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Financing Pharmaceuticals in Transition Economies

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This paper (a) provides a methodological taxonomy of pricing, financing, reimbursement, and cost containment methodologies for pharmaceuticals; (b) analyzes complex agency relationships and the health versus industrial policy tradeoff; (c) pinpoints financing measures to balance safety and effectiveness of medicines and their affordability by publicly funded systems in transition; and (d) highlights viable options for policy-makers for the financing of pharmaceuticals in transition. Three categories of measures and their implications for pharmaceutical policy cost containing are analyzed: supply-side measures, targeting manufacturers, proxy demand-side measures, targeting physicians and pharmacists, and demand-side measures, targeting patients. In pursuing supply side measures, we explore free pricing for pharmaceuticals, direct price controls, cost-plus and cost pricing, average pricing and international price comparisons, profit control, reference pricing, the introduction of a fourth hurdle, positive and negative lists, and other price control measures. The analysis of proxy-demand measures includes budgets for physicians, generic policies, practice guidelines, monitoring the authorizing behavior of physicians, and disease management schemes. Demand-side measures explore the effectiveness of patient co-payments, the impact of allowing products over-the-counter and health promotion programs. Global policies should operate simultaneously on the supply, the proxy demand, and the demand-side. Policy-making needs to have a continuous long-term planning. The importation of policies into transition economy may require extensive and expensive adaptation, and/or lead to sub-optimal policy outcomes.

Key words: agency for health care policy and research; cost containment; decision making, organizational; disease costs; economics, pharmaceutical; health policy; pharmaceutical economics; pharmacy administration; policy making; reimbursement mechanisms

Eastern European economies in transition face considerable challenges in reforming their health systems. These challenges are threefold: firstly, they relate to the general macroeconomic environment which impacts on the availability of resources, secondly, they are often linked to the deteriorating health status of the population and, thirdly, they relate to the effort of local governments to reform the inherited health systems (1-3). One of the areas on which policy-makers place a great deal of attention is the overall cost of health services, in general, and some of its component parts, in particular. Several countries in Eastern Europe have seen the costs of health services increasing significantly in the 1990s.

One factor that has contributed to the escalation of health care costs in several countries in the region has been pharmaceutical expenditure, in particular, increased imports of pharmaceuticals, reflecting international prices. Increased pharmaceutical expenditure in Eastern European economies in transition is in line with what most Organization for Economic Cooperation and Development (OECD) economies have experienced over the past twenty years, both in terms of per capita spending and as a proportion of total health spending.

In view of rising costs and the introduction of new and expensive treatments, policy-makers in transition economies need to consider the status of financing pharmaceuticals also in light of the strengthening of their relations with the European Union (EU). Indeed, a number of Eastern European countries are first in line to start accession negotiations, whereas for others such negotiations have been placed at a later point in time. Relevant experience from other EU countries and other parts of the OECD may, therefore, be quite instrumental in understanding how the pricing, financing, and reimbursement of pharmaceuticals, and the control of pharmaceutical expenditure are practiced, and what the relevant issues facing policy makers are.

The purpose of this paper is therefore to provide an overview of the most important of these measures, highlight the relevant experience from other countries, in particular the EU Member States and other OECD countries, provide a methodological taxonomy of what has worked in practice, and what should definitely be avoided by policy-makers in Eastern European economies in transition.

Section two analyses the stylized facts of pharmaceutical production, in particular, the agency relationships, the patents' issue, and the barriers to entry in pharmaceutical production. Section three explores briefly the dilemma of health policy versus industrial policy in the pharmaceutical sector and its relevance to the policy-making community in Eastern Europe. Section four reviews the relevant policy options for financing and reimbursing pharmaceuticals on the supply side, whereas sections five and six review the relevant evidence on the proxy-demand and demand-side, respectively. Finally, section seven draws the main conclusions.

Stylized Facts of Pharmaceutical Production

Agency Relationships

Pharmaceuticals is not an industry like most others. Apart from the producer and the final consumer of medicines, it involves a number of "third parties", which are responsible for the distribution, the payment and their availability onto the marketplace (Fig. 1).

Figure 1. Agency relationships in pharmaceutical production and consumption (agents involved in selling pharmaceutical products.). OTC, over-the-counter; VAT, value added tax; POM, prescription-only medicines.

Third party payers (governments, statutory health insurance funds, private insurers) are responsible for the payment of medicines, act on behalf of consumers or patients, and take part in reimbursement decisions. Wholesalers are responsible for distributing pharmaceuticals from the source to the retail outlets (pharmacists), and in doing so, are interested in acquiring pharmaceuticals from the cheapest source. Prescribing physicians make decisions on behalf of their patients, since the latter have neither the knowledge nor the information to decide which is the most suitable medicine for their condition. Dispensing pharmacists usually follow physicians' instructions on what to dispense, but their dispensing behavior can be influenced through the incentive structure of their payment method and this is directly related to the type of products they dispense. Finally, Ministries of Finance usually charge value added tax (VAT) or any applicable consumption tax on medicines that are prescribed and consumed. Each of the above agents has a vested interest in the industry and its products.

The Economics of Patents

Following the demonstration by the patentee that a new process or product is new, useful and non-obvious, a patent is granted. The duration of a patent has been raised to 20 years from the time of filing after the enactment of the World Trade Organization treaty in 1995. There is an exemption period until 2005 for countries that have not implemented this treaty. Because firms usually seek patent protection as soon as a potential drug compound (new chemical entity) is identified, a large portion of the patent period can be taken up by the inventor's research and development activities and the regulator's review of the new drug application marketing application (4). Patents are territorial in nature, which effectively means that the patent law prohibits anybody without authority from making, using, or selling any patented invention (5) within a given country only. Therefore, inventors must seek comparable protection in each country in which their patents are to be used. Countries with no patent systems in place provide no protection to inventors. The International Trade Commission estimated that patent piracy may have cost the pharmaceutical industry US$5 billion in 1991 (6).

The patent term provides exclusive, monopoly rights to the manufacturer for the 20-year period and, in principle, disallows any competition during that time period. The owner of the patent also has the right to determine who will have the right to use, make, or sell the patented item and, to a more limited extent, how or where it will be initially exploited (7). The owner also has the right to grant the patent privilege to others through licensing, contracting or other means on a geographic basis, subject to antitrust clauses, which disallow the commitment of antitrust violations.

