The proposed EU transparency directive – will it support the evolving pricing & reimbursement landscape for pharma?

Maarten Meulenbelt discusses the European Commission's long-awaited draft of a new transparency directive and considers its potential impact on industry and regulators.

All eyes are on the European Parliament and the Council as they review a proposal by the European Commission for a new directive relating to the transparency of the measures that national authorities adopt to regulate the pricing and reimbursement of medicinal products[1].

The proposed transparency directive, published on 1 March, aims to address gaps in the current transparency directive (Directive 89/105/EEC[2]) on national pricing and reimbursement measures that it will eventually replace. Directive 89/105/EEC was adopted late in 1988 to facilitate the free movement of medicines in Europe. However, it contains provisions that reflect the pricing and reimbursement conditions that prevailed more than twenty years ago and shortfalls in the legislation have become increasingly visible over the years.

A two-month public consultation on a possible revision of Directive 89/105/EEC was held in 2011[3] and feedback to this consultation was considered in preparing the proposed transparency directive. While the draft directive contains certain provisions that are likely to address gaps in Directive 89/105/EEC, there are some important omissions.

Directive 89/105/EEC was designed to provide an overall view of national pricing arrangements and the criteria on which these arrangements were based. The legislation provides public access to these national pricing arrangements and criteria and permits all companies concerned to verify that national pricing and reimbursement procedures do not constitute import restrictions.

Directive 89/105/EEC was set up to cover basic pricing and reimbursement decisions: price approvals, price freezes, profitability controls and positive and negative reimbursement lists. It was designed to provide two essential procedural guarantees. Firstly, pricing and reimbursement decisions must be delivered by the national competent authorities within 90 days and combined pricing/reimbursement decisions may not take more than 180 days. Secondly, negative decisions must contain "a statement of reasons based on objective and verifiable criteria" and the applicant must be informed "of the remedies available to him under the laws in force and the time limits allowed for applying for such remedies".

Scope extended

According to the commission's 1 March proposal, the new directive would cover new types of complex pricing and reimbursement appraisals, which could not be brought within the language of Directive 89/105/EEC, despite a long list of judgments from the Court of Justice of the EU that have stretched the wording of the legislation to its limits (see, for example, *Commission v Finland*[4]).

A new "blanket" provision is introduced, which states that "any national, regional or local measure… to control the prices of medicinal products or to determine the range of products covered by public health insurance systems" will be covered. Only voluntary contractual agreements – such as risk-sharing agreements or managed entry agreements – and decisions covered by public procurement directives are excluded.

Deadlines for pricing and reimbursement decisions and for combined decisions are to be shortened to 60 days and 120 days, respectively, for originator medicines (15 days for generics), unless the procedure includes a health technology assessment (HTA), in which case the current 90/180-day deadlines are maintained.

The problem of widespread non-compliance with the deadlines by pricing and reimbursement authorities is to be tackled by independent national bodies; these would be empowered to remedy infringements by imposing interim injunctions on the authorities, including daily penalty payments. Monitoring of national measures by the commission would be facilitated by a notification mechanism for all new measures.

The proposed legislation's plan to extend the directive to demand-side measures is particularly welcome. In the CJEU's controversial 2010 decision in *Association of the British Pharmaceutical Industry (ABPI) v Medicines and Healthcare products Regulatory Agency*[5,6], the court ruled that the advertising rules of the medicinal products directive (Directive 2001/83/EC[7], as amended) do not apply to national authorities. In particular, unlike pharmaceutical companies, the authorities are not prohibited from providing financial incentives to prescribing physicians to choose one therapy over another. As a quid pro quo, the CJEU provided that such financial incentives to doctors can be introduced only if the companies involved are able to get access to the studies and evidence used to support the decision, and if they have the right to appeal (as they would for decisions covered by Directive 89/105/EEC). This approach would now be enshrined in the proposed transparency directive itself.

Inclusion of HTA

The inclusion of HTA in the scope of the proposed transparency directive is equally important. HTA has emerged as the main new hurdle in obtaining reimbursement for new drugs. The extent of the potential difficulties can be seen in the first decisions on reimbursement in Germany under the country's so-called AMNOG law[8] on the restructuring of the pharmaceutical sector, where several negative decisions on reimbursement were based on a rejection of the comparator treatment used in the clinical trials. A crucial new provision could help to attenuate such issues: the proposed directive states that member states "should not re-assess the elements on which the marketing authorisation is based, including the quality, efficacy or bioequivalence of the medicinal product".

However, there is a major gap in the proposed transparency directive with regard to how it deals with the increased "Europeanisation" of pricing and reimbursement decisions.

There are multiple examples of trends towards this Europeanisation direction. Firstly, Directive 2011/24/EU[9] on cross-border healthcare provides for the establishment of a voluntary HTA network of national authorities which will co-operate in establishing methodologies and in providing information on "relative efficacy and on short- and long-term effectiveness". A forerunner of such a network is EUNetHTA, which has been investigating joint methodologies and is currently running a pilot project on "rapid relative effectiveness assessment"[10,11]. Such networks must be carefully governed to protect the commercial rights of companies.

Secondly, the new pharmacovigilance rules to be introduced in July on the basis of Directive 2010/84/EU[12] provide for (comparative) post-authorisation safety and efficacy studies at European and national level. Clearly, the findings of such studies will be fed back into pricing and reimbursement decisions.

Finally, more and more countries are cross-referencing each other's drug prices. This can trigger what has been termed a "race to the bottom", especially if references are made to prices in peripheral EU member states where austerity measures are starting to bite ever harder. In this respect, the obligations of Germany's AMNOG to provide "net" sales prices in other member states is an additional cause for concern[13].

A glaring omission of the proposed transparency directive with regard to all these developments and trends concerns judicial review. What court is going to review informal decisions taken during meetings of national authorities? It is clear from experiences with the decentralised procedure and mutual recognition procedure for marketing authorisations in the EU that a legal vacuum can easily occur: in co-ordinated marketing authorisation procedures, the courts in the reference member state will generally not take decisions concerning other member states, and the courts of the concerned member states may refuse to adjudicate at all, claiming that disputes should be handled by the reference member state.

At the level of the EU courts, there is room for improvement as well. The judges of the CJEU in Luxembourg normally abstain from dealing with science. However, a marginal review of only the procedural aspects of EU decisions does not provide adequate legal protection. Obtaining interim relief is exceedingly difficult: the recent decision of the EU General Court on paediatric waivers provides an example of the challenges in this respect[14].

The European Parliament and the Council is expected to complete its first reading of the draft transparency directive later this year. In the meantime, the commission's proposals for the new directive should be welcomed as a major step towards supporting the EU's changing landscape for pricing and reimbursement.

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