EFDA

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Date:

To: Indian drug Manufacturers` Association (IDMA)

102-B Poonam Chambers, Dr A B Road, Worli, Mumbai 400 018, India

Subject: Invitation for stakeholders' webinar conference to Boost Product Marketing Authorization

Ethiopia has been putting tremendous effort into implementing the National Medicine Policy (1993) and Health Sector Development Program (HSDP) for the last two decades. During this period, our country has made huge strides to improve access to safe, quality, and efficacious medicines for the public. The political commitment and good leadership, community mobilization with the concept of community ownership, and strengthening collaboration & partnership have remarkably improved the health system in Ethiopia.

Currently, the government of Ethiopia has committed to improving the quality and equity of health services in the country. To this effect, the Ethiopian Food and Drug Authority (EFDA) has been striving to improve the availability of safe, effective, and quality-assured medicines in Ethiopia through strengthening the health products registration system. Especially, the implementation of the electronic regulatory information system (eRIS) paves the way to prompt communication between EFDA and applicants. As a result, there have been substantial improvements in the product registration timeline in the past few years.

Stretching its commitment, EFDA's zero dossier backlog was one of the main flagship initiatives during the last five years. To realize this, it has adopted, and aligned product registration requirements with the international harmonized practices and implemented risk based marketing authorization strategies.It has also developed a fast-track registration procedure for products of public health concern(e.g., anti-malaria, antiretroviral, anti-tuberculosis medicines, diagnostics and maternal and child health products).Risk based registration approaches such as accelerated registration of products sourced from Stringent Regulatory Authority (SRA) approved manufacturers and waiver of GMP inspection, collaborative registration with WHO, working with government universities to improve quality of assessment are the other strategies already implemented to facilitate access to essential products to the public.

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EFDA ETHIOPIAN FOOD & DRUG AUTHORITY

Though a lot has been done so far, there are also areas that need improvement. The authority is now planning to work closely with its stakeholders and applicants more than ever. This will help the authority to get constructive feedbacks and ways to improve the regulatory system. Hence, our Authority is planned to organize a webnar conference on issues related to registration of pharmaceutical products and other lated matters related Marketing Authorization that the authority has organized on the date of **16/01/2023 G.C. East African time 9:00 am (11:30 Indian Time).**

**Note:** Please use this link for registration of virtual meeting

Zoom Registration Link:
https://jsi.zoom.us/meeting/register/tJApcOiqrTotGNKvnTWQbrhFpBZciLC4IppG

Meeting ID: 944 7123 1726
Passcode: 620228

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Best Regards

Seyoum Wolde
Deputy Director General, Food and Medicines Quality Assessment

CC:

- Ethiopian Food and Drug Authority(EFDA) Director General
- Ethiopian Food and Drug Authority(EFDA) Deputy Director General
- Medicine Facility Inspection Directorate
- Medicine Registration and Licensing Directorate
- Medicine Quality Control Directorate

**Addis Ababa-Ethiopia (EFDA)**