

Republic of the Philippines

Department of Health

OFFICE OF THE SECRETARY

### **ADMINISTRATIVE ORDER March 20, 2012**

No.\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SUBJECT : Revised Implementing Guidelines for the Philippine National**

**Formulary System (PNFS)**

1. **RATIONALE**

The 1987 Philippine Constitution mandates the right of every Filipino to health. It enunciates the policy that “the State shall protect and promote the health of the people and instill health consciousness among them” (Article II Section 15). Furthermore, it provides the adoption by the State of an “integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services accessible to all the people at affordable cost” (Article XII Section 15).

To support these goals, several policies and laws have been passed. These include Republic Act No. 6675 known as the Generic Act of 1988 that was enacted to “ensure the adequate supply of drugs with generic names at the lowest possible cost”. It further states that “in the promotion of the generic names for pharmaceutical products, special consideration shall be given to drugs and medicines which are included in the Essential Drugs List to be prepared within one hundred eighty (180) days from approval of this Act and updated quarterly by the Department of Health on the basis of health conditions obtaining in the Philippines as well as on internationally accepted criteria.”

Executive Order No. 49 (dated 21 January 1993, entitled ”Directing the Mandatory Use of the Philippine National Formulary Volume I as the Basis for Procurement of Drug Products by the Government”) strengthened the advocacy of the Generics Act by ensuring that only essential drugs identified in their generic names will be procured by all government institutions.

Administrative Order No. 163 s. 2002 (entitled “Implementing Guidelines and Procedures in the Procurement and Requisition of Drugs and Medicines by the Department of Health pursuant to Executive Order No. 49”) provides the procedural bases that ensure requisition of essential drugs by the Government sector and the decision system for the inclusion and deletion of drugs in the Philippine National Drug Formulary (PNDF).

The Philippine Health Insurance Corporation (PHIC) Board Resolution No. 265 (dated 15 July 1999) likewise provides that the PNDF Volume I shall be the basis for claims reimbursements for medicines.

The more recent RA 9502 enacted in 2007 provides additional power to the President of the Philippines to impose, upon the recommendation of the Secretary of Health, maximum retail prices over medicines that include, among others, the “drugs and medicines that are included in the Philippine National Drug Formulary Essential Drug List.”

The Philippine National Drug Formulary continues to serve as the national reference for quality and rational selection of the medicines which are vital in achieving the best health outcomes. Given the importance of the PNDF in the attainment of universal access to quality essential medicines, the systems, procedures and processes to formulate and update it needs to be reviewed and enhanced.

1. **OBJECTIVES**

This issuance aims to**:**

* 1. Describe the new systems and procedures for:
     1. the selection of medicines to be included in or deleted from the Essential Drug List hereafter referred to as the National Essential Medicines list;
     2. the development of a new format of the Philippine National Formulary that integrates all three volumes of the previous PNDF which are: National Essential Medicines List, the Formulary Monographs and the Cross-Reference Index, and which shall be referred to as the PNF Manual; and
     3. the promotion of the use of the formulary among the different levels of healthcare managers and providers and the consumers.
  2. Reconstitute the Formulary Committee and describe the implementation arrangements of the Philippine National Formulary System (PNFS).

1. **SCOPE**

This Order shall be applicable to all health facilities, units and offices of the entire government sector insofar as drug procurements are concerned and shall be applicable to the entire health sector (both government and private) insofar as the Philippine Health Insurance Corporation claims for drug reimbursements are concerned**.**

1. **DEFINITION OF TERMS**
   1. ESSENTIAL MEDICINES- These are medicines that satisfy the priority health care needs of the population and which are selected based on the evidence of their efficacy, safety and comparative cost-effectiveness. These medicines shall be made available and affordable. The prioritization of the health care need shall be based on the burden of the disease.

Essential medicines are classified into:

* + 1. CORE MEDICINES – These are the most efficacious, safe and cost-effective medicines for priority diseases and other priority health care needs. These are intended to be available at all times in adequate quantities in appropriate dosage forms and at the lowest possible cost.
    2. COMPLEMENTARY MEDICINES– These are medicines used:
       - 1. as alternatives when medicines in the core list are ineffective or inappropriate for a given individual or when core medicines cannot be made available;
         2. for priority diseases for which specialized diagnostic or monitoring facilities and/or specialized medical care, and/or specialized training are needed;
         3. for non-prevalent diseases that are life-threatening (i.e., likely to cause death if untreated) or that are disabling (i.e., likely to cause permanent disability if untreated);
         4. for diseases or conditions prevalent in a special sector of the population; and
         5. for diseases that are endemic in a particular area or for diseases confined in a limited setting at a given time.

1. **GENERAL GUIDELINES**
   1. The new edition of the Philippine National Drug Formulary shall be referred to as the Philippine National Formulary (PNF) with its inputs, processes and outputs collectively referred to as the Philippine National Formulary System (PNFS).
   2. The Formulary Committee shall be reconstituted and hereafter referred to as the Formulary Executive Council (FEC).
   3. The PNFS shall be operationalized through the FEC with assistance from independent Evidence Review Groups (ERG’s) and a pool of Specialty Experts. The National Center for Pharmaceutical Access and Management (NCPAM) through its Policy and Planning Division shall provide secretarial support to the FEC.
   4. The PNF shall be developed and updated using the Formulary Selection Algorithm which shall describe the step-by-step selection procedure to be employed in determining the medicines to be included in or deleted from the formulary.
   5. For a medicine disapproved for inclusion in the PNF, interested parties may submit an application for reconsideration provided that new or additional data on the medicine is presented. The FEC may consider holding a public forum when deliberating on the reconsiderations.
   6. All evidence summaries, proceedings of meetings of the FEC and the decisions of the Secretary shall be published in the DOH-NCPAM website.
   7. The FEC shall conduct periodic reviews of the formulary with assistance from the ERG or the specialty experts as needed.

H. The PNF Manual shall include the following: the Guidelines on the Rational Use of Medicines, the National Essential Medicines List, the Formulary Monographs and the Cross-Reference Index.

* + - 1. The previously named PNDF Volumes 1-3 (Essential Medicines List, Formulary Monographs and Cross-reference Index) shall cease to exist as independent publications. Together with succinct guidelines on the Rational Use of Medicines, the content of these previous volumes shall be integrated into a concise PNF Manual.
      2. The PNF Manual shall be published upon the recommendation of the Assistant Secretary or Undersecretary of Health in charge of NCPAM and the approval of the Secretary of Health in accordance with the prescribed timelines established in the Generics Act of 1988 and the Cheaper Medicines Act of 2008. The NCPAM shall be responsible for the cost of dissemination and publication of the PNF Manual.

I. Only medicines listed in the PNF Manual shall be procured by all government entities in accordance with Executive Order No. 49 s. 1993. However, exemptions may be granted upon submission of a written request with justification and subject to the approval of both the NCPAM Program Director as embodied in the aforementioned issuance and the FEC. Approval by the FEC will be based on prescribed criteria.

J. The PNF Manual shall be reviewed and updated regularly in accordance with established timelines as provided in RA 6675.

K. The PNF Manual shall be made available in downloadable format from the DOH and NCPAM website.

L. Medicines withdrawn from the Philippine market due to safety reasons shall be deemed delisted from the PNF Manual effective on the date of the order for withdrawal by the Food and Drug Administration.

M. The FEC shall recommend to the NCPAM guidelines for a more comprehensive dissemination of the PNF. Monitoring of the dissemination and use of the formulary manual will be conducted regularly by the NCPAM.

N. The FEC shall recommend to the NCPAM guidelines in the monitoring and evaluation of the PNF.

1. **SPECIFIC GUIDELINES** 
   1. **Formulary Executive Council**
      1. Composition and Qualifications:
         1. The Formulary Executive Council (FEC) shall consist of eleven (11) members representing the scientific and societal perspectives that influence the selection and use of medicines. It shall have as members respected individuals whose collective expertise shall cover the fields of pharmacology, toxicology, clinical epidemiology, pharmacy, clinical medicine, public health, health economics, health social science and law and medicine.
         2. The FEC shall have a Chairperson selected by the Secretary of Health from the eleven members. The chair shall hold his/her position for a period not exceeding three (3) years.
         3. The other members of the committee shall also have terms of three (3) years each.
      2. Disclosure of Conflicts of Interests:

The FEC Chairperson and members shall conform with the principles of integrity and shall therefore declare all circumstances with real or potential conflicts of interests and shall comply with the policy set up for declaring and managing such.

