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# THE PHILIPPINE NATIONAL DRUG FORMULARY

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# Outline

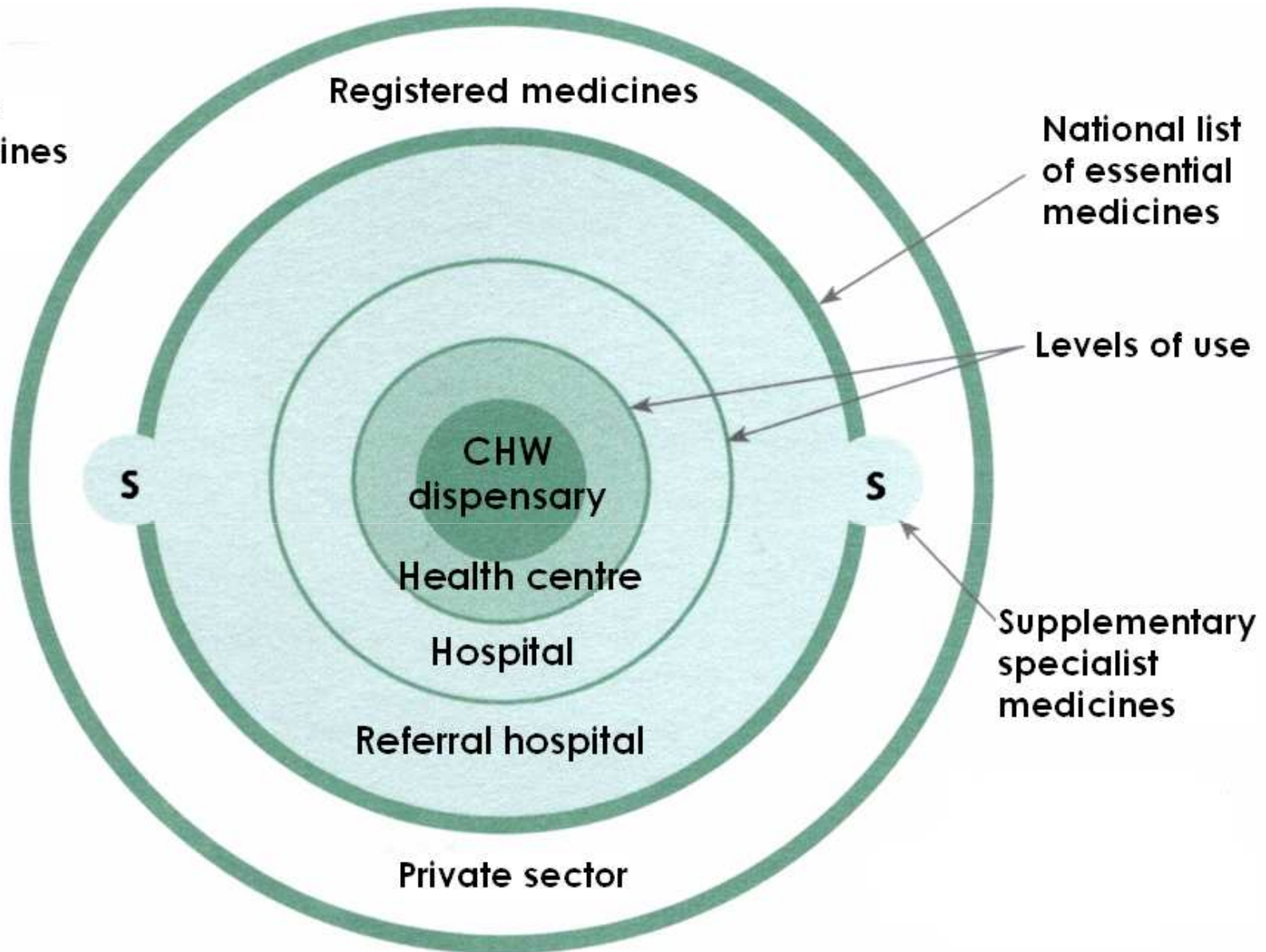
1. Introduction
  2. The Philippine National Drug Formulary (PNDF)  
Volumes 1, 2, 3
    - 2.1. Legal Framework
    - 2.2. Formulation Process of PNDF vol. 1 (Essential Drugs List)
    - 2.3. Bases for drug selection
    - 2.4. Criteria for addition/deletion
    - 2.5. Supporting documents
    - 2.6. Systematic literature review process
    - 2.7. Evidence table
    - 2.8. Algorithms for drug selection/addition/deletion
  3. Conclusions
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# Essential Drugs/Medicines List

