Guidance on Application for Change of Key Personnel and Manufacturing Premises of Pharmaceutical Manufacturers

Introduction

According to the Code of Practice for Licensed Manufacturers and Registered Authorized Persons issued by the Pharmacy and Poisons Board ("the Board"), manufacturers of pharmaceutical products licensed under the Pharmacy and Poisons Regulations (Cap. 138A) must ensure that the following obligations and requirements are met:

(a) approval from the Pharmacy and Poisons (Manufacturers Licensing) Committee ("the Committee") has been obtained prior to any change in key personnel. The key personnel for pharmaceutical manufacturers include the registered Authorized Person, Head of Production and Head of Quality Control; and

(b) approval from the Committee has been obtained prior to any change in manufacturing premises that may affect the quality of the product.

2. 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.

3. This set of guidance notes does not apply to manufacturers solely engaged in secondary packaging operations of pharmaceutical products.

Application for change of key personnel and manufacturing premises

The Drug Office of the Department of Health is the executive arm of the Board and the Committee. Application form for change of key personnel and manufacturing premises is available, free of charge, by downloading from the website of the Drug Office www.drugoffice.gov.hk or visiting the following address in person:

Manufacturers Regulatory Unit
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 8162 Fax: 3904 1225
Email: gmp@dh.gov.hk

Monday to Friday
9:00 a.m. – 1:00 p.m.
2:00 p.m. – 5:45 p.m.
(up to 6:00 p.m. on Monday)
(closed on Saturdays, Sundays and Public Holidays)

2. The completed application form, the relevant completed checklist of supporting documents, together with supporting documents indicated in the checklist, should be submitted by post, by fax, by email or in person to the above address.

3. For application involving change of manufacturing premises, upon completion of commissioning and qualification of the concerned premises or part of the premises, a licensed manufacturer should obtain the Committee's approval ("final approval") prior to the actual implementation of the change. Alternatively, the manufacturer may wish to submit a proposal for change in the premises and seek for the Committee's approval, in principle, of the proposed layout before any construction or modification works take place and the submission of an application for final approval. An inspection by pharmacist inspectors may be conducted at the premises.

4. The application will be considered by the Committee. If approved, a notification letter would be sent to the applicant.

5. In general, no fees are charged. However, for the change that involves issuance of a Licence for Manufacturer with new licensed information, a signature fee (currently $155) will be charged.

6. Any applicant aggrieved by a decision made by the Committee in respect of the application may, in the prescribed manner, appeal to the Pharmacy and Poisons Appeal Tribunal against that decision.

7. Any enquiries on matters related to application should be sent to the Manufacturers Regulatory Unit at the above address.

Notes

1. These notes are only a general guide and must not be treated as a complete or authoritative statement of the law on any particular case.

2. Contents of the Pharmacy and Poisons Ordinance and its Regulations can be found at the Hong Kong e-Legislation website www.elegislation.gov.hk.

3. Documents to be submitted should be controlled in accordance with requirements laid down in Chapter 4, Documentation, of the GMP Guide issued by the Board. This may not be applicable to documents that are not GMP-regulated (e.g. Business or Branch Registration Certificate, tenancy agreement, etc.).

4. Additional sets of floor plans and diagrams may be requested for processing of the application.

5. Additional information specific to the application may be requested during the course of review. Applicant may also submit other relevant information that would support the application.

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LICENSING AND COMPLIANCE DIVISION
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Application for Change of Key Personnel and Manufacturing Premises of Holder of Licence for Manufacturer

FOR OFFICIAL USE ONLY

Date: _____

COP Reference No.: _____ Checked by: _____

PART A DETAILS OF APPLICANT

Name of manufacturer: _____

_____

Address of manufacturer: _____

_____

Name of contact person: _____

Position of contact person: _____

Telephone number: _____

Fax number: _____

Email address: _____

PART B NATURE OF CHANGE

Please tick the appropriate box:

