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 signature of a consultant with expertise in the treatment area and a SA Health Cancer Drug Committee Representative must be obtained to indicate endorsement of the application
* A specialist 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 specialist clinical pharmacist and the SA Health Cancer Drug Committee (SAHealthCancerDrugCommittee.GenericMailbox@sa.gov.au) for review and recording of use. **This may should occur before the Non-Registered Cancer Chemotherapy Protocol is required, but within 5 working days of the Protocol being authorised.**
* SAHCDC will forward information regarding approvals to local LHN committees responsible for governance of chemotherapy and/or Drug and Therapeutic Committees by arrangement.
* **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 (e.g. 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. **Patient details**

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

* 1. **Details of Cancer Chemotherapy Protocol:**

|  |
| --- |
| Protocol Name: |

|  |  |  |  |
| --- | --- | --- | --- |
| Drugs  | Dose | Route | Day |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Premedication / Supportive medication: | Dose | Route | Day |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |
| --- |
| Cycle Frequency: |
| Number of Cycles: |

* 1. **Indication(s) for use**

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

* 1. **Evidence to support use of protocol for proposed indication**

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| Evidence to justify treatment e.g. BCCA protocol, publication, specialist group consensus statement, appropriate guidelines. Please provide literature attached if off label use or not TGA approved |

* 1. **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: |

1. **AUTHORISATION**
	1. **Authorisation by Consultant with expertise in the therapeutic area**

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| --- |
| Name: |
| Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: |

* 1. **Authorisation by SA Health Cancer Drug Committee Representative**

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| --- |
| Name: |
| Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: |

1. **PHARMACY USE INFORMATION**

|  |  |
| --- | --- |
| Cytotoxic or hazardous substanceIf 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: |