Demonstrating Safety, Efficacy, and Quality

The discovery and patenting of a new chemical entity does not mean that manufacturers can bring it to the marketplace immediately. A long series of regulatory hurdles must be overcome before a newly discovered molecule can reach the market. The first of these hurdles is proof of quality, safety, and efficacy: the manufacturer needs to prove that the newly discovered substance has some therapeutic benefit for a given (set of) condition(s) and that it is safe for human use at given dosages, which must be determined. This is done through extensive pre-clinical and clinical trials where the above qualitative attributes are tested on groups of patients. The process of clinical investigation can take up to 10 years and would potentially yield access to a specific market. If the manufacturer is to gain access to several markets it needs to conduct part of the clinical trials locally so that a more representative patient sample is constructed and, in many cases, because local regulatory bodies require companies to do so.

The second hurdle is that of review and approval. After having conducted clinical trials, the

manufacturer submits a dossier New Drug Application to the regulatory authorities, which aims at eventually registering the substance as a medicine for human use. The manufacturer must also specify exactly what clinical conditions the drug will be used for and at what dosages. The regulator, usually a public body, reviews all the evidence from the clinical trials (which includes the records of several thousand patients) and, if the evidence on quality, safety, and efficacy is sufficient, gives approval for the medicine and for the specified clinical conditions applied for. The process of review and approval can be quite lengthy, depending on the completeness of the application on behalf of the manufacturer and the willingness of the regulator to expedite drug approval. It does not necessarily follow that the regulator is always accessible and some regulatory authorities are notorious for taking a long time to approve medicines, especially if the clinical process has no local value added. There is evidence that some regulatory agencies are more approachable and ready to discuss relevant issues with applicant companies than others and this may lead to faster approval. There is also evidence suggesting that some regulatory agencies are more efficient in reviewing a medicine than others, thereby shortening considerably the total review and approval time (8) some companies consider this as an important feature of a country's industrial policy for the pharmaceutical sector and treat it as a determinant of location in a different market (9). The review and approval may take up to three years. Once the review has been completed, the drug is registered and licensed for sale.

Barriers to Entry in Pharmaceutical Production

The preceding paragraphs suggest that the pharmaceutical industry is characterized by significant entry barriers, which limit competition and increase monopolization. In this way, the problems of uncertainty and information asymmetries pertaining to health care markets are also valid in the case of pharmaceuticals (10). The industry is heavily dependent on continuous innovation, more so than any other research-based industry world-wide (11). The proportion of sales spent on research and development (R&D) has increased considerably over the past 30 years, owing in part to an increase in concerns about safety and efficacy of medicines and a decrease in returns from conventional screening techniques for drug discovery. As a result, the cost of bringing a new drug to the market is said to have increased from $54 million in 1976 to $359 million in 1990 (12). Few companies are able to afford this type of cost and this increases monopolization in the industry.

Competition in the pharmaceutical industry is intense, although the largest pharmaceutical company does not possess a global market share in excess of 6 per cent. Between 1994 and 1995, aggregate concentration levels in the industry rose, owing to a wave of industry mergers and acquisitions (M&As). The top ten companies accounted for 32 per cent of the global market in 1995 compared with 28 per cent in 1994 (13). While overall concentration levels remain low, there is product competition at the level of therapeutic sub-categories, where market shares are considerably higher, and many companies are achieving near monopoly positions in specific product markets (11). Price competition in the pharmaceutical industry is limited and is confined mostly in cases where patented products are forced to compete with out-of-patent (generics) equivalents, or, indeed, between in-patent products that are considered to be close substitutes.

Marketing is an extremely costly and important part of pharmaceutical business. Launching a new product does not necessarily imply commercial success. Such success is usually determined by the number of markets in which the relevant new chemical entity (NCE) is marketed. NCE is successful if it is considered "international", i.e., if it is marketed in five out of the seven largest international pharmaceutical markets (USA, Japan, Germany, France, UK, Italy, Canada). It is quite striking that companies of different nationalities have different rates of success in this respect. Furthermore, the cost of successfully launching and marketing a new product is enormous and few companies have distribution networks large enough to successfully penetrate national markets, which are often characterized by cultural peculiarities. These may include different medical practices for similar conditions, different modes of administration for medicines due to local habits (e.g., pills as opposed to injections or suppositories), or even large use of "alternative" medical treatments (e.g., the extensive use of naturally derived medicines in Japan and China).

Health versus Industrial Policy

Pharmaceutical policy, an important component of health policy, ensuring access to safe and effective medicines, presents a unique set of choices for policy-makers. In this area, health policy goals confront in a most direct way those of a specific industrial interest, the pharmaceutical manufacturer. It is, in a sense, where health policy becomes intermeshed with industrial policy. (Other examples of this would be in health promotion policy where health policy directly confronts the interests of tobacco and alcohol manufacturers. However, pharmaceuticals are different in that they are a positive good as the policy-maker relies upon the industry for the supply and discovery of medicines which aim to improve and not harm health.) This potential conflict faced by policy-makers seeking to allocate scarce resources in a market, which possesses unique characteristics on the demand and the supply

side, forms the basis of the pharmaceutical "problem".
Industrial policy is by definition a national policy, seeking to promote specific industrial interests and promote growth and employment. The issues around pharmaceutical industrial policy are quite complex and entail the entire spectrum of regulatory aspects (safety, efficacy, quality), and issues such as research and development support, employment issues, small and medium size enterprise (SME) policies, supporting the university science and research basis, and intellectual property rights protection, among others (14). It therefore involves different government agencies in addition to health-related agencies. The type of industrial policy followed in different European countries has influenced profoundly the strength and innovative capacity of the industry. Indeed, it can be argued that the strength of the pharmaceutical industry and the intensity of its location are related to the type of industrial policy followed by the country in question. In Eastern European economies in transition, a further aspect needs to be taken into account, namely the existence of strong local generics industries. Policy makers in these countries, therefore, need to strike a balance between the research-based multinational producers and the local generics manufacturers.
The source of the pharmaceutical "problem" lies in the unique demand and supply features which have traditionally guided the modern pharmaceutical market. The demand for pharmaceuticals is influenced by the unique three-tier demand structure involving the recipient of the medicine who consumes but does not choose it, the prescriber of the medicine, who chooses, but does not consume nor pay for it, and, finally, the payer of the cost of the medicine consumed, who in most industrialized countries is a third party payer, usually the state, shielding the patient from the full cost of the product. The supply-side of the pharmaceutical market is no less complex. A pharmaceutical company will tend to concentrate its activities in a selection of therapeutic categories and a handful of companies dominate each therapeutic category; by contrast, looking at market concentration across all therapeutic groups, the leading companies in terms of sales do not dominate the world market (13). Therefore, levels of market concentration may be underestimated unless one looks at the fragmented sub-markets that characterize the pharmaceutical market (15). Unlike most other products, prices of pharmaceuticals that reach the market are not related to production costs; rather, manufacturers seek to recover the extensive R&D and marketing costs in bringing a product to market (16,17).
Governments throughout the industrialized world are involved in the pharmaceutical market to a significant degree for a number of reasons. Firstly, governments seek to ensure that pharmaceuticals are safe for human use. Secondly, pharmaceutical products themselves are unique in that they are "life and death" products (18). Thirdly, patent protection creates monopoly positions for the relevant companies and the role of government lies in addressing the public concern that pharmaceutical manufacturers do not charge excessive prices for products that the public requires for health reasons. Fourthly, the unique supply and demand features of the pharmaceutical market, as described earlier, lead governments to intervene to control the costs of health care programs that aim to ensure that people have access to needed medicines. Supranational institutions like the European Commission have taken interest in this area of public policy and outlined general industrial policy actions for their members (19).
Herein, however, lies the dilemma for government policy-makers in countries where the pharmaceutical industry has an active presence and contributes considerably to national research and development, investment, employment, and exports. Government intervention to control pharmaceutical costs risks damaging both the ability of the industry to recover its research and development investment and, subsequently, its willingness to continue domestic activity. The problem also includes the interplay between the research-based industry and the generics industry, or, even to avoid discouraging the generics industry where a research-based industry is not present. In sum, governments face the dilemma of balancing a dual role of encouraging the industry (multinational or/and local, research-based or/and generic) while at the same time attempting to contain the costs of pharmaceutical products. This dilemma is at the very heart of the "pharmaceutical problem" facing policy-makers in most countries (20).
Bearing in mind the pharmaceutical problem, different methodologies have been developed in order to control the total cost of medicines prescribed and consumed within a given country. In broad terms, there are three types of strategies (21) (Table 1).

