Guidance for Industry – Manufacture of Unregistered Pharmaceutical Product for Treatment of Particular Patients

Version 1.0

Drug Office

Department of Health

Contents

1. Background

Licensed Manufacturers

1.1 According to regulation 29(1) of the Pharmacy and Poisons Regulations (Cap. 138A, Laws of Hong Kong), no person shall manufacture any pharmaceutical product on any premises unless he is the holder of a licence to manufacture pharmaceutical products ("manufacturer licence") on those premises. Manufacture of pharmaceutical products includes secondary packaging, which means the labelling, re-labelling, cartoning, re-cartoning or adding additional information (including inserts) to pharmaceutical products which are already enclosed in the container in which they are to be sold or supplied.

1.2 The issuing authority for a licence to manufacture pharmaceutical products is the Pharmacy and Poisons (Manufacturers Licensing) Committee (the "Committee"), an executive committee of the Pharmacy and Poisons Board (the "Board"), subject to any conditions it thinks fit to impose to the licence according to regulation 29(3) of the Pharmacy and Poisons Regulations.

1.3 By exercising the power vested in it under regulation 29(4) of the Pharmacy and Poisons Regulations, the Committee may revoke a licence to manufacture pharmaceutical products or suspend it for a period it thinks fit, issue a warning letter, or vary a condition of the licence, if, in the Committee's opinion, the Licensed Manufacturer has contravened a condition of the licence or any of the regulations provided by the Pharmacy and Poisons Regulations, a code of practice applicable to the Licensed Manufacturer or the GMP Guide issued by the Board, or has been convicted of a drug-related offence.

Registration of Pharmaceutical Products

1.4 As stipulated under regulation 36(1) of the Pharmacy and Poisons Regulations, pharmaceutical products must be registered with the Board before they can be sold, offered for sale, distributed or possessed for the purposes of sales, distribution or other use in Hong Kong.

1.5 The above registration requirement is not applicable in the case of possession or use where the pharmaceutical product or substance is possessed or is to be used for the purpose of treatment by a registered medical practitioner or a registered dentist of a particular patient in accordance with regulation 36(1A) of the Pharmacy and Poisons Regulations.

1.6 Other Ordinances and Regulations in the Laws of Hong Kong, which include but are not limited to the Personal Data (Privacy) Ordinance, Cap. 486 when handling personal data, are applicable and should be observed by a Licensed Manufacturer.

2. Purpose of this Guidance

2.1 This document outlines the requirements relating to the manufacture of an unregistered pharmaceutical product by a Licensed Manufacturer upon the request by a registered medical practitioner or a registered dentist for the purpose of treatment of a particular patient in accordance with regulation 36(1A) of the Pharmacy and Poisons Regulations.

3. Scope

3.1 This document applies to the manufacture of an unregistered pharmaceutical product for the purpose of treatment by a registered medical practitioner or a registered dentist of a particular patient.

4. Guiding Principles

4.1 Unless an equivalent[1] pharmaceutical product is not registered in Hong Kong or overseas, or when a registered product in Hong Kong or overseas is not available in stock or cannot be used to meet the special need(s) of a patient, a Licensed Manufacturer in Hong Kong should not manufacture an unregistered pharmaceutical product upon the request of a registered medical practitioner or a registered dentist for the treatment of the patient.

4.2 Other than an advanced therapy product, a Licensed Manufacturer should only manufacture the unregistered pharmaceutical product for a particular patient in—

4.1.1. a hospital, maternity home or clinic maintained by the Government; or

4.1.2. a hospital, maternity home or clinic managed or controlled by the Hospital Authority established under the Hospital Authority Ordinance, Cap. 113, Laws of Hong Kong; or

4.1.3. a day procedure centre, clinic or health services establishment primarily used for teaching or research relating to medicine or dentistry and that is managed or controlled by a scheduled university specified in Schedule 1 of the Private Healthcare Facilities Ordinance, Cap. 633, Laws of Hong Kong.

