Evidence-Based Decision on Medical Technologies in Asia Pacific: Experiences from India, Malaysia, Philippines, and Pakistan

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ABSTRACT

Background: This paper discusses national programs implemented in India, Pakistan, Malaysia, and Philippines to generate and apply evidence in making informed policy decisions on the approval, pricing, reimbursement, and financing of medicines, diagnostics, and medical devices.

Approval: In all countries, the Ministries of Health are generally responsible for approval of health technologies through various agencies like the Central Drugs Standard Control Organisation in India, Bureau of Drugs and Food Safety in China, and the National Pharmaceutical Pricing Authority. In the Philippines, the National Pharmaceutical Control Bureau, Health Technology Assessment Unit and Medical Device Bureau in Malaysia, and the Drug Control Organization in Pakistan. Product dossiers are evaluated while taking decisions.

Pricing Control: India has a strong price control mechanism through the National Pharmaceutical Pricing Authority. In the Philippines, the Essential Drug Price Monitoring System monitors prices of 37 essential drugs monthly from all drugstore outlets nationwide. In Malaysia and Pakistan, registration pricing of new drugs is negotiated/fixed by the government with the vendor.

Reimbursement: A mix of social, voluntary private and community-based health insurance plans are available in India while the Philippine Health Insurance Corporation is responsible for reimbursement of drugs and medical devices in the Philippines. In Malaysia, no formal reimbursement system is being practiced, and in Pakistan the government reimburses medical claims of its employees.

Financing: In both India and the Philippines, the bulk of health expenditure is out of pocket while the government pays for 20% and 28% respectively in both countries. The public health care services in Malaysia are heavily subsidized by the government with minimum fee being charged to the public. The government of Pakistan gives free medicines to its citizens at the public health facilities.

Conclusions: In the region under discussion, one of the priority areas that the different regulatory agencies would benefit from is human resource development to facilitate the process of evidence-based assessment of health technologies. Higher budgetary allocation and stronger legislation is also needed along with interagency and international coordination and cooperation to harmonize.

Keywords: drug approval, drug financing, drugs reimbursement, pricing.

Background

The Asia-Pacific region has some of the fastest-growing economies in the world, especially with respect to pharmaceuticals. The health-care systems in this area are very dynamic, and there is also a major diversity among its people, political systems, wealth, and state of development. Australia was the first country in this region where data related to pharmacoeconomics (PE) and outcomes research (OR) were made mandatory for health-care policy decisions. In recent years, PE and OR have emerged as important for decision-making in health policy in various countries of the Asia-Pacific region including Taiwan, Thailand, South Korea, China, Japan, and Singapore.

India, Pakistan, Malaysia, and Philippines have, albeit slower than their other Asian counterparts, implemented some systems to generate and apply evidence in making informed policy decisions on the approval, pricing, reimbursement, and financing of medicines, diagnostics, and medical devices. Against the backdrop of a changing canvas, this article will describe the national processes in place in these countries to generate and apply evidence in making informed policy decisions on the approval, pricing policies, reimbursement, and financing policies of medicines, diagnostics, and medical devices.

The methods used while writing this article included a review of various official documents (including Web sites) such as legislations, government issuances, guidelines, and other official documents that portray the process and status of evidence-based decisions on medical technologies. If thought necessary, interviews were also conducted with key resource persons to get expert insights and firsthand data on the research subject. Each author contributed information pertinent to their country.

Approval

India

Approval of new drugs for marketing is the function of the Central Drugs Standard Control Organisation (CDSCO) (http://cdsco.nic.in/; last accessed January 29, 2009) headed by the Drugs Controller General (India) (DCGI). The CDSCO is attached to the office of the Director General of Health Services in the Ministry of Health and Family Welfare, and the DCGI is a statutory authority under the Act and has port offices, zonal offices, and drug testing laboratories functioning under him. Apart from this, the Central government (through the CDSCO) also grants permission to conduct clinical trials before granting marketing authorization. The CDSCO is also responsible for the registration and control of the quality of imported drugs; laying

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down regulatory measures and amendment of Acts and Rules; laying down standards for drugs, cosmetics, diagnostics, and devices; and updating the Indian Pharmacopoeia.

