**LETTER OF REQUEST FOR MINOR INCLUSION**

Date

Honorable \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Secretary

Department of Health

ATTENTION: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Chair, Core Committee

 Health Technology Assessment Council

SUBJECT: Proposal for INCLUSION of **[*NAME OF SPECIFIC HEALTH TECHNOLOGY*; indicate if new dosage strength, net content or immediate packaging for a medicine listed in the formulary]**

Dear Secretary \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_:

The **[indicate name of office, affiliation or company]** proposes the inclusion of **[indicate name of proposed health technology, applied indication, and if new dosage strength, net content or immediate packaging for a medicine listed in the formulary]** in the Philippine National Formulary.

Please find attached **two (2) hard and/or soft copies** of each of the following documents:

1. **Accomplished proposal form, including all appropriate tables;**
2. **FDA-approved product information**
3. **Approved indication in source country and/or stringent regulatory bodies (i.e., US FDA)**
4. **Local Clinical Practice Guidelines (CPG) indicating the potential place of the proposed intervention (with the proposed dosing schedule) in the treatment pathway (preferred)**
	* **If not available, provide a locally adopted international CPG with a certification from the relevant medical society or the hospital’s Pharmacy & Therapeutic Committee (PTC) as proof of the local adoption.**
5. **Letter from the society or Pharmacy and Therapeutics Committee justifying the intended benefits, safety and cost.**

The electronic copy of the documents is sent to hta@doh.gov.ph. We acknowledge that incomplete and/ or late submissions will not be processed.

The HTAC may request additional documents or evidence.

*[Indicate any additional remark]*

Respectfully yours,

**PROPONENT’S NAME**

Designation

Name of Office

Email address, telephone and fax number

*\*If a certificate of exemption is issued by the Phil FDA, a certification from regulatory bodies in the US, European Union, Japan, Canada, Australia or CE mark must be submitted.*

*\*\*Additional documents such as technical specifications may be requested to the proponent if the technology is prioritized. A Non-disclosure agreement will be requested if needed.*

PROPOSAL FORM

# SECTION 1.

| Supplier/Manufacturer details and contact information |
| --- |

| Name of Supplier/Manufacturer |  |
| --- | --- |
| Affiliation |  |
| Company Address |  |
| License to Operate/Registration No. (if applicable) |  |
| Country of Origin (if applicable) |  |

### PRIMARY CONTACT DETAILS

| Name: |  |
| --- | --- |
| Affiliation: |  |
| Position/Designation: |  |
| Email address: |  |
| Telephone no.: |  |
| Mobile no.: |  |
| Postal address: |  |

### ALTERNATE CONTACT DETAILS

| Name: |  |
| --- | --- |
| Affiliation: |  |
| Position/Designation: |  |
| Email address: |  |
| Telephone no.: |  |
| Mobile no.: |  |
| Postal address: |  |

# SECTION 2.

| General information on the proposed inclusion |
| --- |

| GENERIC NAME |  |
| --- | --- |
| BRAND NAME (if any) |  |
| THERAPEUTIC CLASSIFICATION |   |
| FOR PNF - LISTED MEDICINES: |  |
| **Current Dosage Strength  Proposed Dosage Strength** |
|  |  |
| **Current Net Content  Proposed Net Content** |
|  |  |
| **Current Immediate Packaging  Proposed Immediate Packaging** |
|  |  |
| **Current Listed Indication  Applied Indication** |
|  |  |
| MANUFACTURER |  |
| IMPORTER/TRADER |  |
| DISTRIBUTOR |  |

# SECTION 3.

| Summary of justification for inclusion |
| --- |

| Please tick the appropriate box/es: | Concise justification comparing New Medicine and Listed Medicine in the PNF |
| --- | --- |
| * New or proposed dosage strength or net content has a risk-benefit profile comparable to or better than a currently listed medicine;
 |  |
| * New or proposed dosage strength or net content has a cost-effectiveness profile better than or comparable to a currently listed medicine;
 |  |
| * New or proposed dosage strength, net content or immediate packaging will improve compliance;
 |  |
| * New or proposed dosage strength or net content will improve product stability and overall quality.
 |  |

# SECTION 4.

| Details of cost analysis (attach Evidence Table) |
| --- |

| PARAMETER(Indicate information for intended recipient)\* | NEW MEDICINE/ PROPOSED INDICATION/ FORMULATION/ ROUTE OF ADMINISTRATION | CURRENTLY LISTED MEDICINE FOR SAME INDICATION IN THE PNF | REFERENCES |
| --- | --- | --- | --- |
| **COST PER DOSAGE UNIT** (in PHP) |  |  |  |
| NUMBER OF DOSAGE UNITS PER UNIT COURSE |  |  |  |
| TOTAL DIRECT COST PER PATIENT PER TREATMENT COURSE(in PHP) |  |  |  |
| ADDITIONAL COST PER PATIENT PER TREATMENT COSTS(in PHP)1. **Implementation costs:**

*(Cost of drug administration, monitoring, additional diagnostic services, additional equipment, travel, caregiver, etc.)*1. **Intervention costs:** *(Management of adverse drug reactions)*
 |  |  |  |
| TOTAL COST PER PATIENT PER TREATMENT COURSE(in PHP) |  |  |  |
| EXPECTED NUMBER OF PATIENT-TREATMENT COURSES PER YEAR |  |  |  |

\*Cost of medicine based on Suggested Retail Price (SRP).