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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25 October 2022

To: Certificate holders of registered pharmaceutical products

Dear Sirs/Madams,

Update of List of Reference Countries for Registration of Pharmaceutical Products

The Pharmacy and Poisons Board ("the Board") reviewed the stringent requirements of the list of reference countries for the registration of pharmaceutical products containing new chemical or biological entity (NCE). After thorough deliberation, the Board endorsed to include Brazil, China, Republic of Korea and Singapore in the list of reference countries for the registration of NCE. In addition, the Pharmacy and Poisons (Registration of Pharmaceutical Products & Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) established under the Board was tasked to revise the "Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity" according to the decision made by the Board, which will come into effect on 1 November 2022. The relevant content pertaining to official evidence of registration approval of the product would be revised as follows:

3.1.1 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:

(i) two or more of the following countries: Australia, Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany,

Greece, Holland, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, UK and USA; or

(ii) *Brazil, China, Republic of Korea or Singapore together with official evidence of registration approval in at least one of the above 32 countries stated in (i)*

Moreover, the relevant Guidance Notes including (i) "Guidance Notes on Registration of Pharmaceutical Products/Substances", (ii) "Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity", (iii) "Guidance on Application of Certificate of Drug / Product Registration – Advanced Therapy Products" and (iv) "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 1 November 2022 for reference.

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

Yours faithfully,

(T. K. YIM)
Secretary, Pharmacy and Poisons
(Registration of Pharmaceutical Products & Substances: Certification of Clinical Trial/ Medicinal Test) Committee

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