



# PHARMACEUTICAL POLICIES FOR AFFORDABLE ACCESS

**Asian Institute of Management  
Makati City  
24 August 2006**

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Department of Health



# Outline of the Presentation

- The Pharmaceutical Industry
- Current Regulatory Situation
  - Regulated Establishments
  - Regulated Products
  - BFAD output
  - Ratio of FDRO to Establishments per CHD
  - Organizational Constraint
- Policy Interventions leading to affordable access
  - Parallel Importation
  - Botika ng Barangays
  - Botika ng Bayan
  - DOH Botikas
  - Policy Reform (Drug Consignment System, Wholesaling, PNDFS, EDPMS, Other NDP/BFAD Policy Reforms)
- Constraints and Emerging issues
- Recommended Solutions

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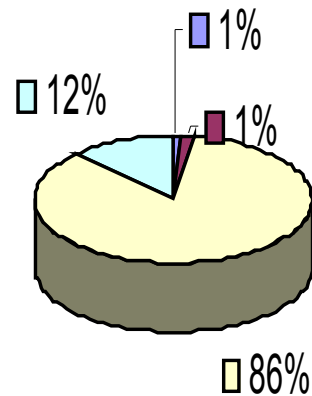
# THE PHARMACEUTICAL INDUSTRY

**Pharmaceutical Market is valued at**

**Php 72-80 Billion**

# THE PHARMACEUTICAL INDUSTRY

Pharmaceutical Industry Situation



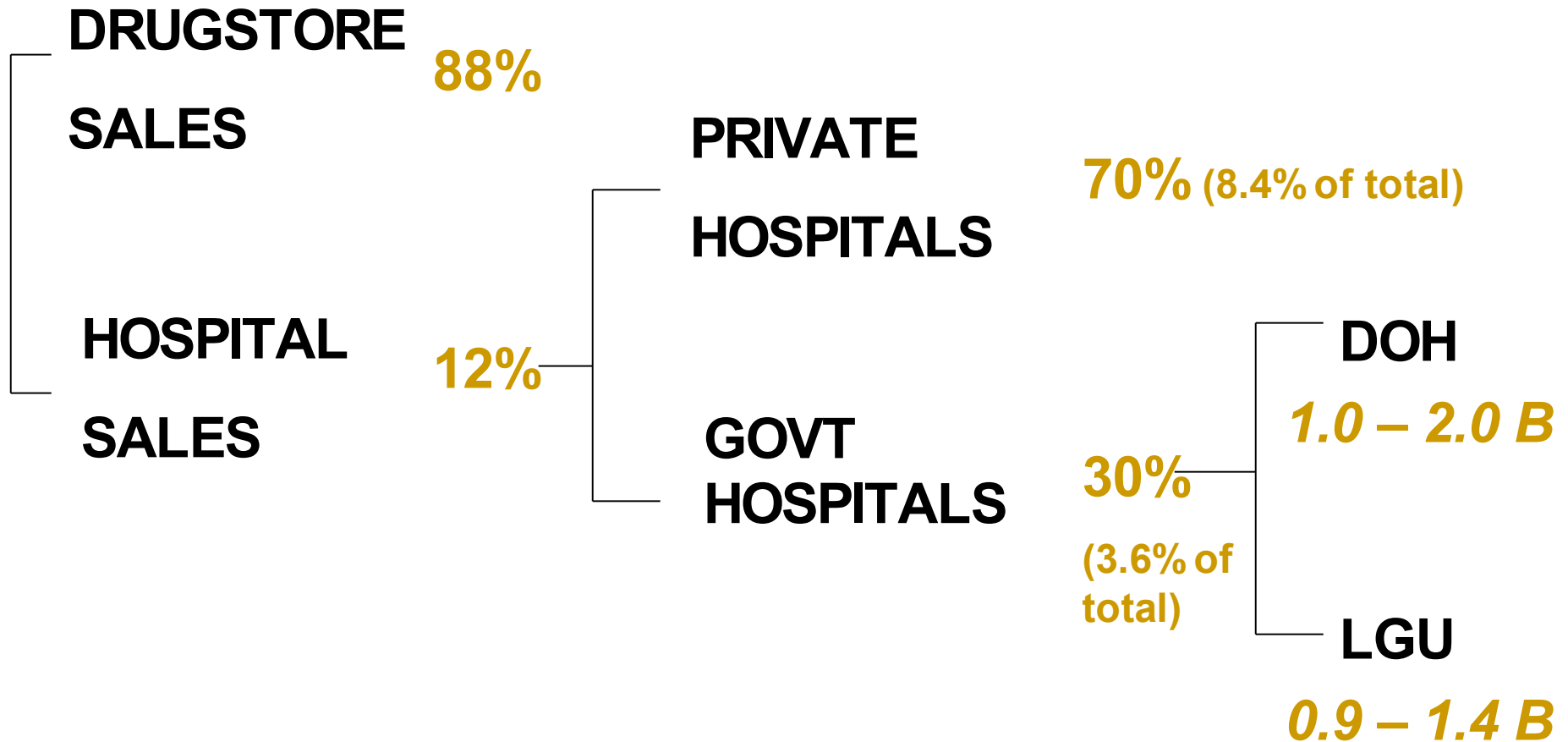
■ Drug Manufacturer	■ Drug Trader
■ Retail Outlet	■ Drug Distributor

Drug Manufacturer	246
Drug Trader	391
Retail Outlet	23,901
Drug Distributor	3,450

## Retail Outlets

Botika ng Barangay	2,338
Botika ng Bayan	1,135
Chinese	210
Drugstore	18,450
Hospital Pharmacy - Government	649
Hospital Pharmacy - Private	1,064
Retail Outlet for Non-prescription drugs	248
Total	23,901

