



GURU NANAK RAMGARHIA SIKH HOSPITAL

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GNRSH/PHAR/FM/016

PHARMACY & THERAPEUTICS COMMITTEE NEW DRUG FORMULARY APPLICATION FORM

For completion by medical representative / supplier. Attach supporting evidence where indicated. Complete forms to be sent to ptc@gnrsh.co.ke

1. APPLICANT & PRODUCT DETAILS

Submission / Company	Date: _____ Company: _____
Representative	Name: _____ Phone: _____ Email: _____
Medicine	Brand: _____ Generic (INN): _____
Product details	Therapeutic class: _____ Dosage form: _____ Strength(s): _____
Pack / supplier	Pack size(s): _____ Manufacturer / Supplier: _____

2. REGULATORY STATUS

Kenya registration	☐ Registered ☐ Pending ☐ Not registered PPB Reg. No.: _____
Other status / guidance	☐ FDA ☐ EMA ☐ MHRA ☐ WHO prequalified Major guideline(s): _____
Market experience	Years marketed globally: ☐ <1 ☐ 1-3 ☐ 4-10 ☐ >10

3. CLINICAL NEED & PLACE IN THERAPY

Indication(s)	Primary: _____ Secondary: _____
Target / setting	Population: _____ Setting: ☐ OPD ☐ IPD ☐ ICU ☐ ED ☐ Other
Place in therapy	☐ First-line ☐ Second line ☐ Later-line ☐ Rescue ☐ Adjunct
Current formulary option(s)	Comparator(s): _____
Why add this medicine?	☐ Better efficacy ☐ Better safety/tolerability ☐ Lower cost ☐ Adherence/convenience ☐ Unmet need ☐ Other
Expected clinical benefit	☐ Major improvement ☐ Moderate improvement ☐ Minor improvement ☐ Comparable

4. EVIDENCE & SAFETY SUMMARY

Highest evidence	☐ Systematic review/meta-analysis ☐ Multiple RCTs ☐ Single RCT ☐ Observational ☐ Other
Key outcome(s)	☐ Mortality ☐ Morbidity ☐ Symptoms/QoL ☐ Hospitalization ☐ Disease progression ☐ Other
Safety / warnings	Common adverse effects: _____ Serious/boxed warning: ☐ No ☐ Yes

Contraindications / interactions	Contraindications: ☐ No ☐ Yes Interaction risk: ☐ Low ☐ Moderate ☐ High
Monitoring required	☐ None/minimal ☐ LFT ☐ Renal ☐ CBC ☐ ECG ☐ Drug levels ☐ Other: _____
Evidence attached	☐ Key clinical studies ☐ Comparative evidence ☐ Safety data

5. ANTIMICROBIAL STEWARDSHIP - COMPLETE FOR ANTI-INFECTIVES ONLY

Classification	☐ Antibiotic ☐ Antifungal ☐ Antiviral ☐ Not applicable Spectrum: ☐ Narrow ☐ Moderate ☐ Broad
Stewardship considerations	Resistance risk: ☐ Low ☐ Moderate ☐ High Culture/sensitivity guidance: ☐ Yes ☐ No

6. COST, PROCUREMENT & SUPPLY

Price	Cost/unit: KSh _____ Cost/course: KSh _____ vs current option: ☐ Lower ☐ Similar ☐ Higher
Budget impact	☐ Cost saving ☐ Cost neutral ☐ Increased cost Estimated difference / annual impact: _____
Availability / reliability	Availability: ☐ Immediate ☐ <1 month ☐ 1-3 months ☐ Special order Supplier reliability: ☐ Good ☐ Fair ☐ Unknown
Storage / supply risk	Cold chain: ☐ No ☐ Yes Shelf life: _____ Stock-out risk: ☐ Low ☐ Moderate ☐ High

7. SUPPORTING DOCUMENTS

- ☐ Product monograph / package insert ☐ PPB registration certificate ☐ Key clinical evidence ☐ Safety data ☐ Price quotation / pharmacoeconomic information
☐ Storage & supply information

8. APPLICANT DECLARATION

Declaration	I certify that the information provided is accurate, current, and supported by available scientific evidence.
Representative	Name: _____ Signature: _____ Date: _____

9. FOR PHARMACY & THERAPEUTICS COMMITTEE USE ONLY

Submission check	☐ Complete ☐ Incomplete / return for additional information Reviewed by: _____ Date: _____
Clinical value	☐ High ☐ Moderate ☐ Low
Safety	☐ Acceptable ☐ Acceptable with monitoring/restrictions ☐ Further review required
Cost-effectiveness	☐ Favorable ☐ Neutral ☐ Unfavorable ☐ Insufficient data
Formulary decision	☐ APPROVED ☐ APPROVED WITH RESTRICTIONS ☐ DEFERRED ☐ REJECTED
Restrictions / conditions	_____ _____
Committee comments	_____ _____
Chair / authorization	Chair name: _____ Signature: _____ Date: _____

Kindly Note: Committee decision should be recorded in the meeting minutes and formulary updated where applicable. Complete forms to be sent to ptc@gnrsh.co.ke