SA Health

Use of a Non-Registered Cancer Chemotherapy Protocol Request Form (Single patient use)

URGENCY:			
Treatment within:	24 hours ☐	1-3 days ☐	4-7 days ☐
AND reason for urgency rating:			

1. GENERAL INFORMATION

This form should be used for individual cases where standard chemotherapy is not suitable for patient treatment, for example when a patient has exhausted all standard chemotherapy treatments, or for rare cancers where very little or no standard treatments exists. Use of this form ensures a documented process of review of suitability of treatment.

The following information is required by the authorising officer, before consideration will be given for approval. Failure to complete all details may result in a delay in approval of the protocol and subsequent patient treatment.

Please note:

- The request requires the following sign off to indicate endorsement of the application:
    - The treating consultant
    - A consultant with expertise in the treatment area/tumour stream
    - SA Health Cancer Drug Committee Representative
- A cancer clinical pharmacist can provide advice about and assistance in completing the requirements of this form
- This approval is valid for the use of this Cancer Chemotherapy Protocol for single patient use only and does not supersede local requirements for approval of individual medicines
- The signed, completed forms should be sent to the site cancer clinical pharmacist and the SA Health Cancer Drug Committee (SAHealthCancerDrugCommittee.GenericMailbox@sa.gov.au) for review and recording of use.
- Once a completed request has been received and recorded by SAHCDC it will be forwarded to the ECPS Clinical Support Team for building of a prescription tool.
    - Medication administration order will be built as per eviQ principles unless applicant or evidence provided recommend otherwise.
- Individual medications included in this protocol (eg. non-formulary or high-cost medicines) will require separate authorisation for single patient use via the SA Health Individual Patient Use (IPU) Medicine Request Form.
- If the medicine is not TGA registered, separate applications will need to be made for supply of the medicine (eg. SAS form, Medicines Access forms)
- Subsequent applications for the use of identical Non-Registered Cancer Chemotherapy Protocols may generate a request to submit the protocol through the Cancer Chemotherapy Protocol Approval and Registration process.

1. APPLICATION

1.1. Patient details

Initials:		
URN:	Date of Birth:	Gender: M ☐ F ☐ X ☐
Patient Location (site/hospital)		

1.2. Details of Cancer Chemotherapy Protocol:

Protocol Name: _____

Medication:	Dose	Route	Day

Premedication / Supportive medication:	Dose	Route	Frequency	Day/Timing

Cycle Frequency:
Number of Cycles:

1.3. Indication(s) for use

Define the indication(s) for which an Individual Patient Use of a Non-Registered Cancer Chemotherapy Protocol Approval is being sought:

1.4. Treatment Intent (may select >1 option)

- ☐ Induction
- ☐ Consolidation
- ☐ Disease modification
- ☐ Curative - aim to permanently eradicate disease
- ☐ Palliative - Aiming to extend life expectancy
- ☐ Palliative - Aiming to relieve and/or control malignancy-related symptoms
- ☐ Palliative - Aiming to achieve remission
- ☐ Palliative - Aiming to delay tumour progression
- ☐ Other: _____
- ☐ Not Known

1.5. Evidence to support use of protocol for proposed indication

Evidence to justify treatment eg. BCCA protocol, publication, specialist group consensus statement, appropriate guidelines. Please provide full text copy of the supporting evidence/literature especially if off label use or not TGA approved

1.6. Applicant Details

Applicant Name:	
Position:	
Clinical Unit, hospital	
Telephone 1:	Telephone 2:
Mobile:	Pager:
e-mail:	

CONFLICT OF INTEREST DECLARATION

Do you have any financial or other conflict resulting from involvement with pharmaceutical companies, which have a bearing on this submission:

No ☐

Yes ☐ → If Yes, tick relevant box and complete explanation below:

Conference funding ☐ Gifts ☐ Travel Expenses ☐ Samples ☐

Honoraria ☐ Industry paid food/refreshments ☐ Research Support ☐

Other (see below) ☐

→ Please provide a brief but clear description of each potential conflict:

I declare, that to be best of my knowledge, all of the information contained in this application is true and accurate.

Applicant Signature_____ Date:

If applicant is not the Treating Consultant responsible for the patient;

Treating Consultant Name:

Signature:_____ Date:

Telephone Number: Pager:

Email:

2. AUTHORISATION

1.7. Authorisation by Consultant with expertise in the therapeutic area

Name:
Signature:_____ Date:

1.8. Authorisation by SA Health Cancer Drug Committee Representative

Name:
Signature:_____ Date:

2. PHARMACY USE INFORMATION

Cytotoxic or hazardous substance If yes was a risk assessment completed	Yes ☐ No ☐ Yes ☐ No ☐ N/A ☐
List precautions: Signature:_____	
Entered in ipharmacy	Yes ☐ No ☐ N/A ☐
Entered in IPU database	Yes ☐ No ☐ N/A ☐
Stock ordered	Yes ☐ No ☐ N/A ☐
Applicant informed of outcome	Yes ☐ No ☐ N/A ☐
Dispensary/Production Informed	Yes ☐ No ☐ N/A ☐
Clinical Pharmacist Informed	Yes ☐ No ☐ N/A ☐
Name:	
Signature:_____ Date:	