

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

Discussion Paper

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1. The policy framework at European level

Pharmaceutical policies are expected to attain multiple goals that reflect three different perspectives: a) public health, mainly focussing on the quality, safety and efficacy of medicines, b) healthcare systems, concerned about access, affordability, pricing and reimbursement issues and c) industrial development, which looks at the pharmaceutical sector as a source of production, income, employment, exports, etc.

Within the EU the responsibility for pharmaceutical policy is shared between the European Commission (EC) and the Member States (MS). The main European Union (EU) organisations involved in pharmaceutical policy are the EMEA (European Medicines Agency), which deals with the technical regulation on quality, safety and efficacy and the DG Enterprise and Industry. Pricing and reimbursement of medicines (the healthcare systems perspective) remains a national competence in the hands of MS, due to the principle of subsidiarity.

Other DGs, such as DG SANCO and DG Research have also a strong and complementary role to play. Apart from being involved in the legal proposals made by DG ENTR, SANCO co-chairs the Pharmaceutical Forum with that same DG. In this framework, it is notably responsible for the working group on the relative effectiveness assessment of the pharmaceutical products. The mandate of that group also aims at containing pharmaceutical costs incurred by national health care systems by providing scientific support to the competent authorities in charge of pricing and reimbursement decisions. In addition, the working group on information to patients on diseases and treatment of the Forum also participates in this objective of costs containment by delivering concrete recommendations for improving the patients' empowerment. On its side, DG RTD that supports and funds pharmaceutical projects, have also some role in pharmaceutical issues.

This particular distribution of responsibilities is not likely to lead to a coherent policy due to the conflicting objectives and expectations of the agencies and stakeholders involved (consumers, pharmaceutical industry, insurers, Member States and European Commission) and to the difficulty of coordinating their actions and policies. There are conflicts between national competences on pricing and reimbursement and the European objective of free movement of goods that together result, for instance, in the phenomenon of the parallel trade of medicines. This practice has been actively promoted by some high price countries as a mechanism of lowering prices, although it is detrimental, from an industrial perspective, for their innovative industry.

Pharmaceutical policies in Europe have experienced a major transformation as a result of the creation and the consolidation of the EU and the Single European Market. Before the establishment of the EU each country was free to design its own pharmaceutical policies. The countries with a strong innovative industry used to apply policies that allowed relatively high prices of pharmaceuticals - high intellectual property (IP) standards, including product patent, and weak or no price controls -, whereas countries without an innovative industry applied lower IP standards and more restrictive pricing policies. This allowed them to enjoy lower prices and to protect their non-innovative industries. The result of that situation was a segmentation of the European market, with price differences that were broadly correlated with national income levels. The innovative industry accepted national price differences as part of the business model.

The evolution of the EU leads to a harmonisation of the IP regulation and of the quality, efficacy and safety rules for marketing authorisation. However, pricing and reimbursement (P&R) policies remained a national responsibility on the grounds that they were an essential tool of social protection policies. The Transparency Directive accepted this autonomy and was only aimed at avoiding national regulators to discriminate products from other Member States in applying their national P&R policies. The new situation brought, however, some unexpected problems: a) the price differences of existing products lead to the practice of parallel trade, which mainly affected existing products, and b) to the convergence in the prices of new drugs, which meant higher prices and pharmaceutical expenditure in countries that in the past benefited of relatively lower prices. Although countries formally retained the right to determine the national price of both existing and new medicines, in fact they have lost the capacity to impose prices for new drugs below those of other EU countries, as companies are not willing to accept price differentials that could make parallel trade attractive.

2. A summary of the related policy debate at European level

The pharmaceutical policy strategies over pricing and reimbursement at European level arose at the beginning of the 80s under the auspicious of the European Commission, mainly through a document by the former DG Industry calling for Member States pricing transparency and price harmonization. The final result of this process was the adoption of the Transparency Directive¹.

This legislative process was followed by an industrial policy communication (Communication on the outlines of an Industrial Policy for the Pharmaceutical Sector in the European Community²) that reflected disparity in the Member States priorities. Following that, the three Roundtables (also called Bangemann Roundtables because of the Commissioner Bangemann) discussed some of the most important issues related to pharmaceutical policy as parallel trade or price convergence. The result was the "Communication on a Single Pharmaceutical Market"³, which suggested some measures, such as to enhance market transparency and competition, to avoid compromising patients' access, etc. But no major actual changes followed.

