The EU Transparency Directive

Changes afoot on pricing and reimbursement

There are currently a number of European legislative initiatives affecting the pharmaceutical sector that are drawing much attention and impassioned debate amongst stakeholders. However, a critical one that seems to have skirted the spotlight – but could very well be the pillar of successful market access – is the recast of the *EU Transparency Directive (89/105/EEC)* on pharmaceutical pricing and reimbursement.[1]

The European Commission's proposed overhaul of the directive is expected to result in medicines reaching the market (and thus patients) faster, in a more predictable and transparent manner. This in turn should lead to an earlier return on investment for companies and their investors. It could also be an important element in a broader strategy to incentivise pharmaceutical innovation, according to the European Federation of Pharmaceutical Industries and Associations (EFPIA).[2]

The fundamentals of the existing law – ensuring that national pricing and reimbursement measures do not create barriers to trade within the European Economic Area – are maintained in the Commission's proposals, but they have been updated to support today's pharmaceutical landscape.

Because the directive was adopted over 20 years ago, it does not provide for the complex and innovative pricing and reimbursement systems that have evolved in member states, not to mention the emergence of generics and the development of increasingly innovative research-based products. As a consequence, there has been a great deal of legal uncertainty and the Court of Justice of the European Union has had to step in to interpret the law on numerous occasions.

A further challenge is that member states regularly exceed the directive's established time limits for pricing and reimbursement decisions, i.e. 90 days for pricing, 90 days for reimbursement or 180 days if combined (90/180 days), and the current judicial remedies available to applicants have resulted in weak (or no) enforcement of these limits. This has led to a situation where products are often available in some European countries years before they come onto the market in others.

For example, Sanofi SA's diabetes product Lantus (insulin glargine) was only approved for reimbursement in Poland this year, despite having been available in many other EU countries for over five years, EFPIA's director market access Edith Frénoy told *MedNous*. Lantus was first granted EU marketing authorisation in 2000.[3]

The Commission has had to strike a balance between clarifying member states' procedural obligations with regard to pricing and reimbursement decisions and complying with the Treaty on the Functioning of the EU, which holds that each member state is responsible for its own health policy. In other words, "the directive does not regulate *what* the member states can do with regard to the pricing and reimbursement of medicines but only *how* they can do it," a Commission spokesperson explained to *MedNous*.

The proposal clarifies the scope and language of the directive to align it with Court of Justice case law and to avoid future controversy over the directive's interpretation. To this end, it now explicitly includes within the scope:

- health technology assessment (HTA) used as part of the decision-making process;
- national, regional and local pricing and reimbursement measures; and
- demand-side measures imposed by health authorities to control or promote the prescription of specific medicines.

Importantly for industry, the proposal excludes voluntary contractual agreements between health authorities and individual companies. These agreements are used by health authorities to guarantee patient access to innovative treatments when standard pricing and reimbursement mechanisms are not deemed appropriate, in particular when higher than normal levels of uncertainty exist regarding the effect of a medicine on patients and society.

EFPIA is in favour of this exclusion, but supports additional amendments that Members of the European Parliament (MEPs) have since proposed to clarify which types of agreements are considered voluntary. Mrs Frénoy said: "It is important to be clear the voluntary contractual agreements are not a second best option when the outcome of reimbursement is negative. Instead, they are a real alternative in specific circumstances, related to the features of the medicine and the uncertainty about effectiveness in real life, uptake and appropriate use".

The scope does not include orphan drugs, but stakeholders are lobbying to change this. The European Organisation for Rare Diseases (Eurordis) maintains that delays with respect to pricing and reimbursement decisions on orphan drugs "are both significant and consistent".[4] Eurordis health policy director François Houÿez told *MedNous* that there are particular challenges for orphan drugs because of "small populations, limited numbers of clinical trials, sometimes not even randomised ones, and few observational data. The agencies that have to assess the value of the orphan drugs have difficulties: limited information means they cannot always apply the methods developed in common diseases."