4.3 Before the manufacture of an unregistered pharmaceutical product for treatment of a particular patient upon request by a registered medical practitioner or a registered dentist, a Licensed Manufacturer must obtain prior permission from the Committee.

4.4 The quantity allowed for access or supply to an individual patient should be monitored. The responsibilities and obligations of the prescribing medical practitioner or dentist as well as the Licensed Manufacturer should also be ensured.

[1] An equivalent product- A pharmaceutical product would be regarded an equivalent product if all of the following criteria were met:

- It contains the same amount of the same active substance or, in the case of liquid dosage forms, the same concentration.
- It is in the same dosage form.
- It meets the same or comparable standards considered in the light of the clinical needs of the patient at the time of use of the product.

5. Responsibilities and Obligations of a Licensed Manufacturer

5.1 All responsibilities and obligations relevant to the manufacture and supply of pharmaceutical products as stipulated in the Pharmacy and Poisons Regulations, the GMP Guide issued by the Board and the applicable Code of Practice for Licensed Manufacturers and Registered Authorized Persons should be fully complied with by the Licensed Manufacturer when manufacturing an unregistered pharmaceutical product for treatment of a particular patient.

5.2 In addition, the Licensed Manufacturer must ensure that the following obligations and requirements are met:

5.2.1. Obtain a letter from the registered medical practitioner or registered dentist stating the special need(s) of the individual patient(s) before the manufacture and make it available to the Department of Health, and to verify the registration status of the medical practitioner or dentist if in doubt. The letter should be kept for at least two years from the date of issue.

5.2.2. Maintain a system to check against the availability of any registered products in Hong Kong or in overseas before submitting a request for permission of the manufacture of an unregistered product locally.

5.2.3. Formulate and manufacture an unregistered pharmaceutical product in accordance with the product formulation and specifications acknowledged by the requesting medical practitioner or dentist.

5.2.4. Submit and return to the Drug Office of the Department of Health—

5.2.4.1. a copy of certificate of analysis and the exact quantity manufactured after the release of each batch of unregistered pharmaceutical product it has manufactured; and

5.2.4.2. at 6-monthly intervals after the release of the product and until the stock is exhausted, provide updates in writing on any change from the initial request for permission and return a copy of the transaction record in specified form[2] for the unregistered pharmaceutical product to the Drug Office of the Department of Health. The transaction record should be supported with documentary evidence of the reconciliation of the quantity with information including, but not limited to—

5.2.4.2.1. breakdown of the quantity required for each patient (if applicable); and

5.2.4.2.2. any disposal, for example, a trip ticket issued by a licensed waste collector.

[2] Format of the specified forms for keeping transaction records of pharmaceutical products can be found in Appendix C (for Part 1 poisons or pharmaceutical products) or Appendix D (for advanced therapy products) in the Code of Practice for Licensed Manufacturers and Registered Authorized Persons

5.2.5. The manufacturer should not supply an unregistered pharmaceutical product which was previously permitted for treatment of a particular patient to any other medical practitioner or dentist unless otherwise justified.

Additional obligations and requirements for Licensed Manufacturers of Advanced Therapy Products

5.2.6. Ensure the treating medical practitioner or dentist would arrange follow-up of the patient if there is a potential for prolonged biological activity after administration.

5.2.7. Have a system to enable the bidirectional tracking of cells or tissues contained in the advanced therapy products;

5.2.8. In case of an out-of-specification product, inform in writing the treating medical practitioner or dentist of the event and the risks associated; and if the product is to be supplied for use—

5.2.8.1. ensure that the treating medical practitioner or dentist has informed the patient about the risk of using the product and obtained the consent from the patient;

5.2.8.2. obtain the written confirmation from the treating medical practitioner or dentist that he or she accepts the product for use before the supply; and

5.2.8.3. report the supply of the out-of-specification product to the Drug Office within 48 hours through the Authorized Person of the Licensed Manufacturer.

Document Information

Version	Date	Description of Change
1.0	August 2021	First version

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