EU – Philippine Health Sector Reform Contract

PHSRC – Pharmaceutical Components 4

Pharmaceutical Division

Strengthening of the DOH Pharmaceutical Chain Management System

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Outline of the Presentation

I. Background/Introduction

II. Objectives

III. Methodology

IV. Findings

V. Conclusions and Recommendations

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Background/ Introduction

Access to essential medicines is part of the fulfilment of the right to the highest attainable standard of health.

Pharmaceutical products and pharmacy services play a major role in ensuring provision of quality healthcare to all.

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Background/ Introduction

Medicines are an integral part of any health care system and the complexity of the current political and economic environment in the Philippines calls for the need to have an overall assessment followed by a continuous initiatives to strengthen and improve the current pharmaceutical supply system.

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Objectives

- To strengthen the pharmaceutical supply management system of the Department of Health (DOH) which includes selection of medicines, forecasting of quantities, procurement, storage and distribution, utilisation review and information flow.
- To review and define the governance structure and implementation framework of the Pharmaceutical Supply Chain Management System in the DOH and its related agencies.

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Methodology

- Used qualitative data collection, that involved document and policy review, individual interviews with key stakeholders, field visits and attendance at relevant workshops which occurred during the assignment period.
- Multistakeholders workshop was conducted to validate data
- Consultation with PD and other Department Heads Chief and Staff

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Findings : On the National Medicines Policy

- ensures the ready and reliable availability of good quality, acceptably safe, and proven effective essential medicines at a price individuals and the community can afford.
- ensures appropriate medicines use through supply management, control of distribution, the provision of improved medicine utilization information and training of health professionals, and through education of the public.

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Major components

- Political will and legal framework
- Right medicines (quality and cost-effective)
- Rational use
- Trained staff

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Benefits of having a NMP

Availability

Affordability

Correct usage

Better health for all

Effectiveness

Safety

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The Philippines Medicines Policy

Anchored on the following principles:

- Access to medicines forms part of the fulfilment of the **human right to health** where government plays a primary responsibility;
- Medicines are ***important in a well-functioning health care system*** as they contribute to the achievement of the broader health objectives of reducing morbidity, mortality and burden of disease;

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The PMP . .

- The State plays the primary role in the progressive realisation of equitable access to medicines to all its citizens, especially the poor. **Filipinos shall not be denied access nor become impoverished because of high drug costs**;

- The Department of Health shall set the directions of the pharmaceutical sector and enforce this policy the PMP, Strategic Directions on access to Medicines for Filipinos 2011-2016.

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The Five Pillars of the Philippine Medicines Policy 2011

Safety, Efficacy & Quality (SEQ)	Availability & Affordability	Rational Use of Medicines	Accountability, Transparency & GGM	Health systems support
To assure the safety, efficacy and quality of medicinal products in the market	*To ensure the continuous availability of essential medicines in the health care system at prices that are within the reach of patients, consumers & the government*	*To promote the rational use of medicines in the public and private sectors using evidence-based and cost-effective treatments that will result in the best health outcomes for patients*	*To institutionalize transparency, accountability and good governance along the registration, regulation, selection, procurement & management of medicines in the health sector*	*To ensure that there is adequate health systems support from government and all stakeholders for the effective implementation of the PMP 2011*

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The PMP Requirements

- Establishment of a National Essential Medicines Facility (NEMF) to provide a national pooled procurement service for DOH programs and a “pull” system for distributing medicines to national and local government health facility.

Finding :

Not yet implemented; a Pharmaceutical Supply Chain Management Unit could absorb these requirements.

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The PMP Requirements

- Establishment of an E-procurement system for the public sector. This web-based procurement, inventory and tracking system for essential medicines at the national and local levels shall be facilitated to better forecast needs, monitor drug prices and institute good management practices.

Finding :

This desirable development has not yet been implemented. The existing NOSIRS does not address this requirement for medicines.

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The PMP

- Permits the consignment of medicines where inadequate financing limits availability of medicines in public health facility. This system should be helpful in ensuring availability of essential medicines when DOH and LGU funding is insufficient.

This undesirable system however, is open to abuse by suppliers and leads to a higher price than can be obtained through competitive bidding.

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On Legislations, policies and issuance

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Laws and Policies Governing Medicines Management

YEAR	LAW or POLICY	NAME	SCOPE
1994	R.A. 7160	Local Government Code	Establishes a system of decentralization so LGUs are given more powers, authority, responsibilities and resources.
2002	R.A. 9184	Government Procurement Reform Act Laws	Procurement by all branches and instrumentalities of government through competitive bidding.

