Excerpts from Chapter 2 – Indonesia Health System in Transition

2.8.4 Regulation and governance of pharmaceuticals

The organization of food and drug supervision in Indonesia is conducted by the government functions at the central and local levels through the National Agency of Drug and Food Control (BPOM) in accordance with the presidential decree No.103 of 2001. For monitoring at the local level, BPOM forms a Technical Implementation Unit (UPT) POM by Decree of Head of BPOM no. 05018/SK/KBPOM about the Organization and Administration of Technical Unit. UPT POM can do testing, investigation, research and dissemination of food and drugs in their respective provinces.

Responsibility of Regulatory Bodies

Drugs, vaccines and medical devices are critical inputs in primary health care, and are vital for several of the health-related Millennium Development Goals (MDGs). Enforcement of Good Manufacturing Practice (GMP) standards has improved in Indonesia. Badan POM is well on the way to achieving its goal of 100 percent compliance with the standards recognized internationally by the Pharmaceuticals Inspection Convention Scheme (PICS). Badan POM has drafted regulations on bioequivalence and bioavailability testing for generic drugs to ensure they are high quality substitutes for originator brands. Enforcement of Good Distribution Practice (GDP) by wholesalers and distributors is not yet as systematic, but Badan POM plans a similar program for achieving compliance over the next five years.

In the public sector, the *Puskesmas* network obtains most of its supply of medicines from the drug warehouse operated by their District Health Office (*DinKes*). District drug warehouses are supplied by multiple public sector supply chains. *DinKes*, some provinces and the Ministry of Health all publicly procure drugs for *Puskesmas*; and use central, provincial and district warehouses to manage inventory. Vaccines are financed and procured by the Ministry of Health, and distributed by Bio Farma to provinces, which distribute to districts.

Availability of a core list of essential drugs for infectious diseases and mother and child health at minimal or no charge is quite good in *Puskesmas*. But variation in district government performance aff ects access to essential medicine for the poor and near poor. A small number of mainly poorer, rural districts have problems with availability due to low budgets, high transport costs and the low procurement price ceilings set by MoH for OGB (Obat Generik Bermerk/Branded Generic Drugs). Availability appears to have improved or been maintained from 2004–2006, though slightly less so in rural areas.

Public hospitals ensure availability of a wide range of medicines principally by entering into partnerships–often some form of profit sharing agreement–with private pharmacies or Kimia Farma to operate on the hospital site. Thus they make use of private sector supply chains, which are more effective than hospitals' own procurement at ensuring availability and managing inventory, though prices paid are

higher than public procurement prices. In order to meet all of the essential drugs needed for the poor and near-poor population, many district governments need to raise the level of public spending on essential primary care drugs.

To improve availability of essential drugs, the effort consists of buffer stock relief for medicine / pharmacy in 476 districts / cities, the implementation of the first phase of treatment with herbs in 60 health centers and 12 hospitals, as well as implementing e-logistic for drugs in 115 districts / cities. It becomes apparent that the problem is not only in the matter of availability, but also in the matter of storage. It was noticed that most of the provincial and district/municipal warehouse do not have adequate and proper storage facilities. Concern was raised on the quality and efficacy of drugs being distributed through warehouse to the beneficiaries (people who seek treatment in primary health care facility) due to poor storage facilities and practices.

Meanwhile, in accordance with Minister of Health regulation (Permenkes) No. 1148/Menkes/VI/2011 regarding Pharmaceutical Whole Saler (in Indonesia, Pedagang Besar Farmasi or PBF), the Ministry of Health has also develop the e-report PBF. The software is an online system to report the fluctuation of drugs supplies at PBF. The Ministry of Health requires the PBF to report their drugs supplies, distribution and inventory every three months. The software application is downloadable from pbf.binfar.depkes.go.id

The MoH procures generic drugs at low prices–but inefficiency in public supply chain management leads to hidden costs. There are high levels of inventory at every level of the system causing high, unquantified and hidden financing costs, and creating the risk of leakage, spoilage or waste through date expiry of medicine stocks. Despite high inventory levels, many districts and *Puskesmas* have a combination of overstocking for some products and stock-outs of others. Problems in supply chain management arise for several reasons that are related to procurement policies and procedures. It will be preferable if similar program as e-Report is also developed to counter this problem at *Puskesmas*.