Part X-A of The Drugs and Cosmetics Act, 1940 and The Drugs and Cosmetics Rules 1945 (available at http://cdsco.nic.in/html/Copy%20of%201.%20D&CAct121.pdf; last accessed February 3, 2009) describes the requirements for approval of a new drug for marketing in the country. A new drug is defined in Rule 122 as a new substance of chemical, biological, or biotechnological origin in bulk or as a prepared dosage form, a drug already approved by the licensing authority that is now proposed to be marketed with modified or new claims, a fixed-dose combination of two or more drugs, individually approved earlier for certain claims, which are proposed to be combined in a fixed ratio, and all vaccines. Before approval, basic information on chemistry, physicochemical information, complete monograph specifications, and data on the formulation including quality control data, animal pharmacology and toxicology and human/clinical pharmacology are reviewed.

India has moved into a product patent regime in 2005, becoming compliant with the Trade Related Aspects of Intellectual Property Rights provisions of the World Trade Organisation (WTO). In a series of amendments to the Indian Patents Act, 1970, the latest and the crucial amendment to the Act was made in March 2005, effective April 1, 2005 [1]. This has spurred new drug development activities in the country, and till date more than 60 molecules have reached the clinical development stage. Although the licensing authority remains the CDSCO (the DCGI being the statutory authority), the detailed dossiers on the preclinical data on the new molecule are evaluated by the Investigational New Drug (IND) Committee set up for this purpose.

The evidence submitted by the company is evaluated, and initially, permissions are given to conduct clinical trials, and after phase III results are submitted and permission for marketing is given.

**Philippines**

In the Philippines, the basic infrastructure and mechanisms operate in pursuance of the country’s major health-related legislations, i.e., the Foods, Drugs, Devices and Cosmetics Act [2], the Generics Act of 1988 [3], the Price Act [4], the National Health Insurance Act of 1995 [5], and other pertinent laws and government issuances. Within this context, the mandates to make decisions over health technologies are delegated among various offices across the health sector bureaucracy.

The Bureau of Food and Drugs (BFAD) [2,6] regulates the production, import, export, sale, and distribution of drugs in the country as well as monitors the quality of products. BFAD is responsible for the issuance of the license to operate to drug manufacturers, traders of drug products, distributors, and drug outlets and for the registration of products such as processed foods, drugs, medical devices, in vitro diagnostic reagents, cosmetics, and household hazardous substances.

Evaluation of applications by BFAD for registration of pharmaceutical products involves examination of product dossiers containing technical specifications of raw materials and finished products as well as certificates of analysis. These are verified for consistency with official references such as the US, British, Japan, European and Philippine Pharmacopoeias and Martindale: The Extra Pharmacopoeia. If there are no specific references and no known specifications of the product, BFAD requires the company to submit validation reports or a certificate of pharmaceutical product from the country of origin or the country where the product is freely sold.

Clinical investigation data (phases I-III) and protocol for local clinical trial are required for new drugs. Products with additional dosage or dosage strength, and those with new indication(s) or route of administration, require phase III clinical trials. Phase IV clinical studies may be asked from products applying for renewal of registration. The protocols for such trials are approved by BFAD.

BFAD works with the following committees for the approval/registration of drugs: 1) an ad hoc committee activated when decision conflicts arise; 2) the Vaccine and Biological Working Group/Immunization Safety Surveillance System Review Board; and 3) the Product Recall Committee.

To give a separate focus on medical devices, an executive order (issued in 1999) created the Bureau of Health Devices Technology to specialize on the regulation of medical devices, health-related devices, radiation devices, and radiation facilities (medical and nonmedical) [7].

