PART 4: STATEMENT OF REQUIREMENTS

1. Participating Health Services

a. The Participating Health Services for this ITS are

   (i) All 'Public Health Services' (as legislatively defined) referred to in Schedule 1 and Schedule 5 of the *Health Services Act 1988*; and

   (ii) Other relevant participating health and health related organisations as follows:

   - CoHealth
   - St Vincent's Hospital (Melbourne) Ltd
   - Ambulance Victoria
   - Gateway Health
   - Cobden District Health Services
   - Police Department (VIC) (Custodial Health Service only)
   - Woomelang and District Bush Nursing Centre
   - Mercy Hospitals Victoria Ltd
   - Robinvale District Health Services
   - Latrobe Community Health Service
   - Sunraysia Community Health Services Ltd
   - The Department of Health and Human Services Victoria
   - Ballarat Hospice Care Incorporated

b. For a full list refer to ITS document Part 6 Reporting Guidelines

2. Scope

a. The scope of this ITS includes Lenalidomide.

b. The scope of this ITS does not include:

   (i) Patients admitted to Participating Health Services on existing non-awarded lenalidomide therapy, at the sole discretion of the Participating Health Service, deemed unsuitable to transition to awarded Good(s) during that episode of inpatient admission.

3. Product Categories

a. Lenalidomide is required for treatment of patients across Victorian Public Health Services

b. The categories required include:

CATEGORY NUMBER	CATEGORY NAME	SUBCATEGORY NUMBER	SUBCATEGORY NAME
534	LENALIDOMIDE	534.01	LENALIDOMIDE 2.5 MG CAPSULE 14
		534.02	LENALIDOMIDE 2.5 MG CAPSULE 21
		534.03	LENALIDOMIDE 2.5 MG CAPSULE 28
		534.04	LENALIDOMIDE 5 MG CAPSULE 14
		534.05	LENALIDOMIDE 5 MG CAPSULE 21
		534.06	LENALIDOMIDE 5 MG CAPSULE 28
		534.07	LENALIDOMIDE 7.5 MG CAPSULE 14
		534.08	LENALIDOMIDE 7.5 MG CAPSULE 21
		534.09	LENALIDOMIDE 7.5 MG CAPSULE 28
		534.10	LENALIDOMIDE 10 MG CAPSULE 14
		534.11	LENALIDOMIDE 10 MG CAPSULE 21
		534.12	LENALIDOMIDE 10 MG CAPSULE 28
		534.13	LENALIDOMIDE 15 MG CAPSULE 14
		534.14	LENALIDOMIDE 15 MG CAPSULE 21
		534.15	LENALIDOMIDE 15 MG CAPSULE 28

CATEGORY NUMBER	CATEGORY NAME	SUBCATEGORY NUMBER	SUBCATEGORY NAME
		534.16	LENALIDOMIDE 20 MG CAPSULE 14
		534.17	LENALIDOMIDE 20 MG CAPSULE 21
		534.18	LENALIDOMIDE 20 MG CAPSULE 28
		534.19	LENALIDOMIDE 25 MG CAPSULE 14
		534.20	LENALIDOMIDE 25 MG CAPSULE 21
		534.21	LENALIDOMIDE 25 MG CAPSULE 28

c. The Respondent may offer products in one, some or all categories.

d. HSV reserves the right not to consider any additional products offered.

4. Not Used

5. Product Offering

a. Respondents are required to complete the ITS document Part 7 Tender Response Worksheet.

b. HSV may not consider any product that is subject to a current HSV Agreement, other than those listed below:

   (i) HPVC2019-058 Pharmaceutical Products and IV Fluids

c. Respondents will ensure that each product is offered in only one subcategory. It is the Respondent's responsibility to ensure that each product is submitted in the most appropriate subcategory.

6. Clinical Trials

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

Product Requirements

7. Standards and Compliance

a. All items offered must comply with relevant Australian Standards, Orders, Legislation and Regulations (collectively 'Compliance Requirements'), or their equivalent International Compliance Requirements. Refer to Appendix 2 – Compliance Requirements for a list of the minimum Compliance Requirements.

b. All therapeutic goods offered must be approved by the Australian Therapeutic Goods Administration (TGA), unless exempt. The Respondent must provide evidence of this (i.e. ARTG certificates) in its response. HSV recommends the use of products in accordance to TGA registered indications.

c. The successful Respondent must provide evidence of ARTG certification to Participating Health Services upon request.

d. HSV may consider, at its sole discretion, products tendered with provisional or anticipated ARTG registration for conditional acceptance, where:

   (i) the Respondent provides HSV 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

   (ii) the Respondent commits to informing HSV of changes in planned or actual registration status as soon as the Respondent becomes aware of any such change.

e. HSV reserves the right not to consider products without confirmed ARTG registration at the time of response.

f. For each product offered, Respondents are to advise each product's PBS status.