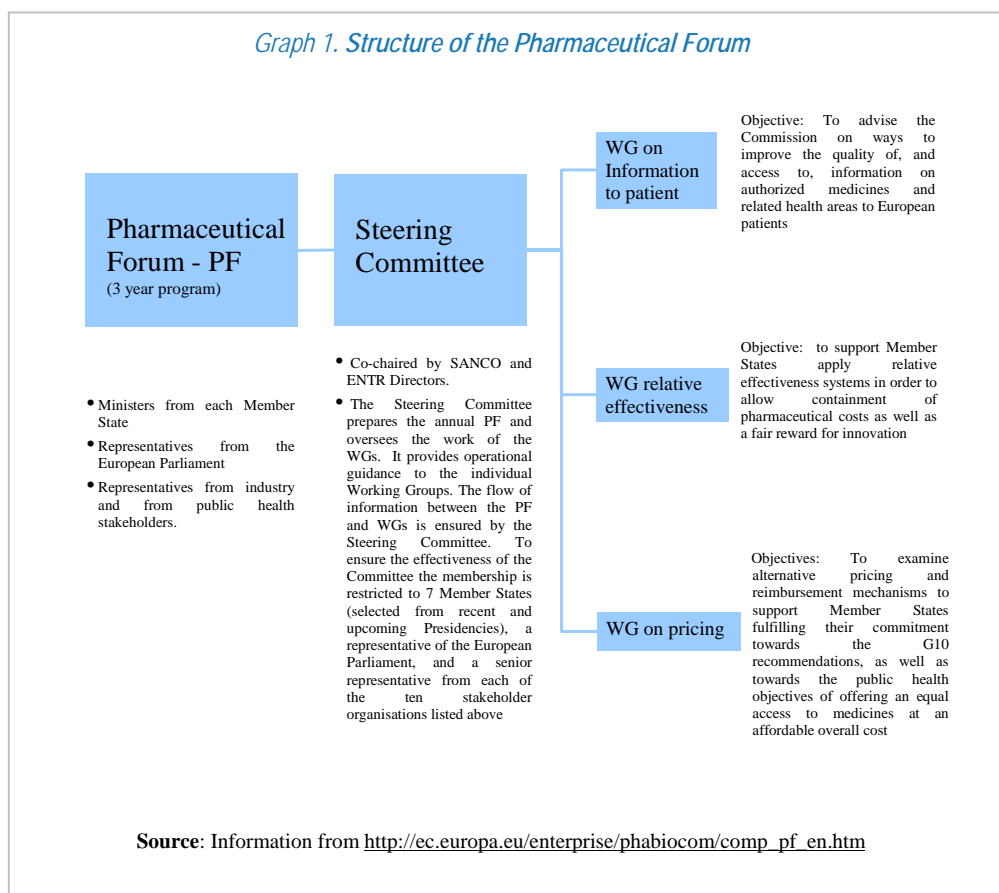
After that roundtables, the G10 (High Level Group on Innovation and the Provision of Medicines) was set up by DG Enterprise, which final outcome was a document with fourteen recommenda-

¹ Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems.

² (COM(93) 718 final).

³ (COM(98) 588 final).

tions. Following these recommendations, the European Commission created the Pharmaceutical Forum in 2005 to take the process forward around three key themes: Information to patients, pricing policy and relative effectiveness (see structure in graph 1).



The consolidation of the EU has brought an extension of the concerns for access and equity. These policy objectives, formerly a national issue, increasingly became a European issue, reflecting the idea that all EU citizens should have the same right to health and hence to access to medicines. However, the convergence of pharmaceutical prices produced the opposite results, as it implied an increasingly higher financial burden for the EU countries with a lower income.

Moreover, higher income EU countries have turned to consider that the rise in pharmaceutical prices could also affect the financial sustainability of their health systems, and have progressively implemented and strengthened cost containment policies that negatively affect the prices and revenues of the pharmaceutical industry.

The policy debated has been compounded by an increasing perception that the European industry was losing its competitiveness and leadership in innovation in relation to the US and Japan⁴. This relative decline is attributed by some stakeholders to the strength and multiplicity of cost-containment P&R policies within the EU.

⁴ A. Gambardella, L. Orsenigo F. Pamolli. "Global Competitiveness in Pharmaceuticals: A European Perspective", DG Enterprise, European Commission, 2001.

For that reason, some new instruments are now being used in order to make Europe again a world leader in pharmaceutical research. In this field it points to the Public-Private Partnership called Innovative Medicines Initiative (IMI)⁵ represented by EFPIA (European Federation of Pharmaceutical Industries and Associations) and European Commission.

3. European and international comparative aspects

Several European and international initiatives have been set up in order to assess the characteristics of pharmaceutical policies from a descriptive and analytical comparative approach.

