

# Invitation to Supply

## Part 5

### Statement of Requirements

Invitation to Supply  
Number:

HPVITS2019-058

Invitation to Supply  
Name:

Pharmaceutical Products and IV Fluids

HPVITS2019-058  
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HEALTH PURCHASING VICTORIA

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# A Introduction

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## 1 Purpose

- a) The purpose of this Part 5 – Statement of Requirements, is to:
- (i) detail the scope and range of products sought under Pharmaceutical Products and IV Fluids
  - (ii) specify the requirements that Respondents and / or their offered products must meet (these requirements also form part of any resulting Agreement between HPV and any successful Respondent)

## 2 Scope

- a) HPV is seeking responses for Pharmaceutical Products and IV Fluids for use in Participating Health Services. The Term of the Agreement is two (2) years plus two optional two year extension periods (eg 2+2+2).
- b) The scope of this ITS includes the supply of:
- (i) pharmaceutical products;
  - (ii) intravenous fluids;
  - (iii) parenteral nutrition solutions;
  - (iv) irrigating solutions; and
  - (v) service requirements.
- c) The scope of this ITS does not include:
- (i) Non-ARTG products purchased by health services from a third-party compounder; or
  - (ii) the use of Filgrastim (category 80,000) in healthy volunteers (i.e. allogenic donors).
- d) Indicative volumes are listed in **Part 6, Tender Response Worksheet** to assist with preparation of the ITS response. As these volumes are indicative only, no representation or guarantees are made with regards to their accuracy, and they shall not give rise to any expectations regarding product sales volumes under any Agreement resulting from this ITS. HPV provides no assurances of the correctness or completeness of this information for forecasting purposes.
- (i) HPV may provide updates to indicative volumes at the time of announcing award outcome and during term of Agreement.
  - (ii) the Respondent will be able to meet ordering volume increases reasonably required by Participating Health Services over the term of any resulting Agreement. It is expected that the Respondent will work with Participating Health Services to achieve this.
- e) For each item offered, Respondents are to provide all information requested in the Part 6 Response Worksheet (TRW). HPV reserves the right not to consider products where the TRW is incorrect or incomplete.

### 3 Product Categories

- a) The categories of Pharmaceutical Products and IV Fluids required under this ITS include:
- Category 1 – Pharmaceutical Products
  - Category 50,000 – Intravenous Fluids
  - Category 60,000 – Total Parenteral Nutrition (TPN)
  - Category 70,000 – Irrigation Solutions
  - Category 80,000 – Biopharmaceutical – Filgrastim
  - Category 90,000 – Therapeutic Group Approach
- b) The Respondent may offer products in one, some or all categories.
- c) Only products that specifically fit within the scope of this contract will be considered, although alternative categories and subcategories may be offered.
- d) Products offered in 'other' categories and subcategories will only be considered where the product meets the specification.
- e) HPV reserves the right to amend the category and subcategory against which the product is evaluated. HPV will determine and finalise each product's category and subcategory as part of evaluation and award outcome. HPV reserves the right not to consider products submitted in an incorrect category.
- f) HPV reserves the right not to consider any additional or alternative products offered.
- g) Intravenous fluid (category 50,000) and irrigation solution (category 70,000) products of the same fluid type, strength and volume will be evaluated against the same sub-category, irrespective of container type or pack size, as their clinical use is considered interchangeable.

### 4 Product Conditions

#### 4.1 Clinical Trials

- a) Participating Health Services may, at their discretion, research or trial new technology or products or use non-contracted technology or products to perform clinical trials at any time during the Term of any resulting Agreement.

#### 4.2 Product Duplication

- a) HPV may not consider any product that is subject to a current HPV Agreement, other than the current HPVC2016-058 Pharmaceutical Products and IV Fluids.
- b) The Respondent will ensure that each product is offered only once.

## 5 Definitions

- a) The following definitions apply to this Part 5 – Statement of Requirements, unless otherwise stated.

