DEPARTMENT OF HEALTH
DRUG OFFICE
LICENSING AND COMPLIANCE DIVISION
MANUFACTURERS REGULATORY UNIT
Room 2550, 25/F, Wu Chung House,
213 Queen's Road East, Wanchai, Hong Kong
Tel.: 2961 8162 Fax: 3904 1225

衞生署藥物辦公室
牌照及監察科
製藥商監管分組
香港灣仔皇后大道東213號
胡忠大廈25樓2550室
電話：2961 8162 傳真：3904 1225

REQUEST FOR PERMISSION OF MANUFACTURE OF UNREGISTERED PHARMACEUTICAL PRODUCT BY LICENSED MANUFACTURER FOR TREATMENT OF PARTICULAR PATIENTS
持牌製造商為治療特定病人製造未經註冊藥劑製品准許的要求

Name of Unregistered Pharmaceutical Product: 未經註冊藥劑製品名稱	
Dose Form: 劑型	Package Size(s): 包裝大小
Detailed Qualitative & Quantitative Composition*: 詳細的成分組合*	
Indications: 用途	
Total quantity of product required: 所需製品的總數量	
Name of Licensed Manufacturer: 持牌製造商名稱	
Address of Licensed Manufacturer: 持牌製造商地址 Telephone Number: 電話號碼	E-mail Address: 電郵地址

Name of Contact Person: 聯絡人姓名	Position of Contact Person: 聯絡人職位
Telephone Number: 聯絡人的電話號碼	E-mail Address: 電郵地址

Name of Responsible Registered Medical Practitioner/Registered Dentist*: 負責的註冊醫生／牙醫姓名*
Telephone Number: 電話號碼 E-mail Address: 電郵地址

* please provide information on a separate sheet where necessary
如有需要，請在單獨的附加頁上提供資料

Please submit the completed form together with the checklist at Appendix 1 and the relevant documents to:
請將填妥的表格連同附錄一的核對清單和相關文件遞交至：

Manufacturers Regulatory Unit,
Drug Office, Department of Health,
Room 2550, 25/F, Wu Chung House,
213 Queen's Road East, Wanchai, Hong Kong
Tel.: 2961 8162 Fax: 3904 1225
Email: gmp@dh.gov.hk

衞生署藥物辦公室
牌照及監察科製藥商監管分組
香港灣仔皇后大道東 213 號
胡忠大廈 25 樓 2550 室
電話 : 2961 8162 傳真 : 3904 1225
電郵 : gmp@dh.gov.hk

DECLARATION OF APPLICANT

We hereby declare that the information given in this request form is true and correct.
我們現聲明此表格內所填報的資料，均全屬確實無誤。

Signature:
申請人簽署 _____

Full name of Signatory:
簽署人全名 _____

Signed on behalf of:
代表持牌製造商 _____

Date:
日期 _____

Company Stamp

Appendix 1

CHECKLIST

Request for Permission of Manufacture of Unregistered Pharmaceutical Product by a Licensed Manufacturer for Treatment of Particular Patients

This checklist indicates the fundamental documents to be submitted for the request. Please put a "√" in the relevant box for documents included for this request. Please provide a written explanation if any of the documents is not available. Additional documents may be requested during the course of processing.

☐ 1. Completed request form

☐ 2. Copy of a letter issued by the registered medical practitioner or dentist for a patient under his or her care which should specify:

- ☐ (a). Special need(s) of the patient and the justification for requesting the manufacture of unregistered products locally
- ☐ (b). Name and intended indication(s) of the product
- ☐ (c). Patient's information (with his or her full name and identification number)
- ☐ (d). Quantity of the product required for the patient and duration of the treatment
- ☐ (e). (For an advanced therapy product containing cells or tissues) The hospital or day procedure centre[1] where the product will be administered to the patient

☐ 3. Detailed and complete qualitative and quantitative composition of the finished product issued by the manufacturer and acknowledged by the medical practitioner or dentist

☐ 4. Finished product specifications[2] acknowledged by the medical practitioner or dentist

☐ 5. An undertaking made by the manufacturer with respect to its obligations and responsibilities (Appendix 2)

☐ 6. An undertaking made by the medical practitioner or dentist with respect to his or her obligations and responsibilities (Appendix 3)

☐ 7. Copy of a certificate of analysis of a representative batch of the product for all tests stated in the finished product specifications if available

☐ 8. Stability data for justifying shelf life of the product

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[1] The definition of day procedure centre is set out in section 2 of the Private Healthcare Facilities Ordinance (Cap. 633).