# THE PHARMACEUTICAL INDUSTRY



# CURRENT REGULATORY SITUATION

## A. BFAD Regulated Establishments (as of June 2006)

<b>Establishment Type</b>	<b>Number</b>
<b>MANUFACTURERS:</b>	<b>12,489</b>
DRUG	246
COSMETIC	176
MEDICAL DEVICE	40
HOUSEHOLD HAZARDOUS	227
FOOD	11,800
<b>TRADERS:</b>	<b>602</b>
DRUG	391
COSMETIC	190
MEDICAL DEVICE	21
<b>DISTRIBUTORS:</b>	<b>7,341</b>
DRUG	3,450
COSMETIC	505
MEDICAL DEVICE	893
HOUSEHOLD HAZARDOUS	222
FOOD	2,271
<b>RETAIL OUTLETS:</b>	<b>23,901</b>
<b>TOTAL</b>	<b>44,333</b>

# CURRENT REGULATORY SITUATION

## B. Establishments vs CHD Manpower Complement per CHD

CHD	No. of Establishments	FDROs	Ratio
I	2656	6	1:443
II	1649	6	1:275
III	4149	11	1:377
IV A&B	6520	12	1:543
V	1840	10	1:184
VI	2248	10	1:225
VII	3924	10	1:392
VIII	1630	8	1:204
IX	1890	10	1:189
X	1536	9	1:171
XI	3229	8	1:404
XII	1778	7	1:254
CAR	741	4	1:185
ARMM	31	3	1:10
CARAGA	609	6	1:101
NCR	9894	100	1:96
<b>TOTAL</b>	<b>44,333</b>	<b>220</b>	<b>1:202</b>

# CURRENT REGULATORY SITUATION

## C. BFAD Registered Products

PRODUCT	NUMBER
DRUGS (Pharmaceutical)	11,135
COSMETICS	9,579
FOOD	20,930
MEDICAL DEVICE	2,137
HOUSEHOLD REMEDY	379
MEDICAL OXYGEN	29
PITC Products	181
DONATION	1,850
VETERINARY	392
HERBAL MEDICINES	18
VACCINES	216
REAGENTS (Diagnostic)	177
Household Hazardous	1,393
<b>TOTAL</b>	<b>48,416</b>

**NO. OF EVALUATORS IN PSD = 32**

**RATIO: 1:1,513**

# CURRENT REGULATORY SITUATION

## D. BFAD Accomplishments NCR (Jan – Jun 2006)

Division	Activity	Demand	Output	Difference	%Ratio
<b>PSD</b>	<b>Product Registration</b>	<b>13,121</b>	<b>8,467</b>	<b>4,654</b>	<b>64.53</b>
<b>LSD</b>	<b>Laboratory Analysis</b>	<b>8,922</b>	<b>8,284</b>	<b>638</b>	<b>92.84</b>
<b>REG I</b>	<b>Inspection (Distributors)</b>	<b>7,926</b>	<b>2,449</b>	<b>5,477</b>	<b>31.53</b>
<b>REG II</b>	<b>Inspection (Manufacturers)</b>	<b>1,968</b>	<b>1,334</b>	<b>634</b>	<b>67.78</b>

# CURRENT REGULATORY SITUATION

## E. Transactional Efficiency and Trends (2003-2005)

### PROCESSED DRUG REGISTRATION APPLICATIONS (2003 - 2005)

2003				
Received	CPR	NODs	Disap- proved	Pending
4723	2613	3325	135	1007

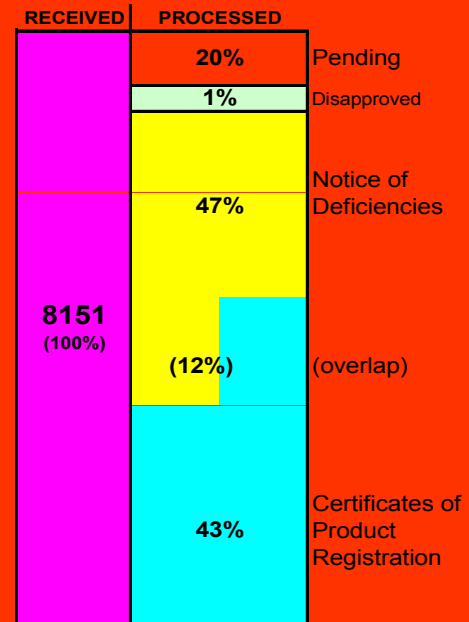
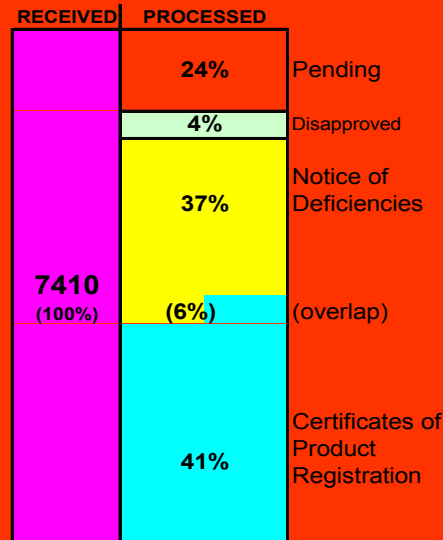
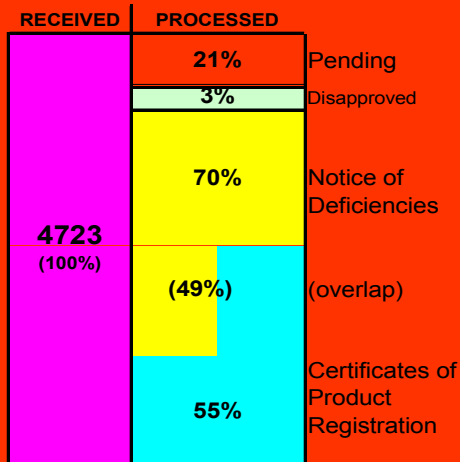
2003