TERM	DEFINITION
Agreement	A contract entered into by HPV and a Respondent for the provision of Pharmaceutical Products and IV Fluids. Comprises the General Conditions, and all Schedules, Annexures of any kind and any attachments.
ARTG	Australian Register of Therapeutic Goods under the control of TGA
Business day	Any weekday not gazetted as a public holiday in Melbourne, Victoria.
ITS	Invitation to Supply
may	Indicates an optional element; it is at the Respondent's discretion to either meet or not meet this element, and failure to meet this element will not have an impact during evaluation.
must	Indicates a mandatory requirement; failure to meet this requirement will result in the submission being eliminated from further consideration.
Participating Health Services	Public Hospitals and other Health or Related Services, as those terms are defined in Section 3 of the Health Services Act 1988 (Vic), that are described in <b>Part 8B</b> .
PBS	Pharmaceutical Benefits Scheme
RPBS	Repatriation Pharmaceutical Benefits Scheme
should	Indicates a highly desirable element; unless justifiable reason exists, not meeting this element may impact evaluation.
SLA	Service Level Agreement
TGA	Therapeutic Goods Administration
will	Indicates an anticipated future condition or requirement to be met.

## B Service, delivery, and support

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### 1 Delivery

- a) Pharmaceutical Products and IV Fluids must be delivered to the location(s) specified by Participating Health Services within the shortest possible timeframe; however, this must not exceed the guaranteed delivery times as specified by Respondents as part of their Response on the HPV Procurement Portal and/or the Time to Delivery as specified in the Draft Agreement, from receipt of order unless otherwise agreed with the Participating Health Service.
- b) The prices tendered include all means necessary to provide suitably-packed goods ensuring safe transport to their delivery points.
- c) The successful Respondent must provide assurances that acceptable storage conditions are maintained during transportation including the availability of cold storage and delivery for items (where necessary) and any limitations and details surrounding such deliveries, including the presence of a cold chain temperature monitoring system.

### 2 Urgent Deliveries

- a) For the purposes of this section, urgent deliveries refers to urgent requests placed by an individual Participating Health Service, and does not include Emergency Events, as described in the Draft Agreement.
- b) The Respondent should be able to receive and action urgent delivery requests 24 hours a day, 7 days a week.
- c) Urgent deliveries must be received by Participating Health Services within timeframes discussed and agreed with the individual Health Services.

### 3 Customer Service and Support

- a) The successful Respondent should be able to deliver 24-hour, 7-day customer service and support to Participating Health Services.
- b) The successful Respondent will nominate at least one Representative to provide support.
- c) The successful Respondent will provide Participating Health Services with representatives that are:
  - (i) inherently familiar with the contracted products;
  - (ii) appropriately qualified;
  - (iii) technically/clinically knowledgeable about the contracted products; and
  - (iv) available to respond to Participating Health Services' queries 24 hours a day.
- d) It is desirable that nominated Representatives have a clinical background or experience.

- e) The level of customer service and support required of Representatives is expected to include (but is not limited to):
  - (i) promptly answering clinicians' queries (including after hours);
  - (ii) providing informational materials; and
  - (iii) providing education and in-service training upon request.

## C General Requirements

### 1 Standards and Compliance

- a) All items offered must comply with relevant Australian Standards (or their equivalent International Standards), legislation, instruments or guidelines (and any relevant amendments, revisions or consolidations), including, but not limited to the following:
- Therapeutic Goods Administration, all relevant Therapeutic Goods Orders (TGO) as approved under section 10 of the *Therapeutic Goods Act 1989*.
  - Therapeutic Goods Administration (V2.1, February 2019), Uniform Recall Procedure for Therapeutic Goods, Commonwealth of Australia;
  - Code of practice for the tamper-evident packaging (TEP) of therapeutic goods (Version 2.0, May 2017);
  - NHMRC (2010), Australian Guidelines for the Prevention and Control of Infection in Healthcare, Commonwealth of Australia;
  - Australian Code of Good Wholesaling Practice for medicines in schedules 2, 3, 4 & 8 (April 2011);
  - Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice (GMP) - 01 January 2017, PE009-13;
  - Therapeutic Goods Administration (2017), Code of practice for the tamper-evident packaging of therapeutic goods; and
  - Therapeutic Goods Administration (2011), Australian Regulatory Guidelines for Medical Devices (ARGMD).
- b) All items offered must be approved by the TGA, unless exempt. The Respondent must provide evidence of any exemptions in its response.
- c) HPV may consider, at its sole discretion, products tendered with provisional or anticipated ARTG registration for conditional acceptance, where:
- (i) the product is likely to have ARTG registration by commencement of the Agreement on 30 October 2019;
  - (ii) the Respondent provides HPV with evidence as part of the tender response that the product is in the process of registration at the time of submission, as well as the approximate anticipated registration date; or
  - (iii) the Respondent commits to informing HPV of changes in planned or actual registration status as soon as the Respondent becomes aware of any such change.
- d) HPV reserves the right not to consider products without confirmed ARTG registration at the time of response.
- e) For each product offered, Respondents are to advise:
- (i) whether or not it is on the PBS
  - (ii) the associated PBS codes; or
  - (iii) whether product has a different PBS/RPBS listing to other generic presentations of the same drug.



