PHARMACY AND POISONS BOARD
HONG KONG
香港藥劑業及毒藥管理局

Your Ref. :
貴處檔號

Our Ref. : DH DO PRIE/1-55/1
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23 February 2023

To: Certificate holders of registered pharmaceutical products

Dear Sirs/Madams,

Updates on Registration Requirement of Pharmaceutical Products containing New Chemical or Biological Entities

Further to the letter issued by the Pharmacy and Poisons Board ("the Board") on 25 October 2022 regarding the update of the list of reference countries for the registration of pharmaceutical products containing New Chemical or Biological Entities ("NCE"), the Board has established the Expert Group on Drug Registration ("Expert Group") on 1 November 2022 for provision of expert opinion on the safety, efficacy and quality of the data submitted by applicants for registration of pharmaceutical products containing a NCE; and advise on matters related to risk management of NCE-containing pharmaceutical products under each application.

In this connection, Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee further reviewed the registration procedure of application for registration of NCE and endorsed that with effect from 23 February 2023, applicant for registration of NCEs could provide documentary proof for registration of pharmaceutical products issued by at least two drug regulatory authorities from any of the current 36 reference countries (including Brazil, China, Republic of Korea, and Singapore). As such, the relevant content pertaining to official evidence of registration approval of the product would be revised as follows:

Official evidence of registration approval of the product (e.g. electronic copy and original or certified true copies of Free Sale Certificates / Certificate of a Pharmaceutical Products) in:

two or more of the following countries: Australia, Austria, Belgium, Brazil, Bulgaria, Canada, China, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Holland, Hungary, Ireland, Italy, Japan, Republic of Korea, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, UK and USA

Moreover, the relevant Guidance Notes including (i) "Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity", (ii) "Guidance on Application of Certificate of Drug / Product Registration – Advanced Therapy Products" and (iii) "Guidance Notes on Change of Registered Particulars of Registered Pharmaceutical Products/Substances" will also be updated accordingly and will be uploaded to the website of Drug Office, Department of Health (www.drugoffice.gov.hk) on 23 February 2023 for reference.

If you have any queries on the above, please contact Drug Office at 3974 4175.

Yours faithfully,

(Julianna LI)
Secretary, Pharmacy and Poisons
(Registration of Pharmaceutical Products & Substances: Certification of Clinical Trial/ Medicinal Test) Committee

c.c. DH DO PRIE/7-15/3