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Cost Containment in the Pharmaceutical Sector: Innovative Approaches to Contracting while Ensuring Fair Access to Drugs

Germany 30 June – 1 July 2008

Synthesis Report

On behalf of the
European Commission
DG Employment, Social Affairs
and Equal Opportunities

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Executive summary

Although pharmaceutical pricing and reimbursement (P&R) systems are national competences, European Union authorities play a key role in harmonising some of the issues related to the pharmaceutical sector (for example, market authorisations), with various DGs (DG Health and Consumers, DG Enterprise and Industry, etc.) having different competences on these issues. A number of political initiatives, such as the recent Pharmaceutical Forum, have also been organised in an attempt to promote the sharing of knowledge, data and best practices in P&R policies.

Pharmaceutical policies in the EU Member States can be summarised as having three main objectives: ensuring access to medicines according to needs, promoting innovation, and controlling and ensuring the efficiency (cost-effectiveness) of pharmaceutical expenditure. To attain these goals, public authorities use both traditional instruments (such as price regulation, cost-sharing based on positive and negative lists, selective financing according to cost-effectiveness or according to added value in terms of health outcomes, public financing of patented products or direct funding and subsidies for research and development) or newer instruments (such as risk-sharing contracts and pay-back mechanisms based on prospective budgets).

However, these objectives often conflict with one another (for example, cost control as against improved access; innovation as against control of expenditure; or innovation as against affordable access), and governments face the hard task of trying to balance these out by implementing different P&R policies.

Various official reports (European Commission, OECD, etc.) have analysed the configuration of P&R systems across Europe and found that, on the supply side, the main trends are:

- **regulation of patented product prices**, mainly to protect consumers against manufacturers' monopoly positions and the lack of demand price-sensitivity;

- limiting the extent **of free pricing**, which can only be found in five European countries, and often with certain restrictions — for example, profit control in the UK — which actually represent a form of indirect price control;

- price control based on **international price referencing**, reference price systems and the establishment of positive and negative lists being common practice;

- the establishment of a **link between price regulation and reimbursement policies** (in roughly half of the countries in Europe);

On the demand side, policies focus mainly on doctors, although generally through soft instruments such as guidelines, and financial incentives are seldom used. Patients are also targeted, via cost-sharing practices, as are pharmacists, namely through generics substitution obligations.

But new pricing and reimbursement trends are also emerging across Europe. **Value-based pricing** systems, in which the results of economic evaluation analyses are used to set prices, are gaining in popularity and will, in the near future, probably replace the traditional methods of cost-plus or international reference pricing. Even traditionally free-pricing countries, such as the UK and Germany, are moving towards a value-based approach. On top of this, new instruments are being created in an attempt to better meet the conflicting objectives of cost control, improved access and innovation. **Risk-sharing arrangements**, for example, seek to address the problem of getting expensive new medicines on to the market when their healthcare outcomes, cost effectiveness and budget impacts are uncertain. This is namely done by drawing up contracts granting pharmaceutical companies financing or reimbursement deals in return for their product meeting a certain number of conditions.

The emergence of these new policies and instruments reflect the continued pressure on public pharmaceutical budgets and the increasing focus on ensuring value-for-money in healthcare systems. In line with these trends, experts and the literature recommend a number of practices, including: selective public financing of prescription drugs, based on economic

evaluations and cost-effectiveness thresholds, as in the UK or Portugal; equitable cost-sharing, as practiced in Denmark and Sweden, where limits to user contributions are set according to previous consumption patterns; improved transparency as regards efficiency, prices and regulatory decisions, in compliance with the EC directive on transparency; the promotion of international non-proprietary name use, in accordance with WHO recommendations; the establishment of appropriate incentives for prescribers, using economic incentives and not just 'soft' instruments such as guidelines.

In this context, different experiences were debated during the Peer Review, including: Germany's new rebate system; Bulgaria's experience with antiretroviral drugs; France's reforms based on agreements between insurance funds and physicians; the Netherlands' "preference policy" which only reimburses the lowest-price of out-of patent pharmaceuticals; Malta's attempts to improve the distribution of pharmaceuticals; Poland's efforts to transform its reimbursement system; and Portugal's attempts to implement reforms aimed at introducing studies on cost-effectiveness.

A number of key issues to the sector were also debated, such as the pharmaceutical market's **increasing globalisation**, which has resulted in an upwards convergence of prices as international trade becomes easier. This is particularly visible in the context of the EU and the single market, where the threat of parallel trade from less developed, lower-priced countries to higher-priced ones, as well as the common practice of reference pricing, have led prices to converge. But this also results in affordability problems for poorer countries, as well as delayed access to new drugs, as pharmaceutical companies tend to launch their products in high-price markets first to make sure they maximise their profits.