* + 1. Specific Functions:
       1. The FEC shall identify the diseases for which medicines need to be included in the formulary based on a continuing review of disease statistics from public and private hospitals and other health facilities, advice from the different specialty societies and input from the programs and offices of the Department of Health and other stakeholders. The selection of these diseases shall be based on their burden, i.e., their frequency and severity. The frequency of disease shall be measured by its prevalence or incidence. Disease severity shall be determined by disability-adjusted life years (DALY) or, in its absence, a consensus of experts.
       2. The FEC shall identify the diseases for which medicines will be listed in the different levels of healthcare.
       3. The FEC shall deliberate on whether the applications will require further expert evaluation by the Evidence Review Groups (ERG) following the criteria it has approved. The FEC then reviews applications for medicines that will not require further evaluation by the ERG and recommend inclusion, deletion or exemption.
       4. The FEC shall forward requests for medicines that it has determined as requiring further evaluation to one of the Evidence Review Groups (ERG) for review. The ERG, through its consultants, shall prepare an evidence summary (ES) considering the set of criteria for inclusion in the Formulary. These criteria will include the medicine's efficacy, risk-benefit assessment and cost-effectiveness assessment that are to be based on systematic review of the medical literature and other references such as clinical practice guidelines and post-marketing surveillance data.
       5. The FEC shall prepare a recommendation based on the evidence summary prepared by the ERG, position papers of the stakeholders and the input of the relevant specialty consultants. All recommendations will be submitted to the Assistant Secretary or Undersecretary of Health in charge of NCPAM, who after review of the recommendation, will then forward this to the Secretary of Health for approval.
  1. **Evidence Review Groups**
     1. Compositions and Qualifications:
        1. The Evidence Review Groups (ERG) will be composed of experts in Clinical Epidemiology or Evidence-Based Medicine.
        2. Qualifications of an evidence review expert are:
           1. Completion of participation in at least one (1) Evidence Based Medicine workshop under a recognized consultancy group;
           2. Active practice or teaching of evidence-based medicine;
           3. Willingness to declare and manage conflicts of interests; and
           4. Willingness to sign the contract of service.
     2. Functions:

The evidence review experts are tasked as necessary by the FEC to review and analyze the results of benefit and safety evaluations of medicines obtained from controlled clinical trials and sound epidemiologic studies.

* 1. **Pool of Specialty Experts**
     1. Composition and Qualifications:

They are specialty experts in various clinical and related disciplines with relevant years of experience and distinction in their fields appointed by the Secretary of Health to assist the FEC when the need arises.

* + 1. Functions:
       1. They shall provide expert opinion regarding a particular medicine;
       2. They shall review and assist in the formulation of relevant clinical guidelines;
       3. They shall provide assistance in the formulation of systems and procedures.
  1. **Specific Guidelines for the Formulary Selection Algorithm**
     1. The FEC shall ensure that each medicine considered for inclusion in the PNF shall be initially assessed based on its quality, efficacy, safety and cost-effectiveness.
        1. The FDA shall provide the initial necessary data to the FEC to this effect, i.e. records of all medicines registered in the Philippine market covered with a Certificate of Product Registration (CPR). The FDA shall likewise provide data on whether the medicine is already in the Philippine market or is still in the process of being registered.
        2. In the event that an application for inclusion of a medicine disapproved by the FEC (due to unsatisfactory therapeutic efficacy or safety reasons where the toxicity or suspected toxicity, potential for abuse and dangerous interactions of the medicine outweigh its therapeutic value) has already been registered with the FDA for market entry, the FEC shall recommend the revocation of its CPR to the Secretary of Health through the Assistant Secretary or Undersecretary of Health in charge of NCPAM. Likewise, if registration of a disapproved medicine is still under process, the FEC shall recommend denial of such application for CPR through the same channels. The FEC shall attach all justifications for such recommended actions.
        3. Medicines not registered in the Philippine market may still be considered for inclusion in the PNF provided they satisfy the criteria for inclusion and can be modified to adapt to local conditions when necessary. Bases for selection will include data obtained from the drug regulatory agency of the country where the medicine is marketed or the certification that it conforms to the provisions of the ASEAN Harmonization.
     2. The FEC shall review the list of medicines in the PNF on a quarterly basis. At least two (2) weeks before the end of each quarter, the FEC shall submit to the Assistant Secretary or Undersecretary of Health in charge of NCPAM the recommended medicines for inclusion in or deletion from the PNF. Such shall be published in the DOH - NCPAM website, upon the approval of the Secretary of Health, in the month succeeding the end of each quarter.
     3. **Bases for medicine selection** will include the following:
        1. Burden of disease that will be measured by its frequency, as indicated by its prevalence or incidence, and by its severity, as indicated by its disability-adjusted life years (DALY) or, in its absence, a consensus of experts;
        2. Efficacy and safety that will be based on objective results and on adequate pharmacological studies including at least Phase III clinical trials;
        3. Pharmacoeconomic analysis of drug therapy/ treatment regimen that will consider not only therapeutic effects but also adverse events and quality economic evaluations;
        4. Appropriateness to the capability of health workers at different levels of health care, taking into consideration the level of expertise required for prescribing, administering and monitoring the safety and adverse effects of the medicines as well the competence of local personnel in making a correct diagnosis; and
        5. Local health problems when concomitant or prevalent diseases or conditions in a special population or in a particular setting may influence pharmacokinetic and pharmacodynamic parameters and modify therapeutic responses.
     4. For **medicines belonging to the same pharmacologic class**, the following preferential factors shall be used in choosing the best possible medicine:
        1. The medicine is the most thoroughly investigated and therefore the best understood with respect to its beneficial properties and limitations;
  2. The medicine possesses clinical utility for the treatment of more than one condition or disease;
  3. The medicine has the most favorable pharmacokinetic properties, e.g., factors promoting better compliance or leading to lesser risk in various pathophysiological states;
  4. The medicine has dosage forms that are easy for the health staff to dispense or that are easily and safely administered to the patient;
  5. The medicine is easy for the patient to take or has greater acceptability among most patients;
  6. The medicine and its dosage forms have favorable stability under the anticipated local conditions in storage facilities;
  7. The medicine is produced in local, reputable manufacturing facilities.

1. The medicines should be formulated as single compounds. **Fixed-ratio combinations** are acceptable only when:
   1. The value of concomitant use of more than one medicine is rational and clinically documented;
   2. ***Plus*** any one of the following:
      * + 1. The therapeutic benefit of the combination is greater than the sum of each of the individual components.
          2. The combination is safer than the use of an individual medicine.
          3. The cost of the combination product is less than or should not exceed the cost of the sum of the individual products.
          4. Compliance is improved.
2. **Criteria for inclusion of new medicines** in the PNF are as follows:
   1. The medicine is needed for the prevention and treatment of conditions not yet covered in the existing list;
   2. The medicine is more effective and/or less toxic than, but, is at least of the same price as another medicine listed for the same indication;
   3. The medicine is of lower cost than, but, is at least as effective and as safe as another medicine listed for the same indication; and
   4. The medicine is deemed essential for a specific DOH health program/project.
3. The **Core List** of the PNF shall include medicines of proven quality, efficacy and safety that have fulfilled ***any*** of the following criteria:
   1. The medicine is the most efficacious, safest and most cost-effective medicine indicated for a priority disease or priority health care need in the Philippines;
   2. The medicine indicated for a priority disease or condition belongs to a pharmacologic class that is not yet included in the PNF;
   3. The medicine indicated for a priority health condition or disease for which there is already one or more therapeutically-equivalent medicines listed in the PNF fulfills ***all*** of the following criteria:
      * + 1. It has a favorable risk-benefit ratio;
          2. It is cost-effective;
          3. It has been thoroughly investigated or used extensively in the clinical setting;
          4. It has favorable pharmacokinetic properties, e.g., factors that improve compliance or allows easy administration; and
          5. It is stable under anticipated local conditions, i.e., it has favorable data from accelerated and long-term studies.
4. The **Complementary List** of the PNF shall include medicines of proven quality, efficacy and safety that will fulfill ***any*** of the following criteria:
   1. The medicine is used as an alternative when the core medicines are ineffective or inappropriate for a given individual or when core medicines cannot be made available;
   2. The medicine is used for priority diseases for which specialized diagnostic or monitoring facilities and/or specialized medical care and/or specialized training are necessary;
   3. The medicine is indicated for a non-prevalent disease that is life-threatening (i.e., likely to cause death if untreated) or disabling (i.e., likely to cause permanent disability if untreated);
   4. The medicine is indicated in diseases or health conditions that are prevalent in a special sector of the population; and
   5. The medicine is indicated for a disease that is endemic in a particular area or confined in a limited setting at a given time.
5. **Criteria for the exclusion or deletion of medicines** from the PNF are as follows:
   1. The medicine has been withdrawn from the FDA registry due to safety reasons;
   2. A more effective or equally effective but less toxic drug becomes available;
   3. In the light of further knowledge, the therapeutic efficacy of the medicine is found to be unsatisfactory;
   4. Toxicity, suspected toxicity, potential for abuse and dangerous interactions outweigh the medicine's therapeutic value;
   5. The medicine has fallen into disuse;
   6. The medicine is no longer deemed cost-effective compared to other therapies; and
   7. The medicine is a fixed-dose combination that does not satisfy the requirements of A.O. 96 s.1990 and the prescribed criteria of the FEC.
6. **Exemptions**
   1. AO No. 163 s. 2002 states that only medicines listed in the PNDF shall be procured by all government entities. Requests for exemptions will be considered provided the following documents are submitted:
      * + 1. Justification for the request;
          2. Scientific evidence of the medicine’s efficacy and safety supported with literature;
          3. Report on the disease burden and its ranking relative to the common diseases seen in the community or health facility;
          4. For non-emergent situations, a comparison of costs for the total regimen of the medicine or its full course of therapy with other comparable medicines listed in the current edition of the PNF Manual; and
          5. Copy of Certificate of Product Registration from the FDA or proof that the medicine has conformed with the World Health Organization Certification Scheme on Quality of Pharmaceutical Products Moving in International Commerce.
   2. FEC members will deliberate on the request with the approval of such based on ***all*** of the following criteria:
      * + 1. The medicine will be used for a national health program ***or*** for a current or potential urgent health situation, where urgent is defined as requiring immediate action to prevent death, permanent disability or a major or irreversible organ dysfunction;
          2. The medicine has proven safety and efficacy; and
          3. The approval for the request shall only be effective for the duration of the national health program or until the urgent health situation has passed or has been adequately addressed.
   3. **Documentation and Forms**
      1. The FEC, for purposes of documentation shall accomplish the following forms. These will include:
         1. PNF Form No. 5 (Evaluation Form for Inclusion of New Medicines, Indications, Formulations and Route of Administration in the PNF – *Major Inclusions*) which is hereto appended as Annex E for all medicines evaluated for inclusion in the PNF. This form shall be chronologically numbered as they are accomplished and shall be logged in an official logbook. PNF Form No. 5 shall have the following data elements:

