The pharmaceutical situation in the Philippines

KENNETH HARTIGAN-GO

Kenneth Hartigan-Go is Deputy Director of the Bureau of Food and Drugs, and manager of the Philippine National Drug Policy Programme.

The objectives of Philippine pharmaceutical policy since 1999 are two-fold: to address the issue of overpricing of multinational drug companies' branded or patented products, and to improve the substandard domestically-produced or imported generic medicines.

Medicines, being regulated goods, cannot be treated as mere trade commodities but should be managed as a health utility. Makers and sellers of drugs have to be licensed, and the ways drugs are advertised and prescribed must be regulated. But enforcement of the rules is weak. In part, the reason may be that personalities take precedence over issues. This is important in the context of this editorial, and should be read as a form of self-criticism and the desire to effect a paradigm shift. We must not continue with "business as usual."

My involvement with pharmaceuticals started when I joined the teaching staff at the Department of Pharmacology at the University of the Philippines College of Medicine. I participated in various government initiatives to improve access to medicines. In 1999, I became deputy director of the Bureau of Food and Drugs (BFAD) and concurrent manager of the Philippine National Drug Policy Programme (NDPP) of the Department of Health (DOH). My job entailed implementation of the 1988 generics drug law. My entry coincided with the attempt to implement the Health Sector Reform Agenda, which seeks to improve pharmaceutical policy and regulatory systems to match current needs.

The concept of generic drug use as espoused in 1988 was a good one. It sought to rationalise the manner by which drugs for use in the Philippines were to be labelled and registered, and instruct medical practitioners on how they should write prescriptions for patients in order to allow for generic substitution at the retail outlet.

There may be some confusion concerning the term "generics". Officially, generic drugs refer to off-patent drugs. However, in the Philippine context, this term is loosely used to mean the scientific name of a medicine and is often referred to as unbranded (i.e., without a proprietary trademark name) drug product identified by the company's name.

The way these "generics" are priced may have contributed to the wrong perception of quality - that branded generics (those with a tradename), although priced a bit higher than unbranded generics, are better. In fact, the breakdown in the implementation of the generics law may have been caused by a perception that generic drugs, manufactured or imported by local companies, are of poor quality because they are cheaper. As a consequence, unbranded generic drugs are not patronised by the prescribers, drug outlets and patients.

The aggregate market share of domestic industry trading in generic medicines (excluding one large domestic company that is involved with transnational activities, with a market share of 20%) is estimated to be approximately 5%. Multinational drug industry market share is 75% of a total market of US$ 1 billion.

The national drug policy began with 5 conceptual pillars, as follows:

P: people empowerment, interpreted as setting up community village dispensaries and empowering people to have choices in the selection of medicines

Q: quality assurance of all drugs for use in the country, particularly generics. This was BFAD's role.

R: rational drug use through the implementation of a national formulary and introduction of advocacy seminars

S: self-reliance and self-sufficiency to develop independence from volatile market forces

T: tailored procurement using the formulary as a basis for government drug procurement.

These pillars were outdated and ineffectual and had to be revitalised along a different strategy. There are several instances where these concepts failed. The Department of Health promoted the community village dispensaries, while neglecting the provision in the pharmacy law requiring the presence of a licensed and registered pharmacist to operate such a drug outlet. Second, there may be quality testing but perhaps no quality assurance from BFAD on the products tested; the description of laboratory results of medicine testing can be aptly referred to as inaccurately precise. The little information that we do get from our laboratory is not swiftly and decisively acted upon. This lends to the perception of lack of transparency. A common industry complaint centres on the slowness of product registration. A moratorium on drug registration recently imposed by BFAD became a concern of the US Trade Representative and was interpreted as Philippines imposing a non-tariff trade barrier. There are irrational fixed drug combinations still in the market. Polypharmacy is still quite evident among clinical practice. Awareness of pharmacovigilance is still quite elemental.

