ANNEXURE B

Application to the Provincial Pharmacy and Therapeutics Committee (PPTC)
Western Cape Government Health

1. All questions must be answered fully.
2. Applications must be received by the PPTC secretariat at least 6 weeks before the relevant PPTC meeting.
3. All applications must be approved by the appropriate District / Regional / Divisional Pharmacy and Therapeutics Committee (PTC).
   Please note: the application must be signed by the chairperson of the District / Regional / Divisional PTC.
4. An economic appraisal of the proposed medicine must be conducted. This should reflect direct and indirect costs as well as a cost-benefit assessment.
5. A motivator-generated summary of the key references must be included in the application (see 4.3.3 below).
6. The following factors will be considered during the evaluation of an application:
   a. The quality of the evidence presented.
   b. The evidence must be outcome based (where appropriate) and be relevant to the indications for which the medicine is requested.
   c. Local context.
   d. Comparisons with other currently available treatment options.

1. Details of the medicine requested

Approved name or International Non-proprietary Name (INN) i.e. generic name	
Trade name (s)	
Manufacturer (s)	
ATC pharmacological classification	
Is the medicine registered with the MCC for this indication?	☐ Yes ☐ No
Presentation / dosage form (tablets / injection / syrup)	
Strength (s)	
Usual *dosage* & *duration* of treatment course	
Is the medicine on the current COMED tender?	☐ Yes ☐ No
Cost per course / month (incl. VAT). If not on tender, a written quotation must be obtained from the company.	

2. Coding status

2.1. Coding status	Current	Proposed
General code	☐	☐
Specialist initiated	☐	☐
Specialist	☐	☐
Specialist defined / specific clinic	☐	☐
Restrictions, please specify:		
Not coded	☐	

2.2. List the proposed clinical indication (s) for the medicine in the Western Cape.
1.
2.
3.
4.

2.3. Indicate the proposed level of prescribing of the medicine for the above indications.	
☐ Clinical Nurse Practitioner	☐ Specialist / Consultant
☐ Medical Officer	☐ Specific clinic
☐ Registrar	Please specify: _____

3. Medicine utilisation

3.1. List the institutions in the Western Cape that will require the medicine.

3.2. Estimate the annual number of patients who will use this medicine in the Western Cape.

4. Supporting evidence

4.1. State the clinical justification for the inclusion of this medicine on the WCGH code list.

4.2.1. List ALL other available medicines within the same pharmacological class as the requested medicine.

4.2.2. List the medicines currently on the WCGH code list with the indications described in Section 2.2.

Medicine	Indication	Regimen e.g. 12 hourly	Duration	Cost per course/month (incl. VAT)	Can the proposed medicine replace this medicine?		
					Yes	No	Possibly
					☐	☐	☐
					☐	☐	☐
					☐	☐	☐
					☐	☐	☐
					☐	☐	☐

4.3. Attach full motivation and supporting literature which must include:

1. The MCC-approved package insert.
2. Approximately 3 key references: electronic and hard copies of peer-reviewed supporting studies e.g. original trials, systematic reviews, or meta-analysis published in acceptable medical journals.
3. A motivator-generated summary of the references included (see point2 above) and cost effectiveness (which includes value for money, prevention of hospitalisation, duration of hospital stay) of the requested medicine (as described in the references provided), compared with the medicines mentioned in 4.2.1 and 4.2.2.

5. Essential Drug List (EDL/EML)

5.1. The medicine requested is:	
☐ Not listed on the EDL / EML	☐ Listed on the Primary EDL/EML (green)
☐ Listed on the Adult: Hospital EDL/EML (yellow)	☐ Listed on the Paediatric: Hospital EDL/EML (purple)

5.2. If not listed on the EDL/EML can this item replace another item on the EDL/EML?		
☐ Yes	☐ No	☐ Not applicable
If yes, give details:		

5.3. Will the Current Standard Treatment Guidelines in the appropriate EDL/EML(s) need to be amended?	
☐ Yes	☐ No
If yes, please attach appropriate evidence-based guidelines to support the rational use of the medicine. (If no guidelines are available, please draft suitable guidelines.)	

6. Declaration

	Yes	No
6.1. Have you ever used samples of the medicine requested?	☐	☐
6.2. Have you ever used the medicine in a clinical trial or assessment?	☐	☐
6.3. Have you ever attended a conference with sponsorship from the manufacturers of the requested medicine within the last two years?	☐	☐
6.4. Have you or your department received funding, grants, or any equipment or supplies from the manufacturers for the medicine within the last two years?	☐	☐
If you answered 'yes' to any of the above questions, please attach full details.		

Date		Name		Signature	

7. Details of motivator

Motivation prepared by:			
Title		Hospital/ institution	
Name		Telephone number	
Designation		Email address	
Department		Fax number	
Signature		Date	
For completion by Medical Superintendent of the above hospital / institution (if applicable):			
☐ Approved		☐ Not approved	
Signature		Date	

8. Approval by District / Regional / Divisional Pharmacy and Therapeutics Committee – for submission to the PPTC

For completion by the Chairperson of the District / Regional / Divisional Pharmacy and Therapeutics committee: This request has been discussed by the District / Regional / Divisional Pharmacy and Therapeutics Committee and is:			
☐ Approved		☐ Not approved	
Title		Telephone number	
Name		Email address	
Designation		Fax number	
Signature		Date	

9. Support by Provincial Pharmacy and Therapeutics Committee

For completion by the Chairperson of the Provincial Pharmacy and Therapeutics Committee:			
☐ Supported		☐ Not supported	
Signature		Date	