NATIONAL HEALTH SECTOR MEETING BRIEF

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What is the Current Situation of Regulation of Health Commodities in the Philippines?

Based on the Situational Analysis of the Philippine Regulatory Landscape And the Appropriate Enabling Environment Towards the Operationalization of Reform on Health Commodities by Dr. Ioana Ursu

BACKGROUND

Regulation of health commodities has three dimensions: 1) mandatory functions, 2) information flow, and 3) working practices or outputs. Issues or gaps in any of these dimensions, may result to problems such as incorrect prices (either too high to cover products, or too low to foster competition), over or under prescribing, increased patient out-of-pocket expenditure, and poor health outcomes.

CURRENT ISSUES TO BE ADDRESSED

- Pharmaceuticals lack pricing and monitoring functions, while devices lack an overall regulated system. Out of the six functions needed for a cohesive and coherent pharmaceutical system, two functions are lacking: pricing and monitoring. Tables 1 and 2 list pertinent findings for the six mandatory functions for pharmaceuticals and medical devices & equipment and the unit or agencies fulfilling each function. With the lack of a regulatory environment for devices, it is virtually impossible to ensure quality, safety, and performance of products in the market.

- There are gaps in coordination between FDA, DOH, and PhilHealth regarding health commodity-related information, work procedures, and type of data used for making decisions; no clearly defined entry point for the Philippine National Formulary; and PhilHealth's capacity to pay is not a major inclusion criteria for Formulary Executive Council (FEC) decisions.

- FDA's capacity and working practices have limited transparency with a huge gap between the expectations of the DOH and hospital practitioners with regard to what FDA does and can actually do; the Drug Price Reference Index (DPRI) methodology has yet to demonstrate its ability to control price; FEC evaluations were found to be hampered by a lack of evidence for decisions, information from FDA, and national standards of practice (or clinical practice guidelines); PhilHealth's purchasing and reimbursement functions were found to be limited because of a lack of forecasting, control over generic prescribing and the use of non-formulary medicines by hospitals, and prices that are not reflective of the anticipated costs for the recommended treatment.

RECOMMENDATIONS

1. **Choose price-reference countries with similar socio-economic levels and geographic challenges for off-patent generic drugs.** For branded medicines, it is recommended to have price negotiations based on Health Technology Assessment (HTA) and External Reference Pricing (ERP). A nationwide price regulation at the level of manufacturers and suppliers is also needed to ensure lowering of prices in both public and private sector.

2. **Continue the institutionalization of the HTA unit** and establish its secretariat and working procedures with the Formulary Executive Council (FEC), National Immunization Technical Advisory Group (NITAG), PhilHealth, future device committee, and DOH programs. PhilHealth's case rates should be taken into consideration when deciding on cost-effectiveness of a health commodity.

3. **Organize a device committee** composed of technical experts from the FDA Standard Divisions and Health Facility Enhancement Program (HFEP) together with a standardized formulary of devices.

4. **Further align AO 2018-002 (Guidelines Governing the Issuance of an Authorization for a Medical Device based on ASEAN Harmonized Technical Requirements) with the ASEAN Common Submission Dossier Template (CSDT) guidelines.** FDA should also make it mandatory to follow all (CSDT) guidelines.

5. **Develop internal working procedures for open and continuous communication between DOH, FDA, and PhilHealth technical working staff.** Steering committees are needed to define and delineate roles according to the data used and generated by each office. Certain data should be made public to increase transparency and public trust (i.e., FDA label indication, demands for PNF inclusion, status of HTA assessments, and clinical guidelines).

ANNEX

TABLE 1. MANDATORY FUNCTIONS AND CORRESPONDING UNITS FOR PHARMACEUTICALS

Functions	Units Responsible	Findings
Regulatory Function	FDA Center for Drug Regulation and Research (CDRR)	There are severe backlogs at this level due to increased number of applications and fewer evaluators.
Scientific Function	Formulary Executive Council (FEC) , DOH Drugs and Therapeutics Committee	There are also severe backlogs at this level due to lack of FEC quorum, Evidence Review Group experts, and FEC's lack of control to evidence submitted.
Pharma-coeconomics	Health Technology Assessment Unit	Mandates and working procedures of this unit are not yet defined.
Pricing Function	Exists partially through Pharmaceutical Division (Drug Price Reference Index or DPRI), PhilHealth Benefit Design Unit	There is no price setting function at manufacturer's level; DPRI is only used to set price at the point of access (public facilities).
Purchasing Function	DOH Programs, and DOH Central Office for Bids and Awards Committee (COBAC), procurement offices of LGU hospitals, PhilHealth	Lack of warehouse space and time required for FDA CDRR Laboratory division to test the goods (2-3 months) cause delay of delivery of goods resulting to stock-outs at local level facilities. In hospitals doing their own procurement, unattractive bid proposals and low prices set up at DPRI results to failure of bidding.
Monitoring Function	DPRI, PMIS (Program Management Information System), quality checks by FDA CDRR, information regarding number of cases captured by PhilHealth	This is only for commodities procured by DOH programs.There is no monitoring of stocks (inventory or stockouts) for PNF medicines procured at facility level. There is also no monitoring of prescribers.

TABLE 2. MANDATORY FUNCTIONS AND CORRESPONDING UNITS FOR MEDICAL DEVICES AND EQUIPMENT (MDEs)

Functions	Units Responsible	Findings
Regulatory Function	FDA Center for Device Regulation, Radiation Health and Research (CDRRHR)	Regulation function is present only for radiation devices. All other devices present in the market did not require an authorization from FDA CDRRHR.
Scientific Function	None (no institution fully fulfilling the scientific function). A small part of it is done by the HFEP.	FDA has no training to evaluate medical devices; the only staff able to do such work is currently available at HFEP. In contrast to medicines, the scientific evaluation of medical devices is not yet clearly defined.
Pharma-coeconomics	HTA Unit	HTA unit was just recently created; pharmacoeconomics capacity should be increased.
Pricing Function	None.	There is no pricing & reimbursement function for devices.
Purchasing Function	DOH HFEP, DOH COBAC, LGUs, DOH facilities	Technical specifications in procurement of devices is not in line with international standards.
Monitoring Function	None	There is currently no monitoring of the type, price, performance, calibration ranges, years of service etc. for any of the devices procured by either DOH or hospitals.

The **NHSM BRIEF** is a background document for discussion during the 3rd National Health Sector Meeting prepared by the Health Policy Development and Planning Bureau in collaboration with the Health Regulation Team.

This Brief is written by Menina Barbara Santiago and Dr. Janice Mandapat-Sanchez, in consultation with Anne Julienne Genuino & Dr. Anna Melissa Guerrero, edited by Ms. Rosa Gonzales, Dr. Gloria Nenita Velasco and Dr. Maria Iris Baltazar, and designed by Jake Matthew Kho and Cherie Tan.