## HTA Minor Inclusion Track Requirements for Drugs and Vaccines Listed in the Philippine National Formulary (PNF)

## General Instructions for the Minor Inclusion Nomination Dossier

* Below are the requirements that make up a complete minor inclusion application dossier for drugs and vaccines. This entire file shall provide the templates of the requirements as listed below.

| **Requirements** | **Details**  |
| --- | --- |
| 1 | Cover Letter |
| 2 | HTA Minor Inclusions Track Nomination Form  |
|
|
|
|
|
|
| 3 | Attachments to the nomination form3.a. Copy of Philippine Food and Drug Administration (FDA) Certificate of Product Registration (CPR) 3.b. Product insert showing that it is approved by the Philippine FDA or any other supplementary document certifying the approval of the package insert3.c. DOH-approved Clinical Practice Guideline (CPG) or locally-adopted CPG by the relevant medical society*In the absence of CPGs: Endorsement letter from DOH-affiliated hospitals or medical societies* |

* Should you have any other queries or concerns or should you require assistance in accomplishing this form, please contact the Technical Secretariat of the HTA Division at telephone numbers (02) 8875-7734 local 260 or 8937-5314 or email at htanominations@dost.gov.ph.

In compliance with Republic Act 10173 (Data Privacy Act of 2012), all personal information provided by the topic nominators shall remain private in accordance with the applicable laws of the country.

The HTA Process Guide defines which type of information is subject to guidelines on information and data handling which requires Non-Disclosure Agreement (NDA).

# COVER LETTER

Date

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

Secretary

Department of Science and Technology

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

 Chairperson

 Health Technology Assessment Council

SUBJECT: Nomination for Minor Inclusion of **[NAME OF SPECIFIC DRUG OR VACCINE]**

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

The **[*indicate name of hospital/society/organization/facility/unit/office*]** 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 2 electronic copies (1 copy in a flash drive and 1 copy uploaded in Google Drive) of each of the following documents:

1. Accomplished HTA Minor Inclusions Track Nomination Form, including all appropriate tables;
2. Soft copies of the full text articles of all cited references in the form
3. Philippine Food and Drug Administration (FDA) Certificate of Product Registration (CPR) *[Note: If CPR is monitored release, please provide at least one (1) published or unpublished results of Phase IV trial or real-world studies on its clinical effectiveness and safety in other settings]*
4. Product insert showing that it is approved by the Philippine FDA or any other supplementary document certifying the approval of the package insert
5. Local or locally-adopted Clinical Practice Guidelines (CPG) indicating the potential place of the proposed intervention (with the proposed dosing schedule) in the treatment pathway (preferred)

*Note: If not available, letter from the DOH-affiliated hospitals or medical societies justifying how the proposed addition to the PNF listing can address gaps of the currently listed form of this drug or vaccine (e.g., using the new form will improve patient compliance as it will need less number of tablets compared to the form currently listed; using the new form can be more accessible since it requires simpler storage requirements compared to the form listed in the PNF)*

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

The HTA Council may request additional documents or evidence.

Respectfully yours,

**TOPIC NOMINATOR’S NAME AND SIGNATURE**

Designation

Name of Health Facility/ Institution/ Organization/ Company

Indicate email address, telephone and fax number

# Minor Inclusion Nomination Form

* *Topic nominators are requested to fill out the entire form.* ***If the requested information is not relevant to the health technology of interest, please state N/A (not applicable).***
* *For those questions requiring evidence in the form of illustrations, attach the evidence as separate items when submitting this form.*
* *All submitted evidence/documents are subject to review and appraisal of the HTA Council.*
* *Topic nominators are asked to identify commercially-sensitive information in their submission that should not be made public. It must be noted, however, that data publication shall still be in accordance with existing laws and policies of the country which require transparency in all government transactions.*

### SECTION 1.

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

| Name of Organization/Company/Society |  |
| --- | --- |
| 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 |   |
| *Please fill out the applicable row in the table below synthesizing your proposed additional PNF listing. If the information required is not applicable to your application, please write “N/A.”* |
| PNF - LISTED DRUG/ VACCINE | **NOMINATED DRUG/ VACCINE** |
| **Current Dosage Strength  Proposed Dosage Strength** |
|  |  |
| **Current Net Content  Proposed Net Content** |
|  |  |
| **Current Immediate Packaging  Proposed Immediate Packaging** |
|  |  |
| **Current Pack Size/Volume Proposed Pack Size/Volume**  |
|  |  |
| **Any other change that will not result in significant difference in terms of bioavailability and meaningful clinical outcomes with PNF-listed drug (specify)** |
|  |  |
| **Current Listed Indication  Applied Indication** |
|  | Is the applied indication the same as the currently listed Philippine FDA-approved indication in the Philippine National Formulary (PNF)?* Yes
* No

Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 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;
 |  |
| * Other changes that will not result in significant difference in terms of bioavailability and meaningful clinical outcomes with PNF-listed drugs.
 |  |

### SECTION 4.

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

| PARAMETER(Indicate information for intended recipient)\* | NEW PROPOSED FORM FOR MINOR INCLUSION | CURRENTLY LISTED FORM OF THE MEDICINE IN THE PNF | REFERENCES |
| --- | --- | --- | --- |
| **UNIT PRICE**(in PHP) |  |  |  |
| TREATMENT REGIMEN FOR PER TREATMENT COURSE*(e.g., X units for X times a day, for X days)* *or***COMPLETE VACCINATION SCHEDULE***(e.g. X doses, starting at age X, X days/weeks/years apart)* |  |  |  |
| NUMBER OF UNITS PER TREATMENT/ VACCINATION COURSE |  |  |  |
| TOTAL DRUG OR VACCINE COST PER PATIENT PER TREATMENT/ VACCINATION COURSE(in PHP) |  |  |  |
| ADDITIONAL COST PER PATIENT PER TREATMENT/ VACCINATION COURSE(in PHP)1. **Implementation costs:**

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

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

### ATTACHMENTS

|  Philippine FDA CPR |
| --- |
| *Provide a copy of the valid Philippine FDA CPR* |
|  Philippine FDA-approved product insert  |
| *Provide a copy of the FDA-approved product insert.* |
| DOH-approved Clinical Practice Guideline (CPG) or locally-adopted CPG by the relevant medical society (if not available: Endorsement letter from DOH-affiliated hospitals or medical societies) |
| *Provide a copy of the DOH-approved Clinical Practice Guideline (CPG) or locally-adopted CPG by the relevant medical society or endorsement letter from DOH-affiliated hospitals or medical societies* |
|  Other Relevant Documents/References |
| *Provide list and actual copies of the references.* |