Table 1. Strategies of controlling pharmaceutical expenditure (26,27)

Firstly, supply-side strategies, target aspects of pharmaceutical supply, namely prices of medicines, profits of manufacturers, number of products in the market, and number of products in formularies. Secondly, proxy-demand side strategies apply to all agents acting on behalf of patients, in particular

prescribing physicians and pharmacists. Measures under this category include provider payment schemes, budgets, prescribed volume, guidelines, and generic policies. Finally, there are policies targeting the demand-side, namely the consumer/patient. Co-payments and over-the-counter policies qualify under this category. The international evidence suggests that pure supply- or demand-side policies co-exist and that the policy mix partly reflects regulators' response to the health & industrial policy dilemma.

Methods of Financing Pharmaceuticals – the Supply Side

The supply-side targets producers and is usually associated with action by the government or the third-party payer on the prices of medicines, the number of products in the market, the interplay between prices and volumes prescribed, the number of products in positive or negative lists, the introduction of a 4th hurdle, and other measures that can be adopted on an ad hoc basis to serve short- to medium-term policy objectives.

Pricing is the most contentious issue in pharmaceutical business. Over time a number of methodologies have been developed and implemented in different countries. In the EU, the main pricing methodologies for newly licensed medicines include free pricing, reference pricing, cost-plus pricing, and profit control. The economic and political implications of each of the above methodologies are vastly different, as each of them serves different policy objectives. The international experience from most of the OECD economies suggests that it is very rarely the case for prices of medicines to be formed freely according to the rules of supply and demand. It is also important to understand that the special features of the pharmaceutical industry justify regulatory action, although there is not a perfect model that would satisfy both regulators and regulated. Pure economic theory can, therefore, go some way in explaining the pitfalls of regulation within the context of pharmaceuticals. With these brief observations, the most important supply-side measures and their implications are explored below, starting with pricing methodologies and with the benchmark free-pricing model and its qualifications.

Table 2. Free pricing for in-patent pharmaceuticals

Free Pricing

Free pricing (Table 2) effectively allows manufacturers to set their own prices in the market, which will be reimbursed by the (statutory) insurer. Pricing freedom exists in the US (in principle, although price discrimination through discounting is very widely practiced, e.g., to he Veterans' Administration, Medicaid, retailers, chain pharmacies, and managed care providers), Germany, and the UK (where it is subject to profit control of the manufacturer). Discounts from the list price demanded by third-party payers, would definitely be desirable if free pricing is to be practiced. Alternatively, free pricing can be combined with fixed pharmaceutical budgets for prescribing physicians and strong policies regarding generic prescribing, promotion, substitution, and dispensing. The relative merits of budgets and generic policies are examined in the next section.

Free pricing allows manufacturers to recoup the costs of research and development and encourages innovation, local high value added, exports, and the overall development of a strategic industry. It therefore meets the objectives of industrial policy. Because of the high cost of the drugs' bill as a result of free pricing, all countries that have it (Germany in Europe, USA, Japan in the rest of the OECD), supplement this by action in other parts of the market. For example, Germany encourages generic prescribing and substitution, where therapeutic alternatives exist, and has a reference price system in place for off-patent products. The latter forces prices of off-patent products downwards. Japan applies a system of periodic price reductions to all products after a certain number of years (R-zone system) and currently considers a reference price system. In the US, third-party payers request and receive discounts from the industry for inclusion of its products in reimbursement lists, in addition to encouraging generic substitution.

Direct Price Controls

As a result of the absence of the normal forces of competition in the pharmaceutical market, many governments intervene to fix prices. A second reason why they do so is because drugs are in part paid for out of public expenditure. In several countries strict price control systems have been the major cost containment measure in the last twenty years. Price controls, if they are not combined with other measures, may lead to perverse incentives through the introduction of new products in the marketplace. In some countries pharmaceutical companies have been trying to bypass strict price controls for old products and competition for off-patented products by launching new products on the market, which are not necessarily innovative. Another problem is the significant increase of pharmaceutical consumption in volume. A new drug starts with an advantage, even if it differs little from a drug already on the market. Prescribing new drugs gives the physician the comforting illusion,

which can be conveyed to the patient, of keeping up to date with medicine, even though his or her reading of serious medical literature may be no more than cursory. Market shares of new products which do not offer real improvements are very high in Spain, Italy, and Germany were strict price control systems or reference price are in force. International studies have found that the contribution of new, but not necessarily novel, products into increasing pharmaceutical expenditure, has been considerable. Although price control is not a panacea, it can be present in a variety of ways, which have important implications for the conduct of health and industrial policy in a given country. These are explored in the next paragraph.

Cost-Plus Pricing and Cost Pricing

Several countries are using price controls in an attempt to assess the innovation of the product or its advantage over existing treatments or at least the price of existing treatments. Within the EU, Belgium is implementing this strategy and France was doing so until the introduction of company revenue budgets. In addition to the relevant products' assessment of innovation, there may be in place other criteria on the basis of which the market price is decided upon, namely performance indicators (local value added, locally performed research and development, employment, exports, etc.). Spain follows a cost-plus methodology (Table 3), among others, whereby it awards (or reimburses) a price on the basis of fixed allowable percentages for the price of the imported active ingredient, basic costs, promotion, research and development, and a fixed profit margin. The regulator also takes into account local performance indicators. Greece follows a cost-pricing approach taking into account the ex-manufacturer price, without considering at all R&D spending.

