Guidance Notes on Change of Registered Particulars of Registered Pharmaceutical Products/Substances

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Pharmacy and Poisons Board of Hong Kong

Contents

1. Registered particulars of a registered pharmaceutical product/substance

1.1 According to the Pharmacy and Poisons Regulations (Cap. 138A), the following particulars of a registered pharmaceutical product/substance are also registered with the Pharmacy and Poisons Board:

1.1.1 the name of the pharmaceutical product/substance;
1.1.2 the specifications of the pharmaceutical product/substance;
1.1.3 the label of the pharmaceutical product/substance;
1.1.4 the package insert of the pharmaceutical product/substance, if any;
1.1.5 the name and address of the manufacturer;
1.1.6 the name and address of the registration certificate holder;
1.1.7 the dose form of the pharmaceutical product;
1.1.8 the quantity or quantities of the dose form contained in the unit package or unit packages of the pharmaceutical product;
1.1.9 the name and quantity of all active ingredients of the pharmaceutical product;
1.1.10 the name and quantity of all excipients of the pharmaceutical product; and
1.1.11 the proposed indication, dosage and route of administration of the pharmaceutical product

2. Change of registered particulars

2.1 A pharmaceutical product/substance is registered if and only if the above registrable particulars are those which correspond exactly with the registered particulars of the product or substance. If any of the above particulars has been changed without approval, the pharmaceutical product/substance will not be regarded as registered under the Pharmacy and Poisons Regulations.

2.2 Applications for change of any registered particulars must be made following these Guidance Notes. Please note that the registered particulars underlined in paragraph 1.1 cannot be changed, which include the name of the pharmaceutical product/substance; the dose form of the pharmaceutical product and the name and quantity of all active ingredients of the pharmaceutical product. Such change(s) would render the pharmaceutical product/substance considered as unregistered, and the applicant may apply for registration as a new pharmaceutical product/substance accordingly. For details, please refer to the < Guidance Notes on Registration of Pharmaceutical Products/Substances >.

3. How to apply for change of registered particulars

3.1 The Drug Office of the Department of Health provides executive and professional support to the Pharmacy and Poisons Board. The registration certificate holder should submit online application for change of registered particulars (CORP) to the Drug Office via the Pharmaceutical Registration System 2.0 (PRS 2.0) at https://www.drugoffice.gov.hk/prs2-ext/client_authentication.jsp

3.2 During the application process, applicants would need to upload the supporting document(s) as specified in Table 1. The uploaded documents should be in text searchable Portable Document Format (PDF) file whenever practicable.

3.3 The original or certified true copies of certain supporting documents, for example, the manufacturer's Good Manufacturing Practice (GMP) certificate, Free Sale Certificate (FSC) or Certificate of a Pharmaceutical Product (CPP), should also be submitted with a covering letter stating the application reference number (i.e. CORP- HKXXXXX-XXXXXXXXX) to the following address:

Drug Registration Unit
Drug Evaluation and Import/Export Control Division
Drug Office, Department of Health
Suites 2002-05, 20/F, AIA Kowloon Tower, Landmark East
100 How Ming Street, Kwun Tong, Kowloon,
Hong Kong
(Enquiries: 3974 4175)

4. General requirements

4.1 In each CORP application, applicant should provide a letter summarising all the proposed changes and listing out the submitted documents. Please also specify in the PRS 2.0 if the application involves a pharmaceutical product/substance supplied to the Department of Health with contract or under direct purchase agreement.

4.2 Please make sure that all the required documents set out in Table 1 have been provided. Please keep your submission in a precise and concise way and avoid redundant documents. Applications with inaccurate data entry, or those with the submitted documents fail to meet the requirements will be not be accepted and the applicant will be required to follow up, such

as making amendments, justifications or clarifications on the application or the submitted documents.

4.3 For change(s) to the product label, package insert, product specification or master formula, please submit a copy in track change mode based on the approved version, as well as a clean copy of the document.

4.4 Supporting documents to substantiate the proposed change(s) may include reputable reference, pharmacopoeia monograph, evidence of approval of the proposed change(s) by drug regulatory authorities, stability test data, analytical report, risk assessment report, bioequivalence data, comparability assessment, etc. Applicants should highlight relevant sections of the supporting documents for easy reference.

4.5 Apart from the required documents set out in Table 1, further information or documentary evidence may be required on a case-by-case basis in order to assure the safety, efficacy and quality of the pharmaceutical product/substance with the proposed change(s).

4.6 Multiple submissions for change of the same change category/registered particular within a certain timeframe* is NOT recommended. It will only be considered on a case-by-case basis. Applicant should revise the existing application to incorporate latest change, or to apply for subsequent change after the existing application has been approved and implemented. Should two applications be unavoidable, applicant is required to provide justification.

(* There is a submitted application (a) still under evaluation or (b) approved but not yet implemented)

4.7 If the application is approved, applicant will be informed of the details of approval and the effective date in writing.