2004				
Received	CPR	NODs	Disap- proved	Pending
7410	3048	2758	311	1770

2004

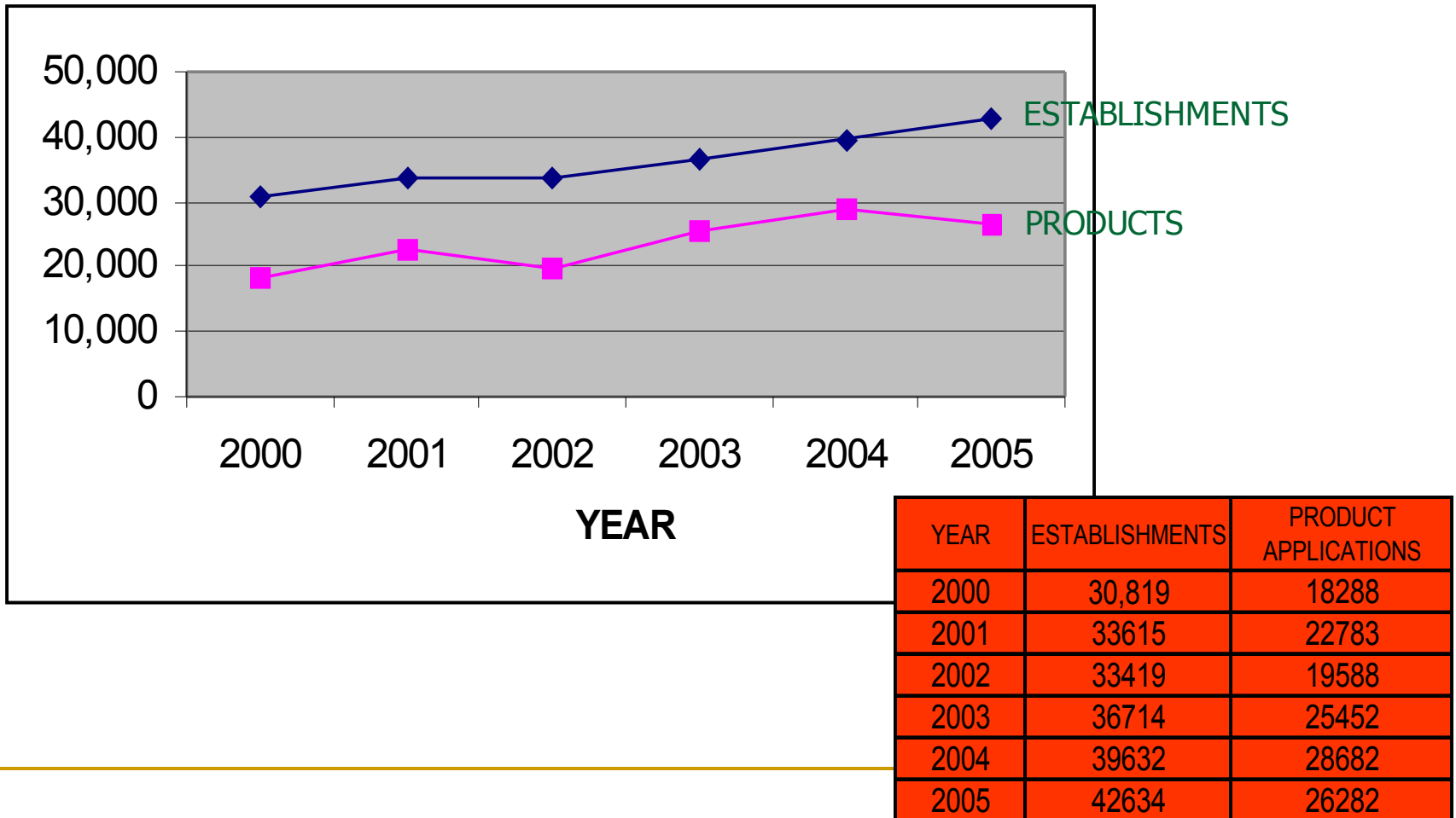
2005				
Received	CPR	NODs	Disap- proved	Pending
8151	3837	3494	93	1656