Table 3. Cost-plus and cost pricing

The above pricing approaches may result in rather complex methodologies and have been opposed very strongly by industry. Regulators wishing to adopt such approaches would need to be aware of their methodological and practical difficulties. Firstly, when trying to assess the innovativeness of the product or its advantage over existing treatments, it is difficult to objectively determine a price advantage for the relevant product and there is a level of arbitrariness. Secondly, there is no objective way of establishing the ”real” price of a single product, on the basis of information submitted by manufacturers, since products share the capital equipment of the company, its overheads, its research and development and promotion costs, as several of the company's products may be promoted together. Thirdly, costs of production and, to some extent, the costs of packaging depend on the level of sales, and a price control system would need to incorporate a formula recognizing that. Finally, there is an implicit bias to award higher prices to those manufacturers that contribute to the national economy.

Average Pricing and International Price Comparisons

According to average pricing, the average recommended price in the market in question is developed by calculating the arithmetic mean of the "standardized" national prices in the other selected markets, known as reference countries. In the EU, two Member States have introduced a system of average prices (Italy from 1994 and the Netherlands from 1996). A variation of this pricing methodology is with wealth adjustments, where regulators create a standardized average and adjust this to the country's gross domestic product (GDP) level, vis-a-vis the pool of reference countries. The Federal Republic of Yugoslavia had a system in place in 1997 along these lines, using Greece, Italy, Austria and Germany as reference countries.

Under international price comparisons, regulators take into account prices in other (usually neighboring) countries when considering prices of pharmaceutical products in their own markets, but do not use these explicitly to calculate averages. Within the EU, Portugal, Ireland, Greece and France to some extent take into consideration the prices of their neighbors when deciding about their own prices. International price comparisons are used in conjunction with other pricing or reimbursement methodologies prevailing in a given country and provide a guide about the price of the active ingredient. The same holds to some extent with average pricing.

Average pricing and international price comparisons usually take into account high price countries and low price countries. This introduces an element of 'fairness' by the policy-maker. Regulators need, nevertheless, to consider a number of points before embarking wholeheartedly on such regulation. Thus, when considering low price countries, lower quartile countries may be used, without considering wealth differentials and differences in intellectual property rights protection. Furthermore, average prices may not reflect real exchange rate movements if they are based on Purchasing Power Parity values. At the other end, if exchange rates are the base of standardization, volatility in money markets may imply regular and, at times important, changes in average price formation. Finally, the selection of countries and their number may be unrealistic and it is quite often the case that

neighboring countries reference each other and this may lead to further about the true price of a drug.
Reference Pricing
Reference pricing operates by grouping (after having specified) similar products together and defining a relative price that will be reimbursed by health insurance funds. The use of a reference price as a reimbursement benchmark, implies that the government will only pay that particular price. Any excess above the reference price has to be paid by the insure. Apart from the variations explored below, that apply to different EU countries and Canada, reference pricing is also used in New Zealand and Australia, and Norway. It was proposed in Greece, Spain, and Finland, but was not implemented. Policy makers wishing to implement reference pricing as a reimbursement mechanism for pharmaceuticals are faced with three main policy dilemmas (Table 4).

Table 4. Reference pricing – policy dilemmas and responses of actors

Firstly, it needs to be decided how the clustering of similar medicines is going to take place. Here, the international experience has suggested three different types of groupings. First, medicines with identical active ingredients are grouped together. This is a very narrow definition of the cluster and, effectively, means that only generic products are included, for instance, all H2-antagonists for the treatment of peptic ulcer, or all beta-blockers for the treatment of forms of hypertension. Second, medicines with pharmaco- therapeutically comparable active ingredients are grouped together, in particular, chemically-related substances. This is a wider clustering which potentially includes different classes of medicines that have similar chemical structure. Third, medicines with pharmaco-therapeutically comparable effects are clustered together, combination drugs in particular. This grouping includes a potentially wide class of medicines that are effective for the treatment of a given condition, for instance, peptic ulcer or hypertension. Germany and Denmark introduced reference pricing along these lines in 1989 and 1993, respectively. The system covered 50% and 20% of the pharmaceutical expenditure, respectively. In Sweden, the reference price version is a system with maximum discount limits for pharmaceutical products with comparable generic equivalents. The authorities no longer reimburse the whole cost of a drug through medical benefits, if a cheaper comparable alternative is available on the market. A maximum discount level (reference price) is established for each drug, equivalent to the price of the cheaper alternative plus 10% and if a more expensive product is used, the patient is required to pay the difference.
The second decision that policy makers need to take is to decide whether patented medicines are to be included in the defined clusters and, if so, whether there should be patented medicines that are excluded from the system and under what criteria. For instance, the second and third forms of clustering analyzed above, may include patented drugs. To be exempted from reference pricing, such medicines may have to have, for instance, an "innovative mode of action", or represent "a therapeutic improvement, if only because of a more favorable side-effect profile". The precise definition of exemption clauses is a difficult and potentially contestable task and each medicine needs to be examined on its relative merits. The Netherlands introduced a reference price system from July 1991 for products judged to be interchangeable, taking account of any side effects by five criteria judged by an independent committee of experts who report to the Association of Sick Funds. The system covers approximately 90% of the market, including in-patent products. The Canadian province of British Columbia has also introduced a reference-based system (low cost alternative) in its programs for seniors since 1994. The system includes in-patent products and clusters medicines that have pharmaco-therapeutically comparable effects.
The third policy-related issue relates to the fixing of the reference price. It needs to be decided whether the reimbursement price will be the lowest of the defined cluster or some kind of average. This decision has significant implications for competition at the lower end of the pharmaceutical market, as well as for the cost of medicines to statutory sickness funds. It therefore bears important health and industrial policy implications. In Germany, the reimbursement price is the lowest of the cluster, whereas in Denmark it is the average of the two cheapest products in the cluster. The review time of the set reimbursement price also needs to be decided, as indeed the variable used for reference (pack size, defined daily dosage, price per mg, etc).
Reference pricing has been introduced with different variations in other European countries as well, which fit local policy objectives. In the Italian variation, from July 1996, the reference price is perceived as the lowest price of a product in a group of identical drugs (same active ingredient, same pharmaceutical form). However, in the group of same drugs, also the drugs with different dosages were included, which determined a penalty for low dosages of several drugs whose price, expressed in cost per mg, was not surprisingly more remunerative than that of the higher dosages. With regard to price, only the cheapest product in the group of drugs, identified as identical, would be

