



Framework for Drug Price Control in the Philippines

Government intervention is needed to address market failures and inequities in the pharmaceutical situation¹

Prices of drugs and medicine are considered to be at levels that produce inefficiencies and inequities [Solon and Banzon 1999]. Inefficiencies are manifested in terms of deadweight loss and 'irrational' drug use, while inequities by the inability of consumers, particularly the income poor, to access appropriate medical services or achieve minimum acceptable levels of health. Deadweight losses (see [Box](#) for a definition of terms) are implied by international and domestic price variations in drugs that in turn suggest markups on manufacturing, distribution and retailing costs, which are likely to be less than what is lost in terms of consumer surplus. Non-tariff barriers to trade, information asymmetries and dominant players at all levels of the industry enable such markups. At the manufacturing level, international patent holders enjoy exclusive rights to manufacture and market drugs for a set number of years, including the decision to locally produce or market a 'branded' drug in a locality. Distribution and retailing markets likewise feature dominant players, which controls over 80% of distribution and another corporation which controls almost 77% of the retail market [DOH 2008]. Private hospitals also exercise market power when they discourage or prohibit patients from purchasing drugs from outside.

Irrational drug use pertains to the use of ineffective remedies, non-compliance with prescribed dosages, and the persistent use of branded drugs despite the availability of equally effective cheaper substitutes. Irrational drug use is enabled by unaffordable prices as well as by information asymmetries across patient and physician, and physician and producer. Patients have little understanding, much less information, on disease processes and how these are treated. As such, the physician effectively has the power to choose what drug the patient will buy, what brand, and even where to buy it. Physicians however may tend to over-prescribe due to lack of, or biased, information. Growing evidence from international literature has demonstrated how corporate sponsorships and gift giving to health professionals and medical organizations influence physician-prescribing behavior and promote irrational drug use. Poor quality signals, which contribute to domestic price variations in drugs of the same type, are another form of asymmetric information.

Market failures and inequities provide 'a-priori' reasons for government intervention and social provision. However, they do not by themselves justify it. Whether or not a government should intervene depends greatly on its capacity to successfully carry out the intervention, otherwise government failure may be worse in the longer run than the market failure it originally intended to correct. For instance, one could argue that current problems in housing or agriculture are directly attributed to the failure of public enterprises, which were originally mandated to catalyze or regulate parts of those markets.

In deciding whether to intervene, costs and benefits of government intervention must be weighed against the costs and benefits of 'doing nothing'. For instance, if price controls are contemplated in order to improve access to drugs, setting prices *too low* may result in retaliatory actions such as withdrawal of supply, or worse deter entry of additional players, undermining the very objective to promote competition. Setting prices *too high* could effectively transfer 'informational rents' to drug suppliers [Solon and Banzon, 1999]. Further, setting prices '*just right*' – at that level that brings down the price of branded drugs while maintaining or increasing the volume sold – could also [artificially] *reduce the demand for unbranded generic drugs* and, inadvertently kill the generics industry in the longer run (particularly if policies to strengthen the generics industry are not fully implemented.)

Another example is if social provision of select essential or merit drugs is contemplated and expectations are raised far beyond what government budgets can meet, creating greater political problems. Direct government procurement and distribution of drugs at subsidized costs could also deter entry by new suppliers who could have serviced government needs but who are unable to at artificially low prices.

Varying degrees of government intervention may be utilized to address these problems

Policy actions depend on which of the above market failures or concerns is to be addressed. These can either be supply-side or demand-side interventions.

Supply-side interventions

International price variations may be caused by barriers to trade, in which case, one response by government is the **removal of trade barriers**. Conceptually, this has been accomplished thru the newly enacted RA 9502, or Cheaper Medicines Law. It is assumed that removing trade barriers will allow for arbitrage across countries, equalizing prices of

¹ The problem of high prices of drugs and medicines in the Philippines has been previously discussed, for instance, Solon and Banzon [1999] and DOH Health Policy Notes [2008]. See Monsod et al [2009] *Background information and context of the proposed framework for the imposition of MRP on selected drugs*. Unless otherwise indicated, this section draws heavily from Monsod et. al [2009] henceforth *Background*

drugs of the same brand, maker and dosage. In doing so, however, complementary policies are required to ensure optimal/expected gains from freer trade. Specifically, policies to enable competition at distribution and retail levels so that price gains are not co-opted by dominant players at these levels as well as policies to facilitate the entry of new importers and ensure the quality of new supplies.

