Updates on HA's Tender Document and Requirements

Briefing to Pharmaceutical Suppliers and Manufacturers

Hospital Authority

29 August 2025

Purpose of Update

- Follow the update regulatory framework of the Department of Health of Hong Kong

- Continue cost-effective pharmaceutical product selection and ensuring **Patient and Medication Safety**, in :
  - Enhancing tenderer’s overall compliance at tender submission
  - Streamlining tendering process and time
  - Improving overall tendering efficiency
  - Encouraging market competition

Rundown

1. **Updates on HA's Tender Document**
   - Manufacturer of the Goods
   - Pharmacopoeia Monograph Compliance
   - Microbiological Test and Microbial Examination Validation Report
   - In English Requirement
   - Marketing Authorisation and Export Certificate Requirement
   - Certified True Copy Requirement
   - Tender Submission
2. **Date of Implementation**
3. **Q&A**

Manufacturer of the Goods

[Tenderer's Schedule B3*(1-4)*, B4*(2)*]

To reduce information to be provided by the Tenderer in respect of each manufacturer of the Goods, where the Goods are registered with Department of Health (DH)

Existing	From 1 October 2025
Tenderer's Schedule B3 (1) Good Manufacturing Practice (GMP) Licence (2) Site Master File (3) Production and quality control facilities (4) Qualification and experience of professional and technical personnel involved in production and quality control Tenderer's Schedule B4 (2) Product Recall System details	This information is no longer required, where the Goods are registered with Department of Health (DH)

Reference:
DH's Guidance Notes on Registration of Pharmaceutical Products/Substances s6.2.5 and s6.2.6 (Version Nov 2022)

Pharmacopoeia Monograph Compliance

[Tenderer's Schedule A5*(1)*]

If the Good is a generic product, the product specifications of the Good must comply with any one of the following:

Existing	From 1 October 2025
(i) BP product monograph (ii) Ph. Eur. active ingredient monograph; (iii) Ph. Eur. product monograph; or (iv) USP product monograph	(i) Pharmacopoeia of the People's Republic of China product monograph; (ii) BP product monograph; (iii) Ph. Eur. active ingredient monograph; (iv) Ph. Eur. product monograph; (v) International Pharmacopoeia product monograph; (vi) Japanese Pharmacopoeia product monograph; or (vii) USP product monograph

Reference:
DH's Guidance Notes on Registration of Pharmaceutical Products/Substances s6.2.9 (Version Nov 2022)

Pharmacopoeia Monograph Compliance

[Attachment to Appendix 1]

If the Good is a generic product, the product specifications of the Good must comply with any one of the following:

Existing	From 1 October 2025
(i) BP product monograph (ii) Ph. Eur. active ingredient monograph; (iii) Ph. Eur. product monograph; or (iv) USP product monograph	(i) Pharmacopoeia of the People's Republic of China product monograph; (ii) BP product monograph; (iii) Ph. Eur. active ingredient monograph; (iv) Ph. Eur. product monograph; (v) International Pharmacopoeia product monograph; (vi) Japanese Pharmacopoeia product monograph; or (vii) USP product monograph

Reference:
DH's Guidance Notes on Registration of Pharmaceutical Products/Substances s6.2.9 (Version Nov 2022)

Pharmacopoeia Monograph Compliance

[Tenderer's Schedule B1(a)*(v)*]

(v) Proof of compliance of the Good with the monograph as published in the applicable Pharmacopoeia:

The Good complies with the following monograph of the applicable Pharmacopoeia:

Existing	From 1 October 2025
Product specifications must comply with any of - BP product monograph - Ph. Eur. active ingredient monograph; - Ph. Eur. product monograph; or - USP product monograph	Product specifications must comply with any of - Pharmacopoeia of the People's Republic of China product monograph; - BP product monograph; - Ph. Eur. active ingredient monograph; - Ph. Eur. product monograph; - International Pharmacopoeia product monograph; - Japanese Pharmacopoeia product monograph; or - USP product monograph

Reference:
DH's Guidance Notes on Registration of Pharmaceutical Products/Substances s6.2.9 (Version Nov 2022)

Microbiological Test and Microbial Examination Validation Report [Part III Folder B B2 *(1)*]

1. Non-Sterile Products

(a) Tenderers must provide a report on the microbiological tests performed on each Good specified in BP/Ph. Eur./USP.

(b) Tenderers may provide a microbial examination validation report in respect of each Good which complies with BP/Ph. Eur./USP, if available.