Transparency and access to reliable information on pharmaceutical prices have traditionally been a problem in this market, and although several initiatives have been launched under the auspices of the European Commission, none of them has yet proved successful. Recently, the PPRI — Pharmaceutical Pricing and Reimbursement Information network, the *Infoprice* project of the Transparency Committee and other initiatives have

made some progress on these issues, but more work still needs to be done to create a European-wide price information system.

Another of the issues discussed during the Peer Review was the lack of **impact assessments** of EU pharmaceutical policies and the limited interest of policymakers in this. Although pharmaceutical policies change often (sometimes to counteract pharmaceutical companies' behaviour), reforms are generally carried out without previous evaluation and without any assessment of whether the practice has actually attained expected objectives. Only a few countries claim to carry out formal impact assessments of their pharmaceutical policies. In many countries, no formal monitoring systems are reported. Where they exist, assessments normally focus only on the budget impact and are limited to the first year of implementation.

1. Cost containment practices of EU Member States: Overview

Over recent decades, there has been a large rise in public expenditure on pharmaceuticals — larger even than the rise in public expenditure on health or than the growth of GDP. To maintain pharmaceutical expenditure at a sustainable level, policymakers have therefore developed a complex range of policies, which seek not only to control public pharmaceutical budgets but also to increase the accessibility and affordability of medicaments, while balancing these aims against incentives for pharmaceutical companies to carry out R&D and innovation.

Traditionally, **cost control measures** have been introduced on the **supply side** of the market and applied mainly on pharmaceutical prices. Almost every EU Member State has some kind of price control mechanism in place, be it direct or indirect. **Price control** has, in the past, typically been based on external references (international comparisons) or on internal ones (existing treatments). However, the emerging trend is to base price decisions on economic evaluation analyses that assess both the costs and the health benefits of new therapies. The instruments used in this regard are wide-ranging — rebates, discounts, and pay-back or price-volume agreements. Reimbursement is regulated through the use of positive or negative lists and cost-sharing schemes. Some countries have established profit control schemes, where the price of the pharmaceutical is not controlled directly, but the profit that the company can earn is.

In order to ensure more efficient expenditure control, cost containment policies also need to shift the emphasis from price control to **demand-side measures**. Indeed, physicians, patients and pharmacists all play an important role in the rational use of medicines, and should therefore be actively engaged in pharmaceutical policies.

Up until now, the use of 'light' or 'soft' instruments — such as prescription guidelines or educational programmes to influence prescribers' behaviour — has been extensive across the EU. Nevertheless, these types of practice have not proved as effective as 'harder' instruments, such as **financial**

incentives for physicians, to encourage them to work towards a more rational use of resources. On the patient's side, different types of cost-sharing instruments (co-payment, co-insurance, deductibles, etc.) have also been implemented in almost all EU Member States, and have proved useful in promoting cost-consciousness and avoiding moral hazard in the use of drugs. Finally, pharmacists can also play an important role, mainly through generic substitution schemes, a practice which has become common across Europe.

But cost containment presents a particular challenge in the single European market, where increased trading opportunities have resulted in the emergence of a common and legal practice known as '**parallel trade**', whereby low-priced countries are able to resell their cheaper but identical pharmaceutical on the higher-priced markets of their neighbours. Paradoxically, the savings that result from parallel trade activities do not benefit either health insurers or consumers, but rather the parallel traders themselves. What's more, pharmaceutical companies' attempts to counter the parallel trade phenomenon and maximise their profits have led prices to converge upwards throughout the EU.

Another key challenge as regards cost containment practices is evaluating whether the policies implemented actually generate the expected outcomes (savings, accessibility, etc.). In practice, however, pharmaceutical policies change frequently and often without prior evaluations or **impact assessments**, thus making it difficult to determine which practices meet the objectives established. Although pharmaceutical pricing and reimbursement (P&R) systems are national competences, recent political initiatives at EU-level, such as the Pharmaceutical Forum or the *Network on Pricing and Reimbursement of Pharmaceuticals in the EU*, initiated under the Slovenian EU Presidency in 2008, should in future serve to improve this situation by promoting information-sharing among authorities in the EU-27. One of the Network's principal goals is to "build on the willingness of authorities to share the results of their work and to consider best practices".

On top of this important role of promoting the exchange of best practice, the European Union also often plays a role in harmonisation in relation to issues affecting the pharmaceutical sector — for example when it comes to

procedures for marketing authorisations. Various DGs of the Commission have competences over different pharmaceutical issues. DG Health and Consumers (SANCO) is responsible for everything relating to health aspects, DG Enterprise and Industry is in charge of pharmaceuticals and competitiveness, and DG Research also play key roles.