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Laws and Policies governing Medicines Management

YEAR	LAW or POLICY	NAME	SCOPE
2000	AO 85	Regulation requirements for a government agency importing a pharmaceutical product with a registered counterpart brand in the Philippines	Provides guidelines for parallel importation
2003	AO 54A	Guidelines on the Processing and Clearance of Importations through Donations, by the DOH.	Provides criteria, FDA and BIHC requirements for importations and donations
2004	AO 168	National Policy on Health Emergencies and Disasters	Contains policy statements related to health emergency preparedness.

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Laws and Policies governing Medicines Management

YEAR	LAW or POLICY	NAME	SCOPE
2007	A.O. 2007 - 0017	Guidelines on the Acceptance and processing of Foreign and Local Donations during Emergency and Disaster Situations	Provides a systematic procedure and roles of HEMS, BIHC, FDA and CHD.
2009	R.A. 10121	Philippine Disaster Risk Reduction and Management Act	Policies and plans for all aspects of disaster risk reduction
2012	A.O. 2012 - 0013	Policies and Guidelines on Logistics Management in Emergencies and Disasters	Defines specific roles in logistics management for HEMS, BIHC, NCPAM, FDA, CHD, LGUs.

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Laws Related to the Activity of the Pharmaceutical Division

YEAR	LAW or POLICY	NAME	SCOPE
1968	R.A. 5921	The Philippine Pharmacy Law	Regulates the practice of pharmacy and the education of pharmacists.
1988	R.A. 6675	The Generics Act of 1988	Provides for prescribing and dispensing and procurement of generic medicines.

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YEAR	LAW or POLICY	NAME	SCOPE
1989	AO 62	Rules and Regulations to Implement Prescribing Requirements under the Generics Act of 1988	Provides guidelines on prescribing medicines defining the content of prescriptions, as well as prohibited vs regulated drugs
1989	AO 63	Rules and Regulations to Implement Dispensing Requirements under the Generics Act of 1988	Provides guidelines on dispensing of medicines according to prescription vs non-prescription; dispensing in drug outlets and in hospitals; partial filling; and list A and List B Drugs.
1989	AO 65	Guidelines on advertisement and promotions to implement the Generics Act of 1988	Provides guidelines on advertisement and promotion of medicines
2000	AO 130	Rules and regulations on generic prescription by government physicians	Provides guidelines on writing prescriptions by physicians employed in government run facilities
2004	169	Implementing guidelines for the exclusive use of generic names or generic terminology in all prescription and orders in all DOH facilities	Provides guidelines on exclusive use of generic names for generic terminology in DOH facilities

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Laws Related to the Activity of the Pharmaceutical Division

YEAR	LAW or POLICY	NAME	SCOPE
2008	R.A. 9502	An Act Providing for Cheaper and Quality Medicines, Amending for the Purpose Republic Act no. 8293 or the Intellectual Property Code, Republic Act No. 6675 or the Generics Act of 1988, and Republic Act No. 5921 Or the Pharmacy Law, and for Other Purposes	Supports the establishment of NCPAM, provides for activities including price monitoring of medicines
	EO 821	"Prescribing the maximum drug retail prices for selected and medicines that address diseases that account for the leading causes of morbidity and mortality"	Specifies medicines that account for the leading causes of morbidity and mortality and their maximum drug retail prices (MDRP)

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YEAR	LAW or POLICY	NAME	SCOPE
2010	AO 5	Establishment of DOH-NCPAM, formerly and adhoc committee called Pharma-50	Attain and sustain universal access to medicines by 2015.
2012	AO 23	Revised Implementing Guidelines for the Philippine National Formulary System (PNFS)	Describe the systems and procedures for selection of medicines in the Essentials Drug List, develop a new format of PNF, and promote the use of formulary

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Laws Related to the Activity of the Pharmaceutical Division

YEAR	LAW or POLICY	NAME	SCOPE
2015	SB 2436 ; HB 5616	An Act Regulating the Practice of Pharmacy in the Philippines, Repealing for the Purpose, R.A. 5921, THE Pharmacy Law as Amended, and for Other Purposes	Regulates the practice of pharmacy in the country