reimbursable. The products whose price were above the reference (cheapest) value would be delisted (no reimbursement at all). In the Belgian variation, reimbursement under health insurance takes place if the price does not exceed the price of any patent medicine containing the same active substances or 110% to 150% of the price of a patent medicine with an equal therapeutic effect.
From the government's or insurance fund's point of view, the weakness of reference price systems is that their introduction does not necessarily decrease the drug budget as the experience of the Netherlands and Germany has shown. In 1993 Germany introduced a range of further cost control measures – a cut of 5% in prices not covered by the scheme and a firm drug budget with penalties for physician associations for exceeding it – despite the continuation of the reference price system. The Netherlands also cut prices by 5 % and introduced average pricing for the part of the pharmaceutical budget that was not covered by reference pricing. Usual criticisms of reference price systems by manufacturers entail arguments such that it distorts clinical decision-making, deprives patients of a choice of treatment and removes incentives to conduct research into new medicines. On the other hand, it should be borne in mind that reference price systems also have attractive features. While the average prices of those products clustered together may be brought down, no firm is denied the market share it can earn by accepting the reference price. A reference price system is fully transparent and once the clusters have been defined and a reimbursement price has been set. Furthermore, if patented drugs are excluded, companies can fix their own prices for these products. Finally, generics may result in higher than market prices due to reimbursement prices being set to an average reference price and this may benefit the local generic industries. Policy makers in transition economies wishing to implement reference pricing, need first of all to define their policy objectives for the pharmaceutical sector and the extent to which they are interested in maintaining a balance between health and industrial policy and, subsequently, to provide adequate answers to the three policy dilemmas identified above.

Positive and Negative Lists

A Positive List includes products that will be reimbursed under a health insurance scheme whereas a Negative List specifies products that will not be reimbursed under health insurance. There is no sufficient evidence concerning the impact of positive and negative lists in containing pharmaceutical costs given that shifting of treatments can take place to products that remain available for prescription. The Department of Health in the UK estimated in 1984 that limiting prescriptions in the seven selected groups could save the national health service up to L100 million a year but afterwards downgraded this to L75 million a year. These expectations were criticized since the Department of Health never published how these figures were calculated. If the list is combined with an attempt to reduce considerable the number of products available for reimbursement, the results can be measurable. In Italy the combination of the average price system with the new positive list and the exclusion from reimbursement of more than 50% of products, had as a result a considerable reduction in pharmaceutical expenditure. (-15.1% between 1992 and 1993). However, it is still early to assess any long-term effects in the country.
Policy-makers need to be aware that negative lists have been criticized that they discourage research in the areas covered by the excluded products, erode the clinical freedom of doctors, and reduce the choice of products available to patients. However, the above arguments have little force if the list consists almost entirely of preparations which are of little or no therapeutic benefit. Furthermore, preparations can readily be bought "over the counter" at a very modest cost. Where this is the case, it can hardly be said that patients are being denied "the best medicines". Most positive lists tend only to exclude cheap products which patients can readily buy "over the counter" and drugs which are close copies of drugs which can be obtained more cheaply by specifying another brand or a generic. Inclusion in a positive list may be used in price negotiations. However, pricing and inclusion in a list should be kept separate.

Profit Control

A profit control system exists only in the UK, since 1957. Prices are set by the pharmaceutical industry and are indirectly controlled through the Pharmaceutical Price Regulation Scheme. This is a non-statutory scheme negotiated between the Department of Health and the Association of the British Pharmaceutical Industry. The Pharmaceutical Price Regulation Scheme regulates the profits which companies make from their sales to the National Health Service (NHS). The scheme does not cover generic products or exports of pharmaceuticals. While the general agreement is negotiated between the Department of Health and the Association of the British Pharmaceutical Industry, individual company details are negotiated between the Department of Health and the company concerned. This operates at the level of a company's total business with the NHS, rather than in relation to individual products. The scheme measures profitability in terms of the return on capital employed. For companies which do not have any significant capital in the UK, it is assessed on the basis of return on

sales. The existing profit target range is between 17% and 21%, with a 25% tolerance margin above that. The scheme allows an average of 9% of turnover for sales promotion costs, with an additional amount in the case of new chemical entities, and includes a maximum allowance of 22.5% of sales on research and development (22). If the profit realized by companies exceeds the profit target, then the company may repay to the Department of Health the excess profit above the 25% tolerance margin. Alternatively, it can reduce the price of some of its products to a level which will ensure that, based on sales forecasts, its profits will not exceed the target level of profit in the coming year. If the profit falls below the target, then the company may be eligible to apply for a price increase.

The profit control scheme allows relatively free pricing and operates in an environment characterized by stability since system is negotiated for a period of time. Exports of pharmaceuticals are not affected since they do not come into the calculation of the rate of return. In this way, UK prices can be thought of as export prices for other markets, through average pricing and international price comparisons. The imposition of further measures (such as price cuts or freezes) is, nevertheless, at the discretion of the regulator. One of the most fundamental features of the profit scheme as it operates in the UK, is the strong link that exists between health and industrial policy. Under the allowed rate of return on invested capital, a firm has an incentive to invest more in research and development since this broadens its capital base and, potentially, its allowable profit. The flip-side of this implication is that it may lead to unnecessary research and development investment.

Pharmacoeconomics: Introducing a Fourth Hurdle

Pharmacoeconomics relates to the determination of a drug's cost effectiveness in addition to clinical effectiveness. It is often described as a 4th hurdle to the extent that cost effectiveness is used as an explicit criterion for a drug's admission to the market in addition to safety, efficacy, and quality. Australia and the Canadian province of Ontario use cost effectiveness criteria explicitly in order to determine reimbursement of medicines by health insurance funds. Within the EU, a number of Member States take into account pharmacoeconomic studies (but never explicitly) to determine the reimbursement level of pharmaceuticals (Belgium [based on the Canadian guidelines], France, Italy, Sweden), others use it as guidelines for prescribing (UK) and in others (Germany), although no official pharmacoeconomic guidelines or principles exist, nor have the government or health funds attempted to provide any, a number of private initiatives have developed. The Netherlands and Portugal are currently developing guidelines for the economic evaluation of pharmaceuticals and these will be used for policy purposes in the near future.

The practitioners understand pharmacoeconomic studies and are able of judging the quality of such studies. Methodologically, such guidelines or principles should favor the commitment of the research-based industry to high-quality products, services and studies. Economic studies should contribute to continuous progress in the quality and efficiency of health care and, if done, should be based on an interdisciplinary approach, ideally integrating medicine, economics and social sciences. Policy-makers in economies in transition need to take into account the above considerations and decide whether they wish to apply a 4th hurdle in their own environment and under what circumstances.

