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Dear Stakeholders

We are pleased to share some of Health Sciences Authority's (HSA) regulatory updates and key initiatives in this issue of NEX2US FLASH. We appreciate your partnership and feedback as we continue in our journey to safeguard and advance public health.

Health Products Regulation Group
Health Sciences Authority

REGULATORY UPDATES

Online Reporting Forms, Risk Classification Tool and Video on Product Defect & Product Recall for Therapeutic Products

January – May 2019

HSA has developed the following electronic resources to facilitate and guide companies on the reporting of product defects and recalls for therapeutic products:

i) **Online Reporting Forms for Product Defect and Product Defect Recall Completion** enhance the reporting efficiency by simplifying the reporting process. Companies no longer have to submit scanned copies of reporting forms that are filled in manually.

ii) Self-help **Product Defect Risk Classification Tool** enables companies to determine if a product defect is considered critical and whether it needs to be reported to HSA.

iii) **Video on Product Defect Reporting and Recall** promotes better understanding by conveying the regulatory requirements and reporting process in an engaging manner.

These resources support companies in fulfilling the necessary requirements for product defect management, which plays an important role in safeguarding consumer health and safety.

Click here for more information

Electronic Labelling (e-labelling) of Therapeutic Products

August 2019

HSA is introducing an e-labelling initiative to facilitate companies' dissemination of package insert (PI) and patient information leaflet (PIL) for therapeutic products through electronic means.

Companies may opt to adopt e-labelling by directing users to the electronic PI and/or PIL via machine-readable codes (e.g. QR code) or URL affixed on the product cartons.

This initiative is piloted for the PI and/or PIL of prescription-only medicines and will be reviewed in the first quarter of 2020. During the pilot period, the electronic PI and/or PIL may be distributed concurrently with the printed copies.

Click here for more information

Revised Heavy Metal limits for Complementary Health Products (CHP)

September 2019 – September 2020

The revised heavy metal limits for CHP has been implemented on 1 September 2019. They include a tighter limit for lead, a new limit for Cadmium and the removal of copper from the list of heavy metals under the Medicines (Prohibition of Sale and Supply) Order.

Existing products already in the market are given a one-year grace period and will need to comply with the revised limits from 1 September 2020.

This revision enhances consumer protection, and at the same time facilitates companies' entry into other markets through compliance with international standards.

Click here for more information

Prohibition of Mercury-added Topical Antiseptics and Cosmetic Products to comply with the Minamata Convention on Mercury

January 2020

The Minamata Convention on Mercury is an International Treaty to protect human health and environment from man-made releases of mercury and mercury compounds. HSA has consulted the relevant industry associations to gather feedback on the proposed regulatory controls ahead of the implementation in 2020.

The following regulatory controls will be implemented with effect from 1 January 2020:

i) Manufacture, import or export of topical antiseptics with mercury or any compound of mercury will not be allowed.

ii) Manufacture for export and import for re-export of cosmetic products* that contain mercury or any compound of mercury above 1 ppm will not be allowed. The local supply of such mercury-added cosmetic products* is currently prohibited.

Currently, there are over 110 countries, including Singapore, who are Parties to this Convention. As a Party, one of the obligations is to phase out the manufacture, import or export of the mercury-added products by 2020.

Click here for more information on the Convention

*Except for eye-area cosmetic products that uses allowable mercury-containing preservatives which do not exceed the stipulated limits.

BILATERAL COLLABORATION

Singapore and New Zealand Mutual Recognition Agreement (MRA) on Good Manufacturing Practice (GMP) Inspection for Medicinal Products

May 2019

Under the ambit of the upgraded ANZSCEP*, Singapore and New Zealand have agreed to a Mutual Recognition Agreement (MRA) on the Good Manufacturing Practice (GMP) Inspection of manufacturers of medicinal products.

With this MRA, New Zealand will now accept the outcomes of the GMP inspections conducted by HSA, Singapore and vice versa. Manufacturers of medicinal products will benefit from avoiding duplication of GMP Inspections, thus saving time and resources.

Click here for more information

*Agreement between New Zealand and Singapore on a Closer Economic Partnership

Australia-Canada-Singapore-Switzerland (ACSS) Consortium – Work Sharing Initiatives

HSA is part of the ACSS regulatory consortium, together with the Therapeutic Goods Administration, Health Canada and SwissMedic. The ACSS is collaborating on work sharing on evaluation of generic medicines and new drug applications. We would like to encourage the industry to submit suitable applications for these work-sharing pilots.

Click here for more information

International Medical Device Regulators Forum (IMDRF) Working Group Meetings

The IMDRF comprises a group of regulators that come together to drive medical device regulatory harmonisation and convergence. In support of IMDRF's harmonisation activities, HSA hosted two technical Working Group meetings in Singapore:

IMDRF Adverse Event Terminology and Coding Working Group (AE WG)
November 2018

The AE WG was formed to develop a harmonised terminology for reporting adverse events (AE) related to medical devices. This harmonisation will contribute to greater consistency and accuracy in the reporting of AE across jurisdictions. The WG had made good progress at this meeting in the finalisation of AE terms and codes relating to the clinical signs, symptoms, conditions and health impact.

IMDRF Good Regulatory Review Practices Working Group (GRRP WG
May 2019

The GRRP WG is developing a guidance to establish good regulatory review practices for regulatory authorities and their conformity assessment bodies. Aligning these practices will enhance the effectiveness and efficiency of pre-market review of medical devices. During this meeting, the WG worked actively to revise the guidance on labelling and instructions for use. The WG also initiated work to develop guiding principles for regulatory agencies' assessment of third -party certification bodies that perform pre-market reviews.