Under the best of circumstances, price gains from the removal of trade barriers may be realized, if ever, only after a **lag**. Private sector players may not have enough information to determine the feasibility of the business, or may fear collusion/retaliatory actions by existing dominant players on the manufacturing, distribution or retail side. Moreover, price gains may not be realized at all for products where the size of the market is small, open markets notwithstanding. For these reasons, government may determine that further measures to bring down prices and improve access may be warranted. For instance, direct or indirect price regulation or demand-side subsidies (discussed in the next section).

Direct price regulation is usually employed to address the matter of monopoly mark-ups. By imposing price caps or ceilings for instance – as in the case of natural monopolies in water or power - it is hoped that prices come closer to their efficient levels, reflecting marginal costs or, at least, short-run average costs. If set to marginal costs, government subsidies would have to make up the difference between marginal costs and average costs so that profits are not negative and the supplier does not close shop. If set to short-run average costs, no further subsidies are supposed to be needed. In either case, information about supplier or monopolist cost curves is required.

In the case of government regulated monopolies in water or power, books of accounts are open to the government regulator who, in turn, determines or validates the average cost curve of the monopolist. Pharmaceutical manufacturers do not qualify for the same regulation however and, thus, books are not open. Alternatively, government can set prices at subsidized rates (that is, at marginal costs) by producing the goods or services itself thru a public enterprise. This however may cause further problems particularly if government has a poor track record in enforcing and monitoring efficiency mandates [Solon and Banzon 1999].

Indirect price regulation thru government procurement and retailing is another option. In this case, government sets reference prices to guide the procurement of drugs and medicines sold at national and local public health facilities, or for reimbursements by public health insurance programs. Note however that these prices are usually meant as limits to reimbursement under public health programs, *and not as market markers per se*. Further, to be effective, the size of government procurement relative to the market shares of identified drugs cannot be trivial. If government procurement of targeted drugs accounts for less than, say, 30% of their markets in terms of volume, then the likelihood that government procurement will have any impact on market prices is small. Reference pricing for purposes of procurement or reimbursement further assumes that government is capable of a fairly sophisticated degree of analysis, evaluation and transparency in its approach.

Again, direct and indirect price regulation may offer a short-term solution to the matter of inefficient (monopolist) pricing, particularly while price gains to open trade have not yet been realized. The longer term, more sustainable solution however is still increased competition from a **strong generic pharmaceutical industry**. The implementation of the Generics Act should therefore remain a priority and should figure into any discussion of policy actions on other fronts.

Demand side interventions

Notwithstanding supply side interventions, demand-side interventions, such as direct subsidies or transfers and improved information and quality signals, may be warranted, especially where inequities remain *despite* well-functioning markets.

In the short term, provision of **direct subsidies** via social insurance or **outright transfers** in cash or in kind most efficiently address inequities and merit good concerns that arise due to affordability constraints (in the longer term, effective poverty alleviation programs.) This could include direct government procurement of essential drugs and their transfer to targeted beneficiaries thru public health programs or through conditional transfer programs. Take note, however, that the procurement and distribution of such drugs, if done at subsidized costs and without a phase out strategy, *will not at the same time be a fair instrument to exert pressure on market prices*. In fact the opposite effect could be created. The explicit/implicit subsidies involved in government procurement and distribution could deter entry, when entry is required to generate downward pressure on drug prices over the longer term.

Better quality signals and improved communications/information programs on the efficacy of drugs is another demand-side intervention. This should help address that form of irrational drug use manifested by hesitancy to use cheaper but equally effective generic drug substitutes (in other words, irrational drug use that is *not* due to affordability constraints).

Systematic drug price control options are available

The direct and indirect price regulatory mechanisms outlined above pre-suppose some measure of universal coverage in social insurance as well as state capability for a sophisticated degree of analysis and transparency in methodology, such as in the case of European countries [Background]. Such conditions are not present in the Philippines however. First, public resources for health are highly constrained and uncoordinated. The National Demographic and Health Survey 2003 reports that only 30% of the household respondents have at least one member in their household covered by public health insurance (PhilHealth) and PhilHealth benefit packages barely

cover outpatient conditions and require substantial co-payments. Annual government spending on pharmaceuticals (including imports, PHIC, DOH, other national agencies, and LGUs) is estimated to account for just Php 10-11B, or 10% of the entire pharmaceutical market, and such spending is fragmented [DOH, 2008]. Second, regulatory capacity, whether for ensuring the quality of generics or for monitoring and analyzing overall market conditions, is weak.

