e.g. climate zone 4), risk management plan or disease programmes, including country-specific treatment guidelines, and will serve as important information for the applicant with regard to the dossier submission.

It is important to note, that, in addition to the application to Swissmedic, the individual dossier will also need to be submitted according to the national requirements to each targeted NRA. Apart from national specifics, the dossier must be essentially the same. The applicant is encouraged to submit the dossier as early as possible in the process. The MAGHP procedure is limited to new registrations and new indications of new and established API's.

For all applications, including those for export only, a Swiss marketing authorisation holder is required. However, an applicant does not necessarily need to be based in Switzerland, but can work through a representative, e.g. a regulatory office.

For further information on the application process, please visit: www.swissmedic.ch/maghp

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