At the European level, the Pharmaceutical Pricing and Reimbursement Information (PPRI) project⁶ is funded by the EC (DG SANCO) and coordinated by the Austrian Health Institute (ÖBIG). The PPRI involves the associate partner WHO EURO, as well as a network of institutions and organisations from all Member States of the enlarged European Union. The objective of the PPRI project is to provide knowledge and information on pharmaceutical systems in the 25 Member States of the European Union.

Different outcomes made by the networks or project initiatives have helped to increase the debate level on the innovative approach on pharmaceutical policies at European level.

First we can point to the document "Guiding principles for good practices implementing a pricing and reimbursement policy", made under the Working Group of Pricing of the Pharmaceutical Forum (May 2007), which looks for a balance between optimal use of resources to maintain sustainable financing of healthcare, access (affordability and availability) to medicines for patients and reward for valuable innovation.

Second, and also under this Working Group of Pricing, a "toolbox exercise" was made with different pharmaceutical practices in order to identify, collect and provide information and evidence on these practices (how to set-up a practice, which are the risks and success factors, etc)

The EU pharmaceutical policies face the challenge of reconciling or, at least, finding an acceptable balance between the earlier mentioned, often conflicting objectives and the peculiar distribution of responsibilities between the EC and the Member States. Cost-containment policies are assumed by some stakeholders to threaten the industrial objectives of promoting a strong innovative industry in Europe, while the establishment of a single market, and the corresponding trends towards the convergence of pharmaceutical prices, are in principle contradictory with the goal of solidarity and equity in access across Member States with high differences in income.

At the international level we can find the OECD's project on pharmaceutical pricing policy⁷, with two main objectives: first, to increase the information on pharmaceutical pricing policy in OECD countries and make international comparisons of policies; and second, to analyze the impacts and implications of policies, particularly focussing on the prices paid by the countries and on pharmaceutical R&D.

⁵ http://imi.europa.eu/index_en.html

⁶ <http://ppri.oebig.at/>

⁷ <http://www.oecd.org/health/pharmaceutical>

4. Main approach concerning pharmaceutical policies

Pharmaceutical policies are a combination of elements or policy practices. All these policies practices cannot be analysed in isolation because they are usually interrelated and they reinforce or counteract each other.

High minimum IP standards is the main mechanism used for promoting innovation. Before the establishment of the Single Market, countries were allowed to set IP protection according to national needs. Joining the EU meant that Member States had to adapt to a single minimum standard, a trend that was later reinforced by the WTO TRIPS agreement. The EU is also trying to promote innovation by means of programmes and subsidies to R&D.

High IP standards, by granting right holders exclusivity rights on their innovations, lead to an increasing monopolisation of the pharmaceutical markets. In order to moderate the effects of monopolisation on prices and expenditure, countries have implemented a large variety of policies, which are usually classified into supply and demand policies.

Demand side policies include a set of practices that affect the reimbursement of pharmaceuticals: positive and negative lists, cost sharing, reference pricing, risk-sharing contracts, tenders, pay-back arrangements, as well as the provision of information and incentives aimed at improving the rational use of medicines and making demand more price sensitive.

The most traditional **supply policy** is price regulation. Price regulation often takes the form of administrative product price control. **Price control and price negotiation** are part of price regulation, mechanism that usually differs from country to country in the way of set-up and configuration. This price negotiation could be explicit (written in the law, for example) or implicit (the habit is to negotiate the price, but it is not written in anywhere). In general terms, direct product price regulation is losing its traditional role in Europe, probably less as a result of an intended policy than because of its decreasing effectiveness in the new context of the Single European Market. Innovator companies are now interested in having similar prices all over the EU – in order to avoid or minimise parallel trade – and are more able than in the past to resist pressures of national regulators to reduce the price of new drugs, because the EU's upwards harmonization of Intellectual Property Rights implies that no agreement in price negotiation might imply, especially for relatively small countries, a delayed access to innovations and to the associated health benefits⁸.

Generic policies include both demand and supply mechanisms aimed at increasing price competition when exclusivity rights expire: fast track registration, lower registration fees, generic substitution, prescription by international non-proprietary name, incentives to prescribers and consumers, etc.

Other **competition policies** – e.g. antitrust policies to limit the potential abuse of monopoly power – are more infrequently used at country level, although they have been used by the EC (for example, the recently inquiry launched by DG Competition into competition in pharmaceutical sector on January 2008).

⁸ Espin J, Rovira J. Analysis of differences and commonalities in pricing and reimbursement systems in Europe. DG Enterprise and Industry, June 2007.