If and when government contemplates some form of price control or regulation therefore, the following options present themselves:

1. Adopt a two-tier pricing system for patented drugs ²
2. Build up of procurement capacity in targeted drugs, to at least 30% of market in terms of volume.
3. Impose MRP but reserved to drugs with both significant contribution to public health goals and where price gains to improved competition may be delayed or may be difficult to realize.

It bears emphasizing that any of these approaches might offer a short-term solution to drug access concerns. However, longer-term structural reforms should be implemented and/or further explored which recognizes the need for balance between the markets for free sales and government supplies. ³ The government cannot supply the entire demand for drugs unless it is prepared to commit to massive public subsidies and drastic price controls and their possible effects.

(1) Two-tiered pricing system. In this approach, the DOH would finalize a list of patented or off patent branded drugs that it intends for use in the public health system. Producing companies would then be invited to convey the prices at which these drugs would be made available to government, with each tablet carrying a distinctive mark and the strips separately labeled to indicate that they are not for sale, but part of the public health care system. The same drugs are kept available in the open market at market prices however. Such a twin pricing system has the advantage of delivering drugs at low costs to the public health care system without distorting the market mechanism. In the case of patented drugs it is conceivable that producers may be willing to accept prices that are close to marginal costs of production plus fixed returns, if allowed to charge market prices outside the system. While patients in the public health system should be free to purchase more expensive patented or branded drugs, this could be achieved through a “balanced-billing” arrangement in which the government would subsidize only the cost of the basic generic alternative (if available), with the remainder being contributed by the patient, thus avoiding the prohibitive cost of subsidizing state-of-the-art patented medicines.

Operationally, such a mechanism would require (i) identification of the government/publicly supported hospitals that are eligible for lowered prices, (ii) a complete procurement system that would cater to the needs of these

hospitals, (iii) supplies to be made direct to the hospitals, (iv) special packaging for supplies to eligible hospitals, (v) a tracking and monitoring system that would confirm end use and detect diversions if any, (vi) clear commitments on payments.

The advantage of this option is that it allows government to ensure that rural and urban poor have universal access to treatments for basic medical needs while avoiding the bureaucratic complications and prohibitive cost of European-style drug price controls and health care systems. At the same time, the continued evolution of private health care markets, including private hospitals, private insurance, and high-cost patented drugs, is facilitated

(2) Build up of procurement capacity for selected drugs.

Indirect price regulation thru government procurement and retailing is another option. In this case, government sets reference prices to guide the procurement of drugs and medicines sold at public health facilities, or for reimbursements by public health insurance programs. These prices however are not meant as market markers per se. Rather it is the size of government procurement that will determine whether there is a potential for affecting free market prices. If government procurement of targeted drugs can account for more than, say, 30% in terms of volume, then there is greater likelihood of some impact on free market prices.

This option obviously requires a greater public outlay of resources than the 10-11% of total market value currently observed. Even more difficult perhaps, greater coordination within the public sector, particularly with the PHIC, whose reimbursements account for about 55% of total government expenditures on drugs [Background]. Establishing reference prices will also require more regulatory capability than what is required for the preceding twin-pricing system. Specifically, establishing and updating international reference prices requires analytic sophistication (whether and how to control for quality or prevailing practices?) as well as data that is usually unavailable for public use, too expensive to procure, or gathered with a long time lag. One risk in international reference pricing is that computed price benchmarks could end up being historical instead of prospective.

On the other hand, if reference prices can be set based on **equivalent average cost curves** then reference prices would be more credible and transparent. By “equivalent average cost curves” is meant cost curves that are generated by a public enterprise under conditions approximating free market (commercial) conditions – that is, at full cost recovery plus reasonable profits. Conditions for the generation of ‘equivalent’ average cost curves are discussed in part IV below.

²-Adopted from what is proposed by Narayan [2007] for India.

³ Ibid.

(3) Selective imposition of MRP. The imposition of MRP could be warranted while the anticipated price gains to improved competition remain unrealized, or if no price gains are expected. The latter may happen if the size of the market is too small for substitutes to enter and challenge a dominant drug. Regardless, the potential costs of imposing MRP, both financially and politically, including the risk of failure, must be weighed against potential public health benefits – in terms of improved access and health outcomes - generated by such imposition.