- f) Preference will be given to products listed on the PBS and/or RPBS.

## 2 Packaging and Labelling

- a) Sterile products will be packaged in a manner that protects the contents from contamination during transportation, storage and handling.
- b) Items will be delivered in accordance with the manufacturer's instructions.
- c) It is desirable for individual product packaging to include (where applicable):
  - (i) whether the product is sterile;
  - (ii) Products with machine readable codes for identification;
  - (iii) whether the product is MRI compatible (implantable products); and
  - (iv) whether the product (or packaging) contains latex or is latex-free.
- d) Products should meet the criteria for barcoding as outlined in clause 3.56 (GS1 and Global Trade Item Numbers (GTINS) in Part 3 – Tender Conditions.

## 3 Evaluation of Packaging and Labelling

- a) For each item offered, Respondents are to provide artwork and/or clear photographic images AND a physical sample of the packaging including (where applicable):
  - (i) outer packaging;
  - (ii) immediate container; and
  - (iii) strip pack (platform packaging).
- b) Where final packaging is not available at the time of submission, the artwork and/or clear photographic images are to be provided at a minimum.
- c) All packaging submitted (both physical form or and images) must be representative of the packaging and labelling of the product that would be available to Participating Health Services.
- d) Where photographic images or artwork are submitted, they are to include:
  - (i) all sides of the outer box or container;
  - (ii) the immediate container; and
  - (iii) both sides of the strip pack (platform packaging).
- e) Refer to Provision of Samples section (C4) below for further information on the process for submitting sample packaging.

## 4 Provision of Samples

- a) As outlined in section C3, above, Respondents are to provide one (1) physical sample of each product offered (except for Schedule 8 and cytotoxic medicines), in addition to artwork and/or clear photographic images for all products offered, in order for HPV to evaluate the packaging, except where this is not possible.
- b) Each product sample is to be labelled with the Respondent's name. This may be affixed to the product sample, provided that they do not obscure the labelling of the package or container. Where this cannot be achieved, individual samples should be placed in a zip-lock plastic bag and a label affixed to the plastic bag.
- c) Medicines listed, or fall within the class of medicines listed in Appendix 2 must be provided packed together, labelled with Critical Care Medicines and separated from all other products offered. Respondents may:
  - (i) Send two separate parcels to the address below; one containing critical care medicines, and one containing all other products offered; or
  - (ii) Send one parcel to the address below containing a separate package inside labelled for Critical Care Medicines specifically.
- d) Samples are to be packaged and delivered separately to the tender submission to the following address by the tender closing date and time:
 

SAMPLES FOR EVALUATION  
 HPVITS2019–058 HPV Pharmaceutical Products and IV Fluids Tender  
 Attention: Obaidullah Fazli  
 Monash Health Moorabbin Hospital  
 Phone: 9928 8723  
 Address: 823-865 Centre Rd, Bentleigh East VIC 3165  
 From (Respondent name):
- e) Where samples are packaged and delivered by a third-party who is not the Respondent, the outer package must clearly indicate who the Respondent is.
- f) All samples (whether packaging only or complete samples) will be stored at room temperature. This includes any items that may normally require refrigeration.
- g) All physical samples provided for visual inspection purposes will be disposed of on completion of the evaluation process.