4.8 In general, prior to the effective date of the proposed CORP, the applicant should recall all pharmaceutical products/substances with the old particulars from the market. As stated in paragraph 2.1, these pharmaceutical products/substances will no longer be regarded as registered pharmaceutical products when the new registered particular(s) is in effect.

5. Implementation of the approved change(s)

5.1 If no effective date is proposed in the application, the default effective date of the proposed CORP will be 180 days from the date of approval.

5.2 If the registration certificate holder needs to change the effective date of the approved CORP, application for change of implementation date (CIMP) should be submitted at least 5 working days before the approved change(s) comes into effect. Unless otherwise justified, postponement of implementation date should not be more than 1 year.

5.3 Registration certificate holder should set the proposed effective date or apply for CIMP based on accurate stock level estimation and logistic arrangement, which could help to minimise the number of CIMP applications.

6. Fees

6.1 For the change of the name or address of registration certificate holder, a signature fee of $155 will be charged for each registration certificate.

7. Required supporting documents

Table 1: Required supporting documents for each category of the proposed change(s)

Proposed Change(s)	Supporting Document(s)
1. Specifications	
1.1 Change in specification(s)	i. Proposed specifications [a] ii Other supporting documents, if applicable [d]
1.2 Change in shelf-life or container closure system 1.3 Change in storage condition	i. Stability test data [b] ii. Proposed specifications, if applicable [a, c] iii. Proposed label and package insert, if applicable [c] iv. Other supporting documents, if applicable [d]
2. Label [e]	
2.1 Change in label	i. Proposed label ii. Other supporting documents, if applicable [d]
3. Package Insert [e]	
3.1 Change in package insert 3.2 Addition of package insert	i. Proposed package insert ii. Other supporting documents, if applicable [f]

Proposed Change(s)	Supporting Document(s)
4. Manufacturer [g]	
4.1 Change in name and / or address of the current manufacturer (This category is for administrative change only which there should be no change in the physical location of the manufacturing site)	i. Soft copy and the original/certified true copy of the manufacturer's PIC/S GMP certificate ii. Proposed label and package insert, if applicable [c] iii. Updated master formula and specification issued by the manufacturer with the new name and/or address (depending on the role of the manufacturer) iv. Declaration letter and/or updated manufacturing flow chart indicating the a) manufacturing process , b) name, address and role of the manufacturer(s) involved and c) proposed updates [h] v. Other supporting documents, if applicable [d, h]
4.2 Change to new manufacturer	i. Letter issued by the current manufacturer to acknowledge the change to the new manufacturer ii. Soft copy and original/certified true copy of the manufacturer's PIC/S GMP certificate iii. Soft copy and original/certified true copy of FSC/CPP of the pharmaceutical product/substance issued by the drug regulatory authority of the country of origin, unless otherwise justified (if change of place of origin appeared on the label is involved) iv. Proposed label and package insert, if applicable [c] v. Updated master formula and specifications issued by the new manufacturer (depending on the role of the new manufacturer) vi. Declaration letter and/or updated manufacturing flow chart indicating the a) manufacturing process , b) name, address and role of the manufacturer(s) involved and c) proposed updates [h] vii. Other Supporting documents, if applicable [d, h]

Proposed Change(s)	Supporting Document(s)
5. Registration Certificate Holder	
5.1 Change in name and/or address of the current registration certificate holder (This category is for administrative change under the same business registration certificate number)	i. Soft copy of the updated business registration certificate ii. Soft copy of the Certification of Incorporation on the change of name (for incorporated companies only) iii. Original Certificate(s) of Drug/ Product Registration of **all** the registered pharmaceutical product(s)/substance(s) involved
5.2 Change to new registration certificate holder	i. Soft copy of valid business registration certificate of the new registration certificate holder ii. Original letter from the current registration certificate holder agreeing to transfer the named registered pharmaceutical products/substances to the new registration certificate holder (please specify the 12 digits business registration certificate number in the letter) iii. Original letter from the new registration certificate holder agreeing to accept the named registered pharmaceutical products/substances iv. Original letter from the manufacturer/overseas marketing authorization holder in record listing the registered pharmaceutical product(s)/substance(s) to be transferred, (i) confirming the change of registration certificate holder and (ii) authorising the new certificate holder to handle all the post-marketing activities in Hong Kong for the named product(s)/substance(s).