Tendering procedures are advocated by international organisations – e.g. the World Bank - for improving competition and transparency and avoiding corruption. In the EU context, it is mainly used for hospital and also for public functions (vaccines, military services, etc.), and in some countries (Malta) it is also used in public ambulatory care. But tendering is not feasible in the case of products under exclusivity, as only one firm is able to procure them, and those products are those that are increasingly responsible for pharmaceutical expenditure levels and growth.

Over the last decade, an increasing number of **risk sharing practices** have been set-up in several countries in the European Union⁹ for pricing and reimbursement of new pharmaceuticals. The rationale of these practices is based on the idea of the presence of uncertainty on the impact of new pharmaceuticals on health outcomes and expenditure. This uncertainty is around, mainly, three elements (budget impact, effectiveness and cost-effectiveness¹⁰) and has relation with the following risks:

- 1) The medicines have not the clinical benefits previously determined;
- 2) Expenditure is bigger than budget availability;
- 3) Prescription of the new medicine is not according with the therapeutic indication¹¹.

Under the concept of risk sharing schemes different types of practices coexist. Some authors exclude global agreements, as paybacks¹² or rebates¹³, under this classification, but not price volume agreements. However, the definition of risk sharing scheme should probably include any agreement that link manufacturer revenues with previously agreed objectives, mainly objectives of volume, utilization or outcomes.

There are two main groups of risk sharing agreements:

1. **Price Volume Agreements¹⁴**: This is one of the less complex and older forms of risk sharing agreement. It is usually applied to single new products where the negotiated price is conditioned by the expected number of units sold (France, Spain). A posterior increase in the number of units sold leads to higher expenditures on the product and, hence, to posterior price reductions or paybacks (Norway).

⁹ Other countries, as Australia, have used also risk sharing practices. See in Wlodarczyk, John; Cleland, Leslie; Keogh, Anne; McNeil, Keith; Perl, Kate; Weintraub, Robert; Williams, Trevor. Public Funding of Bosentan for the Treatment of Pulmonary Artery Hypertension in Australia: Cost Effectiveness and Risk Sharing. *Pharmacoeconomics*. 24(9):903-915, 2006.

¹⁰ Puig-Junoy J, Meneu, R. Aplicación de los contratos de riesgo compartido a la financiación de nuevos medicamentos. *Gestión Clínica y Sanitaria*. Vol. 7. N. 3. Otoño 2005.

¹¹ Defining Risk Sharing. *Pharma Pricing & Reimbursement*. March 2008.

¹² Financial mechanism that requires manufactures (individually or collectively) to return a certain part of their revenue to a purchaser if sales exceed a previously determined agreed target budget/maximum amount.

¹³ Requires manufacturers to return a share of their overall revenue (without a specific target budget/maximum amount being passed) This return is normally based on a percentage of manufactures' annual sales of reimbursed products.

¹⁴ PPRI Definition: Like a framework agreement, a volume control tool. The price of a pharmaceutical is agreed between public authorities and a manufacturer on the basis of a forecast volume of sales. If the actual sales volume exceeds the forecast, the price of the pharmaceutical is usually reviewed downwards.

2. Risk sharing agreements based on results (performance or outcomes guarantee): Under this type of risk sharing agreement several schemes can be found, where sometimes the results are just based on **clinical outcomes** (for example, the pilot collaboration between Pfizer and a Primary Care Trust in UK related to treatment with statins to reduction in low-density cholesterol¹⁵) and sometimes are based on a **cost effectiveness threshold** (specially on NICE experiences – Betaferon or treatment of multiple sclerosis^{16,17}). The last innovation on these agreements is the **money back guarantee**, where the pharmaceutical company pays money back (or gives extra products for free) when the outcomes of the new pharmaceutical fails.

When the price volume agreement is set up for a single product (for example, statins) it is easier to look for a more cost-effective use of them because the prescription will be focused on patients which risks go above a previous set threshold, and this will act as a disincentive to promote the extension of its use. An extreme modality of this type of agreement was used in New Zealand with the atorvastatin, namely “capped budget agreement”, implying that if sales increased above a certain point, the company would absorb this cost¹⁸. New Zealand has used other different modalities on these price volume agreements, as agreements on mean daily doses or capped maximum annual contracts¹⁹.

Another modality of price volume focus on use. In this case, the price is different according to the groups and expected benefits for each group. In an example from Australia (etanercept), the stakeholders (industry, government, etc.) looked for eligibility criteria for the initial prescription and for continuation of treatment²⁰.

Some advantages that we, at first glance, can draw from these practices and experiences are:

- 1) Health care providers, patients and industry will have, under the reimbursement system, medicines that probably might normally not be eligible for reimbursement.
- 2) These practices will help health care providers to have a better budget control, while allowing innovative medicines into the market.
- 3) Patients that can benefit would have early access to innovative medicines.