2. Global perspective on pharmaceutical cost containment

In today's rapidly changing environment, policymakers around the world are faced with a situation where traditional cost containment instruments, such as setting prices based on cost-plus criteria, internal or external references, are becoming obsolete. For example, basing price control decisions on international comparisons makes little sense today, as the prices compared (ex-factory, retail, etc.) usually fail to include the different rebates or discounts applied and do not, therefore, reflect real prices. In some cases the price used in the comparison and the price actually paid can differ by up to 50%, so making the comparisons worthless.

Policymakers are accordingly looking for new cost containment practices, capable not only of controlling public pharmaceutical budgets, but also of increasing the accessibility and affordability of medicines, while balancing those goals against incentives for R&D and innovation.

In particular, value-based pricing is an increasingly common practice in pharmaceutical P&R policies, under which economic evaluation analyses that assess both the costs and the health benefits of new therapies are used as the basis for pricing decisions. Health technology assessment agencies, such as the UK's National Institute for Health and Clinical Excellence (NICE) and the German Institute for Quality and Efficiency in Health Care (IQWIG), are playing, and will continue to play, an important role in providing useful, objective evidence for P&R policy-making decisions. The NICE experience is well-known and has served as a reference for other EU Member State initiatives. IQWIG is expected to introduce a model that works along the same lines in the future. But a major challenge relating to value-base pricing, which was raised during the Peer Review debate, is that of identifying common guidelines for pharmaco-economic studies and evaluations. This is likely to emerge as one of the key matters to be worked on in future years. The experience of Portugal, where mandatory economic evaluation studies for hospital medicine funding decisions have been introduced, could likely serve as an example to follow.

During the Peer Review meeting, several figures emerged, which highlight the importance of keeping pharmaceutical expenditure under control. In particular, OECD countries now spend approximately US$400 per capita on pharmaceuticals each year, representing roughly 17% of total heath expenditure and 1.5% of GDP. But very significant differences exist between countries. In countries such as Hungary, the Slovak Republic and Portugal, pharmaceutical spending represents up to one-third of total health expenditure and more than 2% of GDP. On the other hand, over half of OECD countries spent less than 20% of the OECD average per capita on pharmaceuticals in 2005.

Participants in the Peer Review also discussed some of the major issues relevant to cost control in the global pharmaceutical market. First, parallel trade (within Europe) or cross-border trade (between the US and Mexico), can have a strong impact on the harmonisation of pharmaceutical prices, especially on the European market. In addition, international reference pricing has led pharmaceutical companies to launch strategies that result in quicker access to innovative drugs in high-priced markets and access problems in lower-price markets. Secondly, despite a number of initiatives to facilitate price transparency, including the creation of a common European database, pharmaceutical prices remain opaque. Thirdly, the lack of impact assessments on pharmaceutical policies makes it difficult to evaluate whether or not any given practice contributes to meeting specified goals (access, innovation, cost containment, etc.).

The issue of the **relative effectiveness** of different medicines was also highlighted during the Peer Review. This question is being analysed by a specific working group in the Pharmaceutical Forum, in a bid to set principles for identifying the most valuable medicines and setting a fair price for them. Various existing networks (MEDEV, EUnetHTA, etc.) have been charged with the task of further developing scientific cooperation and information exchanges in this field.

The numerous stakeholders of the pharmaceutical sector were also present during the review, providing their perspective on the challenges that occur within the context of rapidly rising pharmaceutical expenditure. The European Social Insurance Platform (ESIP) stressed the need to build

innovative approaches, capable of addressing this challenge while at the same time taking into account common values such as solidarity and equal access to health services. The Pharmaceutical Group of the European Union (PGEU) highlighted the important contributions made by the pharmaceutical profession to the health system, for example, by helping patients with problems of dependence. They also stressed the need for caution regarding certain practices recommended by experts, such as generic substitution, which, although capable of generating important savings, must respect precise criteria, since changes in medication could generate adherence problems. The Standing Committee of European Doctors (CPME) highlighted some of the key problems that doctors are confronted with today, including prescription guidelines and the suspicions these arouse among some patients, as well as the constant pressure of cost containment on prescription decisions.

3. New cost containment instruments discussed in the Peer Review meeting

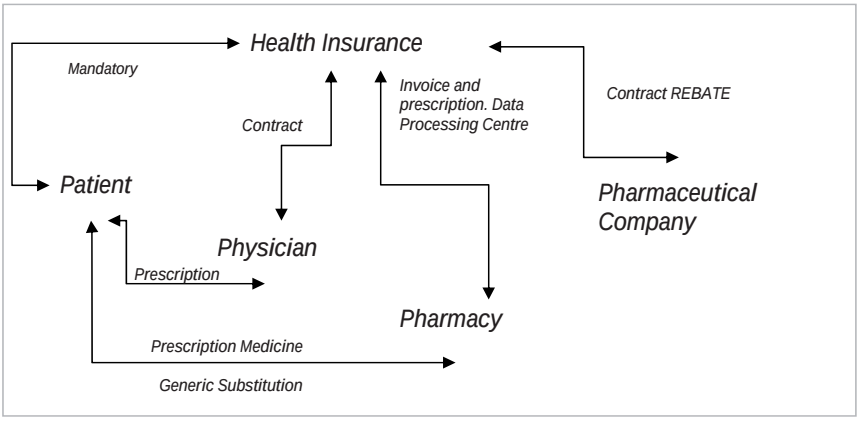
During the Peer Review meeting, participants focused their attention primarily on three new cost containment instruments:

- rebate negotiations, as recently introduced in Germany;
- agreements on budgets for treating illnesses, as seen, for example, in the Bulgarian experience on antiretroviral drugs (ARVs), and;
- different types of risk-sharing schemes.

Rebate negotiations

In the German system, medicines are paid for by health insurance, which is mandatory for everyone, and there are more than 200 competing statutory health insurance funds. Following its Statutory Health Insurance System reform, which took effect in April 2007, **Germany** opened the possibility for pharmaceuticals companies to negotiate selective rebate contracts with health insurance funds (see graph below).

German Rebate System



So far, the scheme has led to the conclusion of approximately 400,000 rebate contracts, mainly on generics (98%), and is expected to produce estimated savings on sales of close to 1% of total pharmaceutical expenditure.

However, a number of issues still surround these rebate contracts, namely the question of whether the EU's public procurement directive 2004/18/EC in fact applies to them. This is a highly controversial point and the legality of some contracts has already been challenged in the courts. The EU Court must now decide whether these agreements are to be considered public contracts or not.

During the Peer Review, other countries presented their experience in relation to negotiations and contracts between insurance funds, the pharmaceutical industry and prescribers. **France**, in contrast to Germany, is working on the demand side, establishing individual contracts between insurance funds and individual prescribers. These contracts will set objectives (for example, 80% of prescriptions to be generic drugs) and provide a bonus for the prescriber if the targets are achieved. In The **Netherlands**, where every individual is also required to have health insurance and competition exists among health insurers, a new *preference policy* has been established, which allows insurers to offer preferential terms for preferred medicines. Hence an insurer can choose to only reimburse the lowest-priced, out-of-patent pharmaceuticals. This could reduce the price of preferred drugs by 80–90%.

Agreements on budgets for the treatment of illnesses: the Bulgarian experience on antiretroviral drugs (ARVs)

Under the Bremen Declaration on Responsibility and Partnership — *Together Against HIV/AIDS* — of March 2007, EU governments, civil society and the pharmaceutical industry agreed to combine their efforts to improve sustainable access to ARV medication for HIV infection.

Bulgaria was designated as one of the pilot countries for this initiative, with the aim of exploring different approaches for providing antiretroviral treatment at an affordable cost, and ultimately ensuring therapy to around 3,000 patients by 2015. The Bulgarian project was launched in June 2007

and, in December 2007, all ARV-producing pharmaceutical companies announced their willingness to participate in the scheme.

Different options were investigated, including price reductions and rebate negotiations. However, the first option was considered not to be feasible as Bulgaria is already one of among the countries with the lowest prices for pharmaceutical and the second option failed to gather a consensus in the Bulgarian pharmaceutical industry, because volumes are relatively low.

Companies nevertheless agreed to participate in a holistic approach. A National Strategy Plan for HIV/AIDS will be adopted and priority targets will be identified. One of the important aspects of this initiative is that the budget will not only address issues relating to medicines but also to prevention, cost-effectiveness, treatment, and stakeholder involvement.

During the Peer Review meeting, it was suggested that compulsory licensing could be used as an instrument to make companies more amenable to cooperation and improve ARV access. Precedents for this approach exist in countries such as Thailand and Nigeria. However, it emerged from the debate that this option should be used with caution and that negotiations and cooperative arrangements with the industry were preferred to compulsory licensing.

Risk-Sharing Schemes

In parallel with the trend towards value-based pricing and the emergence of institutions providing objective evidence for taking P&R decisions (such as NICE), a new approach has recently emerged — that of risk-sharing schemes.

Under such schemes, two parties — usually consisting of the 'payers' (governments, hospitals, etc) and the pharmaceutical industry — draw up contracts between themselves, which lay down the conditions for financing or reimbursing certain medicines.

The rationale behind these agreements is to overcome the uncertainties surrounding the impact of certain new pharmaceuticals in terms of

healthcare outcomes, cost-effectiveness and budgets. Such practices are particularly used to cover new, and often expensive, drugs to avoid risks of budget overspending, over-prescribing, or absence of clinical benefits, while contributing to cost containment, improving access and stimulating innovation.

