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DEPARTMENT OF HEALTH
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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

General Information of Biosimilar Products

As biosimilar products become available and more commonly used in Hong Kong, we would like to provide the information regarding regulatory control and usage of the products for your kind references.

According to the Pharmacy and Poisons Regulations, all pharmaceutical products including biosimilar products must satisfy the criteria of safety, quality, and efficacy before they can be registered with the Pharmacy and Poisons Board (the Board) and be sold in Hong Kong.

According to the World Health Organization (WHO), biological products are distinguished from other products by being derived from living organisms and frequently have complex molecular structures. They require special quality consideration because of the biological nature of the starting materials, the manufacturing processes, and/or the test methods needed to characterize batches of the products. In the context of biological products and having due consideration of the specificities mentioned above, these copy products cannot be considered as identical but merely "similar" to the reference products because of the inevitable differences in molecular structures and quality attributes arising from their different manufacturing processes.

The Board has already promulgated the guidelines for registration of biosimilar products and has come into effect on 1 January 2016. For any biosimilar product that is to be registered in Hong Kong, the product must be proven to be similar to a registered reference product in terms of safety and efficacy. The product will also be labeled to indicate its nature as biosimilar product. The registration certificate holder is also required to comply with the following pharmacovigilance requirements:

(i) report local suspected serious or unexpected adverse drug reactions related to the biosimilar product as soon as possible and within 15 calendar days of receipt of the information;

(ii) submit Periodic Safety Update reports at the frequency required;
(iii) implement a local risk management plan and risk mitigation strategies that take into account the identified and potential risks associated with the use of the reference product; and
(iv) preparation of education materials for healthcare professionals on the specific risks of the biosimilar product and measures to reduce them.

As biosimilar product is similar but not identical to the reference product, healthcare professional should rely on his/her professional judgement and inform their patients if necessary regarding the risk of substitution of reference product with biosimilar product.

Yours faithfully,

(TK YIM)
for Assistant Director (Drug)