Date when the Form was accomplished

Serial No. of the Form

Generic Name

Therapeutic Classification

Indication

Dosage Form/Strength

Route of Administration

Manufacturer

Importer/Trader

Distributor

Compliance Checklist

Evidence Table

Recommendations

1. PNF Form No. 6 (Evaluation Form for Inclusion of New Dosage Strength, Net Content and Immediate Packaging of Medicines – *Minor Inclusions*) which is hereto appended as Annex F for all medicines with new dosage strength, net content and packaging and chronologically numbered as it is accomplished and logged in an official logbook. It shall contain the same data elements as PNF Form No. 1.
2. PNF Form No. 7 (Evaluation Form for Deletion of Medicines from the PNF) hereto appended as Annex G for all medicines evaluated for deletion from the PNF. It shall be chronologically numbered as it is accomplished and logged in an official logbook. It shall contain the same data elements as PNF Form No. 1.
3. PNF Form No. 8 (Evaluation Form for Exemption of Medicines from A.O. No. 163 s. 2002) hereto appended as Annex H for all medicines evaluated for exemption. It shall be chronologically numbered as it is accomplished and logged in an official logbook. It shall contain the same data elements as PNF Form No. 1.
4. Duly accomplished PNF Forms No. 5,6,7 and 8 shall be appended to the Chronological Summary of Drugs to be Included In or Deleted from the PNF ( PNF Form No. 10 ) that shall be submitted quarterly by the FEC if there is any. It is hereto attached as Annex J. It shall likewise be chronologically logged in a separate record book. The PNF Form 10 shall have the following data elements:

Date of accomplishment;

Covered Quarter;

Name of the Assistant Secretary or Undersecretary of Health in charge of NCPAM to whom the summary report is addressed;

Column for the chronological numbering of medicines that were evaluated;

Column of the chronologically listed generic name of medicines that were evaluated together with their dosage form, strength, route of administration;

Column for the general recommendation for inclusion, deletion or exemption;

Proponent for the application for inclusion, deletion of exemption of the medicine;

Column for the Proponent’s main reason for inclusion or deletion or exemption recommendation on a subject medicine;

Column of the FEC’s action on the request. Such may mean concurrence with the Proponent’s argument or the denial of the request;

Signature/s of the FEC Members and Chairperson or his designee.

* + - 1. The FEC on a quarterly basis shall likewise submit an Alphabetical Summary of the Drugs for Inclusion/ Deletion (PNF Form No. 11) hereto appended as Annex K. It shall have similar data elements as that of PNF Form 10, except that the medicines are alphabetically instead of chronologically listed.
      2. The NCPAM, as FEC Secretariat, shall maintain copies of the duly accomplished PNF Forms and shall maintain a database system that shall be linked with the DOH’s Health Commodities Reference Standards Information System (HCRIS).
  1. **Facilitation of Request for Inclusion or Deletion of Medicines in the PNF**
     1. The following individuals or parties, hereto referred as the proponents, may request for inclusion or deletion of medicines, indications, formulation, route of administration, dosage strength, net content and immediate packaging as well as for exemptions: FEC members; Units, Offices and Health Facilities directly under the supervision of the DOH and Health Facilities under the Local Government Units (LGUs); pharmaceutical establishments; and others such as health professionals, members of the academe, non-government organizations, professional societies, officers or staff of health facilities, patient organizations and consumers.
     2. The proponents shall submit Letters of Requests and accomplish the appropriate Proposal Forms prescribed by the FEC. These are the following forms:
        + 1. PNF Form No.1 (Letter of Request and Proposal Form for New Medicine, Indication, Formulation and Route of Administration – *Major Inclusions*) hereto appended as Annex A.
          2. PNF Form No. 2 (Letter of Request and Proposal Form for New Dosage Strength, Net Content and Immediate Packaging – *Minor Inclusions*) hereto appended as Annex B. It shall contain the same elements as PNF Form No. 1.
          3. PNF Form No. 3 (Letter of Request and Proposal Form for Deletion of Medicine from the PNF) hereto appended as Annex C. It shall contain the same elements as PNF Form No. 1.
          4. PNF Form No. 4 (Letter of Request and Proposal Form for Exemption from A.O. 163 s. 2002) hereto appended as Annex D. It shall contain the same elements as PNF Form No. 1.
     3. The proponents shall likewise submit two (2) hard and soft copies each of the following documents required by the FEC, to wit:
        1. Accomplished proposal form;
        2. FDA Certificate of Product Registration and colored photograph or video of product;
        3. FDA-approved product information;
        4. FDA certificate of good manufacturing practice;
        5. Evidence Tables for Clinical Efficacy and Safety Profile and Cost-Effectiveness Analyses

when applicable.

* + 1. Proposal Forms shall include the following:
       1. General information on the medicine;
       2. Specific request;
       3. Summary of justification for request;
       4. Appendices that show scientific proofs or evidences such as studies and scientific journal articles and entries and other accepted legal documents that would justify the inclusion, deletion or exemption of the medicine under review. The scientific proofs or evidences should be summarized in an Evidence Table, copies of which will be attached to the Evaluation Forms;
       5. Details of clinical efficacy and safety profile;
       6. Details of cost-effectiveness analysis when applicable.
    2. Medicines that are deemed essential for a specific DOH health facility or are for specific DOH program/project must be explicitly certified as essential by the DOH requesting unit. These medicines shall be given priority for evaluation by the FEC. The certificate should be submitted by the DOH unit concerned together with the accomplished appropriate PNF Forms and all the necessary proofs, including an Evidence Table.
    3. Pharmaceutical establishments which intend to accomplish Proposal Form No. 1 shall be likewise required to execute an agreement that the same shall submit a monthly inventory and price report on the drugs that they are requesting to be included in the PNF. A database shall be set-up by the NCPAM to ensure electronic submission of the said data requirement.
    4. The FEC, upon receipt of the Letter of Request and Proposal Form duly classified by the Secretariat, shall proceed with the deliberation on the request.
  1. **PNF Formats and Publication**
     1. The PNF Manual shall consist of integration of the following:
        1. National Essential Medicines List;
        2. Formulary Monographs;
        3. Cross-Reference Index.
     2. The Formulary lists the medicines according to Therapeutic Categories and classifies these as Core or Complementary Medicines. The following information will be provided for each medicine:
        1. Generic name;
        2. Brief pharmacodynamic and pharmacokinetic data;
        3. Accepted indications;
        4. Contraindications;
        5. Precautions;
        6. Adverse reactions;
        7. Clinically significant drug interactions;
        8. Weight and/or age specific dosage recommendations and dose adjustments for patients with renal or hepatic disease;
        9. Preparations available in the Philippine market;
        10. Other recommendations regarding proper intake.
     3. Succinct guidelines on the safe and rational use of medicines for the management of the priority diseases will be included.
     4. A List of Primary Care Medicines for all Rural Health Units shall be appended to the PNF Manual.
     5. The Cross-Reference Index includes:
        1. Instructions on the Use of the PNF;
        2. Symbols and abbreviations;
        3. Index of generic names, trade names and categories.
     6. The PNF Manual shall be reviewed every quarter. Updates shall be posted in the DOH website. Such shall be considered as an integral part of the currently published PNF. Publication of hardcopies of PNF Manual shall be on an annual basis, subject to the availability of funds and the usual accounting and auditing rules and regulations.