[2] The requirements for specifications are listed in Chapter 4 of the GMP Guide issued by the Pharmacy & Poisons Board.

☐ 9. One set of prototype sales pack (e.g. outer carton, container label, and other component(s) comprising the sales pack) for each pack size of the product, that should comply with the labelling requirements as stipulated in the Pharmacy and Poisons Ordinance and Regulations

☐ 10. Evidence of registration approval of an equivalent product[3] in Hong Kong or any other country/region (justification for not using a registered product in Hong Kong or importing a registered product from its place of origin must be provided)

Additional documents for an advanced therapy products

☐ 11. Flow chart of the manufacturing process of the product

☐ 12. If the product is not registered in any country or region, clinical and scientific documentation substantiating the safety and efficacy of the product, e.g. evidence showing positive view in safety and efficacy during Phase 2 and Phase 3 or literature supporting the use of the product in the proposed indication(s)

[3] An equivalent product- A pharmaceutical product would be regarded as 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.

Undertaking by a Licensed Manufacturer for the Manufacture of Unregistered Pharmaceutical Product for Treatment of Particular Patients

As a manufacturer of an unregistered pharmaceutical product, namely _____ _____ for the purpose of treatment to be provided to a particular patient named _____ ("named patient"), by the registered medical practitioner/ dentist*, named _____, we are fully aware of the obligations and requirements below.

**Please delete as appropriate.*

Please provide information on a separate sheet where necessary.

Please put a "✓" in the relevant box below.

Availability of Registered Product

☐ Maintain a system to check against the availability of any registered products in Hong Kong or overseas which can meet the special needs of the patient before submitting a request for permission of the manufacture of an unregistered product.

Patient Consent

☐ Ensure that the treating medical practitioner or dentist must inform the patient of—

- the product having not been registered; and
- any other information applicable to the product;

☐ ***For advanced therapy product, in addition—***

- irreversible nature of the product and the need for long-term follow-up and commitment, where applicable;
- if the product includes a bacterial or viral vector, the risk and precautionary measures for potential shedding; and
- the risk of the use of the product.

Return of Documents & Submission of Updates

☐ Submit and return the required documentary evidence and updates including the certificate of analysis, quantity manufactured, transaction records and reconciliation of quantity according to the "**Guidance for Industry – Manufacture of Unregistered Pharmaceutical Product for Treatment of Particular Patients**".

Safety Monitoring

☐ Report adverse drug reactions occurring in the named patient taking the above product to Drug office of the Department of Health in accordance with "**Guidance for Pharmaceutical Industry—Adverse Drug Reaction Reporting Requirements**".

For advanced therapy product only

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

For Advanced Therapy Product Only

Traceability

☐ Ensure that a system is in place enabling bidirectional tracking of cells or tissues contained in the product from donation, through manufacturing to the delivery of the finished product to the use of a medical practitioner or dentist.

Dealing with Out-of-specification Product

☐ In case of an out-of-specification product, inform the treating medical practitioner or dentist in writing of the event and risks associated.

☐ If the out-of-specification product is to be supplied for use—

- 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;
- Obtain a written confirmation from the treating medical practitioner or dentist that he or she accepts the product for use before the supply; and
- Report the supply of the out-of-specification product to the Drug Office within 48 hours through the Authorized Person.

Breaching the above obligations and requirements may result in the case being referred to the Pharmacy and Poisons (Manufacturers Licensing) Committee for consideration of any actions deemed necessary.