- Satisfy the priority health care needs of the majority of the population
  - Available at all times in adequate amounts, in appropriate dosage forms with assured quality
  - At a price the individual and community can afford
  - Selected with due regard to public health relevance, evidence of efficacy and safety and comparative cost-effectiveness
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All the medicines in the world



National list of essential medicines

Levels of use

Supplementary specialist medicines

Private sector

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# Access to Essential Medicines

- Having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk from home
  - A major objective of people everywhere
  - Featured as a primary goal of countries' national medicine policy
  - A priority health issue
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## Range of Access to Essential Medicines

- 1975 – less than half ( $1/2$ ) of the world's population had regular access
  - 1999 – World Medicine Survey showed that the fraction has fallen to one third ( $1/3$ ) but the absolute number of people without access has remained almost unchanged at about 1.7 billion
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# Coverage of Population with Essential Drugs

Group	Percentage covered	Percentage not covered	% of countries falling under each group
1	30%	70%	23%
2	30 – 60%	40 – 70%	32%
3	60 – 90%	10 – 40%	45%

NB. The Philippines was one of the countries under group 1

World Drug Situation  
WHO, 1988

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## Percentage of Population with Regular Access to Essential Medicines in Relation to the Population Size (1999 WHO Survey)

Group 1	Very Low Access	(< 50%)
Group 2	Low to Medium Access	(50 – 80%)
Group 3	Medium to High Access	(81 – 95%)
Group 4	Very High Access	(> 95%)

NB. The Philippines had  
66% access (group 2)

World Medicines Situation  
WHO, 2004

The target of the Philippine NDP – PMU is to attain regular access to essential medicines, at least 85% by 2015.

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# A National Essential Medicines List (EML) is a government-approved selective list of medicines that guides:

- The procurement and supply of medicines in the public sector
- Schemes for reimbursement of medicine costs
- Medicine donations
- Local medicine production

It is a cost-effective means of providing safe and effective treatment for the majority of communicable and non-communicable diseases.

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# The Philippine National Drug Formulary (PNDF)

- A basic component of the National Drug Policy which seeks to bring about availability and accessibility of safe, efficacious and quality essential drugs at affordable cost
  - A crucial step to rationalize drug production, distribution, procurement and consumption to ensure access to health care and to promote rational use by health professionals and consumers
  - Systematic and transparent procedures for defining the national list of essential medicines, on the basis of evidence-based treatment guidelines
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# **PNDF Volumes**

Volume 1 – Essential Drugs List

Volume 2 – Essential Drugs Monographs

Volume 3 – Cross Reference Index

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# Essential Drugs List

## **CORE LIST**

- Includes drugs that satisfy the health care needs of the great majority of the population
  - Should be made available at all times in adequate amounts and in appropriate dosage forms at the lowest possible cost
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# Essential Drugs List

## **COMPLEMENTARY LIST** includes:

- Drugs for treating rare disorders or in exceptional circumstances
  - Alternative drugs when the drug in core list are ineffective or inappropriate for a given individual
  - Alternative drugs when the drug in the core list are not available
  - Drugs with special pharmacological properties
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# Legal Framework

## 1. Republic Act # 6675 (Generics Act of 1988)

An act to promote, require and ensure the production of an adequate supply, distribution, use and acceptance of drugs and medicines identified by their generic names

- Use of generic names/INN in labeling, advertising, prescribing and dispensing
  - Development of Essential Drugs List
  - Information, Education and Communication Campaign
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# Legal Framework

## 2. E.O.#49 s 1993

Directing the mandatory use of The Philippine National Drug Formulary (PNDF) Volume 1 as basis for procurement of drug products by the government

## 3. PHILIPPINE HEALTH INSURANCE CORPORATION BOARD RESOLUTION #265 s 1999

PNDF became the basis for claim reimbursements for drugs and medicines.