1. **IMPLEMENTATION ARRANGEMENTS**
   1. **Office of the Secretary**

The Secretary of Health shall make the final review and shall approve or disapprove the recommendations of the Undersecretary or Assistant Secretary on the PNF.

* 1. **Undersecretary or Assistant Secretary**

The Assistant Secretary or Undersecretary of Health in charge of NCPAM shall provide oversight functions to the FEC.

* 1. **Formulary Executive Council**
  2. The FEC shall establish the systems and procedures of the PNFS.
  3. The FEC shall review all applications submitted for inclusion in or deletion from the PNF or exemption from A.O. No. 163 s. 2002 and make appropriate recommendations to the concerned Undersecretary or Assistant Secretary.
  4. **Evidence Review Groups** (ERG’s) will be requested by the FEC as necessary to prepare the evidence summaries pertaining to the medicines under FEC deliberation.
  5. A **pool of specialty experts** on various disciplines may be called upon by the FEC to provide input during the FEC deliberations.
  6. The **NCPAM** through its Policy and Planning Division shall provide technical and administrative secretariat support to the FEC.
  7. A **representative** from the FDA, the NCPAM, the Philippine Health Insurance Corporation (PHIC), Research Institute for Tropical Medicine (RITM) and other agencies that may be deemed necessary by the FEC chairperson or the Secretary of Health may be called upon to serve as resource persons during FEC deliberations.
  8. The **following Bureaus and Centers of this Department** are instructed to fully support the PNFS and comply with the provisions stated in Executive Order No. 49 as applicable:

The Food and Drug Administration (FDA) shall provide the necessary technical input and essential data requirements such as relative availability of drugs in terms of inventory, prices and market authorizations to the FEC and its Secretariat.

Philippine Health Insurance Corporation (PHIC) – shall condition the use of the PNF as the basis for payments of in-patient and out-patient benefits schemes for medicines and in the accreditation of health facilities and pharmacies for drug reimbursements.

Research Institute for Tropical Medicine (RITM) – shall provide timely information on the trends in resistance rates of antibiotics to microorganisms and latest researches in the prevention, diagnosis and treatment of tropical diseases including vaccines for the control of vaccine-preventable diseases of public health importance.

National Center for Disease Prevention and Control – shall provide information on trends of diseases being monitored by its different offices: (a.) Infectious Disease Office (IDO) (b.) Degenerative Disease Office (DDO) (c.) Family Health Office (FHO) (d.) Environmental and Occupational Health Office (EOHO). It shall likewise promote the use of PNF in all its programs specifically ensuring thatmedicinesused in the Standard Treatment Guidelines or CPG’s are those listed in the PNF*.*

National Center for Health Facilities Development – shall ensure that public health facilities through their DrugTherapeutic Committees (DTC’s) comply with the mandatory use of the PNF. It shall also assist in monitoring compliance with PNF use in health facilities.

Bureau of Health Facilities and Services – shall ensure that the tool in licensing public and private health facilities include compliance with the mandatory use of the PNF.

Health Human Resource Development Bureau (HHRDB) – shall work with the association of medical and paramedical colleges and the Philippine Regulatory Commission (PRC) to integrate the use of the PNF into the pre-service curricula and the in-service training/education and CME courses.

COBAC/MMD – shall ensure the use of PNF as basis for objective, transparent and efficient processes in the DOH procurement and distribution of medicines.

Center for Health Development – shall implement and monitor the mandatory use of PNF in its procurement. It shall also report and give feedback on the status of PNF use in their areas of jurisdiction.

* 1. This Department shall closely coordinate with the Department of Interior and Local Government (DILG) to ensure compliance with the mandatory use of PNF in the procurement of medicines by LGU’s and to assist the DOH in the monitoring and evaluation of the use of the PNF.
  2. The Local Government Units (LGU’s) shall comply with the use of PNF by their Bids and Award Committees (BAC) in the procurement of medicines for government institutions, facilities and shall submit reports to the DOH on the monitoring and evaluation of the use of the PNF in LGU’s.
  3. Government entities including Government Owned and Controlled Corporations and those under public-private partnership arrangement with these agencies shall comply with the mandatory use of PNF in procuring medicines.
  4. The Commission on Audit (COA) shall ensure the use of PNF as the basis for the procurement of medicines by all government agencies.

1. **MANDATORY USE OF THE PNF**
   1. All pharmaceutical establishments and health facilities must have a copy of the PNF. The PNF shall be the basis of the drug establishment’s in-patient counseling and shall be used in giving consumer advice when information about essential medicines is demanded. Such shall form part of the essential documentary requirements that shall be monitored by FDA for purposes of issuing or renewing their License to Operate (LTO) in the Philippine market.
   2. Only medicines that are reflected in the PNF Manual can be requisitioned in the procurement of medicines by all government agencies, i.e. national government agencies and the health facilities under their supervision, government health facilities under the supervision and control of the DOH, devolved health facilities under the Local Government Units and Government Owned and Controlled Corporation.
   3. Every Requisition and Issue Slip (RIS) and Procurement Request (PR), including purchases in times of emergency and authorized under the General Appropriations Act, shall be accompanied by a certification from the requisitioning officer or by the duly authorized officer that the products being requisitioned and procured fall within and conform with the latest edition of the PNF Manual.
   4. Medicines not reflected in the latest edition of the PNF Manual may still be procured as long as these are approved by the Secretary of Health for inclusion in the upcoming edition of the PNF and if such products are already posted in the DOH website. Medicines approved for inclusion in an upcoming edition of the PNF Manual must be covered with the appropriate Department Memorandum and other instruments of announcements.
   5. Only medicines listed in the PNF manual shall be considered for reimbursement or subsidy by the Philippine Health Insurance Corporation (PHIC) for the entire health sector – government and private.
   6. Medical practitioners and all potential end-users shall avail of a copy of the PNF Manual or download it from the DOH or NCPAM website.
2. **COORDINATING INSTRUCTIONS AND TRANSITORY PROVISIONS**
   1. The present members of the National Formulary Committee shall serve as the incoming members of the Formulary Executive Council until such time as determined by the Secretary of Health, upon the recommendation of the Assistant Secretary or Undersecretary of Health in charge of NCPAM.
   2. The NCPAM shall coordinate with the Commission on Audit so that auditors/heads of auditing units shall monitor compliance thereto and shall disallow claims/reimbursements either from regular budget, local/trust funds covering the procurements of drugs and medicines which are not within the latest edition of the PNF.
   3. The NCPAM shall conduct an Information, Education and Communication (IEC) campaign targeting all drug establishments, within one (1) year from the effectivity of this Order to ensure smooth compliance.
   4. Any violation in the compliance of this Order may be subject to the penalties provided in Section 12 of RA 6675.
3. **ANNEXES**
   1. Annex A – PNF Form No. 1 (Letter of Request and Proposal Form for New Medicine, Indication, Formulation and Route of Administration- Major Submissions)
   2. Annex B – PNF Form No. 2 (Letter of Request and Proposal Form for New Dosage Strength, Net Content and Immediate Packaging – Minor Submissions)
   3. Annex C – PNF Form No. 3 (Letter of Request and Proposal Form for Deletion of Medicine from the PNF)
   4. Annex D – PNF Form No. 4 (Letter of Request and Proposal Form for Exemption from A.O. 163 s. 2002)
   5. Annex E - PNF Form No. 5 (Evaluation Form for Inclusion of New Medicines, Indication, Formulation and Route of Administration in the PNF – Major Submissions)
   6. Annex F - PNF Form No. 6 (Evaluation Form for Inclusion of New Dosage Strength, Net Content and Immediate Packaging of Medicines Listed in the PNF– Minor Submissions)
   7. Annex G – PNF Form No.7 (Evaluation Form for Request for Deletion of Medicines from the PNF)
   8. Annex H – PNF Form No. 8 (Evaluation Form for Request for Exemption from A.O. No. 163 s. 2002)
   9. Annex I – PNF Form No. 9 (Evidence Table)
   10. Annex J – PNF Form No. 10 (Chronological Summary of Medicines to be Included in or Deleted from the PNF)
   11. Annex K – PNF Form No. 11 (Alphabetical Summary of the Medicines to be Included in or Deleted from the PNF)
   12. Annex L – Selection of Medicines for Retention in or Deletion from the PNF
   13. Annex M – Selection of New Medicines for Inclusion in the PNF
   14. Annex N – Selection of Core and Complementary Medicines to be listed in the PNF
   15. Annex O- Evidence Summary
4. **SEPARABILITY CLAUSE**

If any provision in these Guidelines, or application of such provision to any circumstance, is held invalid, the remainder of these Guidelines shall not be affected thereby.

1. **REPEALING CLAUSE**

The provisions of AO Nos. 2006-0018, 2006-0018-A, and 2006-0018-B and all other issuances inconsistent with the provisions of this Order are hereby repealed/rescinded and modified accordingly.

1. **EFFECTIVITY**

This Order shall be effective within fifteen (15) days from publication in the Official Gazette.