☐ **1. Change of key personnel (Please fill in checklist in Appendix 1A, and information sheet in Appendix 1B for replacement or addition of new personnel)**

Please specify the change: _____

☐ **2. Change of production area, approval in principle (Please fill in checklist in Appendix 2)**

- ☐ Addition of scope of manufacture
- ☐ Addition of manufacturing line
- ☐ Removal of scope of manufacture
- ☐ Removal of manufacturing line
- ☐ Change of room function
- ☐ Re-allocation and/or re-partitioning of space

☐ **3. Change of quality control area, approval in principle (Please fill in checklist in Appendix 3)**

- ☐ Addition of quality control area
- ☐ Removal of quality control area
- ☐ Change of room function
- ☐ Re-allocation and/or re-partitioning of space

☐ **4. Change of storage area, approval in principle (Please fill in checklist in Appendix 4)**

- ☐ Addition of storage area
- ☐ Removal of storage area
- ☐ Change of room function
- ☐ Re-allocation and/or re-partitioning of space

☐ **5. Change of manufacturing premises, final approval (Please fill in checklist in Appendix 5)**

Approval in Principle COP Reference No.: _____

- ☐ Change of production area
- ☐ Change of quality control area
- ☐ Change of storage area

☐ **6. Others (please specify the change and include the list of supporting documents submitted)**

- ☐ Approval in Principle
- ☐ Final Approval

_____

_____

_____

_____

_____

_____

PART C DECLARATION OF APPLICANT

I hereby declare that to the best of my knowledge and belief that the information given in this application is correct and all the changes have been identified and are being applied for the approval.

Signature: _____

Full name of signatory: _____

Position of signatory: _____

Date: _____

Company Stamp

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Appendix 1A

CHECKLIST

Application for Change of Key Personnel

This checklist indicates the fundamental documents to be submitted for the application. Please put a "✓" in the relevant box for documents included in this application. Please provide a written explanation if any of the documents is not available.

☐ Completed application form

☐ Completed form of "Information Sheet of Key Personnel of Pharmaceutical Manufacturers" (Appendix 1B) for replacement or addition of personnel

☐ Supporting documents for qualifications (including relevant academic/professional qualifications)

☐ Testimonial(s) of relevant working experience issued by the employer(s) (with information such as years of service, position held and job descriptions)

☐ Job descriptions of the proposed key personnel in the applicant's company (if applicable)

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Appendix 1B

Information Sheet of Key Personnel of Pharmaceutical Manufacturers

Name of Manufacturer			
Position of Key Personnel*	☐ Authorized Person ☐ Head of Production ☐ Head of Quality Control	☐ Alternative Authorized Person ☐ Alternative Head of Production ☐ Alternative Head of Quality Control	
Name	**(English)**	**(Chinese)**	
HK Identity Card No.		**Gender***	☐ Male ☐ Female
Telephone No.		**Mobile No.**	
Is the key personnel a registered pharmacist*?		☐ Yes (Reg. No.: _____) ☐ No	
Is the key personnel a registered authorized person*?		☐ Yes (Reg. No.: _____) ☐ No	
Date of Appointment to the Present Position			

Academic and Professional Qualifications

Qualification awarded	Awarding institution	Year awarded

Working Experience

Name of employer	Position held	Period of employment

*Please tick if appropriate

For office use only			
Recognized previously	Yes / No	File ref:	
Previously recognized for	AP / HP / HQC	Date first recognized	

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Appendix 2

CHECKLIST

Application for Change of Production Area (Approval in Principle)

This checklist indicates the fundamental documents to be submitted for the application. Please put a "✓" in the relevant box for documents included in this application. Please provide a written explanation if any of the documents is not available.