Pharmacovigilance and quality of medicine

Pharmaceutical commodities are heavily dependent on import-based drugs. Most pharmaceutical manufacturers in Indonesia import their basic ingredients from abroad. According to Permenkes No. 1010 of 2008, to ensure the quality and Pharmacovigilance drug, pharmaceutical companies must meet a Good Manucaturing Practice (GMP). With the availability of this GMP, the government guarantees that drugs are made to meet the requirement set consistently. GMP includes 10 aspects namely: quality management, personnel, buildings and facilities, equipment, sanitation and hygiene, production, quality control, self-inspection, handling of complaints, as well as documentation of medication

Classification of pharmaceuticals

In Indonesia there is a classification of the drugs, based on the regulation of Minister of Health (Permenkes) no. 917 in 1993 about mandatory drug list. It is later revised through Permenkes no. 949/2000. The classification consists of free drugs (green

circle label), limited free drug (blue circle label, W listed), and hard drugs (red circle label, G listed), and Psychotropic drugs and narcotics (O listed). Green circle and blue circle labeled drugs can be obtained without the use of prescription in pharmacies (over the counter). Over the counter drugs is listed and regulated in the Permenkes No:924/Menkes/Per/X/1993.

As Law no 14 tahun 2001 on Patent Rights stated, the patent rights is given for 20 years (non –renewable). Rules and regulations concerning counterfeit drugs (fake drugs) is set in the regulation of Minister of Health no. 1010/Menkes/Per No. XI/2008 concerning drug registration. It explained that the counterfeit drug is a drug which is produced unauthorized or product-labeling that mimics the identity of other drugs which has distribution license.

Market authorization and advertising

To protect the public from the risk of distribution and use of drugs that are not appropriate due to excessive, improper and misleading drug promotion/advertising, the government requires marketing authorization of all the Pharmaceutical Industry and Pharmaceutical Wholesaler, with the aim of improving prescribing, distribution, and sale or use of drugs. The regulation is enacted by the Head of POM in 2009 and contains Guidelines for Monitoring Drug Promotion and Advertising. The guideline outlines some monitoring towards the advertising of drugs in print media, electronic media and outdoor media. The scope includes all categories of drugs, all promotion activities (above and below the line marketing) including sponsorship in scientific meetings, quiz/lucky draw, and product launch. The source of information could be in the form of formal survey or feedback from the public or sampling. Any breach is punishable by administrative sanction or cease of activity or license revoke or even taken to court of justice.

The provisions regarding the advertising of medicines is regulated in the ordinance of Minister of Health number 1787 in 2010 on advertising and publicity services. The regulations stated that drugs should not be advertised using health worker as a product endorser, and drug advertising must have authorization and meet quality and safety standards issued by the Minister through BPOM. However there are some exceptions, with regards that not all the drugs can be advertised, such as, addictive substances and formula, hard drugs, psychotropic substances and narcotics, except in medical magazines or scientific forum. It is also not allowed to use testimonials in advertising of drugs.

Generic Drugs

Generic drug is usually a drug which patent rights has expired, so it can be produced by all pharmaceutical companies without having to pay royalties. In the market there are two types of generic drugs, which are:

a. Branded generic: "me too" products, mostly active in promotional/advertisement activities.

b. Unbranded generic: No promotion, usually a government project, state or local company.

Domestic drug manufacturers invest more in me-too drug generic versions of patent drugs and give them a trademark/registered brand. Pharmaceutical companies tend to position these products as 'patent medicines' (possibly due to registered brand) even though it is more accurate to be called as 'branded generic'.