As long as the Philippine drug industry does not produce raw materials or fine chemicals, it will never be self-reliant or self-sufficient. Instead, these are imported and undergo toll manufacturing. Interestingly, the tariff for imported finished products is 5% while that of raw materials is at 3%. There is therefore a tendency to import finished drug products rather than to produce finished goods. In addition, industry accuses the government of not offering better incentives. These were cited as reasons for not developing the local technical capability.

Good Manufacturing Practice (GMP) is still just an ideal. There are fewer than ten drug companies complying with GMP. The implementation of full compliance to GMP has been repeatedly postponed. The prevailing argument of domestic drug companies is that they need to continue operating in order to have profits to plough back into investments for their plant's GMP.

Tailored procurement is guided by the principle that government health facilities should only purchase from the National Drug Formulary, which is a generous listing of over 500 generic drugs meant to deal with the 95% of illnesses in the country. However, recent experience of the Department of Health in producing a list of accredited drug companies and weeding out companies of dubious repute still resulted in substandard deliveries.

In May 1999, the following national drug policy principles were defined:

A: Accessibility, affordability and availability of medicines

B: Bills of health more important than the balance of trade

C: Consumer advocacy and informed choice

D: Drug intelligence and drug information

E: Ethical Drug Marketing and Promotion

F: Formulary, as a guide to procurement and health insurance reimbursement

G: Generics

H: Herbal Medicine development (under the purview of the Philippine Institute of Traditional, alternative, & complementary medicine).

The psychology of the drug industry

Domestic drug industry acknowledges its limitations but wants the government to do two things: to hide industry violations from the public so as not to damage their credibility, and to keep supporting them by encouraging the promotion of generic drug use. This has been going on for a decade.

Multinational drug companies, on the other hand, believe that their provision of donations in cash and kind to government projects for indigents should be in exchange for the government not meddling in their pricing structure, as they are quite happy catering to those who can afford their prices.

Regulating promotional activities

Multinational companies often engage in aggressive promotional marketing activities hidden under the guise of scientific educational programmes. They arrange junket trips to tropical resorts in the guise of new product launches and sponsor "relationship-building activities" such as golf tournaments. The industry code of marketing practice was recently revised in order to control such unchecked promotional activities, which contribute to the rising cost of medicines.

Health professionals and patients as a rule do not read package inserts. Medical doctors who do not read about the products they prescribe obtain this information from drug detailmen who are trained by the companies that employ them. The NDPP proposed that these drug representatives undergo regulated training covering subject matters arranged by the government. The industry rejected the idea perhaps for fear that their detailmen might be influenced into considering appropriate ethical business practices.

Industry product stewardship

The health regulatory authority proposed that all sectors of the drug industry be held responsible for every aspect of the drug products' life, inclusive of raw materials, manufacture of finished products or importation of finished goods, stocking, marketing and promotion, distribution and sale at the outlets. In the past, government has inefficiently dealt with various industry units as separate players and components. This proposal would allow government to deal with them as a single entity and will simplify BFAD tracking of good and bad drugs.

Under this scheme, the obligations of various drug companies should not end with defective products but include good drugs that are misused or abused. The industry should provide appropriate education of rational and correct drug use to prescribers, dispensers and users. For instance, there are poor patients who buy medicines a few pieces at a time when their finances permit; the retail outlet may sell them medicines without proper packaging or product information, perhaps without even indicating the expiry date. The industry must be responsible for instructing them on the proper use of the medicines. Methods of product advertising must also be included as product stewardship obligations.

If a drug company misbehaves, this information should be shared with all the industry players so that they will be in the position to police each other above and beyond BFAD monitoring. The value of economic sanction is a compelling tool that the DOH should utilise.

How are prices pegged - market forces or marketing forces?

Drug prices in the Philippines are 40-70% more expensive than those in other Asian countries. There are considerable mark-ups in the value chain for drugs because the Philippines is dependent on importation of raw materials and finished goods. As a consequence, we suffer from transfer pricing, and padding of prices by middlemen.