☐ Completed application form

☐ Copy of Business Registration Certificate, Branch Registration Certificate, or tenancy agreement

☐ Records on change control and other associated systems under the quality management systems (e.g. quality risk management, corrective and preventive actions), with detailed description of the proposed change and implementation plan including actions to be implemented before, during and after the change, in particular, measures to prevent contamination and cross-contamination and to assure product quality during renovation

☐ Originally approved and proposed floor plans, highlighting the concerned premises / part of the premises (if applicable), showing:

- ☐ Location of concerned part of the premises on the whole floor with name, number (if applicable), dimensions and floor area of each room and allotted area
- ☐ Personnel flow
- ☐ Material and/or product flow

☐ User requirement specifications of the premises (except for removal of scope of manufacture or manufacturing line)

☐ Description of pharmaceutical manufacturing activities (e.g. dosage forms; types of processing and/or packaging; production capacity; any handling of highly sensitizing, toxic or hazardous substances; any handling of dangerous drugs defined in Dangerous Drugs Ordinance, Cap. 134, or antibiotics defined in Antibiotics Ordinance, Cap. 137)

☐ Process flow chart(s) of manufacturing process(es) (for addition of scope of manufacture or manufacturing line)

- ☐ Production equipment (if applicable)
  - ☐ A list of major equipment
  - ☐ User requirement specifications for new equipment
  - ☐ Design qualification documentation for new equipment (if available)
  - ☐ Originally approved and proposed equipment layout, showing location, to-scale equipment dimensions in aerial view (if applicable)
- ☐ Heating, ventilation and air-conditioning (HVAC) system
  - ☐ User requirement specifications
  - ☐ Complete schematic diagram showing instrumentation and ducts highlighting relevant parts originally approved and proposed change (if applicable)
  - ☐ Floor plans showing
    - ☐ Location of ventilation points and ducts
    - ☐ Zoning of air-handling units
    - ☐ Air cleanliness classification
    - ☐ Air flow directions and pressure differentials
- ☐ Water treatment system (if applicable)
  - ☐ User requirement specifications
  - ☐ Qualification approach and timeline
  - ☐ Complete piping and instrumentation diagram highlighting relevant parts of the water treatment system originally approved and the proposed change
  - ☐ Floor plan showing location of user points
- ☐ Other utilities (e.g. compressed dry air, exhaust, de-dusting, clean steam systems if applicable)
  - ☐ Relevant supporting documents

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Appendix 3

CHECKLIST

Application for Change of Quality Control Area (Approval in Principle)

This checklist indicates the fundamental documents to be submitted for the application. Please put a "✓" in the relevant box for documents included in this application. Please provide a written explanation if any of the documents is not available.

- ☐ Completed application form
- ☐ Copy of Business Registration Certificate, Branch Registration Certificate, or tenancy agreement
- ☐ Records on change control and other associated systems under the quality management systems (e.g. quality risk management, corrective and preventive actions), with detailed description of the proposed change and implementation plan including actions to be implemented before, during and after the change, in particular, measures to prevent contamination and cross-contamination and to assure product quality during renovation
- ☐ Originally approved and proposed floor plans, highlighting the concerned premises / part of the premises (if applicable), showing:
  - ☐ Location of concerned part of the premises on the whole floor with name, number (if applicable), dimensions and floor area of each room and allotted area
  - ☐ Personnel flow
  - ☐ Material flow
- ☐ User requirement specifications of the premises (except for removal of quality control area)
- ☐ Description of quality control activities
- ☐ Major instruments (for addition of quality control area only)
  - ☐ A list of major instruments
  - ☐ User requirement specifications for new instrument
  - ☐ Originally approved and proposed floor plans showing location and to-scale dimensions of instruments in aerial view (if applicable)

- ☐ Heating, ventilation and air-conditioning (HVAC) system highlighting relevant parts originally approved and proposed change (for microbiological laboratory cleanroom only)
  - ☐ User requirement specifications
  - ☐ Complete piping and instrumentation diagram showing major components and ducts of the HVAC system, highlighting relevant parts originally approved and proposed change (if applicable)
  - ☐ Floor plan showing
    - ☐ Location of ventilation points and ducts
    - ☐ Zoning of air-handling units
    - ☐ Air cleanliness classification
    - ☐ Air flow directions and pressure differentials
- ☐ Air-handling/air-conditioning units for non-cleanroom areas (e.g. microbiological laboratory non-cleanroom area, retention sample room, stability room) (for addition of quality control area only)
  - ☐ User requirement specifications
  - ☐ Schematic diagram showing major components and ducts
- ☐ Impact assessment of capacity of quality control activities

