

# Cost containment in the pharmaceutical sector

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## 1. PGEU

The Pharmaceutical Group of the European Union (PGEU) is the European association representing Community Pharmacists. PGEU members are the national pharmacy associations and chambers in 30 European countries.

Pharmacists make a significant contribution to helping to promote cost containment by helping to ensure rational and appropriate use of medicines, through for example improved adherence. Pharmacists are also key to successful generic substitution policies.

The Peer Review invites comments on three specific areas: price negotiations and tendering procedures, risk sharing agreements, and agreements on budgets for the treatment of illnesses. Given the need to be brief, PGEU will confine its observations to general comments on the paper and specific comments on tendering procedures and risk sharing strategies.

## 2. General Comments on the Discussion Paper

We found the discussion paper to be an excellent exploration of current issues in pricing and reimbursement.

Cost containment policies in the pharmaceutical sector must reconcile a number of competing interests, cutting across industrial, social and fiscal policy. Broadly, these can be outlined as follows: the research based pharmaceutical industry has an interest in limiting market penetration by generic substitutes, in reducing price differentials which encourage or facilitate parallel trade, and in favourable reimbursement decisions for new medicines. Governments in some (though not all) EU Member States link pricing and reimbursement decisions to broader issues of industrial policy with regard to the research based industry. Payers (either governments or social insurance entities) are under growing pressure to control costs, while remaining essentially committed to solidarity based health systems and the optimization of access to medicines. An effective and growing patients lobby is increasingly calling governments to account for reimbursement decisions. All actors in the sector seem to agree on the need to promote innovation in the sector.

In the view of PGEU it is crucial to maintain an appropriate balance between these competing imperatives. In particular, we believe that the optimization of access to medicines, within of course relevant fiscal constraints, is of fundamental importance. The innovative approaches to contracting set out in the paper show that there is scope for effective cost containment policies without either jeopardising access or adopting a pharmaceutical industry 'wish list' of measures. In respect of the questions set out under paragraph 12 of the paper, we would make four points:

- We agree that the proper place for pharmaceutical decision making in the Commission is DG Sanco. The recent DG Enterprise paper on the single market in pharmaceuticals was, for example, wholly slanted towards industrial policy.
- We believe that, although there is scope for increased cooperation between Member States in relation to pricing and reimbursement issues, these should remain unequivocally a national competence.
  - We believe that great caution needs to be exercised in the area of changing the current rules on Information to Patients. In particular, the recent proposals from DG Enterprise go far too far in the direction of facilitating inappropriate publicity for prescription medicines.
  - Finally, Europe needs a profitable, innovative pharmaceutical industry. The key to that however may lie to a significant extent in measures extraneous to pricing and reimbursement systems, such as the science base.

### 3. Pro-competition policies and tendering

One important real and potential aspects of cost containment is pro-active competition policies (see Espin and Rovira page 7).

Such pro-active competition policies may take various forms. First, attempts by the research based pharmaceutical industry to limit generic penetration may be abusive, and thus incompatible with competition law, and as Espin and Rovira note, such practices are currently being investigated the EU Commission. Second, competition within product groups may be encouraged and promoted through reference pricing and generic substitution. The latter is of particular interest to pharmacists, since generic substitution policies require pharmacist expertise not simply in ensuring appropriate substitutions, but also in helping to ensure that the patient is not negatively affected by substitution (for example through confusion leading to reduced adherence.) A third form of pro-active competition policy might be tendering.

In approaching the issue of tendering, it is important at the outset to make a legal distinction.

At its simplest, tendering involves a request to one or more provider of medicines to make a price offer on the basis of a given quantity and in accordance with a particular specification. Such a process characterizes most commercial transactions where the buyer is sensitive to price and there are multiple possible providers. Such tendering can be elaborated with varying degrees of formality.

However, crucially, where the transaction is covered by the European Directives on public procurement, then there is no choice as to level of formality. A transaction would be covered by the European Directives if the procuring body is a public body (in a broad sense, if for example it is supervised by the State or receives the majority of its funding from the State) and the value of the items procured exceeds a certain threshold. Most health authorities and providers of health services will be covered by the Directives. Social insurers may be. (One of the difficulties with the Directives is determining exactly who is covered. For example, in the Community Pharmacy sector State owned pharmacies are required to follow the Directives in Slovenia, but not apparently in

Sweden). It is likely that there is widespread non-compliance with the Directives in Europe as a whole.

While there seems little doubt that tendering has the capability to drive down prices, a number of observations can be made about the European Directives:

- They are primarily intended to promote economic efficiency gains by the elimination of national preference purchasing in the public sector, and non-economic procurement decisions. They also aim to reduce corruption by providing legal remedies for providers who are treated unfairly. The Directives do not take into account the specific requirements of any particular sector. So for example, the tendering procedures in the Directive are wholly unsuitable where there is a need for flexible short term procurement decisions.
- The Directives place highly detailed procedural requirements on purchasers, involving the need to advertise Europe wide in a specified format, strict compliance with a pre-established timetable, a general prohibition on negotiation (there are some exceptions), and no flexibility to change specifications. A well run procurement under the Directive takes a minimum of 3 months. There will frequently a need to take legal advice at various stages during the procurement. Where a number of different procurements need to be undertaken (because of the range of medicines that needs to be procured) the administrative burden may be very substantial.
- As Espin and Rovira point out, in theory the rules do not apply where for reasons of intellectual property there is only one potential supplier. They would not cover patented medicines. However, it might be argued that in fact if medicines are procurable from the wholesale or retail sector, then there are indeed multiple possible suppliers, and this 'single supplier' argument would not hold (I understand that this is the approach taken in Slovenia).
- Once the tender is undertaken, then save for reasons of emergency, the procuring authority is obliged to procure from the winning tenderer (there may be multiple winners under a so-called framework agreement). This of course reduces flexibility, but in certain circumstances may have in fact anti-competitive consequences, by driving potential providers from the market.

In the light of the comments above, it can be argued that while tendering in general terms can be a useful means of enhancing competitive pricing, it is at least arguable that tendering under the terms of the European Directives may cause the sector more problems than it solves.

More generally, whether the European Directives are used or not, where tendering reduces the supply of providers to a small section of all potential suppliers, ('winner takes all') then over the longer term the effect on the market of the exclusion of the majority of potential suppliers may be to reduce competitive pressure and eradicate sources of alternative supplies. It should be noted in particular that smaller providers (including SMEs) will have great difficulty surviving in a purely tender driven market. This is not consistent with overall EU policy toward SMEs, and industrial development in the sector generally.

## 4. Risk Sharing

As Espin and Rovira explain, there are several senses in which this term can be understood in the context of medicine pricing and reimbursement, and it is important to distinguish between them. Price Volume agreements are relatively straightforward from the conceptual and practical point of view. Risk sharing based on clinical outcomes is, however, complex.

On the face of it, such 'clinical' risk sharing offers a genuine opportunity to collaborate with the pharmaceutical industry to bring medicines to patients earlier than would have otherwise been the case, or in circumstances where a re-imburement decision would have been negative.

While PGEU would be broadly supportive of performance based approaches to medicines pricing, there are significant risks. If risk sharing is not to become a recipe for litigation, it should not proceed in a more or less *ad hoc* manner.

In particular, there needs to be a clear framework for at least the following elements:

- Determining where a risk sharing exercise is appropriate at all;
- Criteria and methodology for making assessments of effectiveness;
- The status of interim risk sharing schemes and the implications of discontinuance;
- Patient confidentiality;
- Price changes during the course of the scheme;
- Overall cost burden taking into account additional administrative and monitoring requirements.