## 5 Risk Minimisation

To support risk minimisation strategies associated with medication safety programs, manufacture, packaging and labelling of pharmaceutical products offered preference may be considered for clarity of information and safety features:

- a) Ability to distinguish between look alike and sound alike (LASA) products;
- b) Ability to differentiate between strengths of the same generic drug or different generic drugs packaged in corporate livery. <http://www.tga.gov.au/pmeds/pmbestpractice.htm>;

- c) Product appearance and packaging that minimises risk of administration by the wrong route;
- d) Preference may be given to user ability to differentiate between products that are considered high risk drugs that are subject to selection and administration error;
- e) Use of Tall man lettering if appropriate. An example of the use of Tall Man Lettering is available at <https://www.safetyandquality.gov.au/wp-content/uploads/2018/01/National-Tall-Man-Lettering-List-Nov-2017.pdf>;
- f) Labelling that does not include unsafe abbreviations, for example “ug” for microgram, “u” or “iu” for units;
- g) Products with machine readable codes for identification, batch and expiry dates, for example; GTIN, QR, 3D, RF, Microdot, at the individual package level and ideally on the unit of dose level;
- h) Products (including their accompanying packaging) that are latex-free;
- i) Products that are free of phthalate content, particularly diethylhexyl phthalate (DEHP);
- j) Packaging requiring less shelf space; and
- k) For light-sensitive products, preference may be given to products with light-sensitive packaging per unit dose.

## 6 Reference Sites

- a) HPV reserves the right to call for references for any tendered products. Should HPV ask for references for any submitted products, Respondents should provide a minimum of three (3) references within 2 business days.
- b) References must be:
  - (i) reflective of the type and nature of the offered product; or
  - (ii) currently using the product, or have trialled and evaluated the product within the last 12 months.
- c) HPV reserves the right to verify the information in this response with nominated referees and seek their feedback regarding the acceptability of products offered.
- d) Respondents should not nominate a referee without their express permission.

## D Product Specifications

### Category 1 - Pharmaceutical Products

#### 1. Unit Dose Packaging

- a) Where items are presented in unit doses, preference may be given to products where each unit dose is:
  - (i) visible within the blister packaging;
  - (ii) packaged independently and is easily separable from the next unit of the drug; and
  - (iii) labelled individually and independently of the next drug unit with the following information:
    - generic drug name;
    - strength;
    - form;
    - brand name;
    - batch number;
    - expiry date; and
    - manufacturer.
- b) For oral dose forms, preference may be shown towards products where the Consumer Medicine Information is specific to that product and does not merely refer to another ARTG-registered product.

#### 2. Security Packs

- a) All dosage forms of drugs controlled under Schedule 8 of The Poisons Standard (SUSMP) are to be presented in tamper-evident containers.
- b) Where a Schedule 8 drug is presented in an injectable form, preference may be given to products that are packaged in tamper-evident ampoules.
- c) Preference may be given to security items, including Schedule 11 drugs under the Victorian Drugs, Poisons and Controlled Substances Act (1981) that are:
  - (i) available in small quantities;
  - (ii) packaged in a manner that facilitates accountability of these products (e.g. unit dose packaging, strip packaging); and
  - (iii) packaged in tamper-evident containers (where applicable).

#### 3. Eye Drops

- a) All eye drops offered must be:
  - (i) sterile; and
  - (ii) presented in tamper-evident squeeze droppers.

#### 4. Ear and Nasal Drops

- a) Preference may be given to ear or nasal drops that are presented:
  - (i) sterile; and
  - (ii) in tamper-evident containers.

#### 5. Inhalers and Nasal Sprays

- a) Preference may be given to inhalers and nasal sprays that include a tamper-evident seal.