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# Legal Framework

## **4. RA # 9502 – (Universally Accessible Cheaper and Quality Medicines Act of 2008)**

- Law that serves as the mechanism of achieving better access to essential drugs and better health outcome for all Filipinos
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# Formulation Process for PNDF

## Volume 1 (EDL)

- Schedule review of drug list by sections
  - Stakeholders/interest groups are given drug list for review and for their recommendations
  - Evidence table from interested parties and from the NDIC
  - Collection of comments/suggestions/evidences
  - Consultation/deliberation with resource persons
  - Further review and evaluation by NFC
  - Finalization of EDL by the NFC
  - Endorsement by NFC to the Program Manager of the National Drug Policy
  - Approval by the Secretary of Health
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# Bases for Drug Selection

1. Relevance to diseases prevalent in the country (disease burden)
  2. Efficacy and safety
  3. Benefit/Risk Ratio
  4. Quality
  5. Cost-effectiveness
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# Criteria for Addition

- Drug is needed for the prevention and treatment of conditions not covered by the current list
  - Drug is more effective and/or more safe than a drug listed for the same indication
  - Drug is at least as effective and safe and of lower cost than a drug listed for the same indication
  - Drug is deemed essential for a specific DOH health program/project
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# Criteria for Deletion

- Drug has fallen into disuse and is no longer available.
  - Drug is no longer deemed cost-effective to other therapies
  - Drug is a FDC which does not satisfy the requirements of AO #96 s 1990
  - A more effective or equally effective and safer drug becomes available
  - In the light of further knowledge, the therapeutic efficacy of the drug is found to be unsatisfactory or questionable
  - Toxicity/suspected toxicity or potential for abuse or dangerous interactions outweigh its therapeutic value
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# Supporting Documents

1. Scientific Evidence Table supported with literature review
  2. Report on disease burden and its ranking, relative to common diseases in the hospital
  3. Comparison of costs for the total regimen of the drug or its full course of therapy with other comparable drugs listed in the current edition
  4. Copy of Certificate of Product Registration (CPR)
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# Systematic Literature Review Process

1. Clinical Question: Is drug X a safe and efficacious drug for condition Y?
  2. Comprehensive Search: Medline, Herdin, Cochrane, Embase –through National Drug Information Center
  3. Critical appraisal of abstracts/full text to verify claims (RCT quality, level of evidence)
  4. Examine similarities and differences of findings across studies; may perform meta-analysis
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# LEVELS OF EVIDENCE