Proposed Change(s)	Supporting Document(s)
	v. Original Certificate(s) of Drug/Product Registration of **all** registered pharmaceutical product(s)/substance(s) involved
6. Quantity of the Dose Form in the Unit Package(s) (i.e. Package Size)	
6.1 Change in package size (including the deletion of registered package size) 6.2 Addition of package size [i]	i. Proposed label, if applicable ii. Proposed package insert, if applicable [c] iii. Stability test data, if applicable [b] iv. Proposed specifications, if applicable [a, c] v. Other supporting documents, if applicable [d]
7. Excipients	
7.1 Change in name and / or quantity of excipients	i. Proposed master formula [a] ii. Stability test data [b] iii. Proposed specifications, if applicable [a, c] iv. Other supporting documents, if applicable [d]
8. Indication / Dosage / Route of Administration	
8.1 Change in indication 8.2 Change in dosage 8.3 Change in route of administration	i. Proposed label and package insert, if applicable [c] ii. Other supporting documents [f, j]

* For change(s) to the product label, package insert, product specification or master formula, please submit a copy in track change mode based on the approved version, as well as a clean copy of the document.

Explanatory notes:

a. The release specification and shelf-life specification (if applicable) of the finished product issued by the manufacturer. Please also refer to the <General Requirements for Master Formula and Specifications for Non-Biological Products >.

b. Completed real time stability data at one of the following real time testing conditions, or on-going real time stability data together with at least 6 months' accelerated stability data is required to establish the product's proposed shelf-life and packaging material.

Real Time Testing Condition

Temperature (°C)		Relative humidity (RH)
● 30°C+/-2°C	&	75%+/-5% RH
● 30°C+/-2°C	&	65%+/-5% RH
● 25°C+/-2°C	&	60%+/-5% RH

Accelerated Testing Condition

● 40°C+/-2°C	&	75%+/-5% RH

- Other temperature/relative humidity conditions could be adopted if justified.
- In-use stability data should also be provided if applicable.
- Appropriate labelling of the storage conditions in English and/or Chinese shall be provided on the sales pack.

c. Please also apply for the corresponding category(ies) of change.

d. Supporting documents for the proposed changes may include:

(i) Method of analysis;

(ii) Document(s) which complies with the following pharmacopoeias or ICH / WHO guidelines unless otherwise justified: Pharmacopoeia of the People's Republic of China, British Pharmacopoeia, European Pharmacopoeia, International Pharmacopoeia, Japanese Pharmacopoeia and/or United States Pharmacopoeia;

(iii) Reputable references;

(iv) Documentary evidence of approval of the proposed change(s) by drug regulatory authorities;

(v) Analytical report;

(vi) Risk assessment report;

(vii) Bioequivalence (BE) study data for specific drug(s), unless otherwise justified[1]; and/or

(viii) Comparability assessment of biological products before and after changes, unless otherwise justified.

e. Please refer to the < Guidelines on the Labelling of Pharmaceutical Products >.

f. Please refer to paragraph 6.2.16 of the <Guidance Notes on Registration of Pharmaceutical Products/Substances > for the requirements of supporting documents for change in package insert.

g. Points to note for change to a new manufacturer:

(i) Please refer to the definition of "Manufacturer" under the Pharmacy and Poisons Ordinance, Cap. 138.

(ii) Please refer to paragraph 6.2.5 and 6.2.6 of the <Guidance Notes on Registration of Pharmaceutical Products/Substances > for the requirement of the manufacturer.

(iii) There shall only be one labelled manufacturer under the same product registration.

h. Please refer to the requirements set out in <Supplementary Notes for Application for Registration of Biological Products Involving Alternative / Back Up Manufacturer(s) for Manufacturing Steps > if applicable.

i. Application for new product registration is required for the addition of new presentation(s) of a pack size that has already been registered.

j. For any proposed change(s) in indication/dosage/route of administration which has not been previously registered in Hong Kong, please refer to the <Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity> for details. For such applications, applicants are required to further provide:

(i) Clinical data in CTD format;

[1] Please refer to paragraph 6.2.17 of the <Guidance Notes on Registration of Pharmaceutical Products/Substances> for the requirement of BE data.

(ii) Evidence of approval in at least 2 reference countries[2];

(iii) Tabular listing of the worldwide approval status of the proposed change(s); and

(iv) Comparison table to compare (a) the registered, (b) the proposed, and (c) the approved indication/dosage/route of administration in the reference countries, with the difference highlighted or specified.

8. Disclaimer

8.1 These Guidance Notes serve as a general guide to the applicant for change of registered particulars of registered pharmaceutical products/substances and shall not be regarded as the complete registration requirements or authoritative statement of the relevant laws or its interpretation on any particular case. Copies of the Pharmacy and Poisons Ordinance and its subsidiary legislations shall be referred, which can be purchased by calling the Publications Sales Section of Information Services Department at 2537 1910, or by email at puborder@isd.gov.hk. Contents of the relevant legislation can also be found at the Department of Justice's website at https://www.elegislation.gov.hk/.

8.2 These Guidance Notes list out the documents which are generally required to demonstrate the quality, efficacy and safety of the products. The Pharmacy and Poisons Board reserves the right to revise these Guidance Notes at any time without giving prior notice. Users are responsible for making their own assessment of these Guidance Notes.

[2] Reference countries refer to Australia, Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Holland, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, UK and USA.