2005



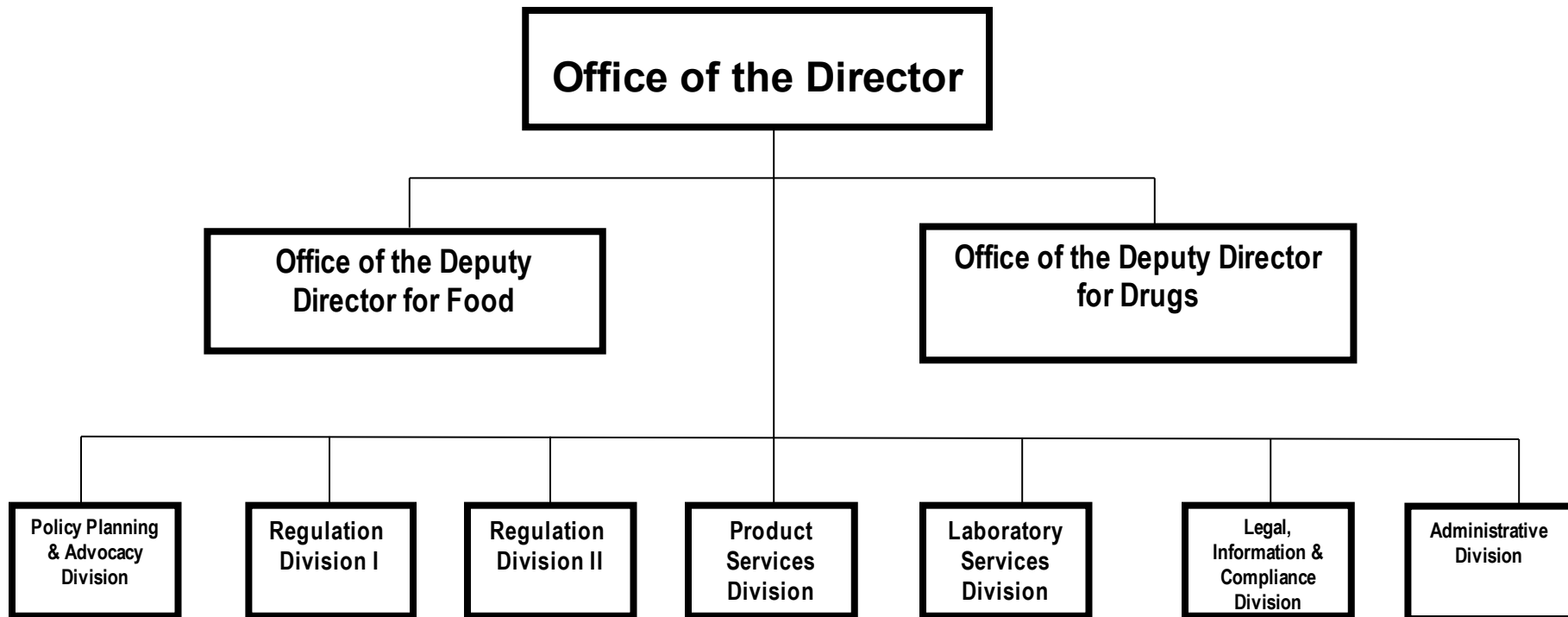
# CURRENT REGULATORY SITUATION

## F. Growth Trends (2000-2005)



# CURRENT REGULATORY SITUATION

## G. Current BFAD Organization under EO 102



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# ISSUES ON ACCESS: MARKET FAILURE

- Monopoly/oligopoly
  - Asymmetric information
  - Imperfect markets (as a consequence of geography, technology, manpower constraints, regulatory/legal constraints)
  - Externalities
  - Macroeconomic disruption (unemployment, poverty, inequality)
  - Pricing and cost of medicine are not made transparent
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# ISSUES ON ACCESS: NET EFFECT OF MARKET FAILURE

- Drug prices are:
  - *obscenely and exorbitantly high*
  - *can be as high as 1600% higher than the cost of a similar off patent product*
  - *balancing (?) health and trade*
- *Social/Behavioral effects:*
  - *Brand drug consciousness.*
  - *Price consciousness*
    - *High cost = good quality drugs*
- *There is aggressive marketing and promotional activities by the industry.*

# ISSUES ON ACCESS: EMPIRICAL OBSERVATIONS/ OUTCOME OF MARKET FAILURE

Retail prices of 100 units (tablets/capsules) of 12 commonly used drugs in five developing Asian countries and Canada, July-September 1995. **All prices in US dollars.**

Drug Name	Strength in mg	Canada	India	Indonesia	Nepal	Pakistan	Philippines
Amoxicillin	250	8	9	10	8	5	22
Amoxil	250	14	10	40	9	8	29
Tagamet	200	25		56		14	95
Cotrimoxazole	48	6	5	7	3	3	20
Seprin	480	6		25	3	5	53
Odofenac	50	30	2	48	2	7	25
Voltaren	50	46	2	52		18	37
Erythromycin	250	6	12	10	10	5	20
Erythrocin	250	9	11	37	11	7	35
Adalat	5	28	2	18		2	40
Inderal	40	15	8	74		28	25
Zantac	150	81	3	150	3	39	95

HAI news (December 1995)

# ISSUES ON ACCESS: EMPIRICAL OBSERVATIONS/ OUTCOME OF MARKET FAILURE

PRICE COMPARISON OF SELECTED GENERIC DRUGS BETWEEN THE PHILIPPINES AND SELECTED ASEAN COUNTRIES. **ALL PRICES IN PHILIPPINE PESOS.**

	<b>Philippines</b>	<b>Thailand</b>	<b>Indonesia</b>
Penicillin G	9.8	4.83	-
Rifampicin	4.5	11.49	5.58
Nifedipine	4.15	-	1.78
Tetracycline	3.45	0.64	1.3
Glibenclamide	3.45	0.93	0.99
Pyrazinamide	2.15	3.17	-
Amoxicillin	2.14	4.27	2.68
Chloramphenicol	1.95	2.21	2.68
Cotrimoxazole	1.55	0.97	1.05
Prednisone	1.55	0.44	0.54
Mefenamic Acid	1.35	0.91	-
Metronidazole	1.07	0.94	0.99

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# CURRENT POLICY INTERVENTIONS FOR ACCESS

## ENVIRONMENT BEFORE 2000: COST-EFFECTIVENESS ON DRUG SELECTION & PROCUREMENT

- **RA 6675 “GENERICS ACT OF 1988”** - ensure the adequate supply of drugs with generic names at the lowest possible cost
  - **EO 49 s. 1993 “DIRECTING THE MANDATORY USE OF THE PHILIPPINE NATIONAL DRUG FORMULARY (PNDF) VOL. I AS THE BASIS FOR PROCUREMENT OF DRUG PRODUCTS BY THE GOVERNMENT”**
  - **AO 51 s. 1988 “Implementing Guidelines for DOH Compliance w/ RA 6675”** – established the formulary system in health facilities and the role of the Pharmacy & Therapeutics Committee
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# CURRENT POLICY INTERVENTIONS FOR ACCESS

