



HNP Brief #7

Pharmaceuticals: Cost containment, Pricing, Reimbursement

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Introduction

Policy makers in many countries are struggling to cope with increasing costs for pharmaceuticals. Pharmaceutical expenses are usually the second or third biggest position in overall healthcare costs after human resource related expenses. Their share of total health care costs can go up to around 50% in developing countries, compared with an average of 14% in OECD countries. This paper looks at the main cost drivers for medicines and discusses options to control costs, trying to provide some guidance for developing a financially sustainable pharmaceutical policy framework.

Drug costs versus overall healthcare costs

The development of pharmaceutical expenses has to be seen in a wider economic context. Curbing expenses is not always the right policy choice. If the population suffers from diseases that have a negative economic impact and are avoidable by providing drug treatment (for example malaria), such treatment should be made available through additional funding. Even in developed countries, significant parts of the affected population are not adequately treated for common diseases such as diabetes.[1] The costs of avoidable complications need to be weighed against the costs of treatment, in order to assess the cost-effectiveness of incremental spending for drugs.

Similarly, if a drug simplifies treatment of a disease and saves money, for example by reducing hospitalization, an increase in spending for such a drug can be economically prudent. Examples are:

- Outpatient management of previously hospitalized schizophrenic patients with atypical neuroleptics
- Shorter recovery times after surgery with new anesthetics such as propofol
- The decline in surgery for peptic ulcers after the introduction of H2-Antagonists

However, if budgets for hospitals - where surgery is performed - are managed separately from budgets for outpatient drug spending, such positive economic effects may be overlooked.

In many cases, however, an increase in drug spending is not offset by economic benefits in other areas; neither does it yield better health outcomes. Such a situation

calls for an analysis of cost drivers and the development of a cost containment strategy that is compatible with overall health and economic policy goals.

Cost drivers on the supply side

Total drug costs are the product of price and volume of all the products purchased; both parameters are influenced by various supply and demand factors. Supply side factors affect primarily drug prices, while demand side factors have a stronger volume effect.

- Innovative treatments with real clinical benefits meet an existing unsatisfied need and drive up costs through higher prices and additional volume, unless this effect is offset by making a previous treatment obsolete.
- Even if the clinical advantage of a new drug over an old one is marginal, manufacturers will invest in marketing to shift demand to the more costly and usually more profitable new treatments.
- Governments tend to regulate drug prices, but some of these regulation models are economically not very effective. Lack of negotiation skills or information sometimes makes it difficult for public sector negotiators to face up to their private sector counterparts.
- Lack of competition, for example if market access is too difficult or the market is too small to be attractive for multiple providers.
- Lack of transparency: government officials with power over market access and price are a potential target for corruption.
- A national industrial policy that interferes with cost containment efforts - if local companies get higher prices than could be achieved by buying drugs internationally.
- In many countries, incentives for providers are geared towards using more or higher priced medicines (for example by allowing physicians to dispense drugs or setting the pharmacist's margin as a percentage of the price).

Cost drivers on the demand side

- Volume is driven by aging populations with increased morbidity, by the spread of diseases such as HIV/AIDS and malaria, but also by increasing purchasing power in many countries: typically, the demand for healthcare services grows faster than

GDP; the likely reason being that health is given priority over other areas of public and private consumption.

- Lack of trust in the regulatory system can drive demand for more expensive, branded drugs imported from developed countries.
- Advertising and promotion efforts by drug companies drive demand among physicians and, if Direct-to-Consumer (DTC) advertising is allowed, among patients.
- Misconceptions about what constitutes state-of-the-art treatment and lack of guidelines for physicians, leading to unnecessary prescriptions.
- Information asymmetry and fragmentation on the buyer side; lack of organizational capacity to assess quality and cost effectiveness of the treatment provided.
- Changes in health care delivery systems can change the cost allocation between system components: A shift from inpatient care for certain conditions to an outpatient model (for example ambulatory surgery) may reduce total costs by reducing expensive hospital bills, but increase expenditure for pharmaceuticals in the outpatient sector.

How drug companies set prices

Like all companies, drug companies use pricing as a strategic instrument for earnings optimization. They do detailed market research and apply advanced economic models to define a price close to the optimal point of the price elasticity curve, at which the product of profit margin per unit and expected sales volume peaks. Manufacturers usually start with an analysis of prices of competing treatment options. If a new product is better than the existing options, the price will be set higher. If it is not really better, the price may be set below other treatment options. The likely impact of various administrative models for price regulation is factored into the calculation. It usually leads to a global price band, which sets the limits for the country representatives that have to negotiate the actual price in a given market.