Industry attributes the high prices of medicines to market forces; this is partly true because medicines are an inelastic product. The conventional supply-and-demand law of economics does not apply to pharmaceuticals. When one is sick, one has no choice but to procure the medicines. The market therefore does not belong to the consumers but to the prescribers and dispensers. The industry then targets the prescribers and dispensers for heavy product promotion.

Prices are pegged in various ways depending on the type and age of the product. Some of the pricing techniques are as follows.

Pricing an innovation patented drug.

Using the cost of materials, plus conversion cost, packaging, marketing and research. When the drug changes hand from the manufacturers to a wholesaler to a distributor to a retail outlet, that cost is multiplied by a percentage for mark-up and profits.

"Follow-the-leader", where a drug company positions itself as a producer of quality branded drug which is priced slightly lower than the market leader brand, but higher than the generic equivalents. This price will fluctuate according to the price set as the brand leader.

Using the price-sensitivity index and reliance on brand equity. This calls for testing what the market will bear and is based heavily on the perception of quality and what people are willing to pay. A company would want to achieve maximal and optimal profits, even though doing so might exclude a large percentage of the population.

A typical illustration is this: company X produces Drug A at cost of P1 but would like to sell at the highest possible profit margin. So the company X adds a trademark or a brand and develops it as a quality product. Company X conducts market research by asking 100 persons if they would buy the product at P10. Perhaps 100% of them will think that the price is reasonable and that they can afford to purchase Drug A. The company then keeps raising the prices until P50 per tablet is reached. Now perhaps only 30% of the 100 persons claim that they would buy the drug at that price. Thirty people buying the product at P50 will still provide the company with a larger profit margin than 100 people buying the product at P10. If the upper 15% of the population is willing to pay the exorbitant price, even though the rest of the population is not, then the company might still choose the higher price because it would result in a higher return on investment.

The use of generics in relation to the Philippine Health Insurance System

The Australian Pharmaceutical Benefit Scheme (PBS) is the model that we in the Philippines hope to emulate. The Philippine strategy was first to require the Philippine Health Insurance Corporation (PHIC), which runs the national health insurance scheme, to reimburse only those medicines found in the National Formulary. This will necessitate the use of generic names (regardless of the brand or trademark). A reference drug price for all generic drugs will be established. Assuming that BFAD can assure the quality of all generic drugs, PHIC will pay only the base generic reference prices. Should hospitals, doctors, or patients insist on a particular brand, they will have to pay the balance of the cost of that premium medicine. Why should the PHIC pay for more expensive branded generics when there are cheaper quality alternatives?

The government is attempting to establish a similar pharmaceutical benefit scheme to undertake price negotiation but this will not prosper without someone assuring that all generic drugs in the market are of good quality. The NDPP is collaborating with the quality assurance group of PHIC because of the mutual concern for quality assurance in clinical practice and for cost containment.

The PHIC has a substantial role to play in lowering drug prices. It has been instrumental in promoting the use of generic names and the use of medicines listed in the Philippine National Drug Formulary in processing drug claims and reimbursements. This listing in the current 5th edition of the Formulary is above and beyond the recommended WHO essential drug model list of 150 drugs.

In future, reimbursements for drug claims will be done according to peer-reviewed and scientifically validated Clinical Practice Guidelines (CPGs) which will promote rational drug use. At a later stage, PHIC will introduce cross-reference pricing.

E-bidding: overcoming the lack of transparency in government drug procurements

In the past, there were companies that existed just to supply government contracts. As all government agencies purchase medicines through a process of bidding, there will be winners and losers. The potential for collusion has become evident. In a study of prices of winning bids within a certain locality, prices for the same products from the same winning bidder can differ by 200% within a period of 30 days of transaction. In addition, awarding of contracts takes some two weeks following committee deliberations.

Transparency in bidding would solve this problem. E-bidding is intended to introduce efficiency and transparency in government drug procurement. In this way, all bidders can monitor and compete with other bids while remaining anonymous. Essentially, this will effect the true reverse auction for drug products to be sold to the government. Furthermore, by consolidating bid requirements from various government health facilities like health centres and hospitals, prices of drugs can be lowered.