8. Packaging and Labelling

a. Sterile products will be packaged in a manner that protects the contents from contamination during transportation, storage and handling.

b. All labels must comply with the *Therapeutic Goods Act* 1989 and the *Therapeutic Goods (Medical Devices) Regulations* 2002.

c. Items will be delivered in accordance with the manufacturer's instructions.

d. 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 (or packaging) contains latex or is latex-free; and

   (iv) products should meet the criteria for barcoding as per GS1 standards.

9. Evaluation of Packaging and Labelling

a. For each item offered, Respondents are to provide artwork and/or clear photographic images of the packaging including (where applicable):

(v) All sides of the outer box or container packaging, including dimensions;

(vi) the immediate container, including dimensions;

(vii) both sides of the strip pack (platform packaging), including dimensions; and

(viii) unit doses, including dimensions (where possible).

b. The artwork and/or clear photographic images are to be provided with appropriate resolution, where possible to the following specifications:
   (i) Image format = jpeg or comparable file format viewable using Microsoft Paint
   (ii) Image resolution = Minimum 1024 x 768 pixels excluding white space around packaging/product
c. All packaging submitted must be representative of the packaging and labelling of the product that would be available to Participating Health Services.

10. Substances of Concern

a. Where relevant, it is desirable for products (including their accompanying packaging) that are latex-free, unless otherwise stated.

b. Where relevant, it is desirable for products that are free of diethylhexyl phthalate (DEHP).

11. Product Information

a. Where applicable, the Respondent may submit a copy of relevant product diagrams, specifications or brochures to assist in accurately identifying products offered.

b. Research papers should not be provided unless specifically requested by HSV.

c. All product information submitted should:

   (i) be in electronic format

   (ii) be in English

   (iii) be specific to the product offered

   (iv) contain the Respondent's company name

   (v) include the product code

   (vi) include a detailed specification of the product

   (vii) include clear diagrams/pictures of the product.

d. Electronic copies should include the HSV Category and subcategory numbers in the filename or identifying metadata.

e. Product information will not be evaluated but is necessary to assist in accurately identifying products offered.

f. HSV reserves the right to exclude products from evaluation when the product is unidentifiable and provided information is:

   (i) Is incomplete as to clause c.

g. Product samples are not to be provided unless specifically requested by HSV.

h. The Respondent should not submit information relating to products that are not called for in this ITS.

12. Risk Minimisation

a. 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:

(i) Ability to distinguish between look alike and sound alike (LASA) products;

(ii) Ability to differentiate between strengths of the same generic medicine or different generic medicines packaged in corporate livery;

(iii) Product appearance and packaging that minimises risk of administration by the wrong route;

(iv) 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;

(v) 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-TallMan-Lettering-List-Nov-2017.pdf;

(vi) Labelling that does not include unsafe abbreviations, for example “ug” for microgram, “u” or “iu” for units;

(vii) vii. 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;

(viii) Products (including their accompanying packaging) that are latex-free;

(ix) Products that are free of phthalate content, particularly diethylhexyl phthalate (DEHP);

(x) Packaging requiring less shelf space; and

(xi) For light-sensitive products, preference may be given to products with light-sensitive packaging per unit dose.

13. Not Used

14. Not Used

15. Recall Process

a. All recalls must be managed in line with the *Uniform Recall Procedure for Therapeutic Goods* (URPTG) (V2.2, December 2019).

b. Within six (6) months of agreement commencement, all recalls and/or hazard alerts will be completed using GS1 Recall OR Recall Health.

c. Class 1 recalls (as defined by the TGA’s *Uniform Recall Procedure for Therapeutic Goods* (URPTG) (V2.1, February 2019)) must also meet the requirements under section Part 5 on Warranty, where applicable.