## ENVIRONMENT BEFORE 2000: REGULATION

- NATIONAL DRUG POLICY PROGRAM
  - BFAD LAW
  - NATIONAL HEALTH INSURANCE PROGRAM (NHIP)
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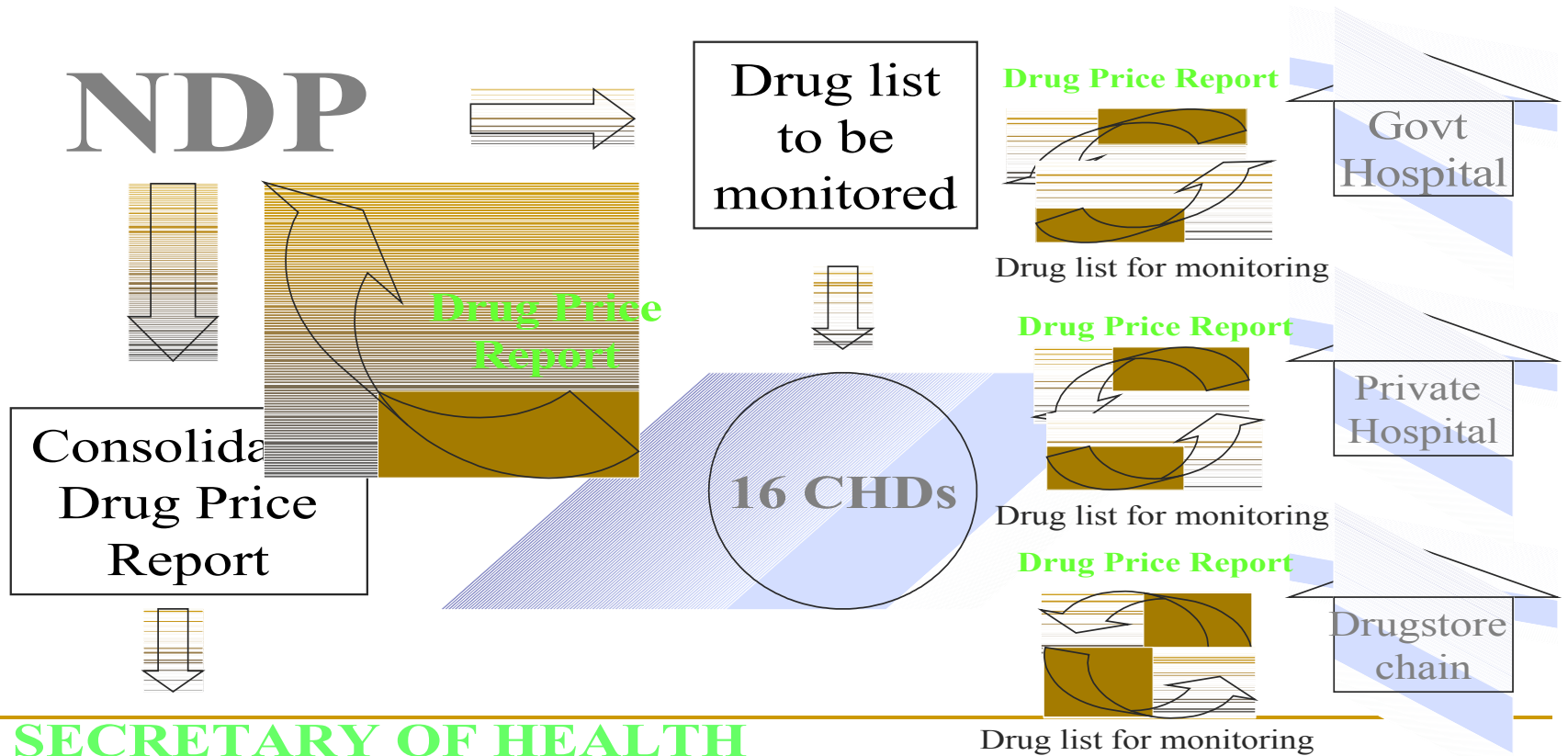
# CURRENT POLICY INTERVENTIONS FOR ACCESS

## ENVIRONMENT BEFORE 2000: PRICE MONITORING & REGULATION

- **RA 7581 “PRICE ACT”** - DOH is the lead agency in identifying essential drugs as “basic necessities” and monitor their corresponding prices
  - **DRUG PRICE REFERENCE INDEX (DPRI)** – basis for reimbursing drugs and medicines in its hospital claims and serve as a guide to drug prices and rational drug selection
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# CURRENT POLICY INTERVENTIONS FOR ACCESS

ENVIRONMENT BEFORE 2000:  
DRUG PRICE MONITORING SYSTEM



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# CURRENT POLICY INTERVENTIONS FOR ACCESS

