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ETHIOPIAN FOOD & DRUG AUTHORITY

Announcement

To all pharmaceutical manufacturers/Medicine market Authorization holders

It's known that SmPC serves as the primary source of information for healthcare practitioners on how to use medicines for the approved indication(s) safely and effectively.

According to Regulation 531 Article 25 issued by a Council of Ministers regulation to provide organization, powers, and duties of the Ethiopian Food and drug authority; it requires the Authority to serve as a center of drug information. Thus, in addition to availing other regulatory information for the public, publishing the updated SmPC by pharmaceutical companies based on their product research and knowledge on EFDA's website is now obligatory.

Now, therefore all pharmaceutical manufacturers /Market Authorization holders of medicine are hereby informed that EFDA has decided to publish updated SmPC of already approved medicine(s) on its website(www.efda.gov.et/). Thus, MAHs are kindly requested to submit an updated SmPC of their product with their current scientific knowledge until July 30, 2023. Please note that failure to submit within the deadline period will results in suspension of the registered medicine unless otherwise justified before the deadline period.

Note:

The SmPC should follow the template which is published on the authority's website and product information guideline.

For generic medicines use the following references while updating the SmPC:

Innovator SmPC from any SRA published information

WHO Public Assessment Report /WHO-PQ RECOMMENDED SUMMARY OF PRODUCT CHARACTERISTICS

<https://extranet.who.int/pqweb/medicines/prequalification-reports/whopars>

SmPC published on electronic medicines compendium

<https://www.medicines.org.uk/emc#gref>

The MHRA published product information

<https://products.mhra.gov.uk/>

Human medicine European public assessment report

<https://www.ema.europa.eu/en/medicines>

Send the SmPC in word and PDF format with the following email address:

ztsegaye@efda.gov.et cc to hbeyene@efda.gov.et and ajemabekele@gmail.com



Handwritten signature: **Amamu Bayene Galuma**
Medicine Registration and Licensing Directorate
Director