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YEAR	LAW/ POLICY	NAME	SCOPE
1992	RA 7581	Price Act	Provides protection to consumers by stabilizing the prices of basic necessities, prime commodities, and by prescribing measures against undue price increases during emergency situation.
2011	AO 12	Implementing guidelines on Electronic Drug Price Monitoring System (Version 2.0)	To provide a more effective and efficient implementation of EDPMS Version 2.0

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Other Regulatory Requirements affecting the Activities of PD

YEAR	LAW/POLICY	NAME	SCOPE
1963	RA 3720	Food, Drug and Cosmetic Act	Establishes standards and quality measures for food, drug, and cosmetic; adopts measures to insure pure and safe supply of food, drug, and cosmetic in the country
1992	RA 7394	Consumer Act of the Philippines	Promulgates and adopts ***consumer product standards*** to ensure product quality and safety; defines and provides guidelines on ***injurious***, ***dangerous*** and ***unsafe products***

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YEAR	LAW/POLICY	NAME	SCOPE
2002	RA 9165	Comprehensive Dangerous Drugs Act	Describes an ***integrated system*** of planning, implementation and enforcement of anti-drug abuse policies, programs and projects
2009	RA 8203	Special Law on Counterfeit Drugs	Prohibits counterfeit drugs, and provides penalties for violations
2009	RA 9711	Food and Drug Administration (FDA) Act of 2009	Enhances and strengthens the administrative and technical capacity of the FDA in the regulation of establishments and products under its jurisdiction; ensures monitoring and regulatory coverage; provides coherence in the FDA's regulatory system

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YEAR	LAW/POLICY	NAME	SCOPE
2010	RA 9994	Expanded Senior Citizens Act	Grants benefits and special privileges to senior citizens
2010	AO 36	The Aquino Health Agenda: Achieving Universal Healthcare for all Filipinos	Provides guidelines, approaches, and resources needed to affect and influence PPP, and benefit Filipinos as they transact in he local health system
2010	AO 17-A	Amendment to AO 2010-17 regarding Guidelines in Surveillance and Response tp Adverse Events Following Immunizations (AEFI)	Provides guidance to stakeholders on the early detection and appropriate response to AEs.
2011	AO 09	National Policy and Program on Pharmacovigilance	Establish and implement the National Pharmacovigilance Program; Set the policy direction for FDA, DOH, and attached agencies
2012	AO 08	Adoption and Implementation of the Pharmaceutical Inspection and Cooperation Scheme (PIC/S) Guides for the GMP for Medicinal Products	Adopts and implements the PIC/S Guides for the GMP for Medicinal Products

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YEAR	LAW/POLICY	NAME	SCOPE
2013	AO 22	Guidelines to Current Good Manufacturing Practice Clearance and Inspection of Foreign Drug Manufacturers	Creates and implements systems of evaluating and assuring GMP compliance of foreign drug manufacturers who sells or offers for sale their products in the Philippines
2013	AO 27	Adoption and Implementation of WHO Annex 5 Guide to Good Distribution Practices for Pharmaceutical Products and Guide to Good Storage Practices for Pharmaceuticals	Adopts and implements good storage and distributions practices among medicine handlers at all levels of the supply chain in the Philippines
2014	AO 34	Rules and Regulations on the Licensing of Establishments Engaged in the Manufacture, Conduct of Clinical Trials, Distribution, Importation, Exportation, and Retailing of Drug Products, and Issuance of Other Related Authorizations	Describes the new requirements for approval of LTO

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On Human Resources and Practices

- There were **88 Pharmacists in the 18 Regions** that performs a range of functions.

The workshop with them revealed the following;

There is a **lack of LGU pharmacists.**

No clear understanding of the Pharmacist Role as HP

Some RHU workers are resistant to change.

There is **no uniformity of documentation**.

There are no instructions for recalled medicines.

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On Human Resources Challenges

Inter-professional working relationships are not good.

There is **no SOP for disposal of expired medicines.**

There are **discrepancies in delivery of medicines.**

There is a need to educate RHU staff on GDP

There is a need to expand awareness on the nature medicines in health workers.

Centralising of all procurement is needed.