¹⁵ Chapman S, Reeve E, Rajaratnam G, Neary R. Setting up an outcomes guarantee for pharmaceuticals: new approach to risk sharing in primary care. *BMJ* 2003;326:707-709.

¹⁶ “As part of the risk sharing plan the manufacturer agreed to monitor the use of these drugs over time and reimburse the National Health Service (NHS) for a portion of total drug costs if the observed cost effectiveness ratio of the drugs did not meet a predetermined threshold”.

¹⁷ Gregory S, Zaric, Bernie J, O'Brien. Analysis of a pharmaceutical risk sharing agreement based on the purchaser's total budget. *Health Economics*. V. 14. N. 8. Pages 793-803. 2005.

¹⁸ Begg E, Sidweel A, Gradiner S, Nicholls G, Scott R. The sorry saga of the statins in New Zealand – pharmacopolitics versus patient care. *NZ Med J* 2003; 116(1170):360.

¹⁹ Puig-Junoy J, Meneu, R. Aplicación de los contratos de riesgo compartido a la financiación de nuevos medicamentos. *Gestión Clínica y Sanitaria*. Vol. 7. N. 3. Otoño 2005.

²⁰ Lu Cy, Williams K, Day R, March L, Sansom L, Bartouch J. Access to high cost drugs in Australia. *BMJ* 2004; 329:415-6.

Some of the problems with these agreements are how to evaluate them and to assess how much it will cost.

5. Price regulation

Price control based on the cost of production has lost its historical role as the main mechanism for cost-containment due to the difficulties to implement it appropriately and to the likely distortions it produces. Other criteria have been progressively introduced, such as setting the price taking as a reference the cost of existing treatments and the price of the product in other countries. The most recent trend in pricing criteria is value based pricing which aims at aligning the prices of new drugs with their value to society, as estimated by means of cost-effectiveness and alternative economic assessment methods. Value based pricing is often applied as a condition for reimbursement, rather than for setting the market price. However, given the scope of health systems financing of medicines and the high price of new products, conditioning reimbursement to a certain price practically implies setting the market price.

Direct product pricing, when applied, is a responsibility of national authorities, while other policies are often decentralised to regions and insurers, according to the structure and level of decentralisation of each particular country.

Most country legislations describe a set of simultaneous criteria for pricing and reimbursement which are often very general and mutually inconsistent. This leaves a lot of room for ad hoc negotiation and administrative discretion. Moreover, price setting and reimbursement decisions are often not transparent.

6. Monitoring and assessment

The overall impression is that pharmaceutical policies are often introduced without a rigorous assessment and planning and that they are often changed as a result of perceptions that the economic agents have adapted to previous policies and made them ineffective, thus justifying a change before their effects can be effective and observed. Formal monitoring and ex-post assessment of policies is not the norm. Some exceptions could be found in countries as Sweden, for example, where a report has been published with the analysis of medicine prices after the introduction of generics substitution²¹.

7. Legal issues and human resources

The EU legislation provides a flexible framework that allows MS a lot of discretion in implementing pharmaceutical P&R policies. Conflicts have however been frequent in the past in the case of parallel trade, when the companies affected tried to avoid it by setting restrictions to wholesalers. The European Court of Justice (ECJ) usually ruled against any measure that limits the working of the single market. Also, the process to assess the appropriate value-based price by NICE has

²¹ http://www.lfn.se/upload/Pressmeddelanden/generiskt_utbyte_engelsk_061010.pdf.

been recently challenged in the courts in a specific case on the grounds of the lack of transparency of the process.

In some countries there might be an insufficient investment in human resources with the capacity to address the economic aspects of pharmaceutical policies. But the OECD survey on economic evaluation²² showed that many countries are able to satisfactorily carry out these practices with a limited amount of human resources. This suggests that, except perhaps for small countries, the lack of appropriate human resources reflects a lack of willingness to implement these approaches rather than a too high financial burden.

8. Future prospects

As far as pricing is concerned, cost-plus pricing is likely to be abandoned in favour of international price referencing and value-based pricing.

Competition will be strengthened by means of reference price systems - which are likely to increasingly turn to therapeutic equivalence to define groups – and by generic policies, mainly, generic substitution, prescription by active ingredient and incentives to prescribers.

Reimbursement is likely to become more selective, meaning that some products might either not be reimbursed by health insurers or consumers will be asked to pay a higher share of the cost of these products.