**Malaysia**

Various agencies such as the National Pharmaceutical Control Bureau (NPCB), Health Technology Assessment (HTA) unit, and Medical Device Bureau (MDB) within the Malaysian Ministry of Health (MMOH) are responsible for regulating medical technologies, including for assessing new medical technologies and to make recommendations for their approval or otherwise.

The Drug Control Authority (DCA) consists of a 10-member committee (Director-General of Health, Director of Pharmaceutical Services, Director of NPCB, consultant physician in the public service, pharmacist in the public service, three persons from any local universities with expertise in pharmaceutical sciences, and two fully registered medical practitioners). The NPCB is responsible for drug regulation and is the best-established organization with laws already in place. It is the executive arm of the DCA.

The function of the NPCB includes product evaluation, product assessment through laboratory testing, Good Manufacturing Practice inspections, processing product certificate and licenses, postmarketing surveillance, and monitoring of adverse drug reaction.

A mandatory registration scheme was implemented in 1984, and “Control of Drugs and Cosmetic Regulations 1984” was gazetted to support this function. Together with this regulation, the “Sales of Drug Act 1952,” the "Poisons Act 1952," and the “Medicines (Advertisement and Sale) Act 1952,” the Pharmaceutical Services Division of the Ministry of Health (MOH) began to regulate the importation, manufacturing, sale, and advertisement of drugs in Malaysia.

The Health Technology Assessment in Health Care Section (HTA Malaysia) was established in August 1995 under the Medical Programme, Ministry of Health Malaysia and has been a World Health Organization (WHO) Collaborating Centre for Evidence Based Practice since July 2004. The unit functions to provide input for technology-related policies, give advice, and provide HTA information to health-care providers and the public, and to coordinate the formulation and implementation of clinical practice guidelines (CPGs) [8].

The HTA unit is the secretariat to the Health Technology Assessment & Clinical Practice Guidelines (HTA & CPG) Council. The HTA & CPG Council is chaired by the Director-General of Health with members representing the Deputy Director-Generals, the state or hospital director, the nursing profession, the Academy of Medicine, universities (medical faculties), the Malaysian Medical Association, and the Association of Private Hospitals. The council sets policies and priorities related
to health technology assessment and reviews, approves, disseminates, and implements CPGs and formulated technology-related policies.

The HTA unit is also the secretariat to the Technical Advisory Committee (TAC), which is a division under the HTA & CPG Council. The TAC is chaired by the Director of Medical Development Division, whose membership includes directors of the following divisions: Medical Practice, Engineering, Pharmacy, Planning and Development, Family Health Development, and Head of Health Systems Research Institute. Through the implementation of the Private Healthcare Facilities & Services Act 1998, the MOH regulates the types, quanta, and locations of technologies and services.

The HTA unit produces two types of reports depending on the urgency of the request. A comprehensive HTA report takes 8 to 16 months to prepare and is sent to external reviewers. The report is prepared based on the analysis, interpretation, and synthesis of scientific research and/or technology assessment conducted by other organizations and also would incorporate any Malaysian data if available. A Technology Review Report is a brief report prepared in response to an urgent health technology information request. This report is prepared within 1 to 2 months, has no external reviewer, and is restricted to only reviews and analysis of pertinent literature, expert opinion, and regulatory status. An HTA report is initiated by a request made by completing the “Request for Health Technology Assessment” form, which is available online (http://www.moh.gov.my). The HTA unit receives health technology assessment topics from various organizations within the MOH for prioritization every 2 years. The TAC prioritizes the technologies to be assessed and presents it to the HTA & CPG Council. Priority setting is conducted so that the request for assessments is in line with the policies and objectives of the organization. Each request is assessed against several priority setting criteria that take into account factors such as the objective of the assessment, capital and recurrent costs, effects on other services and infrastructure, availability of competing technologies, significance of technology, and its level of usage.

To date (June 2006), 42 HTA reports (in-depth assessment) have been prepared and 114 Technical Reviews (rapid assessment) have been conducted [9]. The impact of the health technology assessment program can be seen in areas such as in policy and planning services/facilities, purchasing decision, and regulation of medical devices. Examples of impact on the formulation and planning services/facilities, purchasing decision, and recurrent costs, effects on other services and infrastructure, availability of competing technologies, significance of technology, and its level of usage.

