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

Short Report



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



Held in Berlin (Germany) on 30 June – 1 July 2008, the Peer Review was hosted by the German Federal Ministry of Health. In addition to the host country, nine peer countries took part: Bulgaria, Finland, France, Luxembourg, Malta, Netherlands, Poland, Portugal and Slovenia. Also participating were stakeholder representatives from the Pharmaceutical Group of the European Union (PGEU), the European Social Insurance Platform (ESIP) and the Standing Committee of European Doctors (CPME), together with representatives of the European Commission's DG Employment, Social Affairs and Equal Opportunities, DG Enterprise and Industry and DG Health and Consumer Protection.

1. The policy under review

Pharmaceuticals. It is an atypical and very imperfect market, due to a set of factors: 1) decision to use a drug is usually not taken by the consumer, but by the doctor; 2) the cost of the pharmaceuticals is covered mainly by health insurance funds and not by the end user; 3) there is a high degree of information asymmetry between the provider and the consumer; 4) exclusive property rights, the main response to the public health problem of innovation, adds an additional constraint to the operation of market forces and competition; So normal market mechanisms are inefficient in the case of pharmaceuticals and have to be complemented by interventions. In fact, pharmaceuticals are one of the most strictly regulated markets in all Member States of the EU and elsewhere

The common values and principles for health care systems in the EU, as agreed by EU health ministers in June 2006, are universality, access to good quality care, equity and solidarity. However, pharmaceutical expenditure in most Member States is rising faster than inflation [and/or GDP], making it more difficult for them to implement these principles. So market interventions aim to limit cost dynamics while maintaining the incentive for pharmaceutical companies to continue research and development on innovative drugs.

The Peer Review examined three main issues:

- **Price negotiations and tendering procedures** between health insurers and pharmaceutical companies. These are common in some EU Member States, but quite new in others – including the host country, Germany. There, the rebate contracts for pharmaceutical supplies, particularly non-patented drugs, offer major potential savings. However, the contracting was blocked when challenged in the courts, which held them to be in breach of EU competition law.
- **Risk-sharing agreements** between pharmaceutical companies and health care providers. These are aimed at addressing the uncertainty of potentially desirable health outcomes in the case of high cost medicines. For example, the producer may guarantee a refund if a patient using the product contracts the specific illness that it is designed to prevent.
- **Agreements on budgets for the treatment of illnesses.** The system of third party reimbursement of pharmaceutical companies per package consumed by the insured persons at a predefined price can lead to expenditure rising out of control if the number of patients to be treated is vaguely defined and can be influenced by providers. So 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 on the number of units sold) are helpful for cost control. Agreements on a *price for the treatment of all insured persons* (irrespective of the number of units needed) are also under discussion.

2. Key lessons and aspects of transferability

Among the main points to emerge from the Peer Review:

- **Pharmaceuticals pricing and reimbursement organisations in the EU Member States are looking for ways to share the increasingly heavy workload and avoid duplication of effort.** EU-wide networking and information-sharing can help to achieve this.
- **EU competition law** was not designed for the case of pharmaceuticals tendering, but it has been used in some instances to block procedures which could have produced considerable savings for the public purse. This issue requires consideration at the EU level. In particular, the applicability or otherwise of Directive 2004/18/EC on public procurement procedures should be examined.
- **Good practice** on cost containment needs to be disseminated and compared. One way of achieving this is the **networking of pricing and reimbursement authorities** in the different Member States. This can also promote **benchmarking**.
- Some cost containment practices still in use are more or less obsolete. This applies in particular to price controls (cost-plus, international reference pricing etc.). **There should be a shift in emphasis from managing price (and supply) to managing demand.**
- The **globalisation of the pharmaceutical market** and intellectual property systems is leading to **price convergence, especially for new drugs**. This is putting more pressure on countries with limited health care budgets, which in the past enjoyed relatively lower prices. Some US plans for reimportation of medicines from the EU might increase EU-prices to US levels.
- Within the **single European market**, price convergence has already led to higher pharmaceutical prices in some of the lower-income Member States, as companies are concerned about parallel exports and imports. Some differential pricing and market segmentation may be helpful in the short term – both to consumers in the lower-income countries and to the pharmaceutical producers, whose return often depends more on sales volume than on price.
- **Cost containment measures agreed with the pharmaceutical companies** (paybacks, rebates, risk-sharing etc.) are an important factor, and experience of them should be shared among Member States. However, they are not automatically transferable from one country to another, due to different health care systems and market situations.
- **Industry and other stakeholders**, such as the insurers, consumers and doctors' associations, should be involved in the discussion on **cost containment**.

- **In order to allow competition to work it is essential to promote the transparency of the pharmaceutical markets, especially on the efficacy and safety of the products, the prices actually paid by consumers and insurers, as well as on the price-setting, reimbursing and other regulatory mechanisms** for pharmaceuticals, in general.
- **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), the role of **pharmacoeconomics, value-based pricing, risk-sharing instruments, demand-side measures, conditional reimbursement**, and the problem of **access to innovative high-price medicines**, especially in low-income countries.

Political follow-up to the work of the EU Pharmaceutical Forum is needed at the ministerial level.