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 framework 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 sectors.

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).
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