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The government set up the National Pharmaceutical Pricing Authority (NPPA) on August 29, 1997 (http://www.nppaindia.nic.in/index1Eng.html; last accessed February 15, 2009). This is an independent body of experts consisting of a chairperson in the status of the secretary to the government of India, members having expertise in the field of pharmaceuticals, economics, and cost accountancy, and a member secretary in the status of joint secretary/additional secretary to the government of India. The NPPA was entrusted with the task of price fixation revision and other related matters such as updating the list of drugs under price control by inclusion and exclusion on the basis of the established criteria/guidelines.

The NPPA also monitors the prices of decontrolled drugs and formulations and oversees the implementation of the provisions of the Drugs (Prices Control) Order. In addition to these functions, the Authority also monitors the availability of drugs, identifies shortages, and takes remedial steps; collects and maintains data on production, exports, and imports, market share of individual companies, profitability of companies, etc., for bulk drugs and formulations; and undertakes and/or sponsors relevant studies in respect of pricing of drugs/pharmaceuticals. It is the NPPA that advises the government on changes/revisions in the drug policy, as well as assists the government in parliamentary matters relating to the drug pricing.

As part of its monitoring activity, the NPPA monitors and analyses month-wise price movements of nonscheduled medicines based on ORG-IMS reports. The prices of these formulations are fixed/determined by manufacturers themselves depending on various factors like the cost of production, market competition, the company’s profitability status, etc. The NPPA monitors the prices of nonscheduled formulations through various methods like scrutiny of price lists submitted by manufacturers, analysis of monthly “Retail store audit reports” published by ORG-IMS, and complaints/references received from official and unofficial sources. Studies are also commissioned when deemed necessary by the NPPA from voluntary organizations [13].

**Philippines**

The Price Act of 1992, among other provisions, reinforces the authority of the Philippine president to impose a price ceiling on any basic necessity or prime commodity, upon the recommendation of the Department of Health (DOH) or the Price Coordinating Council, in cases of calamity, emergency, illegal price manipulation, or whenever the prevailing prices rise to unreasonable levels [4].

In compliance with the Price Act, the DOH has authorized National Drug Policy-Compliance Officers and BFAD through the Essential Drug Price Monitoring System (EDPMS) to monitor the prices of 37 essential drugs monthly from all drugstore outlets nationwide [14]. These drugs are identified as essential drugs based on leading causes of morbidity and mortality and the Philippine National Drug Formulary (PNDF). With the institutionalization of the EDPMS, more specific guidelines for drug selection have been issued. The list of EDPMS drugs will now be based on accepted therapies for the prevalent diseases, cost-effectiveness, and cost minimization data from the National Drug Policy Program (NDPP) and the National Formulary Committee (NFC). Philippine Health Insurance Corporation (PhilHealth)-adopted CPGs, and PhilHealth claims reimbursement. Resource speakers from other DOH units, the industry, the academia, the health sector, and other relevant government agencies may also be consulted.

An Order issued to institutionalize and strengthen the EDPMS mandates the DOH to prepare reports to determine the price levels and inventory of essential drug prices classified as basic necessities and identifies price manipulation on essential drugs. An Essential Drug Price Monitoring Oversight Committee reviews all activities undertaken to implement the Generics Law and the Price Act and recommends to the Secretary of Health price ceilings of essential drugs. The NDPP, in collaboration with the NFC and PhilHealth, determines which medicines are classified as essential drugs classified as basic necessities that must be monitored nationwide [15].

This year, the “Universally Accessible Cheaper and Quality Medicines Act of 2008” [16], which aims to bring down the cost of medicines in the country, was signed into law reinforcing the president’s authority to impose the price ceiling for certain drugs.