***ENRIQUE T. ONA, MD***

**Secretary of Health**

**ANNEX A.**

***PNF FORM NO. 1.* LETTER OF REQUEST AND PROPOSAL FORM FOR MAJOR APPLICATIONS**

**LETTER OF REQUEST**

**Date**

**Honorable \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Secretary**

**Department of Health**

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

**Director**

**National Center for Pharmaceutical Access and Management**

**Department of Health**

**SUBJECT: Proposal for INCLUSION of: ( indicate if: new medicine or new indication, formulation,**

**or route of administration for a medicine currently listed in the formulary )**

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

**The ( indicate name of company ) proposes inclusion of ( indicate name of new medicine or new indication, formulation or route of administration for a listed medicine ) in the Philippine National Formulary.**

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

1. **Accomplished proposal form;**
2. **FDA Certificate of Product Registration with colored photograph or video of product;**
3. **FDA-approved product information;**
4. **FDA certificate of good manufacturing practice;**
5. **Evidence Table including risk-benefit and cost-effectiveness analyses, where applicable;**
6. **Other relevant documents ( e.g. clinical practice guidelines, excerpts from WHO documents or other formularies, etc., including photocopies of such ).**

**We understand that incomplete submissions will not be processed.**

**( Indicate any additional remark )**

**Respectfully yours,**

**PROPONENT’S NAME**

**Designation**

**Company /Organization/Office Name**

**Indicate email address, telephone and facsimile number**

***PNF FORM NO. 1:***

**PROPOSAL FORM FOR MAJOR APPLICATIONS**

1. **GENERAL INFORMATION ON PROPOSED INCLUSION**

|  |  |
| --- | --- |
| **GENERIC NAME** |  |
| **BRAND NAME (if any)** |  |
| **THERAPEUTIC CLASSIFICATION** |  |
| **FOR NEW MEDICINES:** |  |
| * **Indication** |  |
| * **Dosage Form/Strength** |  |
| * **Route of Administration** |  |
| * **Dose, Frequency and Duration of Administration** |  |
| **FOR LISTED MEDICINES:** |  |
| * **Current Indication** |  |
| * **Proposed Indication** |  |
| * **Current Dosage Form/Strength** |  |
| * **Proposed New Dosage Form/Strength** |  |
| * **Current Route of Administration** |  |
| * **Proposed New Route of Administration** |  |
| **MANUFACTURER** |  |
| **INPORTER/TRADER** |  |
| **DISTRIBUTOR** |  |

1. **SUMMARY OF JUSTIFICATON FOR INCLUSION**

|  |  |
| --- | --- |
| **Please tick appropriate box/es:** | **Concise Justification Comparing New Medicine and Listed Medicine in the PNF** |
| * **Medicine is for a condition not yet covered in the existing formulary;** |  |
| * **New medicine or proposed indication, formulation or route of administration has a risk-benefit profile better than or comparable to a currently listed medicine ;** |  |
| * **New medicine or proposed indication, formulation or route of administration has a cost-effectiveness profile better than or comparable to a currently listed medicine** |  |
| * **New medicine or proposed indication, formulation or route of administration will improve compliance.** |  |

1. **DETAILS OF CLINICAL EFFICACY AND SAFETY PROFILE ( Attach Evidence Table )**

|  |  |  |  |
| --- | --- | --- | --- |
| **PARAMETER** | **NEW MEDICINE OR PROPOSED INDICATON/ FORMULATION/ ROUTE OF ADMINISTRATION** | **CURRENTLY LISTED MEDICINE FOR SAME INDICATION IN THE PNF** | **REFERENCES** |
| EFFICACY: CLINICAL PERFORMANCE, OUTCOME OF MEDICAL CONDITION |  |  |  |
| SAFETY AND TOLERABILITY |  |  |  |
| QUALITY OF LIFE |  |  |  |
| OTHERS (Indicate) |  |  |  |

1. **DETAILS OF COST-EFFECTIVENESS ANALYSIS (Attach Evidence Table )**

|  |  |  |  |
| --- | --- | --- | --- |
| **PARAMETER**  **(Indicate information for intended recipient) \*** | **NEW MEDICINE OR PROPOSED NEW 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 COST: (in PhP)   1. Implementation costs: ( cost of drug administration, monitoring, additional diagnostic services, additional equipment, travel, caregiver, etc.) 2. Intervention costs: (management of adverse drug reaction treatment) 3. Indirect costs (lost production costs): |  |  |  |
| TOTAL COST PER PATIENT PER TREATMENT COURSE (in PhP) |  |  |  |
| EXPECTED NUMBER OF PATIENT-TREATMENT COURSES PER YEAR |  |  |  |
| QUALITY ADJUSTED LIFE YEARS |  |  |  |
| DISABILITY ADJUSTED LIFE YEARS |  |  |  |

**\* Cost of medicine based on suggested retail price (SRP).**

1. **EVIDENCE TABLE (Please use PNF Form No. 9 )**

**ANNEX B.**

***PNF FORM NO. 2.*  LETTER OF REQUEST AND PROPOSAL FORM FOR MINOR APPLICATIONS**

**LETTER OF REQUEST**

**Date**

**Honorable \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Secretary**

**Department of Health**

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

**Director**

**National Center for Pharmaceutical Access and Management**

**Department of Health**

**SUBJECT: Proposal for INCLUSION of: ( indicate if: new dosage strength, net content or**

**immediate packaging for a medicine listed in the formulary )**

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

**The ( indicate name of company) proposes the inclusion of ( indicate if for new dosage strength, net content or immediate packaging for a currently listed medicine ) in the Philippine National Formulary.**

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

1. **Accomplished proposal form;**
2. **FDA Certificate of Product Registration with colored photograph or video of product;**
3. **FDA-approved product information;**
4. **FDA certificate of good manufacturing practice;**
5. **Evidence Table including risk-benefit and cost-effectiveness analyses, where applicable;**
6. **Other relevant documents ( e.g. clinical practice guidelines, excerpts from WHO documents or other formularies, etc., including photocopies of such ).**

**We understand that incomplete submissions will not be processed.**

**( Indicate any additional remark )**

**Respectfully yours,**

**PROPONENT’S NAME**

**Designation**

**Company /Organization/ Office Name**

**Indicate email address, telephone and facsimile number**

***PNF FORM NO. 2:***

**PROPOSAL FORM FOR MINOR APPLICATIONS**

1. **GENERAL INFORMATION ON PROPOSED INCLUSION**

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

1. **SUMMARY OF JUSTIFICATON FOR INCLUSION**

|  |  |
| --- | --- |
| **Please tick 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.** |  |

1. **DETAILS OF CLINICAL EFFICACY AND SAFETY PROFILE ( Attach Evidence Table )**

|  |  |  |  |
| --- | --- | --- | --- |
| **PARAMETER** | **NEW MEDICINE OR PROPOSED INDICATON/ FORMULATION/ ROUTE OF ADMINISTRATION** | **CURRENTLY LISTED MEDICINE FOR SAME INDICATION IN THE PNF** | **REFERENCES** |
| EFFICACY: CLINICAL PERFORMANCE, OUTCOME OF MEDICAL CONDITION |  |  |  |
| SAFETY AND TOLERABILITY |  |  |  |
| QUALITY OF LIFE |  |  |  |
| OTHERS (Indicate) |  |  |  |

1. **DETAILS OF COST-EFFECTIVENESS ANALYSIS ( Attach Evidence Table )**

|  |  |  |  |
| --- | --- | --- | --- |
| **PARAMETER**  **(Indicate information for intended recipient) \*** | **NEW MEDICINE OR PROPOSED INDICATION/ FORMULATION/ ROUTEOF 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: (n PhP)   1. Implementation costs: ( cost of drug administration, monitoring, additional diagnostic services, additional equipment, travel, caregiver, etc.) 2. Intervention costs: (management of adverse drug reactions) 3. Indirect costs: (lost production costs) |  |  |  |
| TOTAL COST PER PATIENT PER TREATMENT COURSE (in PhP) |  |  |  |
| EXPECTED NUMBER OF PATIENT-TREATMENT COURSES PER YEAR |  |  |  |
| QUALITY ADJUSTED LIFE YEARS |  |  |  |
| DISABILITY ADJUSTED LIFE YEARS |  |  |  |

**\* Cost of medicine based on suggested retail price (SRP).**

1. **EVIDENCE TABLE (Please use PNF Form No. 9 )**

**ANNEX C.**

***PNF FORM NO. 3.* LETTER OF REQUEST AND PROPOSAL FORM FOR DELETION OF MEDICINE FROM THE PHILIPPINE NATIONAL FORMULARY**

**LETTER OF REQUEST**

**Date**

**Honorable \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Secretary**

**Department of Health**

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

**Director**

**National Center for Pharmaceutical Access and Management**

**Department of Health**

**SUBJECT: Proposal to delete medicine listed in the formulary.**

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

**The ( indicate name of company/parties/individuals ) request/s for the DELETION of the following medicine (indicate medicine’s generic and/or brand name) from the Philippine National Formulary.**

