06 May 2024

NOTICE TO RELEVANT STAKEHOLDERS

Dear Sir/Ma'am:

This refers to the draft regulations distributed through the World Trade Organization – Technical Barriers to Trade (WTO-TBT) website (www.epingalert.org) from 20 to 26 April 2024.

Relative thereto, we respectfully invite stakeholders to comment on the notified draft technical regulations from Ukraine, United States, and United Kingdom:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/GBR/86	United Kingdom	**Date of Distribution:** 26 April 2024 **Deadline for Comments:** 25 June 2024	Human medicinal products	The Regulations provide that a "UK marketing authorisation" comprises the following different types of authorisation: UKMA(UK) (Category 1) and UKMA (Category 2), which permit marketing of a medicinal product in all the territories of the UK; UKMA(GB) which does not permit marketing of a medicinal product in Northern Ireland; and UKMA(NI) which does not permit marketing of a medicinal product in Great Britain. These Regulations make amendments to the 2012 Regulations ensure that the correct type of authorisation is referred to.
G/TBT/N/UKR/294	Ukraine	**Date of Distribution**: 24 April 2024 **Deadline for Comments:** 23 June 2024	Medicinal products	The draft Order provides for the approval of amendments to the Procedure for Confirmation of Compliance of Medicinal Products Manufacturing Conditions with the Requirements of Good Manufacturing Practice, approved by the Order of the Ministry of Health of Ukraine No. 1130 of 27 December 2012.
G/TBT/N/USA/1777/Add.1	United States	**Date of Distribution:** 23 April 2024 **Deadline for Comments:** Not indicated	Poison prevention packaging requirements - Addendum	The Consumer Product Safety Commission (Commission or CPSC) is amending the child-resistant packaging requirements of CPSC's regulation to exempt baloxavir marboxil tablets, currently marketed as XOFLUZATM, in packages containing not more than 80 mg of the drug, from the special packaging requirements. XOFLUZA is used to treat the flu, and the drug is taken in one dose within 48 hours of experiencing flu symptoms. The final rule exempts this prescription drug product on the basis that child-resistant packaging is not needed to protect young children from serious injury or illness because the product is not

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Membership:
- International Organization for Standardization (ISO)
- International Electrotechnical Commission (IEC)
- World Trade Organization (WTO) Technical Barriers to Trade (TBT)
  - National Enquiry Point (NEP)
  - National Notification Authority (NNA)

				acutely toxic and lacks adverse human experience associated with ingestion.

To access the notification form, right click the document symbol to open the hyperlink. Should you have any queries on this matter or request for full text of draft regulation in English, please do not hesitate to email us at BPS@dti.gov.ph copy bps.smd@dti.gov.ph.

Thank you.

Sincerely,

FERDINAND L. MANFOSTE
Officer-in-Charge