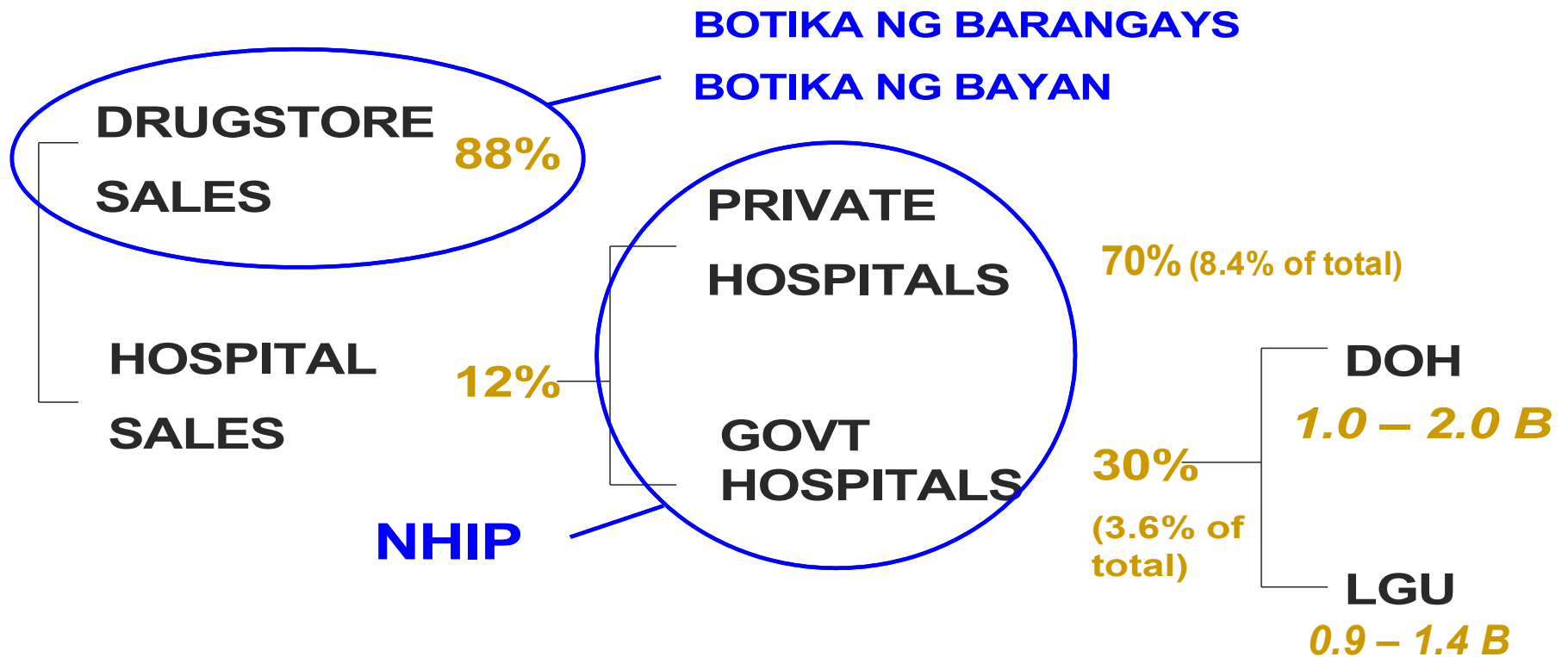
ENVIRONMENT: 2000-2005

GOVERNMENT PROGRAMS TO MITIGATE THE  
HIGH COST OF DRUGS

- Parallel Drug Importation through PITC in  
72 DOH hospitals and 3 LGUs
  - 7,004 Botika ng Barangays nationwide  
and still expanding (as of July 2006)
  - 1,135 Botika ng Bayan outlets  
(as of July 2006)
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# CURRENT POLICY INTERVENTIONS FOR ACCESS

## THE PHARMACEUTICAL SITUATION



# CURRENT POLICY INTERVENTIONS FOR ACCESS

ENVIRONMENT: 2000-2005

GOVERNMENT PROGRAMS TO MITIGATE THE HIGH COST OF DRUGS

PARALLEL DRUG IMPORTATION

PRICE COMPARISON

DEPARTMENT OF HEALTH

LOW COST MEDICINE PROGRAM (Parallel Drug Importation)

as of June 2006

THERAPEUTIC CATEGORY	GENERIC NAME	BRAND NAME	DOH BOTIKA (Nationwide) 2006 Approved Selling Price**	Private Drugstore June 2006 (average)	Peso Savings 2006	% Price Reduction (Private vs DOH Botika) 2006
			A	B	C = B-A	D = (B-A)/B
1 Anti-bacterials	Cotrimoxazole	Bactrim DS 800/160 mg tab *	5.00	31.08	26.08	84%
2		Augmentin 625 mg tab*	78.50	93.33	14.83	16%
3 Anti-hypertensives	Nifedipine	Adalat Retard 20 mg tab*	20.00	40.68	20.68	51%
4	Atenolol	Tenormin 50 mg tab*	9.00	30.78	21.78	71%
5 Oral hypoglycemic (anti-diabetes agent)	Glibenclamide	Daonil 5 mg tab*	3.00	9.90	6.90	70%
6 Anti-anginal agent	Isosorbide dinitrate	Isordil 5 mg SL tab *	2.50	13.78	11.28	82%
7 Bronchodilators	Salbutamol (as sulfate)	Ventorlin 100 mcg x 200 doses inhaler*	234.00	372.02	138.02	37%
8 Anti-psychotics		Serenace 5 mg tab*	10.00	24.25	14.25	59%
9		Serenace 20 mg tab*	18.00	49.00	31.00	63%
10		Serenace 5 mg/ml inj *	39.00	165.25	126.25	76%
11 Anti-epileptics	Carbamazepine	Tegretol 200 mg tab*	7.75	17.10	9.35	55%
12		Tegretol CR 400 mg tab*	15.50	-		-
13		Tegretol 100 mg/5 ml, 100 ml susp.*	149.50	346.25	196.75	57%
14	Phenytoin	Dilantin 100 mg cap *	7.75	25.80	18.05	70%
15 Anti-bacterials	Ciprofloxacin as HCl 500 mg tab	Baycip*	32.50	-		-
						61%