## Evidence □ Based Medicine (EBM)

### **Level A: STRONG EVIDENCE**

Several relevant high quality scientific studies and results are convergent

### **Level B: MODERATE EVIDENCE**

At least one high quality scientific study and several adequate studies

### **Level C: LIMITED EVIDENCE**

At least one adequate study

### **Level D: WEAK OR NO EVIDENCE**

Expert panel evaluation; does not fulfill criteria of scientific evidence

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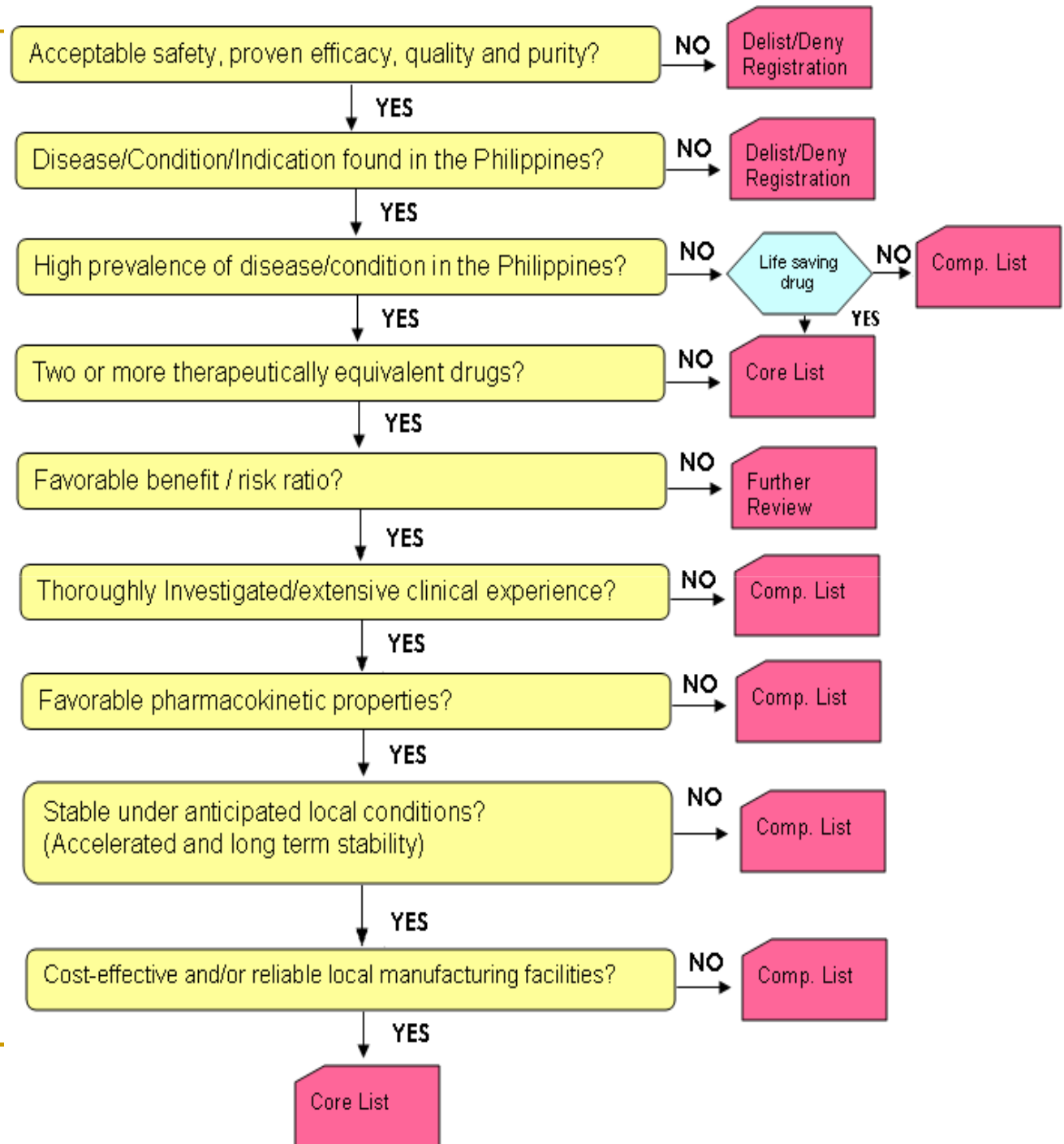
# Validity of Studies on Treatment

