For information

Legislative Council Panel on Health Services

Regulation and Testing of Pharmaceutical Products

INTRODUCTION

This paper gives a brief account of the Government's work in respect of the regulation and testing of pharmaceutical products.

BACKGROUND

Registration of pharmaceutical products

2. Products which fall within the definition of "pharmaceutical product" under section 2 of the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance") must meet the standards of safety, efficacy and quality[1] and be registered with the Pharmacy and Poisons Board ("the Board") in accordance with regulations 36 and 37 of the Pharmacy and Poisons Regulations (Cap. 138A) ("the Regulations") before they can be sold or distributed in Hong Kong. For pharmaceutical products containing new chemicals or biological entities ("NCEs") (i.e. contain active ingredients which have not been registered in Hong Kong), the Board will propose legislative amendments to the Regulations for inclusion of the NCEs concerned in relevant Schedules to the Regulations for the purpose of regulation.

3. At present, Hong Kong adopts a "secondary review" [2] approach in

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[1] For registration of pharmaceutical products, applicants are required to provide the Board with sufficient information to prove that the pharmaceutical products meet the standards of safety, efficacy and quality. Such information includes the master formula, specifications, certificate and method of analysis, manufacturer's licence, the Pharmaceutical Inspectorate Co-operation Scheme ("PIC/S") Good Manufacturing Practice ("GMP") certificate (i.e. PIC/S GMP certificate), certificate of free sale issued by the drug regulatory authority of the country of origin, sale pack label, relevant scientific data or references, and stability test data.

[2] "Secondary review" refers to the consideration of applications for registration of pharmaceutical products based on the results of reviews conducted by recognised drug regulatory authorities.

considering applications for registration of pharmaceutical products containing NCEs. Applicants are required to submit to the Board documentary proof of registration of the pharmaceutical products and certificates of free sale issued by at least two drug regulatory authorities of recognised countries[3], as well as other documents as set out in the Guidance Notes on Registration of Pharmaceutical Products/Substances ("Guidance Notes") issued by the Department of Health ("DH")[4].

4. In the past few years, the Government has introduced various measures to expedite the drug registration process. From February 2015 onwards, legislative amendments relating to NCEs could be made via the negative vetting procedure instead of the previous positive vetting procedure so as to streamline the drug registration process. Following the implementation of the negative vetting procedure, a total of 126 pharmaceutical products containing NCEs have been classified as prescription drugs under the Regulations.

5. To further expedite the processing of applications for registration of pharmaceutical products containing NCEs so that the products are available in the market as early as possible and can benefit more patients in need, the Board agreed to implement the "Enhanced Procedures for Registration of New Drugs" ("Enhanced Procedures") in June 2018. Upon receipt of an application for registration of a new pharmaceutical product by a pharmaceutical company, or when a new pharmaceutical product is covered under the Hospital Authority ("HA")'s "Expanded Access Programme" or other relevant government-subsidised drug programme, the Board will initiate the legislative procedures of amending the Regulations with a view to shortening the time required for registration of the pharmaceutical product. As at November 2018, the DH has handled the registration of 14 pharmaceutical products containing NCEs under the Enhanced Procedures. The time required for processing applications for registration of pharmaceutical products are generally shortened by two to three months after the implementation of the Enhanced Procedures. The drug registration procedures before and after the implementation of the Enhanced Procedures are set out at Annex 1 and Annex 2.

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[3] There are 32 recognised countries listed in the Guidance Notes on Registration of Pharmaceutical Products/Substances issued by the DH, including Australia, Canada, European Union member states, Japan, Switzerland and the U.S.

[4] Other documents include expert evaluation reports on the safety, efficacy and quality of the pharmaceutical products, clinical documentation, risk management plan and proposed package insert of the pharmaceutical products.

6. At present, there are approximately 17 400 registered pharmaceutical products in Hong Kong. Between January 2015 and November 2018, the DH approved a total of 2 595 applications for registration of new pharmaceutical products.

Surveillance mechanism for pharmaceutical products

7. Implementation of a quality assurance system by drug manufacturers is, according to the international strategy on the regulation of drug, the most important and effective means to ensure the quality of pharmaceutical products. Manufacturers must strictly comply with the Good Manufacturing Practice ("GMP") for drugs. The quality of pharmaceutical products is safeguarded through the implementation of the quality assurance system, which covers personnel training, regulations on production workshops and production equipment, requirements on production and packaging materials, requirements on verification of production procedures, certification of inspection, requirements on documentation and record, verification of contractors, and follow-up arrangements after production.

