health
Department:
Health
REPUBLIC OF SOUTH AFRICA

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Tel (012) 395 8000, Fax (012) 395 8918

EXEMPTION REQUEST FORM SUBMITTED TO THE PRICING COMMITTEE IN TERMS OF SECTION 36(2) OF THE MEDICINES AND RELATED SUBSTANCES ACT 101 0F 1965, AS AMENDED

NB: All exemption requests must be lodged by a company registered with the South African Health Product Regulatory Authority (SAHPRA) as the owner of the medicine(s) concerned. Where the medicine is not yet registered in South Africa, the applicant must have obtained a Section 21 permit from SAHPRA prior to submitting an exemption request. Should a Section 21 permit be unavailable, the applicant must provide reasons for lodging the application. The latter must be in a cover letter to be submitted together with this application form.

Competitor: For purposes of this submission the term competitor shall refer to all alternative medicines used for the indication specified under 3.5 and 3.6

1. APPLICANT DETAILS

1.1 Company / organisation name (Organization responsible for lodging the application)	
1.2 Company registration number (SAHPRA licence to be included where applicable)	
1.3 Physical Address	
1.4 Postal Address	
1.5 Telephone Number	
1.6 Facsimile	
1.7 Responsible Pharmacist (RP) Name (where applicable for SAHPRA registered company)	
1.8 RP Mobile Number (where appliable)	

1.9 Representative Name / Contact person	
1.10 Representative / contact person email address / Telephone number	

2. MANUFACTURER / SUPPLIER

NB: This section to be completed where the applicant for exemption is not the owner / manufacturer / supplier of the product/ s for which exemption is applied.

2.1 Company / organisation name	
2.2 Company registration number (SAHPRA licence to be included)	
2.3 Physical Address	
2.4 Postal Address	
2.5 Telephone Number	
2.6 Facsimile	
2.7 Responsible Pharmacist (RP) Name	
2.8 RP Mobile Number (where appliable)	
2.9 Representative Name / Contact person	
2.10 Representative / contact person email address / Telephone number	

3. SUBMISSION DETAILS

3.1 Applicable Section of the Medicines and Related Substances Act 101 of 1965, as amended for which an exemption is sought	*Please mark with an "X" where appropriate*		
	Section 22G	**Section 18A**	**Both Section 22G and 18A**
3.2 Description of the nature of exemption sought ***(e.g. duration and number of patients to be covered in the exemption, should it be granted. Reasons for the exemption application must be included in this section)***	*The description of the nature of the exemption sought may be included as an annexure to this form*		
	3.3.1 Is the medicine registered	YES	NO

3.3 Registration status of affected medicine(s) and availability status in the public sector *(Mark with an X where applicable)*	3.3.2 The medicine is available in State facilities	YES	NO

3.4 Medicine(s) details	**Medicine Name**	**Active Ingredient (s)**	**Dosage Form**	**Applicant name responsible for the medicine (must be registered with SAHPRA)**
	e.g. a) Item 1			
	b) Item 2			
	c) Etc.			

3.5 Medicine Indication(s)	
3.6 Are there any alternative competitor medicines available in the South African market for the indication (s) listed under 3.5 above (Yes/No)	**NB: If yes, attach an annexure / appendix with the list of competitor medicine(s) and their manufacturer(s)*
3.7 Proposed exemption / treatment duration (Commencement and end dates)	

3.8 Number of patients expected to be impacted / involved and location - Province	*(Specify patient location i.e. whether State, Private or both)*		
		No of patients	**Province**
	Public Sector		
	Private sector		

3.9 Details of patient eligibility criteria	
3.10 Implications should the application be unsuccessful	
3.11 Details of patient obligations (if any) should the exemption be granted, including monetary value of any non-drug costs or payment due by the patient or patient's medical scheme	
3.12 Expected duration of treatment	

3.13 Name and address of treating physician *(if more than one, attach an appendix with details of all the clinicians involved)*	

4. LIST OF SUBMITTED DOCUMENTS

Type of Document	Yes / No
4.1 Cover letter addressed to the Pricing Committee chairperson c/o Director: Pharmaceutical Economic Evaluations	
4.2. Annexure with list of competitors (to include manufacturer names) of medicines identified in section 3.4 of this application	
4.3 Study protocol approved by SAHPRA: Yes / No (where applicable)	
4.4 Section 21 permit issued by SAHPRA (where applicable)	
4.5 Statement of consent from the Trial primary investigator(s) (where applicable)	
4.6 Statement of consent from the applicant (manufacturer) representative *(as listed under section 2.4 of this application form)*	
4.7 Other (Please specify)	
4.8 NAME AND SIGNATURE OF APPLICANT REPRESENTATIVE ***(applicant is the organization responsible for this application)***	
DATE:	

4.9 NAME AND SIGNATURE OF RESPONSIBLE PHARMACIST OF THE MANUFACTURER FOR THE MEDICINE(S) LISTED UNDER 3.4	
DATE	

Application form and cover letter to be addressed as follows:

The Pricing Committee chairperson
c/o NM Mpanza
Director: Pharmaceutical Economic Evaluations Directorate
National department Health
Private Bag X828, PRETORIA, 0001

NB: Closing date for applications/ submissions: 30 September each year; no late applications/submissions shall be considered by the Pricing Committee. The outcome of the decision made by the Minister regarding this application will be published on the Department or Health website or any other platform, to ensure transparency.

Applications must be emailed to sepupdates@health.gov.za and cc'd to Ntobeko.mpanza@health.gov.za and mahlogonolo.ledwaba@health.gov.za

NB: All Single Exit Price (SEP) related Submissions must be submitted electronically via email at sepupdates@health.gov.za. No hard copy documents will be received. Submissions lodged in terms of Section 36 of the Medicines and Related Substances Act are for approval by Minister of Health.