The EU Transparency Directive

Further debate on market access

Pharmaceutical companies may have to wait longer than initially expected to find out how fast they will be able to gain access to the European market in future, as policy makers debate new politically sensitive legislative proposals aimed at making pricing and reimbursement decisions more predictable and transparent.

Following concerns expressed by EU member states, the European Commission has modified its proposal for a new directive on transparent pricing and reimbursement procedures for pharmaceuticals, which was first sent to the European Parliament in 2012. The directive will repeal and replace the existing *Transparency Directive (89/105/EEC)* which became European law more than 20 years ago.

A Commission spokesperson told *MedNous* that the latest proposals reflect "a vast majority" of the amendments put forward by the parliament after its first reading earlier this year. As such, this revised version will serve as the basis for negotiations with the Council of the EU.

Key amendments address the streamlining of timelines for pricing and reimbursement decisions, the scope and the remedies procedure for authorities that fail to comply with the time limits.

The Commission had originally proposed that member states be required to take no more than 60 days to issue a price for a new medicine, and no more than 60 days to decide on the reimbursement, or 120 days if the procedures are combined. Although this was an attempt to improve the existing – and regularly exceeded – time limits of 90 days for pricing and 90 days for reimbursement, or 180 days combined, medicines undergoing health technology assessment (HTA) would not have benefited from these reduced time limits.

This differentiation between originator products subject to HTA and those not subject to HTA was criticised during negotiations in the Council Working Party on Pharmaceuticals and Medical Devices. As such, in its new proposal the Commission provides a single time limit of 180 days for pricing and reimbursement of all originator medicinal products, regardless of whether they undergo HTA.

Perhaps more important than the number of days is the reiteration that HTA, when used to support pricing and reimbursement, cannot extend the decision-making process and delay market entry.

In addition to this, Edith Frénoy, director market access for the European Federation of Pharmaceutical Industries and Associations (EFPIA), told *MedNous* that the inclusion of language prohibiting duplication of efforts at regional and local levels is a positive development.

EFPIA also welcomed the Commission's clarification on the scope of the proposed directive, particularly with regard to voluntary contractual agreements between health authorities and individual marketing authorisation holders. In certain circumstances these agreements are considered essential to guarantee patient access to innovative treatments that would not normally be available on national health systems, for example when higher than normal uncertainty exists regarding the effect of a medicine on patients and society. The proposal now explicitly excludes only those agreements that are "truly voluntary", Mrs Frénoy pointed out.

The Commission has also stripped out controversial language that would have allowed damages to be awarded to the applicant or financial penalties to be imposed on authorities failing to comply with the obligatory time limits. Instead, member states will simply be obliged to "ensure that effective and rapid remedies procedures are available to the applicant in case of non-compliance with the time limits". As with the previous proposal, an independent body would be responsible for correcting alleged infringements or preventing further damage to the applicants, but no specific actions are mentioned.

Furthermore, the parliament has persuaded the Commission to change reporting requirements that are meant to keep tabs on member states' compliance. They will still have to file reports containing information on the number of applications received and the time taken to issue decisions, but these will now be required annually rather than semi-annually to reduce the administrative burden.

To further lighten the load, the Commission has removed provisions that would have required member states to notify it of any national pricing and reimbursement regulations they intended to implement.

Clarifications welcome but concerns remain

EFPIA supports both the original proposal and the updated version, but there are still outstanding issues, said Mrs Frénoy. One is the provision that states that intellectual property matters should not interfere with pricing and reimbursement. Though the industry fully supports the proposal's intention in this regard, "as currently worded, it lacks clarity and may be transposed inconsistently into national laws," she said.

Even more daunting than any specific clause is the negotiation process within the Council. This could lead to a substantial watering down of procedural safeguards, Mrs Frénoy warned. There is still a division of views on the scope and the time limits, for example.

The legislation's final adoption has been anticipated to take place in 2014, but Mrs Frénoy says that it is unclear how negotiations will progress because this is not considered a high-priority item for Lithuania, which holds the presidency of the Council from 1 July to 31 December 2013.

She also emphasised that, "this [legislation] is only one aspect of pricing and reimbursement; it won't solve market access problems in the EU. A discussion around equity of access with all partners remains necessary".

This article was written by Karen Finn, contributing editor to *MedNous*.