\*\*rounded to the nearest Php .25

# CURRENT POLICY INTERVENTIONS FOR ACCESS

ENVIRONMENT: 2000-2005

GOVERNMENT PROGRAMS TO MITIGATE THE HIGH COST OF DRUGS

**BOTIKA NG BARANGAY**

**PRICE COMPARISON**

GENERIC NAME	BnB Suggested Selling Price (Generic)	Leading Drugstore Chain Selling Price June 2006	Peso Savings	% Price Reduction (Private vs DOH Botika) 2006
	A	B	C = B - A	D = (B-A)/B
Aluminum hydroxide 225 mg + Magnesium Hydroxide 200 mg per 5 mL susp., 60 mL, Plastic Bottle	26.00	-	-	-
Amoxicillin 250 mg/5 mL powder / granules for suspension * (as trihydrate) 60 mL, Bottle	23.14	80.50	57.36	71%
Amoxicillin 500 mg cap (as trihydrate) *(blister pack) (100/bx)	2.02	7.25	5.235	72%
Cotrimoxazole (800 mg sulfamethoxazole + 160 mg trimethoprim ) tablet/capsule *(blister pack) (100/bx)	1.69	17.50	15.81	90%
Ferrous salt tab equivalent 60 mg element iron, 100 tabs/bottle	0.55	-	-	-
Loperamide 2 mg cap.(as HCL) ,foil pack	1.05	4.10	3.047	74%
Mefenamic Acid 250 mg caps/ tabs, blister pack	0.88	3.00	2.116	71%
Multivitamins( for adults) cap*( foil / blister pack) (100/bx)	1.78	4.95	3.169	64%
Multivitamins for children 60 mL for children per 5 mL syrup, amber bottle	27.11	58.65	31.545	54%
Paracetamol 500 mg tab, blister pack	0.46	1.35	0.895	66%
Povidone Iodine 10% sol. 15 mL, Plastic bottle	24.35	39.25	14.901	38%
Metformin 500 mg tab foil pack	1.61	3.25	1.638	50%
Glibenclamide 5 mg tab Blister pack, 100/box	0.62	5.90	5.276	89%
Metoprolol 50 mg tab	1.63	2.65	1.025	39%
Captopril 25 mg tab foil pack	4.28	8.15	3.873	48%
Salbutamol 2 mg tab	0.36	1.90	1.536	81%
Salbutamol 2 mg/5 mL syrup ( 60mL)*(bottle)	19.83	42.25	22.425	53%

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# CURRENT POLICY INTERVENTIONS FOR ACCESS

ENVIRONMENT: 2000-2005

COST-EFFECTIVENESS ON DRUG SELECTION &  
PROCUREMENT

- AO 145 s. 2004 “Revised Policies and Guidelines for the Institutionalization and Decentralization of the DOH Drug Consignment System”
  - AO 2005-0010 “Guidelines for the DOH Retained Hospitals to Engage in Wholesale Procurement and Distribution of Essential Drugs”
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# CURRENT POLICY INTERVENTIONS FOR ACCESS

ENVIRONMENT: 2000-2005

REGULATION OF PROMOTIONAL ACTIVITIES IN  
GOVERNMENT FACILITIES

- AO 169 s. 2004 “Implementing Guidelines for the Exclusive Use of Generic Terminology in All Prescriptions and Orders in All DOH Facilities”
  - DM 98 s. 2004 “Guidelines Enhancing Informational Transparency on the Transactional Visits of Sales and Medical Representative in All DOH Facilities”
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# CURRENT POLICY INTERVENTIONS FOR ACCESS

ENVIRONMENT: 2005-ONWARDS

RECENT NDP/BFAD POLICY REFORMS

- AO 2005-0001 “Revised Policies and Guidelines Governing Patent and Trade Secret Rights in Relation to the Registration of Pharmaceutical Products”
  - AO 2005-0016 “General Policies and Guidelines Governing Brand Names of Products for Registration with the Bureau of Food and Drugs”
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# CURRENT POLICY INTERVENTIONS FOR ACCESS

