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HSA Initiates Recall of 18 Cosmetic Products In Both Offline and Online Spheres

In the latest example of the Health Sciences Authority's ("**HSA**") firm stance against unsafe health products, the HSA has initiated a recall of 18 cosmetic products which were found to contain potent undeclared ingredients, including mercury, hydroquinone and tretinoin. Apart from taking action against physical retail outlets, the HSA has also directed administrators of online sales platforms to remove web listings of the affected products.

The recall comes off the back of HSA's regular product quality surveillance activities, which involve random sampling and testing of health products marketed locally.

Under the Health Products Act, it is an offence to supply unwholesome health products, which definition includes cosmetic products that:

(a) contain substances listed in Part I of the Third Schedule (which include mercury and tretinoin) unless the presence of such substance is in trace amounts or is technically unavoidable in good manufacturing practice; or

(b) contain substances listed in Part II of the Third Schedule (which includes hydroquinone), in excess of permissible limits prescribed in the Schedule.

The penalty for this offence is a fine of up to S$50,000 (about USD 38,000) or to imprisonment for term not exceeding 2 years or to both.

The HSA actively cracks down on errant retailers in both the offline and online spheres, and this case affirms their wide discretionary powers of enforcement. More information can be found in the HSA's press release here.

Changes to Guidance on Therapeutic Product Registration Effective 1 April 2018

The Health Sciences Authority ("**HSA**") recently announced changes to the Guidance on Therapeutic Product Registration, which took effect as of 1 April 2018. These changes, which were subsequent to consultations with industry stakeholders, were aimed at improving processes to achieve greater transparency and predictability, as well as to lessen the regulatory burden on industry players.

Several of the significant changes are set out below:

- There will be a Turn-Around Time ("**TAT**") of 50 working days for the screening of new drug applications ("**NDA**"), generic drug applications ("**GDA**"), and major variation applications ("**MAV**") which are submitted in the Pharmaceutical Regulatory Information System ("**PRISM**"). The TAT will commence from the date on which the application dossier is received, and cease on the date of acceptance or non-acceptance, or withdrawal of the application. The TAT excludes the time which applicants take to address any input request from the HSA.

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- The verification route for the submission of MIV-1 applications, will have a reduced TAT of 90 working days.
- For clarity to applicants, the HSA has amended the Application Checklists for NDA, GDA, and MAV to include details of documentation requirements.
- There is a new Dossier Clarification Supplement for NDA and GDA, which allows applicants to provide supplementary information and ascertain whether the quality aspects of a therapeutic product proposed in Singapore match those approved by the HSA's reference agencies (EMA, Health Canada, TGA, UK MHRA, US FDA). The approval must have been given within 5 years before the date of submission of the application to the HSA. This change allows the HSA to build on the assessment conducted by its reference agencies, and enhance the efficiency of the abridged evaluation route.
- Updates have been made to the guidelines on the registration of human plasma-derived therapeutic products, and the guidance on Drug Master File ("**DMF**"). These changes help to clarify the requirements for submission and reduce the need for the HSA to raise an Input Request / deficiency query because of the omission of information by applicants and holders of DMF / Plasma Master File.
- The precondition for comparative dissolution profile testing for GDA is subdivided in accordance with a risk-based approach. Requirements may be reduced for generic products in immediate-release solid oral dosage form which are to be registered as General Sale List medicine or Pharmacy-Only Medicine, provided they adhere to compendial standards.
- The precondition for bioequivalence data for GDA is now extended to Biopharmaceutics Classification System (BCS) Class III compounds.

More details can be found in the guidance documents on the HSA website here.