

ALPS EVALUATION CRITERIA FOR UNREGISTERED PHARMACEUTICAL PRODUCTS

The criteria for evaluation of unregistered pharmaceutical products (where registered brands are not available for supply in Singapore) are listed below.

1 Product

- 1.1 Products that fully meet specifications will be given preference.
- 1.2 Products that fully meet current Pharmacopoeial Standards or acceptable equivalent standards will be given preference. Compliance to Pharmacopoeial Standards (BP, USP or EP) and related standards of quality are verified through the product's Certificate of Analysis and/or independent laboratory analysis.
- 1.3 Preference will be given to products that has been evaluated and approved by at least one of HSA's reference drug regulatory agencies.
- 1.4 Preference will be given to products that are registered and/or sold in countries that are members of Pharmaceutical Inspection Co-operation Scheme (PIC/S).
- 1.5 Products with longer shelf life will be given preference.
- 1.6 Product presentation should optimise product identification and promote prevention of medication error.
 - (i) Product images, in addition to label artwork, must be available for both primary and secondary packaging.
 - (ii) Product must comply with the Labelling Requirements under the HSA Therapeutic Products Guidance: Import and Supply of an Unregistered Therapeutic Product for Patients' Use.
- 1.7 The requirement for barcodes will be limited to Injectables. Preference will be given to Injectables that have machine-readable barcodes.
- 1.8 Products that are undergoing HSA registration and are supported by Acceptance for Evaluation (stage 1) notification from HSA will be given preference.

2 Source

- 2.1 Direct supply from the manufacturer is preferred to a wholesaler.
- 2.2 Products from manufacturers which have been audited and found to conform to Good Manufacturing Practice (GMP) standards by a PIC/S member authority or any of the HSA's reference drug regulatory agencies will be given preference.
- 2.3 Manufacturers with valid GMP certificates for Therapeutic Products will be given preference.
- 2.4 Products from wholesalers with relevant wholesaler licences will be preferred.

3 Vendor

- 3.1 The vendor must be a registered business entity with the Accounting and Corporate Regulatory Authority (ACRA).

- 3.2 Vendors that have valid Government Supplier Registration (GSR) status under the Ministry of Finance and meet the minimum financial grade under the relevant supply heads will be given preference.
- 3.3 Vendors that adhere to delivery lot sizes specified; comply fully with the terms & conditions of the contract; and provide the shortest delivery lead-time will be given preference.
- 3.4 Past track records of vendor supply service performance for previous contracts will be taken into consideration.

4 Price

- 4.1 Prices must be competitive.

5 Others

- 5.1 It is the Vendor's responsibility to ensure the completeness and accuracy of the information provided (including supporting documentation requested by ALPS). The requisite information is to be submitted by the deadline specified. If the Vendor fails to submit complete and accurate information by the applicable deadline, it shall be treated as non-submission, which may affect the quality or merit of the Proposal.