Currently there exists such a broad array of risk-sharing schemes that it is difficult to classify them. In cases where the focus is on controlling global budgets, risk-sharing is generally applied through pay-back guarantees. Where the concern is over a single product — for example, a new highly-priced medication — price-volume agreements can be used, although some authors exclude these types of practices. There is also a new emphasis on reimbursement arrangements that are based on results, for instance, clinical outcomes or cost-effectiveness. NICE plays an important role in such schemes through its cost effectiveness threshold: for example, its opinion on the treatment of multiple sclerosis or multiple myeloma, a form of blood cancer.

These schemes appear to present certain advantages, namely: a) they enable medicines that otherwise would probably not be eligible for reimbursement on a regular basis (for instance, medicines with a cost effectiveness ratio above the NICE threshold) to become rapidly available; b) they should result in an improved budget control for the healthcare provider, and; c) they ensure improved access to costly and innovative medicines for patients.

On the negative side, such agreements are highly complex and problems exist when it comes to assessing their effectiveness. In addition, the high administrative costs associated with their implementation mean they are not always a feasible option.

4. Specific problems of access and affordability in new EU Member States

There are wide variations between countries when it comes to accessing new and innovative medicines. These tend to be much more readily available in the EU-15 Member States than in those that joined the EU more recently. Indeed, due to their low GDP per capita and the small size of their pharmaceutical markets, national authorities in many of the new Member States face serious challenges in obtaining access to innovative medicines, such as new cancer drugs or multiple sclerosis therapies.

In this context, the most important challenge is probably affordability. Indeed, a 2007 Eurostat-OECD survey of 181 medicines found that price varied by a factor of two across Member States. However, once GDP per capita was also taken into account, affordability varied by a factor of 17. Moreover, for innovative medicines, the price in new Member States has now almost converged with those in the EU-15. In itself, this is logical enough. A company working in a single European market will have to adopt similar prices across the entire market, even if it does not wish to. Indeed, companies would prefer to differentiate their pricing more, enabling them to boost their sales volumes and so their profits. But the risk of parallel cross-border trade and the influence of reference pricing make differential pricing difficult.

Timing is also a major factor affecting accessibility in Europe. Patients in some Member States sometimes have to wait much longer for a new medicine than patients in other countries. This is partly due to the fact that some national authorities are particularly slow or face lengthy processes for reaching pricing and reimbursement decisions. But companies are also to blame for the situation, with their focus on profit-maximising strategies that entail, for example, launching their product first on the markets where they can get the highest price, and only then making it available in lower-priced markets. Indeed, there exists a demonstrable relationship between a country's price levels and the number of new molecules launched on its market.

The situation poses a real challenge to the EU principles of equality and solidarity. Peer Review members came up with several potential ways forward, including the establishment of clear and consistent links between value and P&R decisions; ensuring an improved use of Health Technology Assessments (HTA); exploring the potential of new pricing and reimbursement practices, etc.

Along these lines, the Pharmaceutical Forum adopted, in 2007, a series of good practice guidelines for implementing a pricing and reimbursement policy, in which patient accessibility is analysed from three perspectives: 1) how to ensure more timely access to valuable innovation; 2) how to provide affordable medicines, and; 3) how to ensure equal availability of medicines. The EU directive on transparency, which sets firm deadlines for making decisions on pricing and reimbursement, should also serve to improve the situation.

5. Future trends in pharmaceutical pricing and reimbursement

Pricing and reimbursement policies can help to emulate a well-functioning pharmaceutical market. However, participants in the Peer Review voiced a broad variety of opinions regarding the effectiveness and feasibility of the existing approaches to pharmaceutical pricing in the EU and elsewhere, underlining the fact that many of the policies and instruments used are not backed up by evaluative research or by any compelling evidence on their actual effects. The meeting focused mainly on four different pricing options, namely: free pricing, cost-plus pricing, international referencing and value-based pricing.

Participants stressed two central issues when examining different pricing options:

1. Pricing approaches need to be assessed in relation to the specific characteristics or typology of the products and countries involved. Different approaches are, for example, preferable depending on whether the products are under exclusivity or not; whether they are reimbursed by health insurers; which countries are applying them; whether the country has a strong, innovative industry; whether the country is home to a predominantly generic industry; the size of the country; etc.

2. Pricing mechanisms must be considered in relation to other policy practices, particularly reimbursement and public financing policies, as well as intellectual property policies.

Free pricing

In a free or market-based pricing system, manufacturers are simply allowed to set their own price at market launch.

Free pricing makes sense in product markets where competition is thriving (e.g. under generic competition) or where high prices do not pose a threat

to public health objectives. And, even if competition is not actually that strong on these markets, it would still appear preferable to maintain free pricing, while introducing pro-competition policies, rather than relying on price control. Paradoxically though, this approach is not commonly used and most EU countries control the prices of generics to a certain degree, for instance, by linking them to the originator's price. This suggests that policymakers in fact tend to opt for price control rather than implementing pro-competition policies, such as setting incentives to make demand more price-sensitive or favouring generic substitution. This attitude could also be interpreted as a means of protecting/subsidising predominantly generic domestic industries.