Innovative pharmaceuticals are much more knowledge products (similar to computer software) than commodities. Most of the costs to bring a product to market are R&D (research and development) costs and costs for marketing and promotion. The manufacturing costs are negligible in comparison. Hence the pricing of novel drugs is not based on the costs of synthesizing the chemical ingredient and pressing the pills – but rather on the societal costs of the problem addressed by this pill and the consumers' or payers' willingness to pay. On the flip side of this equation, companies can increase the production volume at relatively low unit costs. This allows them to sometimes offer the same product at much lower prices in low-income markets, for example through access programs for the treatment of

AIDS, malaria and TB in developing countries. The underlying idea is that the rich countries provide the funding for the innovation, whereas the poorest countries get life-saving medicines at marginal costs.

Generic drug prices usually start at about 20-30% below the branded original. At such a price, generic drugs are more profitable than the original brand (manufacturers do not have to fund large investments in R&D and they have lower marketing expenses). With competition between several manufacturers, the prices can drop significantly. Several widely used generic drugs have become cheap commodities on the global market. However, in some countries with protected local markets, locally produced "branded generics" are priced nearly as high as the original drug. Hence, identifying local market inefficiencies and creating a competitive environment for generic manufacturers is an essential element of any cost containment strategy.

Pricing is a major strategic tool for companies, and drug prices are subject to tough negotiations between manufacturers, regulators and buyers. Various models have been used such as combined price-volume deals (France), profit-based pricing (UK) or pricing based on evidence for economic benefits in Australia, the Netherlands and other countries. They lead to different prices in various countries. Sometimes companies give rebates to major buyers in exchange for volume contracts or favorable positions on formularies, or prices for two or more drugs are bundled in package deals. This diversity of the real world outcomes of pricing negotiations makes companies reluctant to disclose pricing information in detail, which in their experience could weaken their negotiation position versus the buyer side.

Some health economists are suggesting models of differential pricing based on equity.[2] That means that the price of new drugs should be defined based on the ability to pay, for example through a formula that is linked to the GDP per capita of a given country. The industry position however, although various differential pricing models already exist, is not supportive of models that replace the freedom to negotiate with a fixed formula or third-party controlled mechanism. The main concern is that consumers and payers in major developed markets would find ways to either procure the product from a lower-price country or erode the price differential through political pressure. This could happen if the population that does not understand or accept the principle of price differentiation if it plays out to their disadvantage (see the current debate about drug prices in the US versus other OECD countries). Another problem is the income disparity within most middle income countries: while a smaller part of the population is wealthy enough to afford modern drugs at developed country prices, the large majority could not afford a new drug even if it were priced based on an

“equity” principle. Therefore, an equity pricing model might reduce the ability of the manufacturer to make a profit with the wealthy population segment, without solving the access problems for the poor. What is needed is rather segmentation by income bracket (wealthy/poor) than by country, with a model that allows for a steep price differentiation while minimizing the diversion of drugs for the low-income segment to the high-income segment. Possible ways to achieve such a differentiation could be

- Patient assistance programs - free treatment offers for patients under a defined poverty level, administered on an individual basis mainly for rare diseases.[3]
- Substantial rebates or donations for public health programs that are delivered in specialized units so that the drug consumption can be controlled.
- Voluntary licenses to local manufacturers to make a generic version of a life saving product for use in a controlled program.
- Package deals in which a vendor receives a capitation based reward for providing treatment, with quotas for generic and innovative drugs provided based on patient needs.

The TRIPS agreement opens up a possibility to issue compulsory licenses to locally manufacture life saving drugs or import generics under certain conditions. This option has not been used widely yet, but it may have contributed to a number of price reductions and voluntary licensing deals in recent months and years. It is too early to conclude whether the TRIPS agreement effectively brings down the costs of essential new medicines for poorer populations.

Controlling the supply side

Governments as well as private healthcare providers use a variety of strategies to limit the costs of medicines. Some of these act as barriers that restrict access to new drugs, in particular if the procedure entails detailed pharmaco-economic evaluation and lengthy price negotiations:

- Formularies, such as Essential Drug Lists or so-called “Positive Lists” define the drugs that are purchased or reimbursed by the health care provider. Drugs that are not on the list may still get a marketing license and be available in the private market, but they are usually not covered by the pharmaceutical benefit scheme of the institution that issues the formulary.
- Pharmaco-economic assessment or Health Technology Assessment (HTA) – as it is done for example by the National Institute for Health and Clinical Excellence (NICE) in the UK – leads to pricing of new drugs based on expert opinions about its medical and economic benefits. Break-through innovations get higher prices than incremental improvements with limited clinical relevance or mere

variations of existing molecules with no major therapeutic impact.