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

1. **Accomplished proposal form;**
2. **FDA-approved product information with colored photograph or video of product;**
3. **Evidence Table including risk-benefit and cost-effectiveness analyses, where applicable;**
4. **Other relevant documents ( e.g. clinical practice guidelines, excerpts from WHO documents or other formularies, etc., including photocopies of such ).**

**We understand that incomplete submissions will not be processed.**

**( Indicate any additional remark )**

**Respectfully yours,**

**PROPONENT’S NAME**

**Designation**

**Company/Organization/Office Name**

**Indicate email address, telephone and facsimile number**

***PNF FORM NO. 3:***

**PROPOSAL FORM FOR DELETION OF MEDICINE FROM THE PNF**

1. **GENERAL INFORMATION ON PROPOSED DELETION**

|  |  |
| --- | --- |
| **GENERIC NAME** |  |
| **BRAND NAME (if any)** |  |
| **THERAPEUTIC CLASSIFICATION** |  |
| **INDICATION** |  |
| **DOSAGE FORM/STRENGTH** |  |
| **ROUTE OF ADMINISTRATION** |  |
| **MANUFACTURER** |  |
| **IMPORTER/TRADER** |  |
| **DISTRIBUTOR** |  |

1. **SUMMARY OF JUSTIFICATON FOR DELETION**

|  |  |
| --- | --- |
| **Please tick appropriate box/es:** | **Concise Justification and References** |
| * **A more effective or equally effective but less toxic medicine becomes available;** |  |
| * **Its therapeutic efficacy is found to be unsatisfactory;** |  |
| * **Toxicity, suspected toxicity, potential for abuse, dangerous interactions outweigh its therapeutic value;** |  |
| * **It is no longer cost-effective;** |  |
| * **It is a fixed-dose combination that does not satisfy the requirements of A.O. 96 s. 1990.** |  |

1. **DETAILS OF RISK-BENEFIT ANALYSIS ( Attach Evidence Table )**

|  |  |  |  |
| --- | --- | --- | --- |
| **PARAMETER** | **NEW MEDICINE OR PROPOSED INDICATON/ FORMULATION/ ROUTE OF ADMINISTRATION** | **CURRENTLY LISTED MEDICINE FOR SAME INDICATION IN THE PNF** | **REFERENCES** |
| EFFICACY: CLINICAL PERFORMANCE, OUTCOME OF MEDICAL CONDITION |  |  |  |
| SAFETY AND TOLERABILITY |  |  |  |
| QUALITY OF LIFE |  |  |  |
| OTHERS (Indicate) |  |  |  |

1. **DETAILS OF COST-EFFECTIVENESS ANALYSIS ( Attach Evidence Table )**

|  |  |  |  |
| --- | --- | --- | --- |
| **PARAMETER**  **(Indicate information for intended recipient) \*** | **NEW MEDICINE OR PROPOSED INDICATION/ FORMULATION/ ROUTEOF 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: (n PhP)   1. Implementation costs: ( cost of drug administration, monitoring, additional diagnostic services, additional equipment, travel, caregiver, etc.) 2. Intervention costs: (management of adverse drug reactions) 3. Indirect Costs: (Lost production costs) |  |  |  |
| TOTAL COST PER PATIENT PER TREATMENT COURSE (in PhP) |  |  |  |
| EXPECTED NUMBER OF PATIENT-TREATMENT COURSES PER YEAR |  |  |  |
| QUALITY ADJUSTED LIFE YEARS |  |  |  |
| DISABILITY ADJUSTED LIFE YEARS |  |  |  |

**\* Cost of medicine based on suggested retail price (SRP).**

1. **EVIDENCE TABLE (Please use PNF Form No. 9 )**

**ANNEX D.**

***PNF FORM NO 4.* LETTER OF REQUEST AND PROPOSAL FORM FOR EXEMPTION**

**FROM A.O.163 s. 2002**

**LETTER OF REQUEST**

**Date**

**Honorable \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Secretary**

**Department of Health**

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

**Director**

**National Center for Pharmaceutical Access and Management**

**Department of Health**

**SUBJECT: Proposal to EXEMPT the medicine from A.O. No.163 s. 2002 that states that only**

**medicines listed in the PNF shall be procured by government entities.**

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

**The ( indicate name of DOH Unit/other party ) is requesting for the EXEMPTION of the following medicine (indicate generic and brand name) from A.O. No. 163 s. 2002.**

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

1. **Accomplished proposal form;**
2. **FDA Certificate of Product Registration or WHO certification;**
3. **FDA-approved product information with colored photograph or video of product;**
4. **FDA certificate of good manufacturing practice;**
5. **Evidence Table including risk-benefit and cost-effectiveness analyses, where applicable;**
6. **Report on disease burden and its ranking relative to the common diseases in the community;**
7. **Other relevant documents ( e.g. clinical practice guidelines, excerpts from WHO documents or other formularies, etc., including photocopies of such ).**

**We understand that incomplete submissions will not be processed.**

**( Indicate any additional remark )**

**Respectfully yours,**

**PROPONENT’S NAME**

**Designation**

**DOH Unit/ other Party’s Name**

**Indicate email address, telephone and facsimile number**

***PNF FORM NO. 4:***

**PROPOSAL FORM FOR EXEMPTION FROM A.O. No. 163 s. 2002**

1. **GENERAL INFORMATION ON PROPOSED EXEMPTION:**

|  |  |
| --- | --- |
| **GENERIC NAME** |  |
| **BRAND NAME (if any)** |  |
| **THERAPEUTIC CLASSIFICATION** |  |
| **INDICATION** |  |
| **DOSAGE FORM/ STRENGTH** |  |
| **ROUTE OF ADMINISTRATION** |  |
| **DOSE, FREQUENCY AND DURATION OF ADMINISTRATION** |  |
| **MANUFACTURER** |  |
| **IMPORTER/ TRADER** |  |
| **DISTRIBUTOR** |  |

1. **SUMMARY OF JUSTIFICATON FOR EXEMPTION:**

|  |  |
| --- | --- |
| **Please tick appropriate box/es:** | **JUSTIFICATION AND REFERENCES** |
| * **Medicine has proven efficacy and safety;** |  |
| * **Medicine will be used for national health program (indicate program);** |  |
| * **Medicine will be used for an urgent health situation.** |  |

1. **DETAILS OF RISK-BENEFIT ANALYSIS ( Attach Evidence Table )**

|  |  |  |  |
| --- | --- | --- | --- |
| **PARAMETER** | **PROPOSED MEDICINE** | **CURRENTLY LISTED MEDICINE FOR SAME INDICATION IN THE PNF** | **REFERENCES** |
| EFFICACY: CLINICAL PERFORMANCE, OUTCOME OF MEDICAL CONDITION |  |  |  |
| SAFETY AND TOLERABILITY |  |  |  |
| QUALITY OF LIFE |  |  |  |
| OTHERS (Indicate) |  |  |  |

1. **DETAILS OF COST-EFFECTIVENESS ANALYSIS FOR NON-URGENT SITUATIONS ( Attach Evidence Table )**

|  |  |  |  |
| --- | --- | --- | --- |
| **PARAMETER**  **(Indicate information for intended recipient) \*** | **NEW MEDICINE OR PROPOSED INDICATION/ FORMULATION/ ROUTEOF 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. 2. Intervention costs: adverse drug reaction treatment) 3. Indirect Costs: (Lost production costs) |  |  |  |
| TOTAL COST PER PATIENT PER TREATMENT COURSE (in PhP) |  |  |  |
| EXPECTED NUMBER OF PATIENT-TREATMENT COURSES PER YEAR |  |  |  |
| QUALITY ADJUSTED LIFE YEARS |  |  |  |
| DISABILITY ADJUSTED LIFE YEARS |  |  |  |

**\* Cost of medicine based on suggested retail price (SRP).**

1. **EVIDENCE TABLE (Please use PNF Form No.9 )**

**ANNEX E**

***PNF FORM NO. 5.* EVALUATION FORM FOR NEW MEDICINE, INDICATION, FORMULATION OR ROUTE OF ADMINISTRATION IN THE PNF**

**MAJOR APPLICATIONS**

Date accomplished: Serial No.:

Date of Submission of Application:

|  |  |
| --- | --- |
| **MEDICINE** |  |
|  | Generic Name/INN: |
|  | Brand Name: |
|  | Dosage Form and Strength: |
|  | Route of Administration: |
|  | Therapeutic Classification: |
|  | Manufacturer: |
|  | Importer/Trader: |
|  | Distributor: |
| **PROPONENT** |  |
| FEC – INITIATED | Name: |
|  | Designation: |
| DOH UNITS/ DEPT./  HEALTH FACILITY | Unit/Facility Name: |
|  | Representative: |
|  | Designation: |
| PHARMACEUTICAL  COMPANY | Company Name: |
|  | Representative: |
|  | Designation: |
| OTHERS | Name/s: |
|  | Designation: |
|  | Organization/Hospital/Office: |
| **APPLICATION**  **FOR:**  (Please check) |  |
|  | Inclusion of new medicine |
|  | Re-inclusion of medicine with new indication |
|  | Re-inclusion of medicine with previous indication |
|  | Re-submission of application for new medicine |
|  | Change of formulation |
|  | Change of route of administration |
|  | Change of indication for medicine   * New indication * Deletion of previous indication |

