Business Facilitation Advisory Committee
Wholesale and Retail Task Force

Amendment to Pharmacy and Poisons Regulations to remove the requirement to submit the actual sales packs of pharmaceutical products for registration

Purpose

This paper briefs the Wholesale and Retail Task Force (WRTF) of the amendment to Pharmacy and Poisons Regulations (Cap. 138A, "PPR") to remove the regulatory requirement on submission of the actual sales packs of pharmaceutical products for registration.

Background

Current Requirement of Actual Sales Pack for Registration of Pharmaceutical Products

2. The Pharmacy and Poisons Ordinance (Cap. 138, "PPO") and its Regulations provides for the regulation of pharmaceutical products in Hong Kong. Regulation 36 of the PPR provides for the requirements of registration of pharmaceutical products and substance and among others, the current Regulation 36 (4) stipulates that

> "*Representative specimen sales packs of the product or representative samples of the substance shall be made available for inspection by the Committee*[1]*. In the case of products not yet marketed the Committee may accept prototypes of the packs and proposed wordings of the labels on the understanding that these will be replaced by the actual sale packs not later than 6 months after registration of the product or substance*."

3. In order to provide guidance to applicants for registration of pharmaceutical products, the Drug Office of the Department of Health published "Guidance Notes on Registration of Pharmaceutical

[1] "The Committee" here refers to the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee as established under section 4A of the PPO to perform the function relating to the registration of pharmaceutical products and substances.

Products/Substances" (July 2020) ("Guidance Notes") which is available from the Drug Office's website. As specified in paragraph 10(C)(k)(I) and (ii) of the Guidance Notes, the applicant of registration is required to provide:

> *In the case of applications of registration of pharmaceutical substances:*
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> *Sample of the pharmaceutical substance as it will be sold to the purchaser. For imported substance, you are reminded to apply for an import licence before importing the samples. …*
>
> *OR*
>
> *In the case of applications for registration of pharmaceutical products:*
>
> *Scanned image in PDF format (scanning based on 300dpi or higher) or photograph image in JPEG format (pixel size not less than 320 x 200) of your prototype sale pack or sample sale pack, including the inner container/packaging and the unit dose form image of the product sample, clearly showing the complete content of the prototype sales pack and its component(s), for example:*
>
> - *colour and engraving/printing of a tablet/capsule;*
> - *colour of liquid or semi-solid dosage forms (e.g. syrup, suspension, linctus, cream, ointment);*
> - *colour and shape of suppositories/pessaries, etc.;*
> - *shape and appearance of the container.*

Amendment of the current requirements to submit actual sales packs

4. The current requirement of submitting actual sales pack has become outdated with technological advancement (e.g. the widespread use of digital photos), and imposes an unnecessary hurdle to the applicant for registration taking into account the scarcity of materials for certain biological products (including Advanced Therapy Products[2] ("ATPs")) and related ethical issues with providing such materials for regulatory purposes.

[2] Advanced Therapy Products are innovative medical products based on genes, cells and tissues.

5. Accordingly, when the government decided to amend the Pharmacy and Poisons Ordinance to introduce a clear and dedicated regulatory framework on the research and therapeutic use of ATPs in order to safeguard public health and facilitate their development, simultaneously to take the opportunity to simplify the requirement by amending the PPR, and replace the provision of actual sales packs by prototypes of the sales packs of the product.

The Pharmacy and Poisons (Amendment) Ordinance 2020

6. As such, the Pharmacy and Poisons (Amendment) Bill 2019 ("the Bill") which was aimed to update the existing PPO and its Regulations (PPR) to regulate ATPs and among others, include provisions to waive the requirement to submit actual sales pack for registration. The Bill was passed by the Legislative Council on 17 July 2020 and published in the Gazette as the Pharmacy and Poisons (Amendment) Ordinance 2020 ("the Amendment Ordinance") on 24 July 2020. The Amendment Ordinance will come into operation on a date to be appointed by the Secretary for Food and Health by notice published in the Gazette. The Amendment Ordinance revised regulation 36(4) as follows:

> *"Prototypes of the sales packs, and proposed wordings of the labels, of the product or substance must be made available for inspection by the Committee."*

7. Accordingly, upon the enactment of the Amendment Ordinance, applicants for registration for pharmaceutical products will only be required to provide the prototypes of the sales packs, and proposed wordings of the labels, of the product or substance for inspection by the Committee.

Publicity

8. In order to allow various stakeholders to better understand the new regulatory framework for ATPs, a dedicated webpage on the Drug Office of Department of Health website have been set up for publishing draft guidance documents and relevant information in relation to different regulatory aspects for ATPs (https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/atp_regulation.html). Corresponding draft guidance on drug registration of ATPs already indicated that applicant is only required to submit the digital photo of prototype sales pack or sample sales pack. Moreover, prior to the Amendment Ordinance coming into effect, the current Guidance Notes covering all pharmaceutical products will also be

updated to reflect the changes accordingly so as to allow sufficient time for the pharmaceutical trade to understand the new arrangement.

Views Sought

9. Members are invited to note the contents of the paper and offer comments, if any.

Department of Health
November 2020