Generic drugs are used by government program to increase access to health care especially in terms of the ability to buy these drugs. Generic drug does not cost promotion (advertising, seminars, competitions, etc) so that the price can be kept minimum. The producers (the drug manufactures) continued to receive profits, and at the same time the consumers are able to buy them at affordable prices.

The prices of generic drug, i.e. ex-factory/manufacturer price, wholesaler (profit) margin, pharmacy margin (or profit) and any taxes for it is regulated on Decree of Minister of Health (Kepmenkes). 'Patent drug' ('branded generic' drug) is priced at around three times of generic drugs. The selling price from the drug manufacturer or pharmaceutical wholesaler to pharmacy (HNA) is subject to VAT. The final retail price (what consumer pays) is also subject to VAT, but there is a regulation of the ceiling price of these final retail prices (HET).

The generic drug prices are controlled by the Ministry of Health in decree no. 092/MENKES/SK/II/2012 on Generic Drugs, and in the decree of the Minister of Health no. 094/Menkes/SK/II/2012. Kepmenkes no. 92/2012 was set in order to ensure the availability and distribution of the drug to meet the needs of health care, thereby rationalizing the HET for generic drugs specified in the Decree of the Minister of Health No. 632/Menkes/SK/III/2011. HET is valid throughout Generic Pharmacy, Hospital and Pharmaceutical Facility in Indonesia. Therefore, any sale of generic drugs can only be given a maximum price equal to the HET contained in this Kepmenkes.

The Ministry of Health also developed e-Catalog system. The e-Catalog is an electronic information system that contain information about the name, the type of drugs, technical specifications, unit price smallest, and provider factory prices. In e-Catalog price is for the smallest unit, tax and distribution costs. Procurement of generic medicine contained in e-Catalog is carried out by e-Purchasing through direct appointment (no bidding).

National essential drug list

National list of essential drugs is regulated in the decree of Ministry of Health No. 2500 in 2011. The regulation is designed to ensure the availability of medicines for a more equal and accessible by the public. The concept of Essential Medicines in Indonesia was introduced with the release of the National Essential Drugs List (DOEN) in 1980, and with the publication of the National Drug Policy in 1983. Due to scientific progress, the DOEN is revised every 3-4 years, but due to the provisions of Law No. 36 of 2009, DOEN will be revised every two years.

With DOEN the availability of essential medicines and essential will be more attainable because it will correlate with treatment guidelines and formularies in

hospital. The drugs listed in DOEN are paid by the government, so that people can easily to access the drug.

For those who have no insurance, the government has some policies that are intended to moderate private sector medicine prices. It regulates the retail prices of OGB medicines and sets a maximum retail margin of 50 percent for all medicines. It also requires manufacturers to print a recommended retail price (set by the manufacturers) on the pack. Regulated OGB medicine prices are low and are set at the same level throughout the country, regardless of the higher transport and inventory holding costs in some areas. These products account for a very small share of medicines sold in the private sector.

All districts can receive medicines from the 13 central level vertical programs: Acute Respiratory Infection (ARI) (includes Avian Flu and now Swine flu), Contraceptives/Family Planning Supplies, Diarrhea control, EPI, HIV/AIDS, Iodine, Iron, Leprosy, Malaria, Oral Rehydration Salts (ORS), TB, Vitamin A, and Yaws. Although nearly all of the 13 public sector, vertical programs, claim they supply medicines to the private sector, in practice, for other than TB medicines, only very small quantities of public sector medicines are reaching private providers, and even that supply is highly erratic.

Rational drug use

There is little evidence of rational drug use (RDU) being implemented in systematic ways among private sector providers. The RDU situation is highly variable between the many different health care providers. Rather, there are factors and powerful income motivations working against the rational use of drugs. Financial incentives i.e. the profit/income motivation are currently driving irrational use of drugs and use of high cost medicines in cases where a cheaper alternative is available. The Askes scheme has already implemented a restricted formulary and gained major cost benefits and there are high levels of generic medicines use within the faith-based hospital networks.