- Certain expensive drugs can only be prescribed by a limited number of specialists or under the control of a specialized treatment center.

Box: New Zealand

New Zealand’s drug buying agency Pharmac is known for its rigorous approach to approving new medicines for reimbursement. A committee consisting of various experts critically reviews clinical and economic data and decides whether and at what price a new medicine should be reimbursed. New Zealand is among the countries with the lowest prices and total expenditure for medicines. However, critics argue that the system might be too restrictive and patients in New Zealand are denied access to effective new drugs even if they are cost-effective.[4] The listing procedure causes average delays of 30-40 months until a new product is available for reimbursement.[5]

A variety of pricing models for pharmaceuticals are used in different countries:[6]

- Free pricing – no regulatory intervention at the pricing level. The government or health care provider tries to influence drug costs on the demand side through restricted reimbursement and/or market mechanisms such as public tenders or supply contracts.
- Country of origin based pricing: The manufacturer or importer provides data on the price in the country in which the drug is manufactured. This price is either the basis for negotiations or is entered into a formula to set the list price for the given country. In today’s world of globalized supply chains, this approach is outdated: in several typical “countries of origin”, manufacturers have significant economic power and can negotiate relatively high prices, making the model economically ineffective.
- External reference pricing: The manufacturer provides (or the price setting authority obtains independently) price information from a number of countries that have been selected as reference standard. Then a formula is applied to compute the list price. This model is used in many developed and middle income countries. The issues are in the details: currency fluctuations, inflation rates and different market conditions in the reference countries can lead to distortions.
- Volume/price contracts have been used in France to counteract the growth in prescription volume (France has the highest drug consumption per capita in Europe). If a certain agreed volume is exceeded, the administration can impose a price reduction.[7]
- In the UK, the industry operates under a profit control agreement. Prices are set so that manufacturers

reach an agreed profit margin. This model tries to balance the interests of the local research-based industry with the limitations of a government financed health system.[8]

- Some countries have introduced compulsory rebates to counteract growing pharmaceutical expenses. Germany for example introduced a temporary social insurance rebate of 6% and later 16% for innovative drugs that do not fall under a reimbursement limit yet. This created a rebound effect with a 20% increase of drug expenditure in the first half year after the rebates ran out, leading to a search for more sustainable cost containment strategies.

Only a part of the price paid for a drug in the pharmacy goes to the manufacturer. Distribution costs and taxes usually account for 30 up to 50% of the total. Typical wholesale margins are 5-10%, for the retail pharmacist a margin in the range of 15-20% is the norm. Import duties and sales taxes are state-imposed cost elements and can add up to 25% to the retail price of drugs. All these elements need to be considered in a cost containment strategy for medicines.

Market forces and incentives on the demand side

Pharmaceutical markets are imperfect markets with significant “information asymmetry”, meaning that consumers and payers do not have the information to make the best possible choices in the interest of their own health or economic welfare. Strengthening the demand side is necessary to utilize market mechanisms for cost containment:

- Treatment guidelines define what physicians should prescribe for a number of standard indications.
- Information about choices is a key requirement to influence doctors in their prescribing behavior – for example through a regularly updated drug list that shows brand name drugs and available equivalent generics by indication and active ingredient.
- Consumer education helps to sensitize patients for the dangers of over-prescribing and inadequate use of drugs. Consumer groups can be important allies in the fight for a rational pharmaceutical policy.
- Reimbursement limits are in place in many countries, usually for drugs that are off patent. The reimbursement level is set at a generic price (internal referencing). Patients who insist on a more expensive version of the same drug have to pay the difference out of pocket. In some countries, this system is combined with a substitution rule, allowing the pharmacists to dispense a reimbursable generic in exchange for a more expensive product prescribed by the physician. Some countries force the pharmacist to substitute or the physician to prescribe the INN name instead of the brand. In others the physician can mark “no substitution” on the

prescription to ensure that the prescribed brand is dispensed.