#### 6. Injections

- a) Unless stated otherwise, all injectable presentations of drugs must be single-patient use/single dose.
- b) All injectable presentations must be clearly labelled with the:
  - (i) generic drug name;
  - (ii) strength (where applicable);
  - (iii) volume in millilitres;
  - (iv) batch number; and
  - (v) expiry date.
- c) Where an injectable drug is only available in multi-dose, the label must clearly indicate:
  - (i) that the product is for single-patient use only
  - (ii) the bacteriostatic agent.
- d) Where an injectable drug is presented in a disposable prefilled syringe, preference may be given to those with safety needles.
- e) For injectable medicines, the Respondent must indicate in the Part 6 - Tender Response Worksheet:
  - (i) Presence of preservatives
  - (ii) Presence and location of latex
- f) Disposable, prefilled syringes must be presented sterile and in a manner that reduces the risk of injury.
- g) Where an injectable drug is presented as part of a Theatre Pack Presentation, preference may be given to those presented in an outer layer of packaging where the external surface of the inner pack is sterile.

#### 7. Topical Products

- a) Preference may be given to topical products that:
  - (i) are available in a range of sizes, including those suited for single-patient use
  - (ii) presented in tamper-evident packaging.

## 8. Cytotoxic Agents

- a) Preference may be given to cytotoxic agents that are presented in shatter-proof containers or protective packaging.
- b) Preference may be given to injectable cytotoxic agents that are packaged in vials.
- c) Preference may be given to injectable cytotoxic agents that are in solution, compared to powder for reconstitution.
- d) Preference may be given to oral presentations of cytotoxic agents that are packaged in unit doses as specified in Category 1, section 1 (Unit Dose Packaging).
- e) Preference may be given to injectable cytotoxic agents that are compatible with closed-system transfer devices.

## 9. Syringes

- a) Where syringes are presented with an integral needle, preference may be given to those with safety needles.

## Category 50,000 - Intravenous Fluids

### 1.1 Requirements

- a) A range of TGA-registered sterile solutions for intravenous infusion is required, including:
- (i) a range of volumes
  - (ii) a range of concentrations
  - (iii) a range of pack sizes
  - (iv) single and double packs
  - (v) containers suitable for use as a pressure bag.
- b) Intravenous fluids that do not fit into any of the individual subcategories should be listed under "Other". This includes hanger accessories.

### 1.2 Packaging and Labelling

- a) The packaging of intravenous fluids are to be readily compatible with commonly available brands of intravenous administration equipment.
- b) Packaging must perform in a range of clinical settings, including:
- (i) standard infusion
  - (ii) rapid infusion
  - (iii) use with a pressure bag as part of a flush system for pressure monitoring
  - (iv) use with a pressure bag as part of a flush system for rapid infusion.
- c) The labelling of intravenous fluids and additives must be clearly distinguishable from other drugs and types of intravenous solutions. This includes fluid content, percentage and volume.
- d) The labelling of electrolytes should be expressed in mmol/L wherever applicable.
- e) Intravenous fluids must be packaged in a manner that is sufficiently durable to protect the packs or bottles from damage during normal storage, transport, handling and hospital use.

### 1.3 Product Description

- a) For each Intravenous Fluid product offered, the Respondent shall advise in the Tender Response Worksheet:
- (i) Brand name
  - (ii) Type of fluid (e.g. glucose)
  - (iii) Concentrations of each component
  - (iv) Volume in millilitres
  - (v) Packaging:
    - Material (e.g. glass, plastic)
    - PVC (where applicable)
    - DEHP (where applicable)

- (vi) Presentation (e.g. single or double pack)
  - (vii) Graduation markings in millilitres (where applicable)
  - (viii) Type of additive port (e.g. bung) (where applicable)
  - (ix) Hanger or mechanism for attachment to IV pole (where applicable).
- b) For each Intravenous Fluid product offered, the Respondent shall advise on Part 6 - Tender Response Worksheet:
- (i) The requirement for the use of an airway inlet needle during:
    - Standard gravity infusion
    - Use with a volumetric infusion pump
    - Rapid infusion via a pressure bag or rapid infusion device (other than a standard volumetric infusion pump).
  - (ii) If the packaging collapses as it empties
  - (iii) If the pack can be warmed
  - (iv) If the Intravenous Fluid pack is presented in an outer layer of packaging and whether the external surface of the inner pack is sterile.