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Appendix 4

CHECKLIST

Application for Change of Storage Area (Approval in Principle)

This checklist indicates the fundamental documents to be submitted for the application. Please put a "✓" in the relevant box for documents included in this application. Please provide a written explanation if any of the documents is not available.

- ☐ Completed application form
- ☐ Copy of Business Registration Certificate, Branch Registration Certificate, tenancy agreement or logistics services agreement of storage facilities at other premises (if any)
- ☐ Records on change control and other associated systems under the quality management systems (e.g. quality risk management, corrective and preventive actions), with detailed description of the proposed change and implementation plan including actions to be implemented before, during and after the change, in particular, measures to prevent contamination and cross-contamination and to assure product quality during renovation
- ☐ Originally approved and proposed floor plans, highlighting the concerned premises / part of the premises (if applicable), showing:
  - ☐ Location of concerned part of the premises on the whole floor with name, number (if applicable), dimensions and floor area of each room and allotted area
  - ☐ Personnel flow
  - ☐ Material and/or product flow
- ☐ User requirement specifications of the premises (except for removal of storage area)
- ☐ Description of the types of materials involved (any handling of highly sensitizing, toxic or hazardous substances and materials requiring special storage conditions should be specified)
- ☐ Air-handling/air-conditioning units (for addition of storage area only)
  - ☐ User requirement specifications
  - ☐ Complete schematic diagram showing instrumentation and ducts
- ☐ Impact assessment of storage capacity

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Appendix 5

CHECKLIST

Application for Change of Manufacturing Premises (Final Approval)

This checklist indicates the fundamental documents to be submitted for the application. Please put a "✓" in the relevant box for documents included in this application. Please provide a written explanation if any of the documents is not available.

- ☐ Completed application form
- ☐ Copy of Business Registration Certificate, Branch Registration Certificate, tenancy agreement or logistics services agreement of storage facilities at other premises (if any)
- ☐ Records on change control and other associated systems under the quality management systems (e.g. deviation handling, quality risk management, corrective and preventive actions), containing relevant changes and/or progresses
- ☐ Summary of changes from the proposal approved in principle, showing the level of change (e.g. critical, major, minor) and rationale for changes
- ☐ As-built floor plans, highlighting the concerned premises / part of premises
  - ☐ General, showing name, number (if applicable), dimensions and floor area of each room and allotted area
  - ☐ Personnel flow
  - ☐ Material and/or product flow
- ☐ Evidence (e.g. records, photos, videos) showing implementation of proposed actions before and during the change (e.g. material and product protection; utilities protection; access control; renovation progress; post renovation deep cleaning)
- ☐ Premises (if applicable)
  - ☐ Room data (name, room number, area, and function) and specifications (temperature, relative humidity, air quality, air change and differential pressure) of the concerned premises and part of the premises
  - ☐ Commissioning and qualification documentation
  - ☐ Photos of the premises

- ☐ Major equipment or instruments (if applicable)
  - ☐ A list of major equipment/instruments
  - ☐ As-built floor plans showing layout and to-scale dimensions of equipment/instruments in aerial view for both new and existing equipment/instruments (if applicable)
  - ☐ Qualification approach and timeline
  - ☐ Photos of the new equipment or instruments
- ☐ Utilities
  - ☐ All corresponding floor plans and diagrams submitted for approval in principle for the change in premises
  - ☐ Commissioning and qualification documentation
  - ☐ Photos of the new utilities
- ☐ A list of written procedures and associated records on routine operation (e.g. operations in production cleanroom, storage areas and laboratories; environmental monitoring; premises cleaning) relevant to the change

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