*PNF Form No. 5*

**Name of medicine: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Serial No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*PNF FORM NO.5*

**Name of Medicine \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Serial No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **COMPLIANCE CHECKLIST** | **Yes** | **No** | **REMARKS / EVIDENCE** |
| 1 | The medicine or new indication is addressed to prevent or treat priority diseases or health needs in the Philippines. |  |  |  |
| 2 | The new medicine or new formulation has:   1. Good quality; 2. Acceptable safety profile; 3. Efficacy proven using evidence-based selection, including Phase III trials. |  |  |  |
| 3 | The medicine has favorable clinical efficacy and safety profile. |  |  |  |
| 4 | The medicine has favorable cost-effectiveness analysis. |  |  |  |
| 5 | The proposed route of administration is safe and effective. |  |  |  |
| 6 | If the medicine belongs to the same pharmacologic class as a listed medicine:   1. It is the most thoroughly investigated and best understood in terms of beneficial properties and limitations; 2. It possesses clinical utility for the treatment of more than one condition or disease; 3. It has the most favorable pharmacokinetic properties; 4. It has dosage forms that is easy to dispense or is easily and safely administered to patients; 5. It is easy for the patient to take or it has greater acceptability among many patients; 6. The medicine and its dosage forms have favorable stability under anticipated local conditions in storage facilities; 7. It is produced in local, reputable manufacturing facilities. |  |  |  |
| 7 | If the medicine is a fixed-ratio combination:   1. The value of concomitant use of more than one medicine is rational and clinically documented; 2. With any one of the following: 3. The therapeutic benefit of the combination is greater than the sum of each of the individual components; 4. The combination is safer than the use of an individual medicine; 5. The cost of the product is less than or should not exceed the cost of the sum of the individual products; 6. Compliance is improved. |  |  |  |

*PNF FORM NO. 5*

**Name of Medicine:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Serial No.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*PNF FORM NO. 5*

**Name of Medicine: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Serial No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**RECOMMENDATION:**

* FOR INCLUSION AS NEW : \_\_\_ CORE MEDICINE \_\_\_ COMPLEMENTARY MEDICINE
* FOR *EXCLUSION* AS NEW MEDICINE

* FOR RE-INCLUSION WITH: \_\_\_ PREVIOUS INDICATION \_\_\_ NEW INDICATION
* FOR *EXCLUSION* OF MEDICINE APPLIED FOR RE-INCLUSION
* FOR INCLUSION OF NEW DRUG FORMULATION
* FOR *EXCLUSION* OF NEWDRUG FORMULATION
* FOR INCLUSION OF NEW ROUTE OF ADMINISTRATION
* FOR *EXCLUSION* OF NEW ROUTEOF ADMINISTRATION
* FOR INCLUSION OF NEW INDICATION
* FOR *EXCLUSION* OF NEW INDICATION
* FOR *DELETION* OF PREVIOUS INDICATION

**FURTHER RECOMMENDED ACTION FOR DISAPPROVED APPLICATIONS:**

* DENIAL OF APPLICATION FOR CPR
* REVOCATION OF CPR IF MEDICINE IS ALREADY OFFICIALLY REGISTERED WITH FDA

**SUBMITTED BY:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Printed Name

**FORMULARY EXECUTIVE COUNCIL CHAIRPERSON / DESIGNEE**

***PNF FORM NO. 5***

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| **FORMULARY EXECUTIVE COUNCIL**  **VOTING MEMBERS**  **(Printed Names)** | **(Signatures)** |
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**ANNEX F**

***PNF FORM NO. 6:* EVALUATION FORM FOR CHANGE IN DOSAGE STRENGTH, NET CONTENT AND IMMEDIATE PACKAGING OF MEDICINES LISTED**

**IN THE PNF – MINOR APPLICATIONS**

Date Accomplished: Serial No.:

Date of Submission of Application:

|  |  |
| --- | --- |
| **MEDICINES** |  |
|  | Generic Name/INN: |
|  | Brand Name: |
|  | Dosage Form and Strength: |
|  | Route of Administration: |
|  | Therapeutic Classification: |
|  | Manufacturer: |
|  | Importer/Trader; |
|  | Distributor: |
| **PROPONENT** |  |
| FEC INITIATED | Name: |
|  | Designation: |
| DOH Unit/ Health Facility | Representative: |
|  | Designation: |
|  | Unit/Health Facility Name: |
| PHARMACEUTICAL  COMPANY | Company name: |
|  | Representative: |
|  | Designation: |
|  | Unit/Department/Health facility name: |
| OTHERS | Name/s: |
|  | Designation: |
|  | Company/Organization/Office Name |
| **APPLICATION FOR:**  (Please check) |  |
|  | Inclusion of new dosage strength of medicine listed in PNF |
|  | Inclusion of new net content of medicine listed in PNF |
|  | Inclusion of new immediate packaging |

*PNF FORM NO. 6*

**Name of Medicine \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Serial No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| --- | --- | --- | --- | --- |
| **No.** | **COMPLIANCE CHECKLIST** | **Yes** | **No** | **REMARKS / EVIDENCE** |
| 1 | The new dosage formulation of the medicine listed in the PNF:   1. Has good quality; 2. Has proven safety based on sound evidence including at least Phase III clinical trials; 3. Has proven efficacy for the stated indication based on sound evidence including Phase III clinical trials; 4. Has favorable cost-effective analysis. |  |  |  |
| 2 | The new net content of the medicine listed in the PNF:   1. Has good quality; 2. Has proven safety based on sound evidence including at least Phase III clinical trials; 3. Has proven efficacy based on sound evidence including at least Phase III clinical trials; 4. Has favorable cost-effective analysis. |  |  |  |
| 3 | The new immediate packaging conforms to:   1. The regulations of the FDA or DOH: 2. Generic name is clearly written in a bigger font than the brand name 3. Brand name is clearly written below the generic name 4. Current dosage form and strength are clearly written 5. Others 6. The requirements by the Advertising Board |  |  |  |

*PNF FORM NO. 6*

**Name of Medicine : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Serial No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*PNF FORM NO. 6*

**Name of Medicine: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Serial No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**RECOMMENDATIONS:**

* New dosage strength of medicine is approved
* New dosage strength of medicine is disapproved
* New net content of medicine is approved
* New net content of medicine is disapproved
* New immediate packaging is approved
* New immediate packaging is disapproved

**SUBMITTED BY:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Printed Name

**FORMULARY EXECUTIVE COUNCIL CHAIRPERSON / DESIGNEE**

***PNF FORM NO. 6***

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| **FORMULARY EXECUTIVE COUNCIL**  **VOTING MEMBERS**  **(Printed Names)** | **(Signatures)** |
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**ANNEX G**

***PNF FORM NO. 7:* EVALUATION FORM FOR DELETION OF MEDICINE FROM THE PHILIPPINE NATIONAL FORMULARY**

Date Accomplished: Serial No.

Date of Submission of Application:

|  |  |
| --- | --- |
| **MEDICINE** |  |
|  | Generic Name/ INN: |
|  | Brand Name: |
|  | Dosage Form and Strength: |
|  | Route of Administration: |
|  | Therapeutic Classification: |
|  | Manufacturer: |
|  | Importer/Trader: |
|  | Distributor: |
| **PROPONENT** |  |
| FEC INITIATED | Name: |
|  | Designation: |
| DOH UNIT/ HEALTH  FACILTY | Representative: |
|  | Designation: |
|  | Unit/Health Facility Name: |
| PHARMACEUTICAL  COMPANY | Company Name: |
|  | Representative: |
|  | Designation: |
| OTHERS: | Name/s: |
|  | Designation: |
|  | Company/Organization/Office Name: |

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| --- | --- | --- | --- | --- |
| **No.** | **COMPLIANCE CHECKLIST** | **Yes** | **No** | **REMARKS / EVIDENCE** |
| 1 | The medicine has been withdrawn from the FDA Registry due to safety reasons. |  |  |  |
| IF THE ANSWER IS NO, PROCEED TO: | |  |  |  |
| 2 | Any of the following criteria for deletion has been met:   1. A more effective or equally effective but less toxic medicine becomes available; 2. The therapeutic efficacy of the medicine is found to be unsatisfactory in the light of further knowledge; 3. Toxicity, suspected toxicity, potential for abuse, dangerous interactions outweigh the medicine’s therapeutic value; 4. The medicine has fallen into disuse; 5. The medicine is no longer deemed cost-effective compared to other therapies; 6. The medicine is a fixed-dose combination that: 7. Does not satisfy the requirements of A.O.96 s. 1990; 8. Has no rational and no clinically documented value of concomitant use of more than one medicine; 9. Fulfills any of the following criteria: 10. The therapeutic benefit of the combination is lesser than the sum of each of the individual components; 11. The combination isn’t safer than the use of an individual medicine; 12. The cost of the combination product is less than or exceeds the cost of the sum of the individual products; 13. Compliance is not improved. |  |  |  |

*PNF FORM NO. 7*

**Name of Medicine: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Serial No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*PNF FORM NO. 7*

**Name of Medicine: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Serial No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**RECOMMENDATIONS:**

* Deletion of the medicine from the PNF
* Retention of the medicine in the PNF

**SUBMITTED BY:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature

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Printed Name

**FORMULARY EXECUTIVE COUNCIL CHAIRPERSON / DESIGNEE**

***PNF FORM NO. 7***

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| **FORMULARY EXECUTIVE COUNCIL**  **VOTING MEMBERS**  **(Printed Names)** | **(Signatures)** |
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**ANNEX H**

***PNF FORM NO. 8:* EVALUATION FORM FOR EXEMPTION FROM A.O. NO. 163 s. 2002**

Date Accomplished: Serial No.