Other Price Control Measures

Other price control measures include price freezes, across-the-board price reductions, government approval required for price increases, price reductions for exceeding agreed-upon unit sales, limiting the mark-up on imported finished products, establishing me-too prices, requiring up-front industry contributions, having expenditure ceilings or performance requirements in place. These methods are briefly explored below.

A price freeze is a very severe type of price control because prices are frozen while other costs (labor, manufacturing, or, even, research and development) are on the rise. Germany and Italy have often utilized this approach and the UK imposed a three-year price freeze in 1993. Policy-makers can also make the increase in the prices of pharma- ceuticals dependent on government approval. The UK has adopted this approach.

An across-the-board price reduction is said to be very disruptive to the smooth running of a business. It has nevertheless been used as a cost control method by several EU countries such as Italy and Spain, the UK (in 1993) and Belgium (1996).

Price reductions for exceeding agreed-upon unit sales have been used as a method to control the total sales volume of medicines and may be particularly applicable to high volume countries such as France, where the measure has been implemented. As a cost control measure it is arbitrary and relies on expected sales information that is usually submitted at the time of application for market authorization and reimbursement.

Limiting the mark-up on imported finished products implies that regulators fix the price at a level suitable to their own needs, without taking into account relevant costs incurred by the manufacturer. This method has been accused of not contributing to a manufacturer's global research and

development costs and entails a significant amount of arbitrariness.
In me-too pricing, products that are considered 'me-too' are automatically given a price below the original, or, indeed, the last approved price for the same product. It is at the discretion of the regulator what the price differential is going to be. Sweden and France have used this measure.
Up-front industry contributions are a form of indirect price control and requires industry to "pay back" to the government/insurance fund a particular sum for a given year.
Expenditure ceilings have been implemented by several countries in the EU such as the UK, Germany, France, Italy, or Spain, and have taken several forms. Governments may, thus, wish to impose a fixed budget for pharmaceutical expenditure and making industry liable to paying back to the government any excess on that budget. Alternatively, it may be desirable to limit the growth on volume sales in countries where volumes are very high and prices low. A third way might be to have a fixed budget for pharmaceutical expenditure which can be kept by means of limiting/increasing the number of products in a positive/negative list, or to limit the growth of pharmaceutical expenditure to a certain percentage at a given year in terms of value, volume or a combination of both. In addition to deciding how to implement expenditure ceilings, the usual dilemma that policy-makers have is to avoid treating the local and the foreign segments of the industry differently.
Finally, with performance requirements, governments often try to exchange prices for particular products with other economic benefits that a particular company can perform for the country, e.g., exports, employment, locally performed research and development, etc. Most countries have implemented such policies either explicitly or implicitly.
Methods of Financing Pharmaceuticals – the Proxy-Demands side
Proxy-demand refers to action on, primarily, physicians who decide on what is prescribed and consumed by the patient and, secondly, on dispensing pharmacists. Proxy-demand is an effective way of controlling pharmaceutical expenditure since prescribing physicians (and less so pharmacists) act on behalf of patients and making them aware of the implications of their (clinical) decisions is an important tool of raising their cost awareness.
Relevant measures under the proxy-demand would be budgets for physicians, development of generic policies, establishment of practice guidelines, and disease management programs. An issue that is quite a key in the development of proxy-demand measures is the role of information and, in particular, the development of adequate information systems that would allow the monitoring of budgets, practice guidelines, and generic policies, and the diffusion of that information to all relevant parties from prescribing, to dispensing, to reimbursement.
Budgets for Physicians
Several countries have moved towards the introduction of budgets for physicians as a method of indirectly controlling total pharmaceutical expenditure. Physicians are allocated firm or indicative budgets and have incentives to stay within their budget, as is the case in the UK, or incur penalties if they exceed them, as was the case in Germany until 1998. The international experience suggests that if budgets are to yield results, they would need to be firm rather than indicative and those who manage them need to be accountable for their prescribing habits. Policy-makers have the choice of making individual doctors, groups of doctors, or their associations responsible for their budgets. One way or another, maintaining a budget system for practicing doctors, requires an initial investment in information systems that can be considered as a sunk cost from the government's point of view. When in operation, the budget system is associated with administration costs from the doctors' point of view, which also need to be taken into consideration.
Budgets discourage prescribing physicians from using new and expensive products, encourage generic prescribing and help control growth of pharmaceutical expenditure. They can be combined with policies to gradually place more emphasis on primary care and alternatives to in-patient care where this is possible. For instance, firm budgets in the UK allowed "fundholding" general practitioners to keep any savings on them provided they would use these to develop their practice. Firm pharmaceutical budgets, on the other hand, may tempt physicians to a cheaper alternative first, and only if this fails to produce results, to incur the high cost of a more expensive product. This may not be in the patients' interest and adequate safeguards, such as prescription audit, need to be in place in order to ensure that this does not result in malpractice. In order to save on their budgets, doctors may increase their referral rates. Again, evidence from the international experience differs and depends on how the rest of the system actually functions. Thus, initial evidence suggests that, contrary to expectations, fundholding in the UK has made little difference in the referral rate. Several studies compared fundholding practices and non-fundholding and suggested that fundholding general practitioners (GPs) have not reduced the cost of their prescribing, but the increase of the costs of their prescribing was slower than that of non-fundholders. This was achieved by prescribing more generic products. By contrast, in Germany budgets created incentives for office doctors to refer patients to

hospitals. In Germany this would mean in-patient care. The overall drug budget seems to have been very effective in its first year of operation. The overall drug budget for 1993 was not exceeded by 9%, with reference pricing also in place since 1989. These savings are due both to a reduced number of prescriptions compared to 1992 (-10.4%) and a reduced value of each prescription (-4.6%). However, referrals to other specialists increased by 9% and referrals to hospitals where drug budgets do not apply increased by 10%.

Generic Policies

Generic prescribing. Several countries have attempted to encourage generic prescribing particularly through encouraging "cost awareness" among doctors. Generic prescribing has acquired considerable significance in the UK, and the 1991 reforms that introduced the "fundholding" scheme, partly evaluate GPs' performance according to the share of their drug budget that they spend by prescribing generically. In the Netherlands, the government has launched an information campaign among doctors to increase their knowledge of generic alternatives to branded products. This has helped towards greater generic prescribing. For instance, 20% of amoxycilin prescriptions were generic in 1988 whereas in 1992 it was nearly 60% (23). In Germany, the government has also placed budgetary restraints on doctors which "encourage" them to prescribe generically, which were subsequently withdrawn. Active promotion of generic prescribing makes sense in countries where prices are high.