Monthly data collection of drug prices is decentralized to local units of BFAD. Data sources include pharmacies of leading government and private hospitals in terms of bed capacity and leading private drugstore chain in terms of sales, covering only those outlets located in the capital city or province in the region concerned [17]. This information on drug prices as well as levels of inventory will be a part of the evaluation of the overall performance of retail outlets and wholesalers and will be a relevant factor in the issuance and renewal of their licenses to operate. Annually, the drug prices would be compared with international prices.

A joint effort of PhilHealth and the DOH led to the publication of a range of drug prices of top 185 drugs collected from a sample of drug points of sales across the country (Drug Price Reference Index [DPRI]). This aimed to make the public aware of the appropriate price of medicines and achieve price transparency as an initial step to empower consumers and improve access to medicines. PhilHealth is also developing a scheme to reduce and control its own cost for drugs by utilizing a DPRI as basis for reimbursement of medicines. The DPRI is a list of reference prices implemented as the ceiling price for the reimbursement of certain drug preparations. PhilHealth will only reimburse up to the DPRI price. Otherwise, the exact amount of the drugs will be paid.

The DPRI is hoped to promote rational and fair drug pricing, rational use of drugs, and drug price transparency.

**Malaysia**

The prices of new technologies are negotiated through a central purchasing system between the MMOH and the vendor for the public sector. Nevertheless, in the private sector there is no formal pricing control mechanism.

**Pakistan**

The Drug Registration Board is responsible for the registration and pricing of new medicines. The Drug Act of 1976 is vague about the price policy except in asking for fixing a price that is reasonable and affordable by the public. From 1976 to 1993 the medicines pricing was carried out on a case-to-case basis. In the mid-1990s, the government did some innovations for price fixation, but later this was discontinued. Since 2002 the prices of all medicines have been fixed independently. In 2008, the government formulated a Price Advisory Committee, which is expected to control the prices of either the top 100 most commonly used molecules or the essential medicines, recommended by the WHO [18].

**Reimbursement**

**India**

Social security for health care is not new to the Indian ethos—exemplified at its simplest in the form of a collection of a
fund by villagers to support a household with a sick patient. Nevertheless, health insurance was introduced formally only in 1912 when the first Insurance Act (the current version of this Act is dated 1938) was passed. In 1972 the insurance industry was nationalized and 107 private insurance companies were brought under the umbrella of the General Insurance Corporation. When the Insurance Regulatory and Development Act was enacted in 1999, private and foreign agencies were allowed to enter the market.

Even today, only about 3% to 5% of Indians are covered under any form of health insurance [19]. The Indian health insurance scenario is a mix of mandatory social health insurance, voluntary private health insurance, and community-based health insurance. This includes those covered under the Central Government Health Scheme (CGHS; 4 million beneficiaries), the Railways Health Scheme (1.2 million), and the Employees’ State Insurance Scheme (0.3 million), all examples of social health insurance. Premiums collected by private health insurance agencies are a meager 0.3% of the total health expenditure, further emphasizing the lack of general acceptance of the concept risk pooling [20].

Enacted in 1948, the Employees’ State Insurance Act was the first major legislation on social security in India. The scheme applies to power-using factories employing 10 persons or more and to nonpower and other specified establishments employing 20 persons or more, with employees’ earnings up to Rs 7500 per month being covered, along with their dependents. The current coverage stands at more than 8,400,000 employees and 35,300,000 beneficiaries across 22 States and Union Territories. The benefit package is quite comprehensive in its coverage of health-related expenses and includes the cost of medicines. The Employees’ State Insurance Scheme is financed by a three-way contribution from employers, employees, and the state government.

The CGHS was started by the Ministry of Health and Family Welfare, Government of India in 1954 with the objective of providing comprehensive medical care facilities to central government employees, their family members, and pensioners and other select individuals with over 43,00,000 beneficiaries. This scheme allows beneficiaries reimbursement of health-care expenses, and a “Package Rate” has been fixed at approved hospitals across the country that includes, apart from the lump-sum cost of inpatient treatment/day care/diagnostic procedure, the cost of medicines. The amount that a beneficiary is entitled to depends on his or her basic pay/pension. No formal system is described for the inclusion or exclusion of medicines in this list.