Global caps on expenditure are likely to become more popular, while risk-sharing contracts will probably be progressively introduced for high cost products for severe diseases, with uncertain health benefits and a high cost.

9. Impact assessment

The empirical evidence on the impact of pharmaceutical policies is surprisingly limited. A recent study²³ by the prestigious Cochrane Collaboration found only eleven examples of well documented impact of P&R policies, most of which referred to reference pricing practices in the US and Canada.

There is compelling evidence that the affordability of medicines across European countries varies substantially and so does the take-up time, although it is less clear whether and how this substantially affects the health of citizens across MS.

Different assessments have been made recently about some selected pharmaceutical policies. In the report made by Espin and Rovira²⁴ six pharmaceutical policies (price control, cost-sharing,

²² Survey of Pharmacoeconomic Assessment Activity in Eleven Countries, 2003, OECD Health Working Papers, No. 4 (<http://www.oecd.org/dataoecd/27/25/2955828.pdf>).

²³ Aaserud M, Dahlgren AT, Kosters JP, Oxman AD, Ramsay C, Sturm H. Pharmaceutical policies: effects of reference pricing, other pricing, and purchasing policies. *Cochrane Database Syst Rev.* 2006 Apr 19;(2):CD005979.

²⁴ Espin J, Rovira J. Analysis of differences and commonalities in pricing and reimbursement systems in Europe. DG Enterprise and Industry, June 2007.

reference pricing, payback, incentives for good prescribing practices and generics policies) have been evaluated according with literature review, document sent by representative of the MS and expert opinions. This exercise has helped to look for good practices to exchange, because each practice has a final discussion with key messages, risks and key success factors. As a summary of this report, a toolbox exercise, has been made by the DG Enterprise under the Pharmaceutical Forum in order to synthesize some of the final findings.

The main conclusions on the evidence of the impact of the former policy practices are:

Evidence of impact will always be a contentious issue. The gold standards in study design for assessing causality are controlled experiments, which are seldom feasible in the field of policy. There is no consensus on what constitutes a valid and reliable design, but we are rather confronted with a heterogeneous set of reviews each one using different criteria, with analyses based in varying combinations of empirical evidence, logical reasoning, technical and value judgements, and so on.

Probably no two studies have used exactly the same methodology and literature reviews use different criteria to include studies in the review and to assess validity. Most studies are impossible to reproduce; therefore we must rule out the possibility of bias due to vested interests or technical errors and trust the author's capacity and honesty. Accepting the former constraints and assumptions – and others not mentioned here – we are able to formulate a few statements on the evidence of impact of the six practices selected in the study.

Price control

Direct product price control of pharmaceuticals is criticised by most authors, and specially by individuals close to the interests of the manufacturers, because it is said to be difficult to implement in a fair and efficient way and if it is effectively applied to lower the prices of innovative products beyond a certain level, is claimed to remove the incentives for innovation. These types of effects are, however, not convincingly documented. Pricing based on a set of international prices in countries with similar characteristics looks quite reasonable for a small country that has no capacity to impose its own criteria and preferences. Finally, pricing based on economic evaluation and profit control make a lot of economic sense, but are again not convincingly assessed. Probably the main difficulties in assessing price control practices is the relative vagueness of its formulation, the fact that they have been applied for a long time and without radical changes in most countries. This makes it difficult for observational studies to find clear cause-effect relationships.

Cost-sharing

Cost-sharing is an old practice, as well, which has been frequently assessed: it seems reasonable to assume that cost-sharing is likely to disproportionately affect the most vulnerable individuals and households - low income and high need/use of expensive services. These negative effects can be overcome if the payment has the appropriate safeguards: criteria for exclusion of diseases and individuals, expenditure caps, etc.

According to the responses to the questionnaire, there is been a limited monitoring and follow-up of the effects of this practice in most countries, beyond the calculation of aggregate volume of payments by the patients. However, Denmark, Finland and Sweden, in order to manage their individually defined cost-sharing systems, have set up a patient-level reporting system, that allows the analysis of the impact of cost-sharing in terms of equity, accessibility and other micro-economic impact variables; serving as basis for system of progressively decreasing cost-sharing by patients.

No assessments were reported on impact of cost-sharing on expenditure and utilisation/access.

Reference pricing

Reference pricing has been relatively well studied, but only some of its modalities – especially, generic reference pricing – and the research is concentrated in a few settings: Canada (British Columbia), Germany, etc. It is often difficult to separate the effects of reference pricing and generics policies, two policies which are often implemented together. There have been claims from big pharmaceutical companies that therapeutic reference pricing reduces the incentives for incremental innovation, which is assumed to play a key role and be the main form of attaining – step by step – major innovations in a cumulative way. Some studies and experts have also concluded that reference pricing does not actually promote competition, in the sense that prices do not fall below the reference pricing.