## Category 60,000 - Parenteral Nutrition Solutions

### 1.1 Requirements

- a) A full range of ARTG-registered nutrition solutions for parenteral administration with a range of percentages of constituents is required. This includes:
  - (i) fat emulsions
  - (ii) amino acid solutions
  - (iii) combination parenteral nutrition solutions
  - (iv) injectable vitamins
  - (v) injectable trace elements.
- b) Where applicable, the packaging containers of parenteral nutrition solutions offered should be readily compatible with commonly available brands of intravenous administration equipment.
- c) Fat emulsions must include either soybean, olive oil or fish oil emulsion bases (at a minimum).
- d) Amino acid solutions may include those:
  - (i) with and without electrolytes
  - (ii) with and without peptides.
- e) Combination parenteral nutrition solutions may include:
  - (i) amino acid and glucose
  - (ii) amino acid, glucose and fat emulsion
  - (iii) with and without electrolytes
- f) Injectable vitamins may include:
  - (i) fat soluble, water soluble and fat and water soluble
  - (ii) those for adult and paediatric patients.
- g) Injectable trace elements may include:
  - (i) a range of presentations, including ampoules and preloaded syringes
  - (ii) those for adult and paediatric patients.

### 1.2 Product Description

- a) For each Parenteral Nutrition Solution offered, Respondent shall advise the following information in the Tender Response Worksheet:
  - (i) Brand name
  - (ii) Type of Parenteral Nutrition Solution as per (e.g. fat emulsion, amino acid solution)
  - (iii) Volume in millilitres
  - (iv) Patient age range (e.g. adult, paediatric)
  - (v) Individual constituent/s concentration/s (e.g. 10% amino acid solution)

- (vi) With or without electrolytes (where applicable), with electrolyte concentration specified in mmol/L
  - (vii) Type of oil based emulsion (where applicable) (e.g. fish, soybean, olive)
  - (viii) With or without peptides (where applicable)
- b) Packaging:
- (i) Material (e.g. PVC, glass)
  - (ii) Presentation (e.g. ampoule, prefilled syringe, single pack)
- c) For each injectable vitamin and injectable trace element offered, the Respondent shall provide a complete list of the vitamins or elements included and their concentration in the relevant column of the Tender Response Worksheet.

## Category 70,000 - Irrigating Solutions

### 1.1 Requirements

- a) A full range of ARTG-registered volumes and percentages of sterile irrigating solutions is required, including:
- (i) aqueous chlorhexidine
  - (ii) aqueous chlorhexidine and cetrimide
  - (iii) glycine
  - (iv) sodium chloride 0.9%
  - (v) water
  - (vi) ringers and lactated ringers solution.
- b) Irrigating solutions are to be offered in a range of presentations, including pour bottles and those for use with irrigation sets.

### 1.2 Packaging and Labelling

- a) Irrigating solutions must be clearly labelled:
- (i) 'for irrigation'
  - (ii) in a manner that readily differentiates between different types of irrigating solutions
  - (iii) in a manner that readily differentiates them from intravenous solution.
- b) Pour bottles must be sufficiently rigid so that they do not distort and cause spillage of contents during normal handling and use.
- c) The caps of pour bottles must:
- (i) be tamper evident
  - (ii) remove cleanly and be readily replaceable
  - (iii) have no rough, sharp or protruding edges.
- d) Where irrigating fluids are designed for use with an irrigation set, they must be readily compatible with commercially available irrigation sets.
- e) For each Irrigating Fluid product offered, the Respondent shall advise in the Tender Response Worksheet:
- (i) Brand Name
  - (ii) Type of fluid (e.g. aqueous chlorhexidine)
  - (iii) Concentration, expressed as a percentage
  - (iv) Volume in millilitres
  - (v) Packaging:
    - Material (e.g. PVC, glass)
    - Presentation (e.g. pour bottle).
- f) Where Irrigating Fluids are presented in an outer layer of packaging, the Respondent shall advise if the external surface of the inner pack is sterile in the relevant column of the Tender Response Worksheet.