As for products under patent protection or other forms of market exclusivity, free pricing has but limited justification. Indeed, the purpose of patents is not to provide unconstrained market power (monopoly) to the right-holder as this could enable certain right-holders to abuse their privileged position and enrich themselves at the expense of society. Instead, the patent system is aimed at improving a society's well-being, by preventing suppliers from reaping free benefits from someone else's innovation and ensuring that innovators that invest and take risks are rewarded for their efforts. So, in line with general economic thinking, it is believed best that, although good reasons exist for legally creating or allowing such monopolies, these should be regulated in the public interest. In fact, the US seems to be the only major developed country in favour of free pricing for products under exclusivity, and where the demand side of the market is expected to counteract the power of suppliers in the marketplace.

Price control

The pharmaceutical market is imperfect. Prescribers are often not sensitive to or even aware of the prices of the drugs they prescribe due to informational and incentive problems. This can result in higher levels of prescribing for some products that cost much more than available substitutes but deliver very similar benefits to patients. What's more, patients are not price sensitive due to the high levels of public and third-party financing and their lack of knowledge about pharmaceutical products. These demand-side problems

lead most countries to implement some form of pricing scheme in order to ensure that drugs are prescribed in a way that delivers value for money.

Various price regulation schemes exist and can be based on numerous criteria — cost-plus formula, international price referencing, negotiated prices, differential prices, etc. — and many countries use several criteria.

Ideally, cost control criteria and mechanisms should be predictable and leave only limited discretion to regulators so as to reduce uncertainties for producers, while minimising the risk of regulatory capture and corruption.

But, like free pricing, price control also raises a number of problems and some of the established practices increasingly appear to have become outdated and inefficient.

a) International reference pricing

Despite the widespread use of international reference pricing around the world, such an approach is probably an option only for smaller countries, because it implies de facto acceptance of the pricing decisions and criteria of the referenced countries.

What's more, reference pricing has the unfortunate consequence of causing global drug prices to rise. Indeed, as innovators increasingly market their products first in high-price countries, international reference pricing will tend to align the prices of countries that apply such a system with those of high-price countries, making many drugs inaccessible for people in less developed countries. A second disadvantage of such a system is that poorer countries will also experience a delay in accessing innovative products.

b) Cost-plus approach

Under the cost-plus approach to price control, governments set prices by calculating how much a medicine costs to produce and then adding on a reasonable profit margin. In the past this approach was very popular in a number of countries and sectors, and even today some still see it as a valid option. However, it is often criticised for its lack of rationale and its predictably perverse effects on efficiency. Indeed, if a producer already

knows that all costs incurred, plus a certain profit rate, will be allowed and eventually reimbursed, he will have little incentive to be efficient and minimise production costs. Consequently, cost-plus price regulation has a tendency to reward inefficiency.

One of the main problems with the cost-plus approach is the regulator's inability to gather any reliable evidence on producers' actual costs or efficiency. In Brazil, price negotiations for ARV drugs relied on information regarding the cost of production incurred by public producers. It is however doubtful whether this particular system could work in different settings. Information on production costs could be easier to obtain in the context of markets under generic competition. However, as mentioned above, in such situations, making competition effective is probably a better option than controlling the price through regulatory decisions.

In the case of pharmaceuticals where patents still apply, cost-plus mechanisms are even less appropriate because the cost of production usually accounts for just a small fraction of the price. For example, the annual cost of ARV therapy fell from roughly US$15,000 to $150 when Indian generics came onto the market, so suggesting that only around 1% of the market price of a new patented pharmaceutical stems from manufacturing costs. The remaining 99% therefore reflects monopoly pricing in relation to competitive prices. While it may be argued that this is one way of reimbursing company R&D costs, in fact, it has been estimated that R&D costs for new drugs amount to only around 15% of total sales revenue, with an additional 24% for advertising and marketing. What's more, R&D costs are "sunk costs" which cannot objectively be allocated to single products. Given such a cost structure, it is very difficult to derive a predictable, fair and meaningful price by applying a cost-plus criterion. The market price, both under a competitive market and under a regulated monopoly, should reflect the value of the product to consumers or to society, not just the costs actually incurred by producers. It should also act as a signal to innovators, telling them which types of innovations are valued and to what extent, and guiding their decisions to invest in R&D and take risks, rather than the other way around.