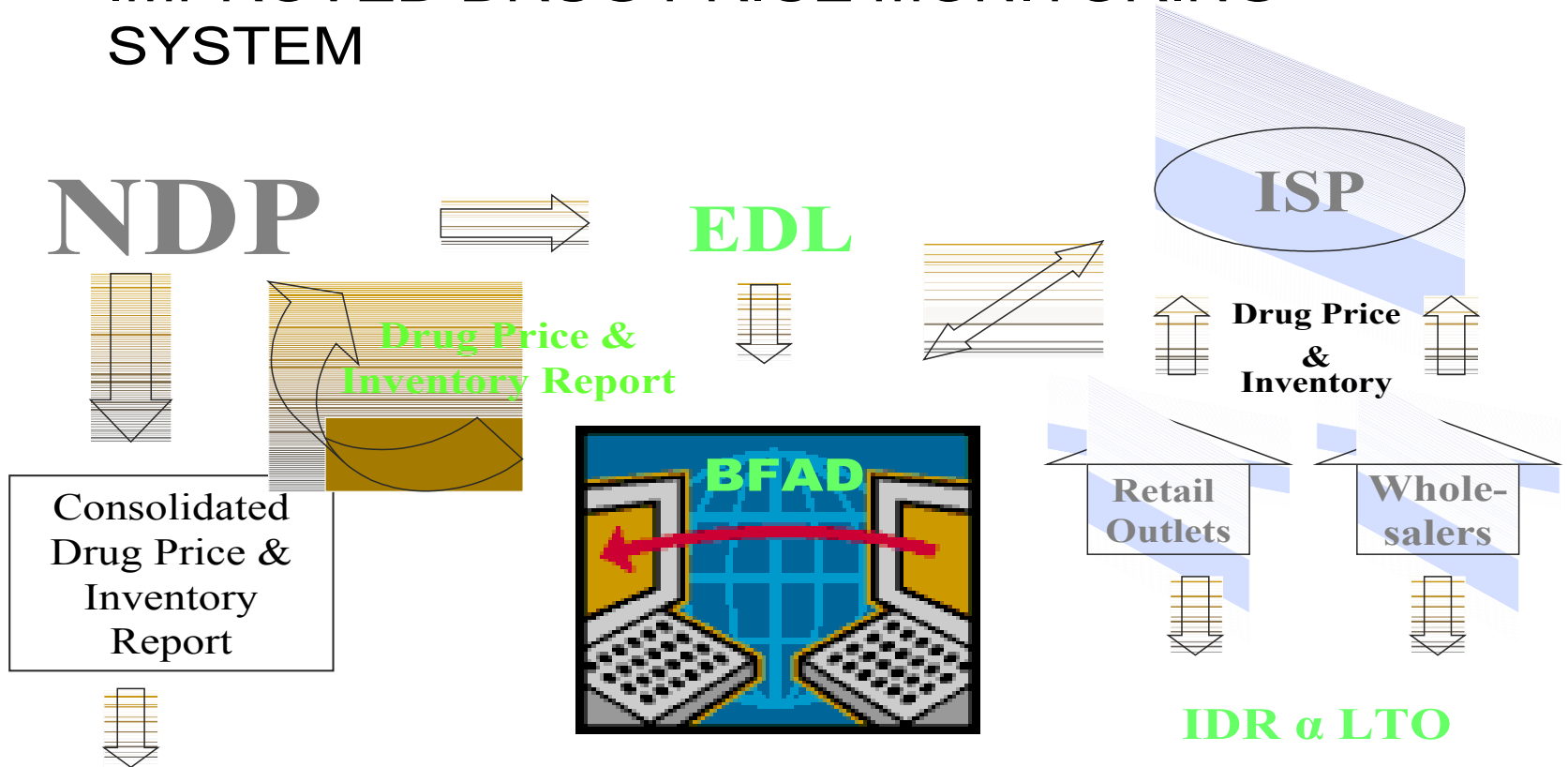
ENVIRONMENT: 2005-ONWARDS

RECENT NDP/BFAD POLICY REFORMS

- AO 2006-0009 "Guidelines Institutionalizing & Strengthening the Essential Drug Price Monitoring System (EDPMS)"
  - AO 2006-0018 "Implementing Guidelines for the Philippine National Drug Formulary System"
  - AO 2006-0021 "Supplemental Guidelines to Administrative Order (AO) 67 s. 1987, Revised Rules and Regulations on Registration of Pharmaceutical Products and Bureau Circular 05 s. 1997 in Evaluating New Drug Applications"
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# CURRENT POLICY INTERVENTIONS FOR ACCESS

ENVIRONMENT: 2005-ONWARDS  
IMPROVED DRUG PRICE MONITORING SYSTEM



SECRETARY OF HEALTH

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# OUR INTENTION...

- Increase the number of outlets that provide half-priced quality medicines
  - Improve regulatory capability of NDP and BFAD to address the issues on access as well as safety, efficacy and quality of pharmaceuticals
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# CONSTRAINTS & EMERGING ISSUES

- Capacity of BFAD to absorb demand for testing
  - Optimum ratio between FDROs and Drug Establishments
  - Information linkage between BFAD and other Government Offices/Units for verification of quality pharmaceuticals
  - Complementary Role of the CHDs, LGUs, and other entities
  - Organizational re-structuring
  - Regional Harmonization and International Trade
  - Price Differential and Economies of Scale in Drug Procurement
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# RECOMMENDED SOLUTIONS

- **Capacity to conduct test:**

- Policy adoption that will accredit Test Laboratories and Bio-availability/Bio-equivalence Centers (which may be owned by Private parties, LGUs, NGOs, Academic Institutions that have no link with industry players)
- Expansion of laboratories to all CHDs
- Income retention sharing

- **Optimizing ratio of FDRO to Establishments**

- Deputization of Trained Health Workers in CHDs to perform related Regulatory works which requires less technical training (e.g. monitoring of compliance to Generics Law, Consumer Act, Price Act, ADR)
- Employment of Contractual FDROs
- Income retention sharing

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# RECOMMENDED SOLUTIONS

- **Information Asymmetry:**
    - Automation of BFAD
    - Publication of information in the internet
    - Involvement of the Commission on Audit to enforce rules at the LGU level
    - Establishment of an Information System that integrates or enhance information sharing between the CHDs and LGUs data on drug access
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# RECOMMENDED SOLUTIONS

- **Rationalize the role of the CHDs, LGUs, and other parties**
  - Deputization of Trained Health Workers in CHDs to perform related Regulatory works (e.g. monitoring of compliance to Generics Law, Consumer Act, Price Act, ADR)
  - Strengthening the capability of the CHDs to perform test, audit establishments, and post-market surveillance of regulated products
  - Employment of Contractual FDROs by the CHDs related regulatory works (e.g. monitoring of compliance to Generics Law, Consumer Act, Price Act, ADR)
  - Establishment of an integrated reporting and information system between the CHDs and the LGUs
  - Establish incentive system to sustain regulatory roles of the CHDs (e.g. income retention sharing)
  - Accreditation of Third Party Organizations who will monitor compliance to Price Act, Generics Act, Consumer Act

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# RECOMMENDED SOLUTIONS

- **Re-structuring BFAD**

- Structure that is based on the major products regulated
  - Adv: More focused transaction, daily transaction for any product, integrated information between product and establishment, experts/specialization development is enhanced, greater flexibility to adopt standards, effective implementation of mandate



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# RECOMMENDED SOLUTIONS

## ■ Regional Harmonization

- Revision of current standards to facilitate regional and international trade without compromising domestic standards on safety, efficacy, and quality
  - Transfer of knowledge to CHD FDROs on new and emerging doctrines in drug regulation as a consequence of harmonization
  - Information sharing on drug prices of essential drugs across national boundaries
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# RECOMMENDED SOLUTIONS

- Unity of Prices and Economies of Scale:

- Options:

- Push for a National Policy where essential drugs requirement of the Government Sector will be sourced from one procurement office similar to PS-DBM

(This may require a separate law; or the GPPB may be asked to craft a policy that defines certain essential drugs as common commodities across LGUs, Government Hospitals that be procured in bulk)

- National Price Bidding of National Demand Estimates of selected essential drugs, where Government will only reimburse drugs at lowest responsive price offer

(This can be undertaken by PHIC using the Australian PBS model)

- Drug Price Reference Indexing (This is an on-going project between DOH and PHIC)
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# RECOMMENDED SOLUTIONS

- **Unity of Prices and Economies of Scale:**
    - Options:
      - LGUs through ILHZ will undertake resource pooling for bulk procurement
      - Retained Hospital now authorized to undertake wholesaling will undertake procurement for interested LGUs/Botika ng Barangays
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**PARA SA  
BAYAN!**