- Randomized controlled trial
  - Adequate follow-up
  - Clinically relevant outcomes
  - Intention to treat analysis
  - Levels of blinding
  - Baseline characteristics
  - Patients/groups treated equally
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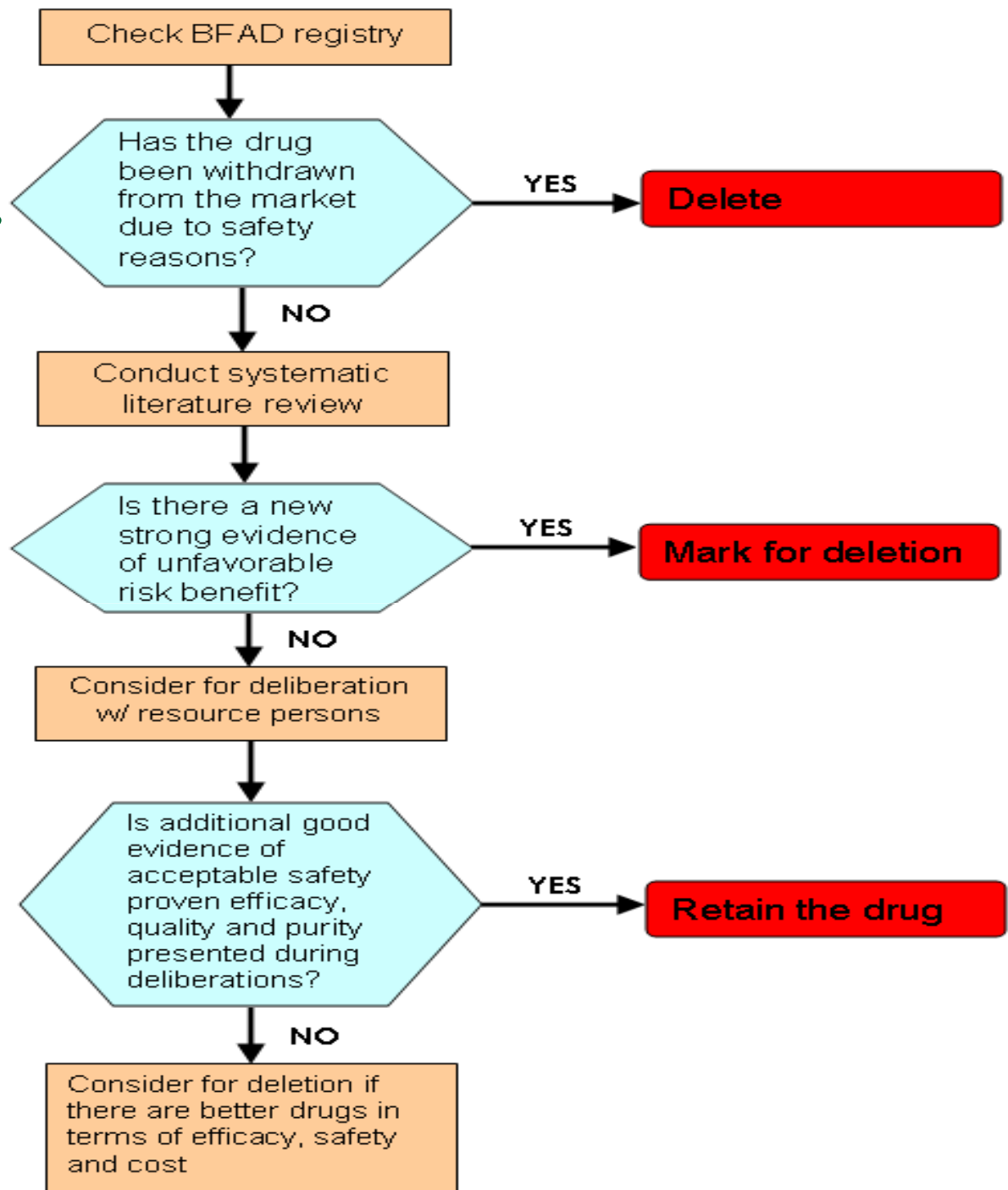