Private insurance (through approximately 12 general insurance companies and 25 third party administrators) covers about 11,20,000 individuals with almost 90% enrolled with the four public sector insurance companies. Nevertheless, private insurance is not the answer for India’s objective of equity, efficiency, and quality in health because it tends to select for the affluent classes, covering the healthiest and the wealthiest, resulting in limited social gain [19].

To provide financial risk cover to the poor, the government of India announced a Universal Health Insurance Scheme in 2003. Under this scheme, health care was provided for families below the poverty line for relatively small premiums (subsidized heavily by the government). Unfortunately, the coverage has been poor—perhaps because the public sector companies who were required to implement this scheme find it to be potentially loss-making and do not invest in marketing it, resulting in very low levels of awareness. An important reason for failure has also been that the poor find it difficult to pay the premium for a potential future benefit, foregoing current needs.

The National Rural Health Mission was launched in 2005, seeking to provide accessible, affordable, and quality health care to the vulnerable section of the rural population. Health insurance is promoted through this scheme in an attempt to mitigate the distress of households in seeking health care by reducing out-of-pocket expenditures (it is reported that three-fourths of the total out-of-pocket health expenditure is spent on drugs) through risk pooling. Importantly, the government has promised to subsidize the premiums for such insurance schemes so that patients below the poverty line are benefited.

**Philippines**

The Philippines National Health Insurance Act requires that reimbursement of claims for drugs is based on the latest edition of the PNDF unless explicit exception is made by PhilHealth [21]. In pursuance of this cause, PhilHealth established the HTA Committee in 1999 to develop reimbursement policies on medical claims based on quality measures, i.e., cost-effectiveness of tests and treatments. The HTA Committee, consisting of an Expert Panel drawn from various medical fields, conducts drug assessments, evaluates the safety and effectiveness of medical devices and medical and surgical procedures, and appraises and disseminates CPGs developed by local medical societies.

The NFC is the functional unit that formulates the PNDF. Decisions over drugs by the NFC are crucial because government entities are mandated to procure only drugs listed in the PNDF. Also, all drugs listed in the PNDF are reimbursable under the National Health Insurance Program [22,23]. The NFC uses the Formulary Selection Algorithm as a step-by-step evidence-based drug selection process to formulate the PNDF [24,25]. Proposals for the inclusion or exclusion of drugs are deliberated and subsequently decided upon using a consultative and participatory process with different panels of experts from medical schools, the Philippine Medical Association, specialty and subspecialty societies, government and private hospitals, pharmaceutical companies, and other stakeholders [26].

In addition, PhilHealth maintains a Positive List (consisting of 36 medicines) which is a compilation of non-PNDF drugs reimbursed by PhilHealth. For making this list, data are obtained on safety and cost-effectiveness from the results of clinical trials, postmarketing surveillance studies, adverse drug reaction reports from local and international sources, and local retail drug costs. Only systematic reviews of randomized controlled trials (RCTs) and individual RCTs are included by the HTA Committee in the drug assessments. Nonrandomized comparative clinical trials are considered if there are no RCTs or if there is an ethical reason for not conducting RCTs. If the drug is found to be more cost-effective and poses no additional risk compared with the standard drug, then it is recommended for inclusion in the Positive List provided that it is used for the conditions for which it was found effective. In 2000, PhilHealth included drugs in the Positive List that were lifted from three adopted CPGs: community-acquired pneumonia, hypertension, and urinary tract infection.

CPGs that PhilHealth adopts undergo critical appraisal that involves a systematic search for local and international guidelines. These guidelines are screened for relevance to the needs of PhilHealth. To confirm the validity of methods, PhilHealth utilizes the AGREE Instrument and an appraisal checklist developed by the HTA Committee in 1999 to develop reimbursement policies on medical claims based on quality measures, i.e., cost-effectiveness of tests and treatments. The HTA Committee, consisting of an Expert Panel drawn from various medical fields, conducts drug assessments, evaluates the safety and effectiveness of medical devices and medical and surgical procedures, and appraises and disseminates CPGs developed by local medical societies.