- Some countries (for example Germany) introduced reimbursement ceilings for clusters of therapeutically equivalent drugs, even if some of these drugs are still patent protected. The contentious point is the definition of therapeutic equivalence, given the diversity of real world cases in comparison to the controlled clinical trial populations from which data on drug efficacy and safety are obtained.
- Co-payments for reimbursed medicines are used to shift a part of the drug costs to patients and create an incentive for cost-conscious consumption of medicines. They can become a hurdle to access for poor people or for chronically ill patients. Many systems take this into account by creating exemptions. Co-payment levels are defined as a percentage rate (some countries reimburse for example 80% across the board, others differentiate according to the severity of the indication) or as a flat contribution independent of the price of the medicine. The latter has an additional cost-saving effect by discouraging people with minor illnesses from seeking medical consultation: it may be cheaper to buy a flu medicine out of pocket than to get a prescription and pay the flat dispensing charge.
- The use of certain expensive drugs can be controlled by pre-authorization for reimbursement through the third party payer.
- A pharmacist margin that is defined as a percentage of the retail price creates an incentive for the pharmacists to recommend and sell the most expensive drugs. This can undermine a policy that builds on lower cost generic drugs for the basic health needs of the population. Several European countries have abandoned the percentage margins over the last years and introduced flat distribution fees for pharmacists, combined with a “generic substitution” rule that allows or even forces pharmacists to dispense a low cost generic even if the doctor prescribes a branded product.
- Prescriber budgets have been introduced for example in Germany to address the volume increase that cannot be tackled by reimbursement limits. Doctors face a reduction of their honorarium if their prescriptions in a given quarter exceed a set budget. This led to a significant increase in generic prescriptions.
- Formularies with preferred products: The government or purchasing institution (Pharmacy Benefit Manager) negotiates a price in exchange for a “preferred drug” position on a drug list (formulary), for example by selecting one out of five statins. Other statins can still be prescribed, but higher prices or co-payments act as disincentives. The preferred drug gets a high market share in exchange for the low price. As an extension, tiered formularies set different co-payment levels depending on importance and cost-effectiveness of a drug.

Generally, all approaches to manage clinically and economically rational use of drugs require a system that allows monitoring of prescribers and dispensing pharmacies. Ideally, such a system integrates patient, prescriber and dispensing unit in a web-based, real time application that allows processing of prescriptions and claims and issues a warning if supplier actions are outside the scope of guidelines and plausibility (e.g. too early re-fills of prescriptions, geriatric drugs prescribed for children, two drugs with the same mechanism of action given to one patient, possible interactions between drugs).

Box: Albania

In 2004, Albania's health insurance was facing a challenging mix of cost drivers: rapid uptake of new expensive drugs, enhanced by fraud and collusion between some health professionals who tried to "play the system", led to a cost explosion. The administration responded by introducing price labels for all licensed products to prevent pharmacists from overcharging, and physician budgets to create a sense of accountability among prescribers. Insurance auditors perform spot-checks to identify cases of fraud, which can lead to a withdrawal of the professional license. The reimbursement list identifies the cheapest out of several identical products, which sets the reimbursement ceiling. The initial impact of these measures was encouraging, but it remains to be seen whether the effects can be sustained.

Value and outcome based approaches

Pharmaceutical companies are launching new preparations every year. Some of them offer significant new treatment options for diseases that have been poorly treatable before. Others improve existing treatments, save costs or are more convenient. Again others are just variations of existing treatments with no significant benefit in terms of clinical outcomes, costs or convenience. Several developed countries have introduced a component of scientific and economic assessment (Health Technology Assessment, HTA) of a new drug before reimbursement is granted and a price is set or negotiated. The underlying concept is "value for money": a private individual is free to choose premium price products simply based on individual taste and status (for example an expensive watch instead of a cheap one that is as precise in measuring time). In contrast, administrators of solidarity funds have to apply rational criteria based on price and proven outcomes, not perceived value.

However, the process leading to the classification of a certain product as more or less innovative is controversial. Outcomes in real life can differ from clinical trial outcomes – certain types of patients are usually not well represented in clinical trials such as pregnant women, children or older people with multiple diseases. Some long term benefits of established medicines were observed only after these drugs had been on the market for several years or even decades - for example the potential of aspirin to prevent arterial thrombosis.

Health economics is a relatively new field of research, and data on economic benefits of a drug are, in most cases, meaningful only in the economic context (health care system) in which they were obtained. All this limits the options for developing countries to establish HTA as a routine instrument to establish a price for a new drug or decide on its inclusion into the reimbursement list. A possible future option would be the establishment of a collaborative HTA institute that serves a number of countries and provides opinions on new drugs, looking specifically at parameters that are relevant in a developing country context. In the absence of such a resource, countries should make use of their own scientific capacity to collect information from existing HTA institutions, for example those in the UK (NICE), Australia or the Netherlands, and apply it with common sense within their domestic context. The decision making process (usually happening in a commission) should, however, not be in the hands of physicians alone, who in doubt would vote rather for that against a new treatment. It makes sense to include clinical pharmacologists, epidemiologists and health economists to balance the medical viewpoint. These decisions also require political leadership and a strategic perspective anchored in the general public health strategy.