Bringing the cost of medicines down and the plans to establish DOH generic drugs

One possible way of lowering the cost of medicines is for the government to enter into the market as a competitor. The DOH can import affordable and quality raw materials from the Asian region and contract the manufacturing of DOH generics through reputable GMP-compliant toll manufacturers. In this way, DOH can control the raw materials and eliminate transfer pricing, pay toll manufacturers a reasonable price, eliminate the fanfare of promotional activities and deliver these drugs directly to government health facilities. But this is still only a plan.

Parallel importation

The counterfeit drug law and its implementing rules and regulations were reviewed recently. Counterfeit drugs were erroneously defined to include unregistered branded products brought into the Philippines, where the brand is already registered locally. Because this sentence protected exclusive distributorship and in effect monopoly, the regulation was modified. BFAD checked and registered multinational drug products from India and the Department of Trade and Industry undertook the purchase of those drugs in the open market in India and the importation of these same branded products. These medicines were then sold in various government hospitals. Parallel drug importation of cheaper yet equal quality branded drugs was initiated. The parallel import price was only approximately 20% of the price one will normally pay at commercial drug outlets. In essence, the government entered into competition with the multinational drug industry in the Philippines. The results so far have been a court case against the government and possible US trade sanctions on the Philippines.

Clinical trials or marketing seeding trials with experience endpoints?

Despite the commonality of medical problems in many nations, there are unique needs in a developing country. One example is access to affordable generic medicines proven to be effective and safe. While there are global initiatives in the testing of new chemical entities (NCE) for general diseases, drug development for diseases unique to developing countries is given lower priority. Moreover, poorer sectors of society have difficulty affording the price of newly developed medicines.

In the Philippines, there are clinical trials for NCE and trials to test the claims of generic drug industry. These are officially regulated by the BFAD. Unfortunately, there are also marketing trials with experience endpoints disguised as clinical trials that pass unregulated. Good R&D drug companies comply with BFAD regarding the submission of research protocols that include important assessment parameters.

In theory, the generic drug industry submits bio-equivalence studies but the credibility of generic drug companies remains weak. The government has imposed compliance to Good Manufacturing Practice (cGMP) as another parameter for quality assurance, but this is not adequately implemented.

Among many possible initiatives, regulators may be empowered in various ways: establishing a national clinical trials database, requiring only medical centres spontaneously reporting adverse drug events (ADEs) to participate in clinical trials, and strengthening hospital therapeutics committees to create ethical and technical review committees to oversee the unregulated experience-endpoint marketing trials.

Generic substandard drugs

Recent evidence of substandard drugs has surfaced supporting many medical doctors' mistrust for government guaranteed "quality" generic drugs in the country. The ineffectual administration and enforcement of the law allows erring but politically powerful drug companies to challenge the government, even resorting to litigation. The resolution of this problem appears to rest heavily on legalities, while neglecting the original mandate of the government to protect public health and safety.

In these circumstances, how can the generics law be implemented to effect access to drugs by the masses? Who will ever trust generic drugs in the market ? How can generic substitution be ethically permitted at the drug outlet level? Drugstores persistently flout the law by selling prescription drugs without prescription and we entrust the professional commercial pharmacists to follow the regulation. Some of these drug outlets would not even produce and identify the sources of their violative products because they wished to protect their illegal sources.

If substandard drugs are not addressed appropriately to the satisfaction of health professionals and consumers, the generic drug law cannot be implemented. Secondly, the government will be incapable of managing the more menacing counterfeit drugs because of lack of courage and conviction. BFAD laboratory management systems and consequent actions on violations must be strengthened in order to promote the credibility of the government towards ensuring quality drugs. Legal due process is important but must take into consideration technical inputs from the regulatory staff and the need to protect the greater concern of the public health interest.