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Evidence-Based Decision on Medical Technologies

Apart from evaluating drugs, PhilHealth also conducts evidence-based health technology assessments on devices, diagnostics, and medical and surgical procedures. Results of these evaluations serve as inputs into the development of benefit packages for health services.

**Malaysia**

There is no reimbursement system in the public sector because health services are very heavily subsidized by the MMOH, with a minimum fee being charged to the public. For the poor and disabled, these facilities are made available for free.

**Pakistan**

All registered medicines by the DCO are eligible for marketing and reimbursement, although the government only reimburses expenditure on medicines incurred on treatment in public sector health facilities. State and Para state organizations such as the Pakistan Armed Forces, Pakistan Railway, and Pakistan Television Corporation, etc., either have their own health-care system or reimburse medical claims of their employees [27]. Nevertheless, the pricing and reimbursement mechanism of these organizations is not documented. In the North West Frontier province, the provincial health department selects medicines through competitive bidding on the basis of quality and price for the purchases in the public sector health institution in the province.

**Financing**

**India**

Financing for drugs occurs through several sources, including tax-based public sector, that comprise local (2.2%), state (14.4%), and central governments (7.2%), in addition to numerous autonomous public sector bodies; private sector including the not-for-profit sector, organizing finance for their employees either directly or through insurance; households through out-of-pocket expenditures (68.8%); insurance schemes; and through external grants and loans (2%). In India there is a clear urban–rural, rich–poor divide. Thus, affluent, urban populations and those working in the unorganized sector have only the tax-based public and private facilities to depend on for free or subsidized care, and private facilities depending on their ability to pay [28].

The estimated health expenditure in India for the year 2001 to 2002 was approximately Rs 108,732 crore, accounting for 4.8% of the gross domestic product (GDP) expenditure, with the share for drugs being about 12%, although this ranges from a poor of 2% in Punjab state to 15% in Tamil Nadu and 17% in Kerala [1].

Although reimbursement schemes are not common in India, poor patients have access to several free health-care programs in the country run by the government under which drugs are provided free. One of the largest schemes is the “Rashtriya Arogya Nidhi” (erstwhile National Illness Assistance Fund) (set up in 1997) where funds have been made available to assist patients below the poverty line coming to All India Institute of Medical Science or other central government hospitals for treatment of their specific life-threatening illness. Grants are given to the hospitals to be used on an as needed basis. There is a Technical Committee to advise the Managing Committee on technical matters such as nature of illness to be covered for assistance under the scheme and other ancillary issues. Thus, relevant to this article, the following items are paid for: pacemakers, cardiac and other stents, vascular shunts and drugs including anticancer chemotherapy, immunosuppressive drugs, antituberculosis (TB) drugs, anti-D, antihemophilic globulin, erythropoietin, blood and blood products/plasma for patients of burns. The government also runs several national programs that provide free drugs for poor patients, including the National AIDS Control Program, National Leprosy Eradication Program (http://www.whoindia.org/EN/Section3/Section122_1215.htm; accessed February 15, 2009), National Vector Borne Diseases Control Programme (http://www.nvbdc.gov.in/aboutus.html; accessed February 15, 2009), and National Tuberculosis Control Program (http://www.tb.cindia.org; accessed February 15, 2009).

**Philippines**

The Philippines spends only about 3.3% of its GDP for health, with per capita health expenditure at ~$45 (in 2005) (http://www.nscb.gov.ph/stats/pnha/2005/healthexp.asp; accessed February 25, 2009). Only 28% of the health expenditure is provided for by the government (16% from the national government and 12% from the local government). The bulk of the expenses on health (48%) are paid by the patient. Social health insurance provided by PhilHealth covers about 10% (http://www.nscb.gov.ph/stats/pnha/2005/sources.asp; accessed February 25, 2009).