Signature	Signatory's name in block letters	
Date (DD/MM/YY)	Office Capacity of Signatory	Company stamp

Undertaking by a Treating Medical Practitioner/Dentist

Referring to the request for permission of the manufacture of an unregistered pharmaceutical product, namely _____, for the purpose of treatment to be provided to a particular patient under my care named _____ _____ ("named patient"), I am fully aware of the obligations and requirements below.

Please provide information on a separate sheet where necessary.

Please put a "✓" in the relevant box below.

Patient Consent

☐ Inform the patient of—

- the product having not been registered and the safety, efficacy and quality having not yet been evaluated by the Pharmacy and Poisons Board; and
- any other information applicable to the product ;

☐ ***For advanced therapy product, in addition—***

- irreversible nature of the product, where applicable;
- the need for long-term follow-up and commitment, where applicable;
- if the product includes a bacterial or viral vector, the risk and precautionary measures for potential shedding;
- the risk of the use of the product, including risk of treatment failure and potential impact of the treatment on future therapies.

Appropriate Use of Product and Patient Care

☐ Take responsibility for prescribing the unregistered product, for overseeing the patient's care and any follow-up treatment in accordance with the applicable code of professional conduct or discipline.

Safety Monitoring

☐ Report serious adverse drug reactions occurring in the named patient taking the above product (excluding advanced therapy product) to the manufacturer or the Drug Office of the Department of Health (www.drugoffice.gov.hk/adr.html).

For advanced therapy product only

☐ Report serious or unexpected adverse drug reactions occurring in the named patient taking the above product to the manufacturer or to Drug Office of the Department of Health (www.drugoffice.gov.hk/adr.html).

☐ Arrange follow-up of the named patient if there is a potential for prolonged biological activity after administration.

For Advanced Therapy Product Only

Traceability

☐ Keep the record of treatment involving the use of the product in accordance with the "**Guidance on Record Keeping for Medical Practitioners, Dentists and Institutions providing Advanced Therapy Product Treatment**".

Dealing with Out-of-specification Product

☐ In case I have been informed that an out-of-specification product has been manufactured, before the acceptance of the product for use, I should—

- Consider the associated risks assessed and provided by the manufacturer;
- Inform the patient about the risk of using the product and the obtain consent from the patient of either using or not use the product; and
- Confirm whether the product is accepted for use and provide the confirmation to the manufacturer before the supply.

I am fully aware of the above obligations and requirements, and understand that relevant codes of professional conduct issued by the Medical Council or the Dental Council where appropriate, as well as the codes of practice for the Licensed Private Healthcare Facilities issued by the Department of Health, where applicable, should be followed.

Signature	Signatory's name in block letters (Registration No.:_____)	Date (DD/MM/YY)

Statement of Purposes

Purpose of Collection

This personal data are provided by licence applicants for the purposes of application for licences under the Pharmacy and Poisons Ordinance, the Antibiotics Ordinance and the Dangerous Drugs Ordinance. The personal data provided will be used by DH for the following purposes:

(a) Proof of eligibility for a licence
(b) Assessment of whether the applicant is a fit and proper person to be granted a licence

2. The provision of personal data is voluntary. If you do not provide sufficient information, we may not be able to prove your eligibility for a licence, or to assess whether you are a fit and proper person to be granted a licence.

Classes of Transferees

3. The personal data you provide are mainly for use within DH and the Pharmacy and Poisons Board. Apart from this, the data may only be disclosed to parties where you have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance.

Access to Personal Data

4. You have a right of access and correction with respect to personal data as provided for in sections 18 and 22 and Principle 6 of Schedule 1 of the Personal Data (Privacy) Ordinance. Your right of access includes the right to obtain a copy of your personal data. A fee may be imposed for complying with a data access request.

Enquiries

5. Enquiries concerning the personal data provided, including the making of access and corrections, should be addressed to:

Senior Pharmacist
Licensing and Compliance Division
Drug Office
Department of Health
Room 2550, 25/F, Wu Chung House,
213 Queen's Road East,
Wan Chai, Hong Kong.
Tel: 2961 8028