21 July 2022

Re: HSV Thalidomide Analogues Restricted Distribution Program general information

Dear suppliers,

The following information provided is relevant to Thalidomide analogues which may require the usage of a restricted distribution program (RDP) in clinical practice.

A RDP is considered a platform or program submitted for approval by the TGA as part of a Risk Management Plan at the time of application for ARTG registration of a specific medicine.

The following information is general information only.

Any information and specifications provided as part of any indicated Invitation To Supply (ITS) activity will supersede the information listed below.

RDP 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 conveniently review one another's recent verifications and/or records

xii. Ability for users from different Health Services to be able to review one another's verifications and/or records

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

xiv. Ability for user to address issues with dispensing verifications after standard business operating hours

xv. Ability to export patient verifications and records in a readable and user-friendly format

Should you have any general questions or queries regarding the general information listed above please direct them to pharmaceuticals@healthsharevic.org.au.

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