Generic substitution. While the term of generic substitution tends to have a variety of meanings, it has been defined as a notional practice by which community pharmacists would be authorized to dispense the generic version of a medicine even when a doctor had prescribed it by brand name and without the GP's express knowledge or permission (24). A number of European governments have clearly assisted the demand for generics, particularly in Germany, the UK, and The Netherlands, where they have sought to stimulate competition. However, more recently even, several southern European countries, as well as Belgium, are starting to introduce measures favoring generic medicines in an attempt to combat rising costs. One stimulus to generic growth has been generic substitution, i.e., allowing the pharmacist to dispense/substitute a generic equivalent where the physician has prescribed a branded product. However, substitution rights vary quite considerably in different Member States. Such rights may be of limited nature, i.e., requiring some form of consent from the prescribing doctors (Belgium, Denmark, Italy, Spain, Ireland, Portugal, and Luxembourg), or banned as is the case in France and Greece. Promotion of generics is not allowed in Italy, Belgium, or Greece. Exceptions to the above are Germany, The Netherlands, and the UK, where promotion of generics is strongly encouraged.

Looking at two of the EU's strongest generic markets, it is possible to see that substitution remains limited. In Germany, for instance, substitution is permitted only if the doctor expressly indicates on the prescription that substitution is possible or if he writes the prescription generically. In The Netherlands, generic substitution is permitted but the doctor must agree and the patient be informed. When deciding whether substitution is appropriate, the doctor may also stipulate the appropriate substitute. However, to ensure flexibility in the dispensing of medicines in The Netherlands, a formal dialogue has been established between doctors and pharmacists associations which pre-agree lists of medicines which may be substituted.

Generic dispensing. Providing financial incentives to pharmacists is another method that can be used by governments or statutory insurance funds to help stimulate the sale of generic medicines. One example of this has been in The Netherlands, where a major boost to generic dispensing was provided by the Drug Reimbursement Scheme of 1991, which enables pharmacists to keep one third of the savings made via the use of the cheaper generic drug alternatives. However, pharmacists are still required to seek approval from the prescribing doctor and must inform patients making the substitution. The situation is markedly different across the border to Belgium, where the pharmacists receive a fixed percentage of the purchased price for all medicines. Consequently, Belgian pharmacists have nothing to gain financially from dispensing a generic medicine. Indeed, the system in Belgium actually results in a lower income for pharmacists, since the percentage they receive remains the same, but is calculated on a lower amount. In principle and assuming that pharmacists have the power to dispense generically, a progressive margin encourages them to dispense the more expensive drug, and a flat fee does not provide any financial incentive to dispense the cheaper drug. By contrast, a regressive margin provides such an incentive also if it is associated with pharmacists' being able to keep part of the difference between the more expensive branded product and the generic.

The above issues analyzed, particularly those of generic substitution, generic prescribing, and generic dispensing, are in no way independent of each other; in fact, they are in many ways interrelated. The first link is cost and the necessity to reduce, or, at least, contain the drugs' bill. The second has to do

with the stages that different agents (physicians, pharmacists, etc.) step in the process of drug cost containment. Governments or statutory health insurance funds would therefore need to consider integrated policies on this matter rather than only focusing on single elements of them.

Influencing the Authorizing Behavior of Prescribing Physicians

In addition to allocating (fixed) budgets to physicians or promoting generic substitution analyzed in the previous paragraphs, further attempts can be made to influence the authorizing behavior of doctors. Several ways are available in principle, although the degree of compliance by the medical profession differs as indeed the seriousness with which such measures are pursued by the insurance fund or the government. Thus, individual physicians or practices that have shown to have high authorization patterns, may be warned, threatened or subjected to financial penalties. But that involves the close and up-to-date monitoring of such physicians through efficient information systems that may not be in place in transition economies. Another way of influencing physicians' authorizing behavior is by changing their method of payment. A change from payment per item of service to capitation may in this context desirable. In fee-for-service systems, doctors can be faced with changed incentives by altering the fee relative value scale, or indeed a switch to capitation. Policy-makers in different countries need to assess the political feasibility of such changes and their impact of their decisions on the medical profession and society at large.

Assessing medical practice is an additional way of exerting control on prescribing physicians and this can be achieved through practice guidelines for the (recommended) treatment of different conditions. Practice guidelines and medical references have been developed in many EU countries, but their success is not always guaranteed. These entail positive or indeed negative guidelines; the former recommend a "prescribing path" for a given diagnosis, whereas the latter recommend courses of action that should not be undertaken. An example of the former are the practice guidelines in the UK, whereas an example of the latter are the medical references in France. The design of these guidelines and references needs to be the product of a consensus debate with the medical profession. The monitoring of whether these are followed in general practice pretty much depends on the availability of information systems at the local and central levels and the possibility of enforcing them through incentives or even penalties.

Disease Management

Disease management is an attempt to improve the quality of care while reducing costs. Disease management takes a systems approach to medical care and is based on outcomes-based research. It identifies the course of treatment that is suggested by the medical literature to offer the best possible outcomes seeking to avoid treatments that are not shown to be effective. Disease management requires sophisticated protocols and individual patient monitoring. It can be drug cost increasing, while decreasing physician and in-patient care or drug cost reducing, depending on the type of protocol followed. Although disease management schemes are quite widespread in the US they are still on an experimental basis in a few EU countries (e.g., France).

Methods of Financing Pharmaceuticals – the Demand Side

In addition to focusing on the supply-side through measures on prices, revenues, the number of products in the market and lists, among others, and the proxy-demand side, through action on prescribing physicians and dispensing pharmacists, patients can also be made accountable for the cost of pharmaceuticals they consume. The two most significant methods of targeting patient consumption, is by means of cost-sharing and promotion of the market for over-the-counter medicines, the latter enabling them to make their own decisions to the extent this is possible.

Cost-Sharing

Cost-sharing is a means of transferring part of the cost of medicines to the consumer, depending on the consumer's eligibility, income level, drug type or class and whether it is absolutely essential, and pack size. A co-payment by the patient is usually required to obtain the medicine. Consumers pay either a flat fee per prescription or per item on the prescription, or a proportion of the value of the prescription, a flat rate according to pack size, or a combination of the above. A co-payment along these lines is markedly different from a deductible, which effectively means that consumers are responsible out-of-pocket up to a certain limit, before the third-party payer covers anything. The equity, efficiency, cost awareness, and revenue raising capacity of each of these forms of cost-sharing are quite different and policy-makers in transition need to evaluate these as well as define their policy objectives quite carefully. For instance, if equity has precedence over cost awareness and revenue-raising capacity, then a means-tested share of the value of the prescription may be a better option than a high deductible, or even a flat fee. A flat fee, on the other hand, does not increase consumer awareness about the cost of drugs and the best way to think about it is by means of hypothecated taxation.