Pricing

16. Price Variation

a. The maximum Unit Price for each of the Goods from the successful Respondent will be as set out in Schedule 3 of the Draft Deed of Standing Offer Agreement.

b. The maximum Unit Prices must remain fixed for the Term (as defined in Part 1, Clause 2 (a)) and no further adjustment of the Unit Prices shall take place, except:

   (i) as detailed in the price review mechanism set out in Item 9 of the Draft Deed of Standing Offer Agreement Supply Schedule; or

   (ii) as expressly provided otherwise in the Draft Deed of Standing Offer Agreement.

c. The successful Respondent agree to vary the maximum Unit Price where a Good's PBS List Price falls below or increases above the price available under the Draft Deed of Standing Offer Agreement.

d. The successful Respondent must, within 24 hours from when the relevant PBS List Price falls below the Unit Price:

   (i) notify the Organisation of a price variation; and

   (ii) ensure the maximum Unit Price under the Draft Deed of Standing Offer Agreement is no higher than the PBS List Price at any given time except as set out in the Draft Deed of Standing Offer Agreement.

e. Where the PBS List Price increases above the maximum Unit Price, the successful Respondent may submit notice to the Organisation requesting a variation of the maximum Unit Price at no more than the PBS List Price.

f. If the successful Respondent submits a notice, the Organisation must adjust the maximum Unit Price accordingly, to become effective as at the relevant date published in the PBS Schedule.

g. Except as expressly provided otherwise in the Draft Deed of Standing Offer Agreement or any Purchase Order Contract, the maximum Unit Prices for the Goods will be exclusive of GST, "free into store" and include all packaging, transport, insurance, loading, unloading and storage costs, up to the point of delivery of the Goods, including unloading of the Goods at the Delivery Point.

h. The parties may, by mutual agreement, agree on additional delivery terms if the Participating Health Services requires delivery requiring special handling or urgent delivery (other than the conditions set out in item 19 of the Supply Schedule).

i. The successful Respondent must not impose any minimum order charges.

j. If the successful Respondent fails to submit a notification within the timeframe set out in the Draft Deed of Standing Offer Agreement, the Participating Health Service may:

   (i) seek a Reimbursable Expense from the successful Respondent due to the delay in the variation of the Unit Price; or

   (ii) terminate the Order Contract.

k. Any agreed variation to the maximum Unit Price must be in writing.

l. The parties may, by mutual agreement, agree on additional delivery terms if the Participating Health Services requires delivery requiring special handling or urgent delivery (other than the conditions set out in item 20 of the Supply Schedule).

17. Not Used

18. Price review

a. Upon request by the successful Respondent or HSV, a price review in anticipation of a further term under an option review, will be subject to the following:

   (i) will be initiated by HSV or the successful Respondent up to six months prior and agreed by the Contractor and HSV no later than one month before option review;

   (ii) response to pricing review must be submitted in the format requested by HSV and must be completed in full;

   (iii) any changes to the pricing, irrespective of whether it is an increase or reduction must be accompanied with the supporting evidence and justification; and

   (iv) no response by the successful Respondent will be deemed as an acceptance of the current Agreement terms and conditions for the option period term.

b. HSV reserves the right to negotiate price review outcomes with the successful Respondent.

Delivery

19. Electronic Data Interchange

a. The Participating Health Services prefer to exchange orders, payments, acknowledgements, invoices, remittance notices and other records (Data) electronically, in place of tangible documents. Successful Respondents are required to work with the Participating Health Services to achieve this outcome.

20. Delivery

a. Goods will 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 HSV Procurement Portal and/or the Time to Delivery as specified in the Draft Deed of Standing Offer 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.

d. All deliveries are bound as per the Deed of Standing Offer Agreement, clause Acceptance and Rejection of Deliverables.

21. 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 state-wide emergency situations.

b. The Respondent should be able to receive and action urgent delivery requests 24 hours a day, 7 days a week.

c. Urgent deliveries should be received by Participating Health Services within timeframes discussed and agreed with the individual Participating Health Services.

d. Any additional costs associated with Urgent Deliveries shall be clearly outlined in the User Guide tab of the ITS document Part 7 Tender Response Worksheet and shall be discussed and agreed with the ordering health service prior to acceptance of any urgent order.

Support

22. Training

a. Upon request by a Participating Health Service, successful Respondents will deliver a training package and/or training materials to facilitate the introduction of their Deliverables and associated restricted distribution programs to clinicians in their operating environment.

b. Training requirements may include (but are not limited to):

(i) face-to-face training at Participating Health Service sites (i.e. in-service training)

(ii) off-site study days for clinicians

(iii) updates and refresher training on Deliverables

(iv) training materials.

23. 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 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

(iv) available to respond to Participating Health Services' queries

c. It is desirable that nominated Representatives have a clinical background or experience.

d. 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 on-site clinical support (if requested)

(iii) providing informational materials

(iv) providing education and in-service training upon request.

e. Representatives must comply with Participating Health Services' local policies regarding engagement with Participating Health Service staff.

f. It is desirable that Respondents provide operational support with patient and clinician registration to support transition period and migration of relevant restricted distribution program data where applicable.