In other words, the criteria for identifying drugs to be covered by MRP should satisfy two criteria simultaneously (or, criteria 2 given criteria 1 is satisfied) which are aligned with the specific inefficiencies and inequities which motivated intervention in the first place.⁴ These criteria are:

Criteria 1: Evidence of (or potential for) deadweight loss.

Initially, this may be indicated by both (a) international price variations which are not obviously attributable to local demand conditions, and (b) dominance of a patented drug in the local market, as evidenced by little or no close substitutes. The latter could further indicate that the size of the market is too small for substitutes to exist, even when gains to competition are fully realized.

Criteria 2: Drugs that can contribute greatly to public health goals.

Drugs that could qualify under this criteria would necessarily be those that could either (i) reduce disease burden in the overall, guided by leading causes of morbidity and mortality (e.g. cardiovascular diseases, infectious diseases), (ii) reduce disease burden to the income poor, and (iii) reduce disease burden to mothers, children and infants (in line with MDG goals).

Drugs required for epidemics or national disasters, if they are not readily accessible or available or available only in an inequitable manner, may also be considered for MRP for obvious public health reasons.

Setting the MRP: generating equivalent average cost curves

As in the case of natural monopolies, MRP levels should ideally be pegged to short-run average costs of manufacturers. Since the probability is low that such costs will be voluntarily or truthfully revealed by manufacturers, the next best option would be for government to set MRP levels based on

equivalent average cost curves directly generated by government itself. Directly generating equivalent and *credible* average cost curves would entail an independent public entity – say the Philippine International Trading Corporation (PITC) or the PITC-Pharmaceutical Inc, (PPI) – undertaking the procurement, importation and retailing of selected drugs *at full cost recovery plus a reasonable profit*. Full cost recovery implies paying and/or accounting for all attendant costs (e.g. financing, search, contracting, shipping, inventory, marketing, distribution, operations, taxes), including explicit or implicit subsidies from the state.

For instance, as it stands, the PPI currently operates under conditions far from free market or commercial conditions, thus its “prices” may not be considered fair or credible as MRP levels. On the supply side, government procurement laws bind the PPI, which, on the one hand, decrease costs thru transparent bidding but, on the other, increase costs thru prohibitions on bidders due to the Flag Law, prescribed timetables on the bidding process, prohibition on the naming of brands, and other features. On the demand side, the PPI absorbs no marketing, inventory, or obsolescence costs when procuring for DOH -related clientele (i.e. retained hospitals and *Botika ng Barangays*), but does so *implicitly* in its trading activities with privately owned *Botika ng Bayans*. Moreover, the business decisions of the PPI as regards the latter operations – which would seem to be the relevant one for establishing MRPs - including what to supply and how costs are accounted for, may, to a large degree, be circumscribed by the mandate to lower the prices of essential drugs to “50% below 2001 price levels”. If however, for at least a few business cycles, the PPI is able to make business decisions and price products to properly account for the abovementioned costs as well as other costs (e.g. cost of money, credit risk and so forth), its prices may be used as basis to establish fair MRP levels.

Operating at full cost recovery is necessary to ensure that a valid or credible yardstick by which MRP levels is set. The exercise would have the added effect of demonstrating to potential players the viability of entering the market (notwithstanding possible threats from dominant players), thus facilitating the onset of competition. In which case, PITC and PPI need not stay in the business. Staying indefinitely in fact could risk the onset of the usual inefficiencies that public enterprises are prone to, introducing new distortions into the market.

Box. Definition of Terms

Deadweight loss – a measure of how much society is worse off due to prices set higher than competitive prices (such as due to monopolist pricing or taxes). Basically, the value of the lost output due to higher prices is larger than the revenues gained from these mark-ups

Demand side intervention - government interventions directed towards changing consumer behavior or purchasing power

Information Rents – private profits generated due to the possession of relevant information

Lag – the time between the implementation of a policy and its effects

Marginal Cost the change in costs for a given change in output. In a competitive market, rational firms would produce that level of output where the extra revenue gained from one more unit of output just equals the extra cost of producing it. That is, where prices are equal to marginal cost.

Non-tariff barriers – barriers to trade other than tariffs, such as import bans, import licenses, restrictive packaging or manufacturing qualifications, product standards, restrictive domestic laws and the like.

Short-run Average Cost - cost per unit of output in the short-term. For a natural monopolist, operating at that point where price equals average cost will allow the firm to break even.

Supply-side intervention - Government interventions directed towards affecting the quantity or quality of supply

Tariff barrier – barriers to trade in the form of taxes imposed on imports or exports

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