Cost-sharing can potentially increase awareness provided that different rates of co-payments exist with respect to income levels. The increased co-payment from patients contributes to requesting medicines sparingly and, if carefully targeted, co-payments can contribute to public finances. At the other end of the spectrum, policy-makers need to consider that co-payments have several negative effects. Thus, most medicines are necessities and for many patients the issue is that of budget constraint and affordability. Cost-sharing, therefore, imposes an additional financial burden to the consumer. There is considerable evasion from co-payments and there is evidence on that from several countries, in particular, Italy, Spain, and Greece. The argument that co-payments increase consumer awareness as to the costs of medicines is not a valid one on equity grounds for patients, particularly those of lower incomes; choice may, therefore, be reduced and treatment may be affected. It should be a valid argument for physicians who ultimately decide on what to be consumed by the patient. Finally, there is no evidence suggesting significant effects of cost-sharing on total spending. If anything, spending has increased, as the evidence demonstrates for the cases of the UK and France. The reason why in both countries co-payments have not worked is directly related to the share of the population which is exempt from paying.

Exemption according to eligibility varies between EU Member States (25). The proportion of the cost paid by the patient varies by type of drug in Denmark, France, Greece, Italy, and Portugal, and for certain classes of drug in Belgium. In Germany, it now varies according to pack size. It is flat rate in the UK and for some drugs in Belgium and a standard proportion of the cost in Spain. There is no co-payment in The Netherlands. There are extensive exemptions in Belgium, France, Germany, Denmark, Spain, Italy, and the U K. Almost all EU countries have, thus, used cost-sharing to reduce demand for pharmaceuticals to some extent, but it has never been the most important mechanism for cost containment. Meaningful comparisons of the revenue from cost-sharing between Member States are difficult to make because schemes vary in the extent to which benefits are provided. Nor has the extent of cost-sharing continuously been increased. Cost-sharing may be strengthened at a time when the economic situation deteriorates and then reduced when economic prospects improve. This may be in line with fiscal requirements, but must take into account equity considerations. Or the extent of cost-sharing may depend on which political party is in power at any particular time. It is the easiest way to add revenue to the government purse, although it is always the case that considerable parts of the population are exempt. Governments usually introduce co-payments on an ad hoc basis and are going to continue to do so. However, there is no evidence to suggest significant effects on health spending.

Switching Products to Over-the-Counter Status

The option of delisting more and more products from reimbursement is an increasingly popular route for governments and health insurers, despite all the evidence showing that doctors often negate any savings by prescribing more expensive alternatives which are still reimbursable. Governments usually do not combine delistings with a reduction in the overall reimbursed pharmaceutical budget. Prices of the over-the-counter products were increased where price liberalization exists for over-the-counter medicines and this is an additional burden for the consumers.

Switching to over-the-counter status presents several advantages for third-party payers and industry. For the third-party payers primarily because they are no longer responsible for reimbursing over-the-counters and the burden has been shifted to the consumer. Manufacturers in principle favor over-the-counter switch and the advantages are focused around the loss of the patent protection and the threat of generic competition. In this case the manufacturer can advertise the branded product directly to the consumers without facing competition from an unknown similar generic product. An additional potential advantage for manufacturers is that delisting provides an outlet to declining sales of mature prescription-only products. In the US, the volume of over-the-counter purchases tends to outnumber physician-prescribed products by 3 to 2, although growth in value terms for the over-the-counter sector may lag behind that of the prescription market. In this way, the product life can be extended and the opportunity is available to enter new over-the-counter therapeutic categories, thereby widening the product's usage. While this is taking place, delisting eases the pressures in the prescription-only market and, thus, new more expensive products can be launched. Where price liberalization for over-the-counters exists, manufacturers also benefit from pricing freedom and the potential of increased overall sales. Policy-makers need to be particularly careful vis-a-vis pricing since specific indications of certain medicines may be available over-the-counter and on prescription in which case over-the-counter pricing freedom may cost more to publicly funded systems. Usually, prescriptions are reimbursed under the statutory schemes, whereas consumers are fully responsible when selecting without a prescription.

At the same time, there are certain disadvantages associated with delisting and policy-makers need to be watchful. Switches to over-the-counter status may not mean lower prices for consumers. They

will imply lower prices only if co-payment levels were high under prescription-only status, whereas if the drug was fully reimbursable before, the cost is now shifted to the consumer. There are also additional problems which need more attention such as safety issues and therapeutic misuse which may create further costs and public health problems. It is also argued that consumers are unable to select the most appropriate product. Governments and third party payers should balance the "negative" effects with savings from visits to physicians and outpatient departments and the possibility of extending the use of useful treatments which are quite expensive.

Options for Transition Economies

This paper has highlighted a number of policy options for the financing of pharmaceuticals in different settings. Policy-makers in Eastern Europe in their pursuit of a fair system of pricing and reimbursing pharmaceuticals within their jurisdiction, need to take into account the stylized facts of pharmaceutical production as they apply to an industry that is multinational in nature and largely monopolistic by definition. They also need to take into consideration the features of pharmaceutical production and distribution as they apply to their own countries and evaluate the overall environment in which health and pharmaceutical policy operates. The international experience has suggested that there are no clear-cut answers to the problem of containing pharmaceutical costs.

Table 5. Applying pharmaceutical cost containment measures in transition economies

Table 5 summarizes most of the evidence presented and draws some lessons for transition economies, which, nevertheless, need to be specified further at the national level. A number of general conclusions can be drawn, however. Most certainly global policies are needed, i.e., policies operating on the supply- the proxy-demand and the demand-side at the same time. Furthermore, policy-making needs to have a long-term planning perspective with an essence of continuity to the extent that this is possible. One very important lesson from the international experience in this area is that policy measures in this area are usually adopted on an ad hoc basis and in order to serve short-term fiscal objectives. While the previous sections have provided an extensive menu of policy options, clearly, limitations apply to their application in different economies in transition. These limitations relate to the current regulatory framework for pharmaceuticals in transition, the evolutionary process in which health policy and health reform in transition operates, and the applicability of different measures in each of these economies. Policy-makers would therefore need to fill all regulatory gaps, decide what policy objectives need to be fulfilled and ensure that choices do not cancel each other. Several options outlined in the previous sections require extensive investment in order to operate smoothly. Such investment needs to be seen as a sunk cost whose feasibility needs to be evaluated under current and future budget pressures.

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