Another approach to share risks and manage costs of pharmaceuticals is compensation based on outcomes. This is a fairly new idea, currently applied in the UK in a risk sharing scheme for multiple sclerosis.[9] The underlying concept is that the drug company gets paid for a certain treatment outcome. Areas in which such a model could make sense are chronic diseases that are manageable with relatively expensive drugs, providing measurable parameters for treatment success. For example could the drug treatment of diabetes within a given institution or limited territory be "outsourced" to a specialized provider, with compensation based on achievement of certain levels of HbA1c, a lab indicator for good diabetes management. If the parameters are set correctly, the provider should have an incentive to offer the most cost-effective treatment. Such an arrangement should, in the long run, lead to total systems savings due to a reduction of the number of diabetes related complications – which are responsible for most of the cost burden of this disease.

Adaptive behavior of market participant

All potential modules of a cost containment strategy have their downsides. Restrictive formularies and substitution rules are difficult to implement against the interests of strong professional groups (pharmacists, physicians). If economic arguments and rationing appear to displace medical progress and doctors can no longer offer the treatment they consider adequate for their patients, they will try to mobilize the public against such policies.

Pricing and reimbursement models create adaptive changes on the provider side that can undermine their sustained effectiveness. Reimbursement limits for certain drugs may lead to a shift to other drugs that have higher reimbursement rates. Budgets can lead to “cream-skimming” meaning that providers refer difficult patients to higher level institutions – thereby increasing total costs while staying within their own budgets. Reimbursement ceilings can lead to price convergence and competition for market share through free samples or other inducements – instead of creating price competition to the benefit of consumers and payers.

Every strategy has to consider the options for monitoring of provider and patient behavior in a given system – we can only influence what we can measure – and balance incentives carefully to minimize unwanted consequences. Furthermore, cost-containment strategies should be built as modular, dynamic solutions that are regularly reviewed and updated in order to remain effective.

Integrated policy choices

Pharmaceutical cost containment policies are always a mix of different measures, based on the starting situation and the given objectives: staying within a given budget while at the same time providing adequate treatment to the target population. On a global scale, the incentive for pharmaceutical companies to continue investing into research and development needs to be maintained. The following paragraphs describe some standard combinations of policies that are applied in a number of countries:

A strict **EDL (Essential Drug List) based policy** approach is the best choice for **countries with very limited resources**. Only drugs on the EDL based formulary are procured (mostly generics), distributed and reimbursed. Such a system requires optimization of procurement and distribution, with visible efforts to assure quality in the distribution chain - to ensure acceptance of the selected products. Otherwise the perception of “cheap = bad quality” can undermine the policy. If a country has a functioning secondary and tertiary treatment levels, it will need additional restricted formularies (binding drug lists) that provide the drugs for

these higher treatment levels. Such formularies typically include some more expensive biologicals and branded drugs. Prescribing of those should be restricted to a few licensed institutions and specialists, who get a defined budget for these drugs. Adequate procurement methods need to be chosen (pooling if possible). Independent experts, such as clinical pharmacologists and economists, should be involved in the development of the formulary and the budget setting.

Countries with a functioning pharmaceutical market and a majority of services delivered through **private sector providers** may want to focus on a **generic drug policy** as a corner stone of their cost containment strategy. This is a combination of information about generic drugs, preferential market access for quality generics as soon as a new drug is off patent, competitive procurement mechanisms such as tenders and preference rankings on formularies, incentives for doctors to prescribe and pharmacists to dispense generics (for example prescription budgets for physicians, INN based prescriptions and flat dispensing fees for pharmacists) and reimbursement limited to the generics price for off-patent drugs.

Middle Income Countries are facing an increasing burden of non-communicable, chronic diseases with a high potential for costly late stage complications. This may be a reason to start experimenting with various forms of **contracting with providers** to share risks and create a framework for **outcome-based diseases management** in addition to the standard policy tools. The knowledge base for such strategies is still limited, but rapidly growing in particular in the US and some European countries. A functioning health information system is required to determine valid outcome parameters. Pharmaceuticals can be integrated in service provision contracts with a mix of generics – for the majority of uncomplicated cases – and innovative products, for those patients who don't respond well to standard treatment.

On a general note, all pharmaceutical policy choices have their up- and downsides, and create reactions in the markets that are not necessarily predictable. What is important is a clear vision for the mid term policy goals and the tricky balance between cost containment, health outcomes, economic benefits for the system as a whole and the “comfort factor” of having access to modern treatment alternatives even if these are not essentially better in terms of outcome. Under the umbrella of this longer term vision, however, specific policies and administrative measures need to be adaptable without too much “institutional pain” in case they lose their desired effect over time.

Additional information, resources

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