The national coverage of PhilHealth currently stands at 76% or roughly 69 million Filipinos. In 2007, 32% of the reimbursements by PhilHealth were made for drugs and medicines. These are mostly for inpatient benefits and comprise about 5% of the total national expenditure for drugs and medicines.

Medical care, including medicines and vaccines, are provided free for the high-burden and highly endemic diseases in the Philippines. These include TB, malaria, schistosomiasis, filariasis, rabies, HIV/AIDS, and some common primary health problems. These are covered by the DOH and delivered at the Primary Healthcare Centers and Barangay Health Units. The National Center for Disease Prevention and Control formulates these vertical programs, whereas the Center for Health Development leads the monitoring and utilization.

**Malaysia**

The public health-care services in Malaysia are heavily subsidized by the government, with minimum fee being charged to the public. Drugs that are made available through the public health-care system are controlled through the Ministry of Health Drug List, which was first introduced in 1983, and contains 1403 products. The selection of drugs to be included in the formulary is based on their safety, efficacy, quality, and budget implications. This list is reviewed periodically by the Drug List Review Panel chaired by the Deputy Director-General of Health (Research & Technical Support) assisted by 16 working committees consisting of senior consultants and pharmacists from the MOH on various categories of specialties. The drug review is based on clinical advantage, best and current treatment options, current and previous usage, prescribing pattern, approved dosage and indication, and cost of treatment. The panel meets twice or thrice a year to consider proposals for additions, deletions, alteration of dosage form/formulation/indication/category of prescriber for the MOH Drug Formulary. From 2000 until 2006, a total of 254 drugs have been deleted from the Drug List and 199 drugs added [29].
Pakistan

The government of Pakistan gives free medical care (including medicines) to its citizens at the public health facilities. In addition, there are special Zakat funds (meant for the poor) at the disposal of the tertiary and teaching hospital administration. Besides, all federal vertical programs for the prevention and control of major communicable diseases such as TB, hepatitis, malaria, leprosy, and common primary health problems provide medicines and vaccines for treatment and prevention free of any cost.

For the formal sector of Pakistan, medical charges including medicines are usually reimbursed by some system. Nevertheless, these groups are only a fraction of the total population. The rest of the population rely on private out-of-pocket financing for health care, mainly doctor fees and medicines.

Although health care in Pakistan is mainly a provincial subject, issues related to drugs, medicines, and health insurance overlap between provinces and the federation [30]. Pakistan spends about 2.5% of its GDP on health care, and in 2005 the per capita health expenditure was US$15. Nevertheless, in terms of finance and delivery, the private sector provides almost two-thirds of health care to the population [31].

Conclusions

In this article we described the national processes in place in India, Philippines, Malaysia, and Pakistan to generate and apply evidence in making informed policy decisions on the approval, pricing policies, reimbursement, and financing policies of medicines, diagnostics, and medical devices. Regulation of drugs and medical devices requires adequately trained technical individuals who are capable of applying evidence in policy decisions. Additionally, they should be familiar with related policies and procedures. In the region under discussion, one of the priority areas that the different regulatory agencies would benefit from is human resource development to facilitate this process. Support from the government in terms of higher budgetary allocation and stronger legislation is also needed to strengthen the regulatory functions of the concerned agencies. Interagency coordination should also be reinforced to maximize the use of limited resources. An area of concern across the region is the paucity of regulation of devices.

It is also necessary to promote intercountry cooperation to allow the sharing of best practices as well as to harmonize practices across the region. Because complementary medicines (including strong local traditional medicines like Ayurveda in India) are very popular there is a need to promote the concepts of PE and OR in these areas as well.

Business models to sustain the operations of these regulatory agencies must be explored. Nevertheless, this should be done in a manner that will maintain the integrity and credibility of the processes. Lastly, there should be a policy on disclosure of conflict of interest among concerned committees and personnel.

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