

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

Host Country Report

Federal Ministry of Health

Cost containment: Initial status in EU Member States

The pharmaceutical market is one of the most strictly regulated markets in all Member States of the EU. This is due to the occurrence of severe market failures especially because the coverage of costs is mostly secured by health insurances and not by the patient in need of pharmaceuticals. Therefore normal market mechanisms are inefficient in the pharmaceuticals market and have to be complemented by interventions.

Interventions have to address the common values and principles of healthy systems in the EU" as agreed by EU health ministers in the ESPCO council on 2nd June 2006¹:

- universality of health care systems;
- access to good quality care;
- equity;
- solidarity.

Given the dynamic developments in pharmaceutical innovation it is a difficult task for Member States to guarantee those common values and principles while pharmaceutical expenditure is rising from year to year. The pharmaceutical expenditure in most EC Member States is growing faster than inflations and expenditures for other sectors of health care; market intervention therefore are targeting at limiting cost dynamics but in the same time offering a chance to pharmaceutical companies to get an incentive to continue research and development on innovative drugs.

Pharmaceutical pricing: Types of interventions²

The following main types of interventions can be differentiated in EC countries:

- price regulation;
- direct expenditure control e.g. by rebates, discounts, payback mechanism and price volume agreements;
- profit control systems;

¹ Council Do. 10173/06.

² The list follows the classification scheme for interventions proposed by Espin/Rovira, Analysis of differences and commonalities in pricing and reimbursement systems in Europe", Escuela Andaluza de Salud Publica 2007.

- monitoring of prescription patterns and management of quotas/budgets mainly aimed at physicians;
- cost-sharing between patients and insurances by co-payments;
- substitution of brands by less expensive comparable products mainly by pharmacists;
- positive lists of reimbursable products issued by state or insurance;
- reference pricing (limitation of reimbursement to cost levels of comparable products).

The variety of cost containment instruments in the 27 EU Member States and severe differences in the overall structure of the health systems (following either the tradition of the social security systems of the Bismarck model or the state systems in the Beveridge model or mixed forms of systems) makes it difficult to compare and transfer the functioning of pharmaceutical expenditure control in the EU. However, an exchange of views on innovative practices can provide a basis for amelioration of the national instruments that are currently applied by Member States.

Specific topics of the Peer Review

In order to limit the scope of discussion and to enable an in-depth examination of current techniques the peer review will be limited to

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

Price negotiations and tendering procedures between insurances and pharmaceutical companies are relatively common in some EU Member States but quite a new instrument for the German social security system. Para. 130 sec. 8 of the Social Code part V (SGB V, legal basis for health insurance) provides a possibility for rebate agreements between pharmaceutical producers and statutory health insurances. First experiences show that there is a large potential for economies by tendering the supply of pharmaceuticals, especially in the field of non-patented drugs. However, legal proceedings against the tendering procedure lead to a court finding where the tendering practice was assessed as illegal due to EU competition law. An infringement procedure concerning an alleged non-compliance of the tendering procedure with EU directive 2004/18 has been started by the European Commission. These legal procedures highlight the need for an in-depth analysis of the role of tendering in pharmaceutical cost-containment, especially the specific nature of the pharmaceutical market for products to be used in the statutory health insurance financed by public means.

Risk-sharing agreements are a very interesting extension of the price negotiation agreements. They target at agreements on the practical benefit of a certain pharmaceutical product and contain e.g. money-back guarantees if a patient using a pharmaceutical products suffers from specific illnesses which should be prevented by the pharmaceutical products (e.g. a patient suffering

from osteoporosis and using an osteoporosis drug breaks his leg – the cost of the drug will be reimbursed to the health insurance by the pharmaceutical company).

Agreements on budgets for the treatment of certain illnesses can enhance the financial sustainability of the health insurances. The current system remunerates pharmaceutical companies per package consumed by the insured persons. This leads to difficulties if the number of patients treated is unsure. Therefore agreements about paybacks (returning excess revenues to the insurance if sales exceed a previously determined target) and price-volume agreements (price agreements about differentiation conditional to the number of units sold) are helpful for cost control. Finally, even agreements about the price for disease treatment for all insured persons (irrespective of the number of units needed) are discussed. We want to assess practical options for better cost control and additionally give specific consideration to the need for price differentiation in new Member States, according to GDP levels. In that regard we want to take account of the experiences made under the German presidency initiative on sustainable access to ARV drugs. In that framework Germany together with the European Commission initiated negotiations with pharmaceutical companies on price differentiations for life-saving drugs against HIV/AIDS. Bulgaria is the first pilot country of this initiative. In the course of these negotiations, questions of treatment budgets and price-volume-agreements have arisen. This specific initiative relates directly to the general political task of securing access to innovative and high-priced pharmaceutical products.