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On Human Resources Challenges

- There is a **transport problem** due to budget constraints so Provincial Pharmacists cannot easily perform their supervision and monitoring functions
- RHUs have **poor storage** – space, shelving, temperature.
- ComPac **allocation is based on national rather than local prevalence rate.**
- There is **overstocking of slow moving medicines** e.g. aspirin, enalapril, hydrochlorthiazide.
- Some LGU staff have relationships with suppliers which leads to **collusion in the procurement process.**

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On Human Resources Challenges

- They desire **distribution** of medicines direct to RHUs not to LGUs in order **to avoid conflict of supply.**
- **Medicines are out of date due** to lack of coordination between PD and ROs.
- **Quantity delivered does not agree with RIS** (what was ordered by the RHU).
- There is a need for an **organised distribution system.**
- There should be a designated person to **receive delivered medicines at each RHU.**
- Generally people (patients) know that medicines are free at RHUs, but this is not always the case.

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On Human Resources Challenges

- Some people believe that these medicines are donated by politicians.
- Some politicians hoard medicines for electioneering.
- Brand named medicines are in use because patients are dependent on the behaviour of prescribers. Prescribers do not always order generic medicines.
- Effect of commercials and the recommendation of celebrities causes patients to seek brand name medicines.
- Patients erroneously believe that brands are more effective and safer.

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On Human Resources Challenges

- Incentives are given to health workers by suppliers to use brand name medicines.
- There is a **need for PSCM seminars** to be held at LGU level.
- There should be performance incentives to encourage best practice, e.g. the best performing RHU should be recognised in some way.
- RHUs generally **do not have stock cards.**
- They don’t know that they should be using stock cards.
- RHUs don’t have a budget to purchase stock cards.

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On Medicine Supply and Distribution

- The devolution of the national health care system has resulted in a three-tier level of care being managed by three different political/administrative units, namely;

  national,

  provincial and

  municipal/city

  The last 2 referred to as **Local Government Units (LGU).**

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On Medicine Supply and Distribution

- **Vertical Programs**
- **Medicine Access Programs**
  - **Managed independently**

- **Contracted Third Party Supply**
- **Utilization data not reliable – NOSIRS does not serve the purpose as enabler**

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Conclusions

The identified areas which require strengthening or alteration include:

- **Planning and forecasting** of medicine requirements.
- **Vertical programs** for medicine supply plus constantly expanding **medicine access programs.**
- **Duplication of medicine procurement** at national and LGU level and certain medicines procured by vertical programs.
- **Non-compliance** to formulary (PNF) medicines.

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Conclusions

- **Confusion** about the respective roles of **the PNF and the Philippine EML.**
- Local **purchase** of medicines through **non-competitive bidding.**
- Slow and **tedious manual systems** in inventory management.
- **Limited human resource** capacity at LGU and facility level.
- **Lack of consistency** in the use of generic medicines.

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Conclusions

- Too **many report forms** which are based on various program requirements.
- Past introduction of the **consignment system** for medicines.
- Difficulty **in calculation of medicine usage** at facility level.
- **“Push” system** in use rather than **“Pull” system.**
- **No effective monitoring** of the entire pharmaceutical supply chain.

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Recommendations

1. **Creation of a National Pharmaceutical Center** that has 3 divisions:
   1.1. Pharmaceutical Supply Chain Management Division
   1.2. Quality Use of Essential Medicines Implementation Division
   1.3. Policy, Planning, Program Development and Research Division

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Recommendations

This change in structure will allow the following to happen;

- consolidation of medicine purchase to obtain lower prices through pooled procurement could be done.
- medicines access programs does not need to be individually managed.
- management of pharmaceutical forecasting, procurement request, storage and distribution would be undertaken by one

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Recommendations

2. Standard Operating Procedures (SOPs) to be developed – Center's Operations Framework - Operational System

4. The qualified Human Resource

3. A Clear Implementation Plan

Short-term

Medium-term

Long-term

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Current developments . .

- **Supply Chain and Procurement Management Cluster** was set up in March, 2018
- **Health Commodity Waste Management and Disposal** Study just completed hopefully to result to the revision of the 2011 DOH HCWM Manual – this will complete the loop for PSCM
- Strengthening **Good Distribution and Storage Practices in DOH and Health Supply Chain Workforce Performance Management Framework for DOH Pharmaceutical Warehousing and Distribution** Studies also just completed
- The **revitalization of the F1+ Botica ng Bayan implements a SCM process** that will contribute to the true usage data if followed

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In closing,

Efficient Pharmaceutical Chain Management is essential to

1. ensure **ACCESS to QUALITY and COST-EFFECTIVE** Medicines
2. prevent unnecessary **WASTAGE** to happen

We look forward to a **true change in the PSCM for a better Philippines . . . It's more fun in the Philippines1**

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