8. Since January 2016, the Board has been a member of the Pharmaceutical Inspection Co-operation Scheme ("PIC/S"), and adopted a regulatory regime similar to those of the regulatory authorities of other PIC/S member authorities (including the U.S. Food and Drug Administration, the U.K.'s Medicines and Healthcare Products Regulatory Agency and Australia's Therapeutic Goods Administration). The Board and other PIC/S member authorities require all manufacturers selling or distributing pharmaceutical products (including locally produced and imported products) in their jurisdictions to comply with the PIC/S GMP.

9. Moreover, the DH maintains close liaison with drug regulatory authorities of other countries and regions through the PIC/S notification mechanism. If a PIC/S member authority suspects that a pharmaceutical product may have problems in respect of safety, efficacy and quality, or that a drug manufacturer fails to meet the GMP requirements, it will notify other affected PIC/S member authorities of the issue within a short period of time for them to take follow-up action. The DH will keep in view the latest international position and development regarding the regulation of pharmaceutical products.

10. The DH normally does not conduct sampling checks on pharmaceutical products at the time of import to avoid delaying their

import to and supply in the local market. This practice is in line with the international strategy on the regulation of drugs. On the other hand, the DH has put in place a regular market surveillance mechanism, under which the DH collects samples of pharmaceutical products from suppliers and the market for analysis according to risk assessment for the purpose of monitoring the safety, efficacy and quality of pharmaceutical products. In general, the analysis covers the content of the active ingredients of a product and other requirements of the pharmacopoeia (e.g. testing for microbiological quality and dissolution test for tablets) on different dose forms. Sterility tests are also included in the analysis of sterile preparations.

11. Where non-compliance with the standards of safety, efficacy and quality or other relevant requirements is suspected, the DH will conduct an investigation immediately. Where necessary, the DH will require the supplier concerned to recall the product and make a public announcement of the issue on its website or through a press release. From January 2014 to November 2018, over 98.5 percent of the samples of pharmaceutical products collected and tested by the DH under the regular market surveillance mechanism passed the tests. The DH handled about 80 recall cases of pharmaceutical products in the same period.

Enforcement and disciplinary actions of the Department of Health

12. The DH has an established mechanism in place to conduct blitz inspections at licensed Authorised Sellers of Poisons ("ASPs")[5] (commonly known as "pharmacies" or "dispensaries") and Listed Sellers of Poisons ("LSPs")[6] (commonly known as "medicine companies") to check whether sellers of pharmaceutical products comply with the statutory requirements and licensing conditions. The DH also conducts test purchases at ASPs and LSPs from time to time to combat illegal sale of prescription drugs[7] or unregistered pharmaceutical products.

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[5] ASPs refer to retailers authorised by the Board under section 11 of the Ordinance to carry on a business of retail sale of poisons (including Part 1 poisons and Part 2 poisons). In general, Part 1 poisons are drugs that are used for treatment of more serious diseases or that have more serious side effects. Under section 21 of the Ordinance, Part 1 poisons shall be sold at registered pharmacies or dispensaries by a registered pharmacist or in his presence and under his supervision. Part 2 poisons are drugs used for treatment of less serious diseases with less side effects.

[6] LSPs refer to retailers authorised by the Board under section 25 of the Ordinance to carry on a business of retail sale of Part 2 poisons.

[7] Some of the Part 1 poisons may be classified as prescription drugs by the Board on the basis of their potency, toxicity and potential side effects, and included in the Third Schedule to the Regulations for the purpose of imposing more stringent

13. Where a violation of the law or the practising guidelines is found, the DH will take immediate action including joint enforcement action with the Police. From January 2015 to October 2018, the DH conducted 4 607 and 29 906 inspections at ASPs and LSPs respectively, and handled 52 and 6 convicted cases of illegal sale of prescription drugs by ASPs and illegal sale of Part 1 poisons by LSPs respectively. The details are as follows:

Year	Number of inspections at ASPs	Number of convicted cases of illegal sale of prescription drugs by ASPs	Number of inspections at LSPs	Number of convicted cases of illegal sale of Part 1 poisons by LSPs
2015	1 214	14	7 977	2
2016	1 209	16	7 956	1
2017	1 220	13	7 874	1
2018 (Jan to Oct)	964	9	6 099	2
Total	**4 607**	**52**	**29 906**	**6**

14. The DH will refer non-compliance cases involving ASPs to the Board, which will then appoint a Disciplinary Committee in accordance with section 16 of the Ordinance to hold an inquiry. The Disciplinary Committee may make the following decisions:

(a) disqualify the ASP;
(b) remove the premises of the ASP from the register of premises; and
(c) issue a written warning to the ASP.