One of the few (indirect) price control systems that have apparently been relatively successful from both an industrial and public health perspective is the UK's Pharmaceutical Price Regulation Scheme (PPRS). Under this system, independent firms were given responsibility for auditing the cost of production and determining a profit rate assumedly related to the value of innovative activities. However, the system has been recently challenged by an Office of Fair Trading (OFT) report, which pointed out that neither production cost cuts or profit caps ultimately help to guarantee that prices reflect the therapeutic value of the drugs companies are supplying to the market. Based on these findings, the OFT recommends switching to a value-based pricing system.

c) Value-based pricing

The problems encountered in the above-mentioned approaches have led to the recent emergence of a new trend — that of value-based pricing, under which individual products are assessed for cost-effectiveness. Indeed, this would seem to be the most theoretically sound and feasible approach when it comes to pricing new patented products.

In such systems, value is not assessed by production costs, or by calculating the aggregate willingness of individual agents to pay for a drug. Indeed, patients and prescribers have neither the required information nor the incentives to make efficient decisions. Instead, the value of a medicine is based on objective assessments of the value-added produced by a new product in terms of improved health outcomes, savings in treatment costs, etc.

But value-based pricing also represents a challenge, in that it requires considerable technical capabilities and hard work to provide regulators with the information they require. One of the best-known examples of this kind of work is the UK's National Institute for Health and Clinical Excellence (NICE), with its cost-effectiveness threshold for new drugs. However, obtaining this type of information on a country-by-country basis would entail a wasteful duplication of analyses and, ideally, EU Member States should work together to pool their information. They would then be able to customise it to their

own unique conditions, thus enabling enable each one to make independent decisions on pricing and reimbursement (P&R).

The R&D industry appears to have somehow accepted the rationale of value-based pricing, now often using pharmaco-economic assessments as a tool to negotiate P&R for new products. However, local generic industries, which have thus far enjoyed privileged protectionism, are likely to oppose the approach, since prices are likely to be lower than under alternative systems. As for medicines where the patent has expired, value-based pricing should in any case not be applied, as the innovative contribution of a new product is only supposed to be rewarded by patents and other IPR during the period of market exclusivity, not beyond.

One of the main obstacles to the introduction of value-based pricing is that policymakers are often reluctant to determine explicit and precise criteria for its application, such as cost-effectiveness thresholds. This is namely due to pressure from certain interest groups, which argue that the diseases from which they suffer deserve higher thresholds than the rest. These, however, are not technical judgements but value judgements that must to be resolved through the political process.

Key issues and future trends

Participants in the Peer Review further stressed the importance of taking account of the fact that pricing policies cannot be designed, analysed or evaluated independently from **financing and reimbursing policies**.

For example, public and third-party financing of drugs will inevitably increase demand and indirectly affect prices. At the same time, it will also make demand less price-sensitive.

Although some countries claim that their pricing and reimbursement decisions are taken independently, this is more likely to simply be wishful thinking, reflecting institutional or legal traditions, or a refusal by policymakers to explicitly recognise the market power they have as monopolists.

But a situation where pricing and reimbursement were actually independent activities would in fact represent a worst case scenario. For example, let us assume that a new medicine can be used for two separate purposes with different effectiveness. The pricing authority accepts the high price proposed by the producer. Based on that price, the financing authority decides to restrict reimbursement to the case where it is most effective, leaving the second group of patients without a potential treatment. On the other hand, an integrated P&R approach would allow the public authority to negotiate the reimbursement of the two purposes at a lower price, resulting in the same revenue or benefit for the producer and the same cost for the health system. It goes without saying that the second, integrated P&R approach is likely to provide a more satisfactory, win-win outcome for all parties.

P&R policies in the EU have however become more complicated due to the logic of the **single market** and the expectations and demands for equal access to medicines across Member States. While the single market is ultimately likely to result in a single European price for each medicine, in an attempt to discourage parallel trade, a single price would also mean different affordability across Member States, due to the considerable disparities in income. To make a single European price compatible with equitable access, given the current income disparities, the only option therefore, would be some form of income redistribution — a possibility which is likely to remain remote, given the clear acceptance of social policies as a national, rather than EU, responsibility.

Nevertheless, some recent developments could facilitate the co-existence of a single European price with equitable access — namely the introduction of confidential discounts. Indeed, this would enable a single European list price to coexist with **variable discounts** and, hence, with different effective prices across, and maybe even within, EU countries. In fact, this is actually how the system works in the US, where public insurers normally require lower prices and each insurer then negotiates the best price it can. Unfortunately, such a system would not necessarily guarantee improved accessibility across EU Member States, as it is likely that the larger and more affluent countries, based on their larger market power, would be able to negotiate larger discounts than the smaller, lower-income countries. Moreover, it would

raise a host of questions like: *Can a market without price transparency be called a market? Would it have the intended benefits of a single market? Is this the kind of market the EU is aiming for? How would managers and regulators be made accountable for their decisions?*

An effective equity pricing system in the EU would require discounts to be agreed politically and then accepted by all Member States on the basis of objective criteria. For example, effective (discounted) prices would somehow have to be linked to an indicator of wealth or welfare such as GDP per capita. Again, this does not represent a technical but a political problem, and a dilemma the EU has been unsuccessfully struggling with for several years.

