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SOUTH AFRICAN
ONCOLOGY
CONSORTIUM

APPLICATION FOR INCLUSION ONTO THE GUIDELINES Administrative Information Application Form

Pharmaceutical companies may submit applications for inclusion of therapies into the existing SAOC Treatment Guidelines.

Process

Submissions are to be addressed to the Chairman, SAOC URC Committee.

Submissions will be reviewed by the URC Committee taking into account the SAOC URC Guidelines and the objectives of the SAOC.

E-mail submissions and application form to maryke@saoc.org.za

a) Particulars of the Applicant/Company (Invoice Purposes)

<i>Company Name:</i>	
<i>Business address:</i>	
<i>Postal address:</i>	
<i>Telephone no:</i>	
<i>Fax no:</i>	
<i>E-mail address:</i>	
<i>VAT number</i>	

SOUTH AFRICAN ONCOLOGY CONSORTIUM LIMITED Reg Nr 2001/011467/06c)

Directors: **G Demetriou (Chair); D Chetty; B Green; K Gunther; B Rapoport; W Szpak; M Vaithilingum; SD Moodley**

"The SAOC strives to ensure that the care of all patients with cancer is of a high standard and quality and is appropriate to the individual needs of all patients, while taking into account available resources."

<i>Person responsible for Submission Information</i>	
<i>Name:</i>	
<i>Telephone no:</i>	
<i>E-mail address:</i>	

b) Particulars of the Oncology Drug

Product	
<i>Proprietary name:</i>	
<i>Pharmacological classification:</i>	
<i>Dosage form:</i>	
<i>Approved name(s):</i>	
<i>Strength(s) per dosage unit:</i>	
<i>Descriptive name of Biological medicine:</i>	
<i>Route of administration:</i>	

Guidelines for Pharmaceutical Company Applications for SAOC Treatment Guideline Inclusions**Format**

The application must be in writing.

Details included in the application should include but are not limited to:

1. The indication applied for should be specified in detail e.g. Disease – metastatic breast cancer indications
 - a) First-line treatment of metastatic breast cancer in hormone-refractory patients with prior exposure to anthracyclines in the adjuvant setting;
 - b) First-line therapy of metastatic breast cancer in hormone-refractory patients where anthracyclines are contra-indicated.
2. The regimen with dosages and costs for a 1.8m² patient. Costs should include the costs of expected supporting medications e.g. anti-emetics and growth factors.
3. Cost per cycle and total cost of treatment plus cost including supporting treatment
4. A summary of available evidence supporting the application. All supporting data referred to in the summary should be attached.
5. A summary of the existing registered indications for the specific drug by the MCC, the FDA, and the European Regulatory Agency.
6. Package insert of the proposed product

7. Numbers needed to treat
8. Summary of budget impact assessment (analysis)
9. A brief summary of why patients need this treatment
10. Comparison between available treatment modality and the proposed treatment in terms of cost and clinical efficacy
11. Please indicate how the requested product should read in the guidelines
12. Is the product on EML and what is the Tender price?

Requirements for Submission

Regulatory approval: The therapy should be registered by the MCC, FDA and the European Regulatory Agency for the indication applied for.

Level of evidence: Level 1 evidence should be available and published. Where conflicting study results or controversy exists, this should be indicated and other supporting data providing “proof of concept” submitted e.g. the use of taxanes in adjuvant breast cancer. In exceptional cases showing clear and compelling benefit above the current standard of care, unpublished data e.g. major congress presentations, will be considered. In such instances the slides presented should be submitted, as well as supporting level 2 evidence.

c) Declaration and signature

The undersigned hereby declare that it is understood that an administration fee will be levied for the review of submissions. This administration fee is levied per drug submitted. This fee does not guarantee inclusion onto the guidelines.

It is hereby confirmed that administration fees will be paid within 30 days of invoice issued and proof of payment will be sent to accounts@saoc.org.za

.....
Applicant Signature

.....
Date of application

.....
Name and Designation