Time limits

The future time limits for pricing and reimbursement decisions are already being hotly debated in parliament. The proposal reduces the limit from 90/180 days to 60/120 days for innovative medicines not subject to HTA procedures. However, it maintains the existing time limits of 90/180 days for medicines that are subject to HTA. EFPIA is calling for a single set of time limits for all new medicines because it says a system with dual time limits provides little value given the widespread use of HTA in national processes.

As for generic medicines, the Commission is proposing to reduce the time limits from 90/180 days to 15/30 days when the reference product has already been priced and included

in the country's public health insurance system. This is considered to be a key aspect of the proposal as it is expected to significantly reduce the financial burden on both patients and member states by allowing generics to reach the market earlier. It would also eliminate the de facto exclusivity that innovator companies often benefit from even after their drugs come off patent.[5]

Though there is a general consensus that the time limits for generics should be shorter than those for new medicines, some MEPs believe authorities would not realistically be able to comply with the 15-day limit and are thus proposing longer limits.

To make sure pricing and reimbursement authorities comply with the time limits, the proposal requires member states to appoint an independent body that would have the authority to award damages to the applicant or impose financial penalties on authorities for non-compliance. Mrs Frénoy noted, however, that the financial penalties "could be easily replaced by a mechanism of automatic reimbursement if time limits are not complied with".

Although the Commission spokesperson said that the penalties would provide more legal certainty for pharmaceutical companies, some MEPs such as Bernadette Vergnaud would like to see this clause removed. The vice-chair of the Committee on the Internal Market and Consumer Protection, suggests that it is "difficult to accept that an authority should be required to pay damages to a pharmaceuticals firm as a result of its failure to comply with a time limit".[6]

The proposal puts in place other new provisions to avoid delays by making pricing and reimbursement procedures more uniform across member states. For example, during the pricing and reimbursement decision-making process, member states would not be allowed to reassess the elements on which a marketing authorisation is based, i.e. the quality, safety, efficacy or bioequivalence of a medicinal product. Certain stakeholders and MEPs also want the article to specify that reassessment of the criteria for orphan designation should not be permitted in pricing and reimbursement decisions.

Another clause stipulates that pricing and reimbursement applications "may be submitted at any time" but MEPs and industry have sought to include language that clearly states that companies may submit applications immediately after a positive opinion of the European Medicine Agency's (EMA) Committee for Medicinal Products for Human Use or the competent national authority.

The Commission has further clarified that enforcement of intellectual property rights (IPRs) are independent from pricing and reimbursement decision-making processes. As such, the proposal makes it clear that pricing and reimbursement authorities should not take into account claims of possible patent violations when deciding on the pricing and reimbursement applications of generic manufacturers.

Although the pharmaceutical industry welcomes this clarification, Mrs Frénoy cautioned that the proposed language "could be understood as precluding originators from invoking their patents against decisions and measures affecting the pricing and reimbursement of originator products (as opposed to decisions relating to the pricing and reimbursement of generics) and suggests that an application for pricing and reimbursement approval cannot form evidence in a case before competent national patent courts claiming an actual or imminent infringement of intellectual property rights". This goes beyond the directive's original objective and "would curtail the property rights and judicial protection of originator companies," she added.

There are mixed views on other enforcement-related proposals, such as a requirement for member states to file a semi-annual report with the Commission and publish in an 'appropriate publication' details on the number of applications received in the previous year, the amount of time taken to issue decisions for each application and an analysis of the main reasons for any delays, including recommendations for meeting the legal timelines.

Furthermore, in a push for greater transparency and early dialogue, the proposal requires member states to carry out a public consultation on any plans to adopt or amend pricing and reimbursement regulations, and communicate to the Commission the details of any such draft measures before adopting them. It gives the Commission three months to comment on the draft measures, in particular on whether they may be incompatible with EU law.

Member states would also have to communicate their assessment criteria to the Commission, with justification "based on objective and verifiable criteria" for including a product in the public health insurance system or for excluding a product. MEPs have expressed concern that these are national matters.

Next steps

The European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) is due to vote on amendments to the proposal on 18 December 2012 and a first reading in plenary is provisionally scheduled for May 2013.[7] The Commission envisages the law's adoption in 2014, with a deadline for transposition by member states in 2015, but this will depend on how negotiations progress.

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