ALPS EVALUATION CRITERIA FOR PHARMACEUTICAL PRODUCTS

1 Product

1.1 Product(s) registered for sale in Singapore by the Health Sciences Authority (HSA) will be given priority.

1.2 Products that fully meet specifications will be given preference.

1.3 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.

1.4 Generic products that demonstrate therapeutic equivalency to the Singapore reference product will be given preference.

1.5 The proposed shelf life of the product must be supported by stability data. Products with longer shelf life will be given preference.

1.6 Products should have good sales record in Singapore and/or other developed countries.

1.7 Product presentation should optimise product identification and promote prevention of medication error. (Refer to Annex 1)

1.8 Preference will be given to products that have machine-readable barcodes. (Refer to Annex 2)

1.9 Upon satisfactory appraisal, a small quantity of a new product may be purchased first to assess distributor's service performance and product quality before purchase of a larger quantity is considered.

2 Manufacturer

2.1 Products from manufacturers which have been previously audited and found to conform to Good Manufacturing Practice (GMP) standards by a PIC/S member authority or any of the HSA's benchmark GMP inspection authorities will be given preference.

2.2 Manufacturers with valid GMP certificates for Therapeutic Products will be given preference.

2.3 Manufacturing capacity and the ability to supply products in minimum batches will be taken into consideration.

2.4 Past track records of products manufactured for previous contracts will be taken into consideration.

3 Vendor

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

3.2 Vendors that are registered with the Expenditure and Procurement Policies Unit (EPPU) under the Ministry of Finance and meet the minimum financial category under the relevant supply headings will be given preference.

3.3 Vendors with GDP certification by HSA will be given preference.

3.4 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.

3.5 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 and samples 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.

Product Presentation

1 General Considerations

1.2 Essential information such as the generic name, dosage strength/concentration, expiry date and route(s) of administration should be presented more prominently than other mandatory information such as name/logo of the manufacturer/product owner, batch number and storage condition. As far as possible, products should not look alike and attempts must be made to differentiate them.

1.3 Text should be in a font size that maximizes legibility. The size of generic name should be larger than the proprietary name.

1.4 Use of colour

(a) Text colour should contrast clearly with the background colour.

(b) Colour scheme should be consistent throughout the primary and secondary packaging.

(c) Use of colour should be considered to draw attention to product differences (e.g. dosage strength/concentration) and not be a fixed part of a company trade dress that permeates in the same manner from product to product.

(d) For products with different strengths, stronger colours (e.g. red) are preferred for higher strength products and light shades for lower strength products (e.g. black).

(e) Different strengths and presentations of the same product or different products from the same manufacturer should always be clearly distinctive. The same tone or hue should be avoided.

1.5 Specific storage conditions should be highlighted.

1.6 The primary packaging should be tamper-resistant and tamper-evident.

2 Ampoule/Vial

2.1 The strength should be stated as the total quantity of the active pharmaceutical ingredient per total volume.

2.2 Positive messages should be used to describe route of administration e.g. “For Intravenous Use Only”.

2.3 Use of paper labeling is preferred but an area must be left free for inspection of contents.

2.4 Labels should not come off during use and should be printed with indelible ink.

2.5 Additional requirement for ampoules:

(a) The product name should be printed longitudinally along the length of ampoules.

(b) For ampoules enclosed in individual plastic wraps, the generic name and strength should be clearly displayed on the paper seal.

2.6 Additional requirement for vials:

(a) Where the flip cap is coloured, it should use the predominant differentiating colour that has been used on the label and carton.

(b) For multi-dose vials, preservatives and shelf-life after opening should be highlighted.

3 Tablets/Capsules Blisters

3.1 The generic name, strength, batch number and expiry date should appear over each blister pocket. In cases where blisters are small, generic name and strength should be repeated in a pattern across the entire strip with the expiry date and batch numbers at both ends or on the side of each blister to assist with identification of partly used packs.

3.2 Tablets should be aligned in a manner that allows for easy cutting of the blister strips.

3.3 Blister strips should be made of non-reflective, matte foil to enhance the readability of the information presented.

3.4 Blister strips should have round corners and smooth edges to prevent finger cuts.

3.5 Calendar blister packs should be avoided with the exception of oral contraceptives.

4 Oral Liquids

4.1 The strength of liquid oral preparations should be stated as the total quantity of the active pharmaceutical ingredient per 5 mL volume and should be intuitive for usual dosing.

4.2 For oral liquids with paediatric indications, the diameter of bottle necks should be a minimum of 20 mm.

5 Additional Considerations for Cytotoxic Products

5.1 Oral dosage form in patient packs or blister packs are preferred.

5.2 Ready-to-use or ready-to-administer Injectables are preferred to those that require reconstitution and/or further dilution.

5.3 In-use shelf-life and storage conditions must be supported by in-use stability data. Products with longer in-use shelf-life at room temperature will be given preference.

Barcodes

1 The requirement for barcodes will be limited to Injectables.

2 Preference will be given to Injectables that have machine-readable barcodes.

3 The information contained with the barcode should include product identification.

(a) GS1 GTIN Item Identifier (specifically GTIN-13) is preferred.

(b) Where GTIN is not used, a unique product identifier with a minimum of 7 characters is required.

4 Consideration will be given to products with barcodes that comply with GS1 General Specifications.

5 Matrix 2D barcodes are preferred although linear 1D barcodes are also acceptable. Addition of either will only be considered if it does not incur cost.

6 Print-on barcodes are preferred although stick-on barcodes are also acceptable.

7 Location of the bar codes

(a) Barcodes are preferred on both the primary and secondary packaging. If barcodes can only be added to one type of packaging, having them on the primary packaging is preferred.

(b) For single unit packs e.g. 1 amp/vial per box, having barcodes on the secondary packaging is acceptable if the vendor is unable to provide barcodes on the primary packaging.

(c) For multiple unit packs e.g. 10 amps/vials per box, having barcodes on the secondary packaging alone will not be sufficient.