## Category 80,000 - Biopharmaceutical - Filgrastim

### 1.1 Requirements

- a) Unless stated otherwise, all injectable presentations of filgrastim must be single patient use/single dose.
- b) All injectable presentations must be clearly labelled with the:
  - (i) drug name
  - (ii) strength (where applicable)
  - (iii) volume in millilitres
  - (iv) batch number
  - (v) expiry date.
- c) Where an injectable drug is only available in multi-dose, the label must clearly indicate:
  - (i) that the product is for single patient use only
  - (ii) the bacteriostatic agent.
- d) Disposable prefilled syringes must be sterile and presented in a manner that reduces the risk of injury. Preference will be given to disposable prefilled syringes with safety needles.
- e) For each injectable presentation offered, Respondents must identify the presence of latex and/or PVC in the both the product and its accompanying packaging.

### 1.2 Cold Chain

- a) Filgrastim is to be transported in a sealed container that includes ice packs and a thermometer.

### 1.3 Patient Kits

- a) Preference will be given to Respondents who agree to provide patient kits, or any individual component of these packs, free of charge upon request by a Participating Health Service. HPV reserves the right to request physical samples of patient kits from the Respondent.
- b) Patient information packs may include (but are not limited to):
  - (i) travel packs;
  - (ii) patient information materials;
  - (iii) sharps containers;
  - (iv) thermometers; and/or
  - (v) ice packs.

## Category 90,000 – Therapeutic Group Approach

A therapeutic group approach describes the competitive tendering of pharmaceutical products with distinct chemical entities, which provide an equivalent clinical effect.

All products offered in this category, with reference to the type of medicine, must comply with the all specifications outlined in Section D – Product Specifications, as appropriate.

### 1 Scope

a) The scope of this category includes the supply of:

- (i) Ephedrine;
- (ii) Tenofovir disoproxil; and
- (iii) Tenofovir disoproxil-emtricitabine.

## E Appendices

### Appendix 1 - Product List

See part 6, Tender Response Worksheet

### Appendix 2 - Critical Care Medicines

This list is referenced from *The Australian Medicines Handbook*

Medicine Class	Medicine Name
IV general anaesthesia	midazolam
	propofol
	thiopental
Inhaled anaesthetics	desflurane
	isoflurane
	methoxyflurane
	nitrous oxide
	sevoflurane
Non-depolarising neuromuscular blockers	atracurium
	cisatracurium
	mivacurium
	pancuronium
	rocuronium
	vecuronium
Depolarising neuromuscular blockers	suxamethonium
Alpha2 and imidazoline agonists	clonidine injectable
	dexmedetomidine
Anticholinergics (anaesthesia)	glycopyrronium
Drugs for reversing neuromuscular blockade	sugammadex
Local anaesthetics	bupivacaine
	levobupivacaine
	lidocaine (lignocaine)
	prilocaine
	ropivacaine
Sympathomimetics	adrenaline (epinephrine)
	dobutamine
	dopamine
	noradrenaline (norepinephrine)
Injectable nitrates	glyceryl trinitrate
Injectable antihypertensives	clevidipine
	diazoxide

Medicine Class	Medicine Name
	hydralazine
	labetalol
	metoprolol
	nimodipine
	sodium nitroprusside
	verapamil
Injectable antiarrhythmics	adenosine
	amiodarone
	atropine
	digoxin
	esmolol
	flecainide
	isoprenaline
	sotalol
Other drugs affecting haemostasis	tranexamic acid
	vitamin K
Prostacyclins	epoprostenol
	iloprost
	treprostinil
Thrombolytics	alteplase
	reteplase
	tenecteplase
	urokinase
Injectable antiepileptics	brivaracetam
	lacosamide
	levetiracetam
	phenobarbital (phenobarbitone)
	phenytoin sodium
	valproate
Injectable antidotes	atropine
	calcium gluconate
	digoxin-specific antibody
	flumazenil
	glucagon hypokit
	naloxone
Drugs for reversing anticoagulation	idarucizumab
Drugs electrolyte imbalance	potassium (injectable)