Savings were reported by some countries, but no information was provided on how these savings had been estimated. Changes in access are assumed to be, in general, limited, except for some reported increases in out-of-pocket payments and the possibility of discontinuation in the availability of products.

Payback

Payback is a very new practice and the evidence on its impact is therefore close to nil.

Some countries reported the estimated savings with no clear information on how they were computed. Payback is not assumed to affect access, given that patients are not involved. The opinions on its possible impact on incentives for innovation differ. The practice is deemed appropriate for MS with low GDP, where price-reductions are hard to obtain.

Prescription incentives

Incentives for more efficient prescribing are not a single practice, but a large set of heterogeneous practices, sometimes excluding each other and sometimes reciprocally reinforcing each other; for instance, convenient unbiased information on the characteristics of medicines, guidelines for rational use, and financial incentives linked to some prescription targets might be implemented simultaneously in order to obtain a larger impact. Some of the existing incentives for more efficient prescribing – especially, financial incentives - have a documented effectiveness, but many countries are reluctant to incorporate performance incentives in the system of retribution of the health personnel.

Generics policies

As in the case of prescribing incentives, a generics policy is usually the result of a combination of both demand and supply side practices. There are in the literature a substantial number of studies showing the impact of given generics policy practices, such as generic substitution by the pharmacist. Generic policies have been applied for a long time, supported by selective reimbursement, differential cost-sharing, patient and prescriber information and education. In recent times, generics policies have been complemented by reference pricing and stronger financial incentives to pharmacists and prescribers.

Several countries claim that they have carried out budget impact evaluations of generic policies, though few provide data. Assessments seem to focus on utilisation and pharmaceutical expenditure, while overall health expenditure and health outcomes are usually not covered. Most respondents assume no negative impact on innovation. It has also been noted that the impact of generics policies cannot be evaluated standalone from different related practices, in particular reference pricing.

To sum up:

Direct product price control based on cost-plus approaches seems to be progressively abandoned in practice in the EU and substituted by either alternative pricing criteria – international prices, pharmacoeconomic criteria, etc – or replaced by reimbursement policies, including more complex cost-sharing schemes –that foresee annual expenditure caps and decreasing co-payments - and reference pricing. Reference pricing and generics policies face both a challenge which limits its effectiveness: the lack of incentives for efficiency on the demand side, leading to the choice of value for money, would allow consumers and insurers to take full advantage of generic competition. For innovative drugs competition is legally excluded through patent protection and other exclusivity rights. The most rational approach to pricing innovative products which constitute a real monopoly is to control the prices according to a certain cost-effectiveness threshold criterion, which could provide the right incentives for private R&D and innovation.

10. Arguments of the different interest groups

The innovative industry claims that cost-containment policies are harming the necessary profitability and attractiveness of R&D and innovation in Europe. Its argument is that high prices are necessary for ensuring the continuation of the past flow of innovations in the future. The innovative industry also claims that parallel trade is unfair, as it is the result of a single market for the movement of pharmaceuticals and high price differences that were not decided by the companies but are the result of national price regulation.

Insurers and health policy makers claim that innovation has been shrinking due to other causes, such as the inefficiency of the innovation process, and that companies try to set unsustainably high prices for new products that bring a limited or no added value to the consumer.

The consumers in Europe are often dissatisfied when they are aware that the access to some medicines in their countries is lower than in other MS, but they are seldom concerned by high

drug prices, because universal health systems collectively take all or most of the burden of pharmaceutical expenditure. Moreover, the industry has been able to align many patient associations to their interests, making them a lobbying force to the government and to the health in the request of access and rapid take-on of new expensive drugs, sometimes of dubious therapeutic value.

Some users associations and individual researchers challenge the present system of innovation that relies on strong IP rights and high prices of new medicines. This debate is now going on at the WHO Intergovernmental Working Group (IGWG) although it mainly focuses on the medicines that disproportionately affect developing countries. One of the options proposed as an alternative or a complement to the IP system is the separation of the market for innovations and the market for products, e.g. by implementing a prize fund that would reward needs-based innovation itself, leaving the product market to work under competition.

11. Assessment of transferability aspects

There does not seem to be major legal constraints for the transferability of good practices to EU countries. Reference pricing, price control based on international price referencing and pay-back arrangements seem to be some of the practices that have spread across EU MS by imitation or demonstration effect.

Interest of adopting value based pricing seems to be growing. NICE is apparently the benchmark for countries willing to progress in that direction.