There were attempts to improve the image of domestic drug industry engaged in generic drug production. Many of the projects (movie trailers and the first national drug congress) were disallowed by higher authorities. Domestic industry refuses to compete with the marketing and promotional activities of bigger players. As a consequence, many do not have confidence in their capabilities. Knowing that they do not have cGMP and that they get away with government's weak enforcement of the regulation on quality, local companies rely on government to protect their tenuous reputations.

The role of therapeutics committees

The NDPP is encouraging the development of therapeutics committees through technical assistance. These committees are established within hospitals to ensure the use of formulary, clinical practice guidelines, ethical clinical trials, rational drug use and manage pharmacovigilance issues. They should be allowed to make local decisions which affect the quality of health care and in particular drug use within the context of their hospital needs and should challenge the BFAD when there are substandard drugs detected in the market.

National drug policy and national security issues

I have argued that national drug policy contributes in some ways to national security issues. One example is the proliferation of substandard drugs. These substandard drugs can be functionally considered fake or counterfeit medicines. They undermine the credibility of the government and in particular that of the DOH. In the light of the high cost of branded drugs, the generic alternatives being proposed by the government are viewed to be substandard because of the evidence being collected by BFAD.

There are six arguments. First, lives are put at risk. Patients using substandard drugs may not be aware of this and therefore become unwitting victims of government and industry neglect.

Second, the quality assurance of any medicine is a primary obligation of the industry. The role of government is to validate whether the industry has in fact performed this obligation. Given the limited amount of resources of the government in inspection and counterchecking, once there are violations, the government must exercise its duty to protect public interest above the interest of the erring companies.

At present, despite 13 years of implementing the generics law intended to promote cheaper access to local drugs, doctors and patients still do not trust Filipino generics companies and their products because they are still providing substandard medicines. Doctors and patients would rather use expensive branded multinational

drug companies' products. Many lives could have been saved had there been better and cheaper medicines produced or imported by Filipino companies.

Third, the industry has always been given the benefit of the doubt when their products are found violative or inferior. In the first place, all products allowed on the market by BFAD should have been assured as efficacious and safe, and of good quality. The legal process to resolve this problem can take a year.

Fourth, DOH, among other government agencies, buys medicines through a bidding system. Even after various attempts to clean up procurement system through the introduction of strict accreditation process, weeding out over 250 suppliers, some of the remaining 70 or so suppliers are still found to be delivering substandard medicines. This is a national security issue because it undermines the confidence of the public and the health professionals towards the government.

Fifth, importing substandard medicines from abroad after obtaining BFAD license and certificate of registration should be treated as a form of economic sabotage.

Finally, there is no self-reliance in our local industry to produce our own medicines. This is a serious security issue in case of war, trade sanctions and globalisation, particularly when the Asian Free Trade Agreement (AFTA) comes into effect, domestic drug industry may not be able to compete internationally.

By 2002 there will be AFTA, and a little later trade globalisation and retail liberalisation will come into effect. Filipino industry will not be able to survive these phenomena if government continues to protect substandard Filipino companies. This misplaced protection promotes the industry's incompetence and inefficiencies. These issues may backfire on the current administration in 2004, an election year.

The Philippines and Australia

The health care industries in both countries share common views about most technical matters - such as the need for formal rationing on the basis of cost-effectiveness, the need to control market forces in the interests of the wellbeing of the entire population, the value of encouraging generic drugs for price control, and so on.

The opposing forces are also much the same. In particular, multinational drug companies are dominated by concern for profit and market share, and they have many allies in the prescribing and retailing sectors.

This said, Australia has clearly been more effective for a wide range of historical and socio-economic reasons. It serves as a model and a stimulus for less fortunate countries like The Philippines, and indeed most countries in the world. It is therefore with some concern that we have read about the increase in influence of the drug companies as a consequence of recent changes in Australia's Pharmaceutical Benefits Advisory Committee. If Australia loses its way, the flow-on effects to many other countries could be harmful.