Existing	From 1 October 2025
- BP; - Ph. Eur.;or - USP	- USP; - BP; - Ph. Eur.; or - JP

Reference:
Pharmacy and Poisons Board of Hong Kong Requirement of Microbiological Quality of Registered Pharmaceutical Products in Non-sterile Dosage Forms s3 (Version Date: 1 August 2021)

Microbiological Test and Microbial Examination Validation Report [Tenderer's Schedule B2*(1)*]

1. <u>The above Good is a non-sterile product:</u>

- Microbiological tests on the above Good have been conducted by a Laboratory in accordance with the testing methodology and acceptance criteria specified in BP, Ph. Eur. or USP.
- A microbial examination validation report of the above Good which complies with BP, Ph. Eur. or USP:

Existing	From 1 October 2025
- BP; - Ph. Eur.;or - USP	- USP; - BP; - Ph. Eur.; or - JP

Reference:
Pharmacy and Poisons Board of Hong Kong Requirement of Microbiological Quality of Registered Pharmaceutical Products in Non-sterile Dosage Forms s3 (Version Date: 1 August 2021)

In English Requirement

[Tenderer's Schedule B1(a)*(p,r-u)*]

Part I Clause 4a*(ii)* Tender Submission
Where certain information is in a language other than English or Chinese, a true, accurate and complete English or Chinese translation certified by the translator stating his relevant qualifications must be provided with the original foreign language document

Existing	From 1 October 2025
"in English" requirement for (p) Method of Analysis (r) Stability data with recommended shelf-life and storage condition (s) Post-reconstitution or post-dilution stability data (t) Certificate of analysis (u) Bioequivalence studies	Remove "in English" requirement
(r) Stability data with recommended shelf-life and storage condition	Add "supporting the shelf-life and storage condition as currently registered with the Pharmacy and Poisons Board of Hong Kong" to Stability data

Reference:
DH's Guidance Notes on Registration of Pharmaceutical Products/Substances s6.2.10, 6.2.11, 6.2.12, 6.2.17 (Version Nov 2022)

Marketing Authorisation and Export Certificate Requirement [Tenderer's Schedule B1(a)*(n)*]

(n) Where the Good is manufactured outside Hong Kong:

Existing	From 1 October 2025
a certified true copy of its marketing authorisation ("Marketing Authorisation") issued by the regulatory authority in the overseas country / place which has to be a PIC/S Participating Authority, or where the Good is registered for export only, a certified true copy of an export certificate ("Export Certificate") issued by the regulatory authority in the overseas country / place from which the Good is exported which has to be a PIC/S Participating Authority; or	Add "…which the Good is exported which has to be a PIC/S Participating Authority; or in the case of Good registered under the "1+" Mechanism, the "1+" Mechanism reference country/ place"

Reference:
Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity (Version November 2024)
Guidance on Application of Certificate of Drug/Product Registration — Advanced Therapy Products (Version 3.1), s4.2

Addition of clause (f) will be withheld until further notice and the drug tender template from 1 October 2025 will remain status quo

Certified True Copy Requirement

(Part 1 Clause 2(a))

From 1 October 2025

"**certified true copy**"
means a copy of a document that is certified as a true copy by any one of the following persons:

(a) an official of the government;
(b) a notary public;
(c) a lawyer;
(d) a professional accountant;
(e) an officer of a court of law; or
(f) a professional company secretary (practising in the place where the copy is certified) and if the copy is certified in Hong Kong, a professional company secretary practising in Hong Kong;

Companies Registry

Reference:
Sections 775 (Certified Copy) of the Companies Ordinance (Cap. 622)
Companies Registry External Circular No. 3 / 2021 dated 18 November 2021

Remark:
i) A professional company secretary practicing in HK means a member of the Hong Kong Chartered Governance Institute ("HKCGI") (formerly known as The Hong Kong Institute of Chartered Secretaries ("HKICS")) holding the professional designations of FCG* / FCS* / HKFCG* or ACG* / ACS* / HKACG*, and optionally in combination with the professional qualifications of CS* / CGP*
ii) A professional company secretary practising in the place means a member of The Chartered Governance Institute ("CGI") holding the professional designations of either FCG* or ACG*, and optionally in combination with the professional qualifications of CS* / CGP*

Certified True Copy Requirement

[Tenderer's Schedule B1(a)*(m)*]

As the Certificate/ Licences can be verified in public domain, remove "certified true copy" requirement

Existing	From 1 October 2025
(m) A certified true copy of the Certificate of Drug/Product Registration of the Good issued by the Pharmacy and Poisons Board of Hong Kong	Remove certified true copy requirement

Certified True Copy Requirement

[Tenderer's Schedule B4*(1)*]

As the Certificate/ Licences can be verified in public domain, remove "certified true copy" requirement

Existing	From 1 October 2025
(1) A certified true copy of the relevant registrations/ licences, such as the Wholesale Dealer Licence, Antibiotics Permit, Wholesale Dealer's Licence to supply Dangerous Drugs; and	Remove certified true copy requirement

Tender Submission

[Part I Clause 4*(b)*]

(b) After a Tenderer has submitted its Tender Submission, the Authority may require the Tenderer to provide further information within such time as specified (and if no time is specified, within 5 working days), failing which the Authority may deem the Tender Submission incomplete

- Please take note of HA given validity period to reply
- HA will critically review any request to extend the reply period

Date of Implementation

- HA shall implement the new tender document and requirements with effect from **1 October 2025**

Enquiries

- General Enquiries
  - Email: **PPSemail@ha.org.hk**

- Tender Specific Enquiries
  - HA contact person stated in the tender document

Q & A