Finally it must be acknowledged that most of the problems faced by pharmaceutical policies (questionable value for money as regards some new products, unequal access across Member States, out-of-control expenditure growth) are linked to the predominant system of promoting innovation though exclusive IPR. Some of the solutions should therefore be searched for in this policy area. Improving the quality of patents is certainly a promising option. Recent proposals suggest developing alternative systems of incentives to innovation that would complement or substitute for the prevailing system. One of the most appealing ideas could be the separation of the market for innovations from the product market. A multi-billion **innovation fund** would reward medical-pharmaceutical innovation in itself, and products could then be produced under competitive conditions. Since innovation is a global public good, some proposals point to the option of financing such a fund through an international R&D Treaty, under which countries would contribute to financing R&D according to their GDP and would then have free access to all resulting innovations. Of course, all these options are at an early stage of development, but they should not be discarded, especially in light of the limited progress that has been made so far in improving access to new medicines and the modest advances attained in some crucial areas, such as neglected and rare diseases.

6. Lessons learned and conclusions from the Peer Review

- Good practices on cost containment need to be disseminated and compared. This can be achieved through the creation of networks among pricing and reimbursement authorities in different Member States. Another way is to try to promote consistent impact assessments of pharmaceutical policies and disseminate the results in order to identify the best practices according to different objectives (innovation, access, cost containment, etc.).

- Industrial and public health goals often conflict in pharmaceutical policies. Although the Peer Review acknowledged the importance of promoting a dynamic innovative European industry, there was a common call for a more social, public health perspective in European pharmaceutical policies.

- The Review found that some cost containment practices still in use today have become relatively obsolete. This is particularly the case of price controls (cost-plus, international reference pricing, etc.). Governments should accordingly shift their emphasis away from price and supply management instruments and towards demand management policies, focusing primarily on doctors and pharmacists.

- The globalisation of pharmaceutical markets is tending to cause prices to converge upwards, so putting more pressure on countries with limited healthcare budgets. This price convergence is mainly due to: 1) countries using international reference pricing as a criterion to set the price; 2) the fear of parallel trade, which has led pharmaceutical companies to implement profit-maximising strategies, under which they first launch their pharmaceuticals in higher-price markets. As a consequence, lower-income countries face increasing problems of access to new medicines.

- Cost containment measures agreed in collaboration with pharmaceutical companies (pay-backs, rebates, risk-sharing etc.) seem to provide win-win opportunities, and the experience obtained from them should be shared among Member States. However, they are not automatically transferable from one country to another, due to different healthcare systems and market situations.

- It is essential to promote transparency in pharmaceutical prices and regulatory decisions. Related to the first issue, some European initiatives are being promoted in order to build a common European pricing database.

- Future issues will include the search for an efficient working model (for example, through IQWiG, the German Institute for Quality and Efficiency in Health Care), pharmaco-economics, value-based pricing, risk-sharing instruments, demand-side measures, conditional reimbursement, and the problem of access to innovative high-priced medicines, especially in low-income countries.

http://www.peer-review-social-inclusion.eu

Cost containment in the pharmaceutical sector: Innovative approaches to contracting while ensuring fair access to drugs

Host country: **Germany**

Peer countries: **Bulgaria – Finland – France – Hungary – Luxembourg – Malta – Netherlands – Poland – Slovenia – United Kingdom**

Pharmaceuticals give rise to conflicting interests. On the one hand, it is important for doctors and their patients to have wide and equitable access to the drugs they need for treatment and, accordingly, for costs to be affordable, while at the same time avoiding over-prescription and wasteful use. On the other, it is equally important that the companies producing pharmaceuticals are able to make sufficient profit to make investment in new drugs worthwhile. Given the social dimension together with the fact that it is public agencies or health insurance funds rather than the final consumers who are effectively the purchasers of pharmaceuticals, the price mechanism, unlike in other markets, cannot be left free to determine the balance between supply and demand.

Containment of the cost of pharmaceuticals which nevertheless ensure adequate provision to the drugs needed is a common objective across the EU. There are, however, different approaches to the pursuit of this objective which in some degree reflect differences in the structure of the healthcare sector across the EU and which can limit the extent to which practices adopted in one country are transferable to others. Despite this, exchange of views and experience can be valuable in suggesting the means of improving current methods.

The Peer Review will focus on the following issues:

- price negotiations and tendering procedures between insurance and pharmaceutical companies;
- risk-sharing agreements between pharmaceutical companies and health care providers;
- agreements on budgets for the treatment of illnesses (cost-controls).