15. Disciplinary matters concerning LSPs will be submitted directly to the Board for consideration. The Board and the Disciplinary Committee will make independent decisions on disciplinary matters concerning licensed drug retailers on a case-by-case basis. From January 2015 to November 2018, the Board handled 44 and 39 cases involving disciplinary actions against ASPs and LSPs respectively.

16. In addition, it is a violation of the relevant requirements under the Public Health and Municipal Services Ordinance (Cap. 132) for licensed

restrictions on their sale at ASPs.

wholesale dealers to sell pharmaceutical products that do not meet the quality or safety requirements. The DH will conduct investigation and may institute prosecution against offenders after obtaining legal advice from the Department of Justice. From January 2015 to November 2018, the DH handled 12 convicted cases of violation of the Public Health and Municipal Services Ordinance by wholesale dealers.

17. The DH will refer convicted cases to the Pharmacy and Poisons (Wholesale Licences) Committee for consideration of disciplinary action. The Committee is established by the Board under regulation 26 of the Regulations, and may make the following decisions:

(a) revoke a wholesale dealer licence;
(b) suspend a wholesale dealer licence for a specified period;
(c) issue a warning letter to the licensed wholesale dealer; and
(d) vary a condition of the wholesale dealer licence.

ADVICE SOUGHT

18. Members are invited to note the content of this paper.

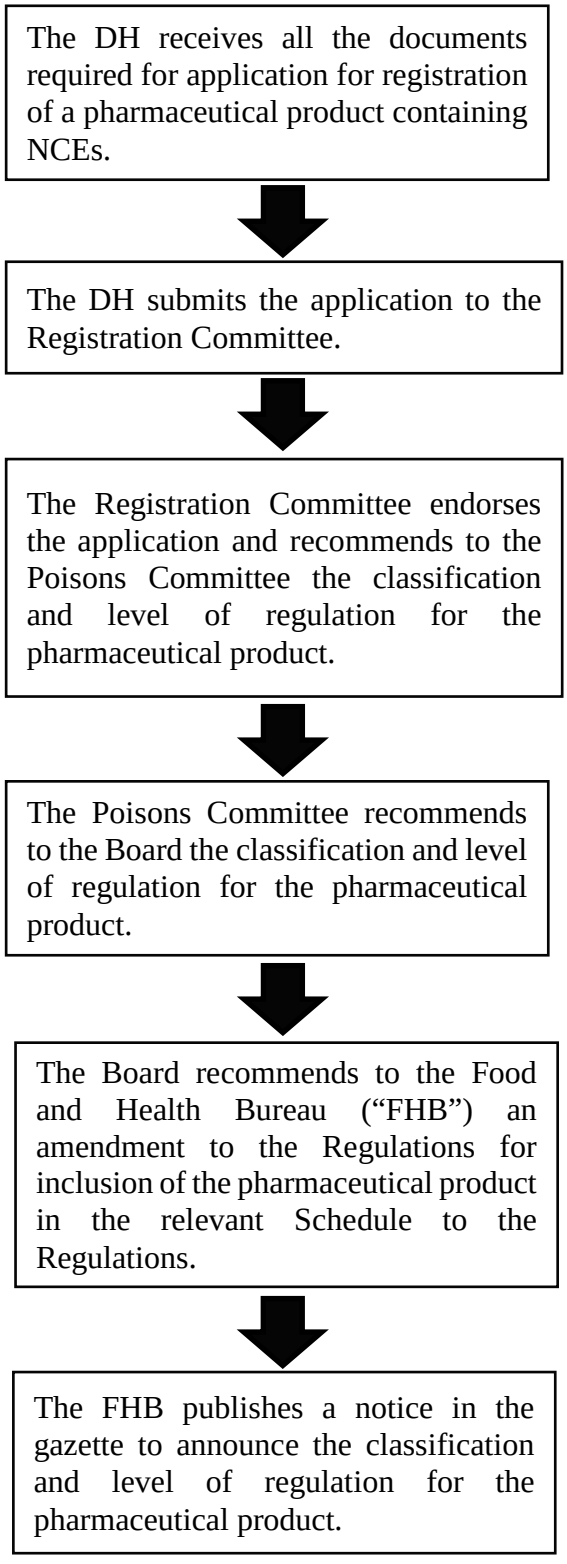
ENQUIRY

19. For any enquiries, please contact Mr Dan Chan, Assistant Secretary for Food and Health (Health), at 3509 8956.

Food and Health Bureau
Department of Health
December 2018

Annex I

Procedures for Registration of Drugs before Implementation of the Enhanced Procedures for Registration of New Drugs



Annex II

Procedures for Registration of Drugs after the Implementation of the Enhanced Procedures for Registration of New Drugs