Generic policies are likely to be more difficult to apply in countries that have a strong branded generics industry likely to oppose them. They might also depend to a large extent on the attitude and position of the medical profession. The attitudes of the medical profession are likely to be a key factor in the feasibility to introduce incentives to prescribers.

Global budget agreements are not likely to be transferable, as they depend on the precise historical experience and relationship in negotiations between the industry and the national insurers. Agreements between insurers and a single company for a high price product seem the most easy to transfer to other countries, but they require a high monitoring capacity.

Practices such as the UK PPRS scheme and risk-sharing agreements – and value-based pricing - might not be as easily transferable, as they require a certain regulatory culture and a degree of openness and fair play by the industry and the regulators in negotiating.

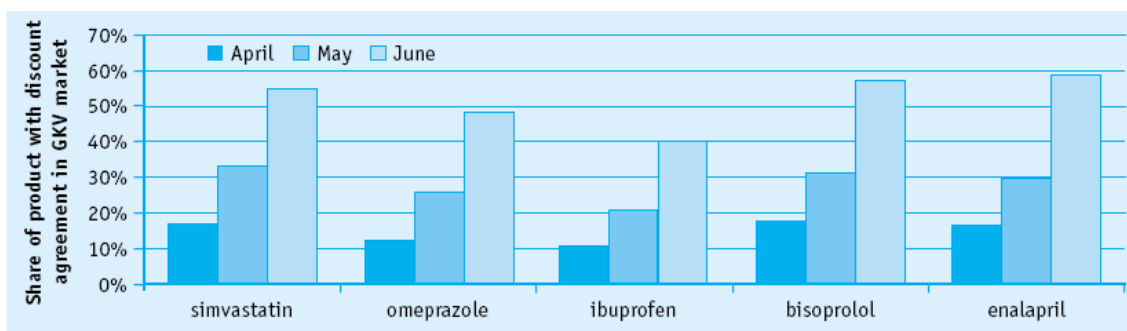
Changes in cost-sharing arrangements are also difficult to implement as they usually are a hot political issue likely to find a strong opposition from social groups that might lose with their introduction.

Concerning discounts and tendering, there is now a debate in Germany about the new instrument²⁵ that gives the possibility for rebate/discount agreements/contracts (under price negotiation) between pharmaceutical industry and sickness funds (statutory health insurances). First

²⁵ Para.130 sec. 8 of the Social Code part V of the Act to Strengthen Competition in the Statutory Health Insurance System (GKV-Wettbewerbsstärkungsgesetz or GKV-WSG for short), which took effect on April 1, 2007.

data after the introduction of the Statutory Health Insurance System reform (April 2007) show that top-selling active ingredients were on a discount agreement (Graph 2).

Graph 2: Market Share of Discounted Versions of Leading Substances - 2007



Source: IMS Health Germany. PPR IMS Sept 07

Two legal points under discussion about this new instrument: first, whether rebate agreements are, according to the procurement law, public contract; second, if so, it is needed a tender before signing it. For the National Health Insurance Authority the rebate agreements are public contracts²⁶, so they need to be publicly tendered.

Since this is not a legal document we will not go on details about these issues, but some points have to be underlined about rebate and tenders:

- The use of rebates could be an alternative to control expenditure in countries in with low GDP per capita or countries without price regulation where normally price are relatively high. They would allow to control parallel trade.
- Tender procedures can only be used for products with no exclusivity rights. This have to be taking into account in countries as Germany because it is the third country in the world (after US and Spain) with the highest share of market for new product launched in the last five years (about 25% share of the market).

Discounts are a current practice in the US (Veterans Administration, Medicaid and other public programmes).

12. Key issues for debate at the Peer Review meeting

- Do innovative approaches to contracting ensure fair access for patients to drugs?
- Is the system/strategy for promoting innovation effective and efficient?
- Single European price vs. multiple national prices: Is some form of equity pricing feasible in the EU, as a way to improve access across Member States?

²⁶ According under Section 99(1) Act Against Restraints of Competition (Gesetz gegen Wettbewerbsbeschränkungen - "GWB").

- Are Member States willing to and what are the constraints for introducing value-based pricing? What kind of coordination among Member States would enhance and facilitate the introduction and appropriate application of value-based pricing?
- How could the transparency of the pharmaceutical market and the evidence on the impact of pharmaceutical policies be improved?
- Role of EC vs. national authorities/centralised decision making. EU pharmaceutical policies responsibility almost exclusively with DG Enterprise and Industry, not so much with DG Health and Consumer Protection (DG SANCO).
- The role of information to patients and advertising.
- Is the system/strategy for promoting innovation effective and efficient?