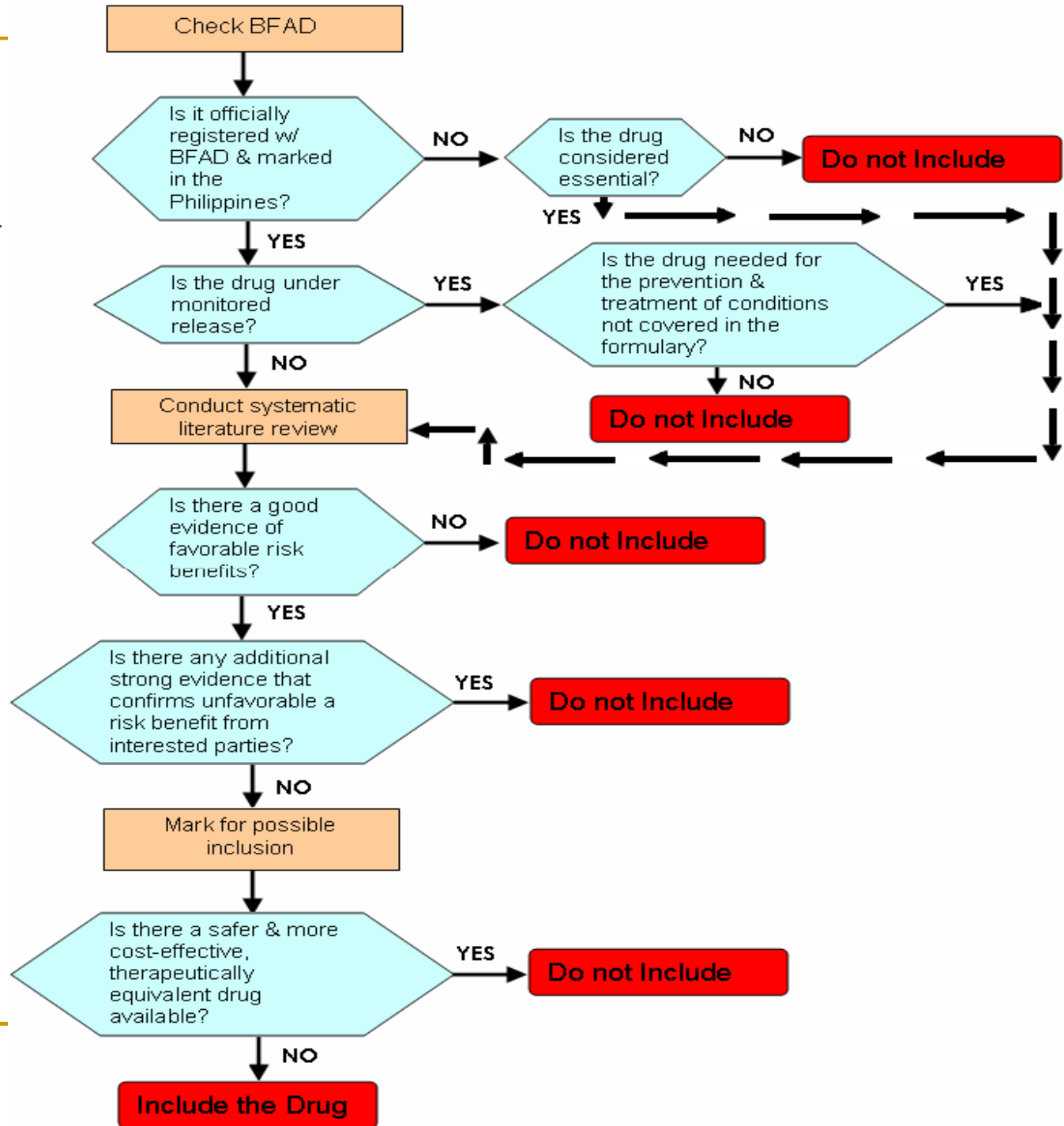
# Drug Selection Process Algorithm



# Process Algorithm for Deletion of Drug from the PNDP



# Process Algorithm for Review of New Drugs for Possible Inclusion



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## Conclusions:

1. The Essential Drugs Concept has become increasingly accepted particularly in the public sector in developing countries. Its appropriate application throughout the world remains a challenge.
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## Conclusions:

2. The Essential Drugs Concept and the use of a National Essential Drugs List are more relevant today than ever > 20 years after enactment of RA 6675. We need to continue to develop methods and means to reinforce, expand and implement the essential drugs concept to improve access to essential medicines in both public and private sectors.
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## Conclusions:

3. There is need for political and professional commitment in implementing the National Essential Drugs List as a basic component of the National Drug Policy, monitoring its progress continuously and evaluating the program periodically to achieve the best outcome.
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**Thank You!**

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