Date of Submission of Application:

|  |  |
| --- | --- |
| **MEDICINE** |  |
|  | Generic Name/ INN: |
|  | Brand Name: |
|  | Dosage Form and Strength: |
|  | Route of Administration: |
|  | Therapeutic Classification: |
|  | Manufacturer: |
|  | Importer/Trader: |
|  | Distributor: |
| **PROPONENT** |  |
| FEC INITIATED | Name: |
|  | Designation: |
| DOH UNIT/ HEALTH  FACILITY | Name/s: |
|  | Designation: |
|  | Unit/ Health Facility Name: |
| PHARMACEUTICAL  COMPANY | Company Name: |
|  | Representative: |
|  | Designation: |
| OTHERS | Name: |
|  | Designation: |
|  | Company/Organization/Office Name: |

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| --- | --- | --- | --- | --- |
| **No.** | **COMPLIANCE CHECKLIST** | **Yes** | **No** | **REMARKS/EVIDENCE** |
| 1 | All the following documents have been submitted for requests for exemptions:   1. Justification for the request; 2. Scientific evidence of safety and efficacy supported with literature review for the specific medicine; 3. Report on the disease burden and its ranking relative to the common diseases seen in the community; 4. Copy of Certificate of Product Registration; 5. For non-emergent situations, the comparison of costs for the total regimen of the medicine or its full course of therapy with other comparable medicines listed in the current edition of the PNF. |  |  |  |
| 2 | The following criteria have been met:   1. The medicine will be used for a national health program (specify program); 2. The medicine will be used for an urgent health situation or emergency (specify situation); 3. The approval for exemption will only be effective for the duration of the national health program or until the urgent health situation has passed or is adequately addressed. |  |  |  |

*PNF FORM NO. 8*

**Name of Medicine: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Serial No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*PNF FORM NO. 8*

**Name of Medicine: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Serial No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**RECOMMENDATIONS:**

* Approval of application for exemption
* Disapproval of application for exemption

**SUBMITTED BY:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name

**FORMULARY EXECUTIVE COUNCIL CHAIRPERSON / DESIGNEE**

***PNF FORM NO. 8***

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| **FORMULARY EXECUTIVE COUNCIL**  **VOTING MEMBERS**  **(Printed Names)** | **(Signatures)** |
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**ANNEX J**

***PNF FORM NO. 10:* CHRONOLOGICAL SUMMARY OF MEDICINES TO BE INCLUDED IN OR DELETED FROM THE PNF**

Date accomplished:

TO: (Name of Assistant Secretary or Undersecretary of Health in charge of NCPAM)

SUBJECT: **CHRONOLOGICAL SUMMARY OF MEDICINES TO BE INCLUDED IN or DELETED FROM THE PHILIPPNE NATONAL FORMULARY**

QUARTER COVERED:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| NO. | MEDICINE  (Generic name, dosage form & strength, route of administration) | RECOMMENDATION  (inclusion/deletion) | PROPONENT | REASON FOR INCLUSION/ DELETION | ACTION |
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*PNF FORM NO. 10:*

Prepared by:

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| --- | --- |
| **FORMULARY EXECUTIVE COUNCIL**  (Printed Names) | (Signatures) |
| **MEMBERS:** |  |
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| **CHAIRPERSON:**  **11** |  |

**ANNEX K**

***PNF FORM NO.11 :* ALPHABETICAL SUMMARY OF MEDICINES FOR INCLUSION IN OR DELETION FROM THE PHILIPPINE NATIONAL FORMULARY**

Date accomplished:

TO: (Name of Assistant Secretary or Undersecretary of Health in charge of NCPAM)

SUBJECT: **ALPHABETICAL SUMMARY OF MEDICINES FOR INCLUSION IN OR DELETION**

**FROM THE PHILIPPINE NATIONAL FORMULARY**

QUARTER COVERED:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| NO. | MEDICINE  (Generic name, dosage form & strength, route of administration) | RECOMMENDATION  (inclusion/deletion) | PROPONENT | REASON FOR INCLUSION/ DELETION | ACTION |
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*PNF FORM NO. 11:*

Prepared by:

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| --- | --- |
| **FORMULARY EXECUTIVE COUNCIL**  (Printed Names) | (Signatures) |
| **MEMBERS:** |  |
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| **CHAIRPERSON:**  **11** |  |

**ANNEX I**

***PNF FORM NO. 9-A:* EVIDENCE TABLE 1**  (to be attached to both *Proposal Form* for proponent and *Evaluation Form* for FEC use)

Application for: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Serial No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medicine: Generic Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Brand Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**E V I D E N C E T A B L E 1**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **NO** | TITLE/ AUTHOR  YEAR/JOURNAL | STUDY DESIGN | PARTICIPANT DESCRIPTION | INTERVENTION | RESULTS/OUTCOMES | | | | | GRADE OF EVIDENCE | REMARKS |
| **EVENTS** | TREATMENT DRUG GROUP | | CONTROL DRUG  GROUP | |
| (including adverse events) | No. of events \* | Total # of patients | No. of events \* | Total # of  patients |
|  |  |  |  |  |  |  |  |  |  |  |  |
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\*group means with standard deviations may be reported if the data are continuous

***PNF FORM NO. 9-B:*  EVIDENCE TABLE 2: GRADE TABLE** (to be attached to both *Proposal Form* for proponent and *Evaluation Form* for FEC use)

Application for: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Serial No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medicine: Generic Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Brand Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**E V I D E N C E T A B L E 2 : G R A D E E V I D E N C E P R O F I L E T A B L E**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **QUALITY ASSESSMENT** | | | | | | | **SUMMARY OF FINDINGS** | | | | | **Importance** |
| **No. of patients** | | **Effect** | | **Over-all**  **Quality** |
| **No. of**  **Studies** | **Design** | **Limitations** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other**  **considerations** | **Intervention** | **Control** | **Relative**  **(95% CI)** | **Absolute** |
| **Outcome:** | | | | | | | | | | | | |
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| **Outcome:** | | | | | | | | | | | | |
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| **Outcome:** | | | | | | | | | | | | |
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| **Outcome:** | | | | | | | | | | | | |
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| **Outcome:** | | | | | | | | | | | | |
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**ANNEX O**

***PNF FORM NO. 12:* EVIDENCE SUMMARY FOR FEC** (to be attached to each *Evaluation Form* for FEC use)

Application for: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Serial No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medicine: Generic Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Brand Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**E V I D E N C E S U M M A R Y T A B L E**

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| **PROPOSED MEDICINE OR PROPOSED CHANGE** | **RISK-BENEFIT ANALYSIS** | **COST-EFFECTIVENESS ANALYSIS** | | **QALY** | | **REMARKS** |
| **Level of Acceptability** | **Type of Modeling** | **Level of Acceptability** | **Source of QALY Information** |
| Generic Name: |  |  |  |  |  |  |
| Brand Name: |  |  |  |  |  |  |
| Indication: |  |  |  |  |  |  |
| Formulation: |  |  |  |  |  |  |
| Route of Administration: |  |  |  |  |  |  |
| Dosage Strength: |  |  |  |  |  |  |
| Net Content: |  |  |  |  |  |  |

**ANNEX L. *SELECTION OF MEDICINES FOR RETENTION IN OR DELETION FROM THE PNF***

Yes

Yes

Consider for DELETION if there are better medicines in terms of efficacy safety and cost.

Consider for DELETION if there are better medicines in terms of efficacy, safety and cost.

Yes

DELETE

No

Mark for DELETION

No

Yes

DELETE

No

DELETE

Yes

Exclude

Yes

No

Exclude

Exclude

No

Exclude

Yes

Exclude

No

**ANNEX M. *SELECTION OF MEDICINES FOR INCLUSION IN THE PNF***

Exclude

No

Complementary

No

Complementary

No

Complementary

No

Delist or disapprove request for inclusion

Complementary

No

No

Core

No

No

No

ANNEX N. ***CLASSIFICATION INTO CORE AND COMPLEMENTARY MEDICINES***