Award

24. Conditional Acceptance

a. Products may be designated as 'Conditionally Accepted' for the following reasons:

(i) Where products offered are not 'known and accepted' but represent value for money; or

(ii) Where products are inactive and have not been in use for at least 12 months.

(iii) Provisional or anticipated ARTG registration;

(iv) Provisional or anticipated PBS listing; or

(v) Where minimum data information is not provided e.g. UNSPSC code.

b. Products designated as 'Conditionally Accepted' may be subject to desktop and functional evaluation by health services.

c. Pricing will be as per response position and cannot be amended post Agreement acceptance.

25. Key Performance Indicators

a. Refer to Part 5 Draft Deed of Standing Offer Agreement clause 5 and Schedule 1 – Supply Schedule, Item 17.

26. Service Level Agreement

a. Refer to Draft Deed of Standing Offer Agreement clause Service Level Agreement.

27. Transition

a. Noting the operational and clinical complexities associated with Lenalidomide transition, where an award outcome requires a brand transition, Participating Health Services may transition to the awarded Good(s) over the course of up to 3 months from contract commencement, and/or for up to 3 months from acceptance of care for transferred patients from another institution.

(i) Notwithstanding the above clause 27a), patients on lenalidomide therapy prior to contract commencement and/or transferred from another institution on a non-awarded lenalidomide product, that are deemed clinically unsuitable to transition, must transition to the awarded Good(s) as soon as considered clinically suitable.

28. Award Scenario

a. HSV has a strong preference to award category Lenalidomide on a sole supply basis, to the product that best meets the Participating Health Service needs and offers overall best value.

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) with and without: 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 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. Disposable, prefilled syringes must be presented sterile and in a manner that reduces the risk of injury.

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.

3 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.

4 Cold Chain

a. Products to be transported in a sealed container that adequately maintains the product temperature at recommended storage conditions.

b. Where available for cold chain products, Respondents should provide stability data for temperature excursions.

5 Value adds

a. Submitted price(s) should represent Single Trade Unit Price and comply with Part 3 – Clause 5 – Submitted prices.

b. Respondents are encouraged to offer and describe any current or proposed value-adds for products including but not limited to, the provision and maintenance of associated equipment for administration to patients, patient support programs, compassionate access programs and associated transition requisites.

c. Proposed value-adds (if applicable) will form part of the Value for Money Assessment under Part 1 – Clause 8 and will be evaluated in accordance with Part 2 - Clause 21 - Evaluation process.

6 Lenalidomide

a. Product submissions under Category Name Lenalidomide (Category Number: 534) should have:

(i) Product packaging clearly distinguishable between different strengths and different quantity pack sizes.

(ii) Product packaging clearly identifying relevant pregnancy safety warnings such as ‘Do not use if pregnant’ or ‘Potential for human birth defects’.

(iii) Product packaging as a blister package with foil strips as opposed to a bottle.

(iv) Foil blister strips that do not have dummy or false tablet/capsule cavities.

(v) Individual unit doses (tablet/capsule) of different strengths clearly differentiable using visual markers or identifiable print on each unit dose.

b. Must have a TGA approved restricted distribution program to facilitate the clinical supply of Lenalidomide in alignment with current TGA requirements at the time of contract commencement with the following desirable characteristics:

(i) Ability for the users to search and retrieve patient and prescriber details and submit a new verification application

(ii) Drug information, strength and pre-set dosage pre-populated on the verification form

(iii) Upon selecting a product, system should auto filter and show valid strength and pre-set dosage

(iv) Ability for the user to enter "Other" dosage

(v) Vendor to keep drug related information (including but not limited to drug name, strength, and dosage) up to date

(vi) Ability for the verification form to show additional entry fields for woman of childbearing potential (field in software to report result and date of pregnancy test)

(vii) Verification form to capture "Number of capsules dispensed", "Date of dispensing" and "Submitting user"

(viii) Ability for user to enter a reason with no text limitation when managing verification requests outside of standard supply protocols

(ix) System should be able to auto detect and alert clinicians of verification requests outside of standard supply protocols

(x) Ability for user to address issues with dispensing verifications in real time via a Respondent managed support service

(xi) Ability for users from the same Health Service to be able to review one another's verifications and/or records

(xii) Compatibility with Health Services' internet web browser(s) where an internet web-based service is utilised

(xiii) Ability for user to address issues with dispensing verifications after standard business operating hours