Pricing and Reimbursement for Pharmaceuticals in the European Union: European Commission Proposes Revised Transparency Directive

1. MÄRZ 2012

Today, the European Commission adopted its proposal for a new Directive relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of public health insurance systems ("Transparency Directive" or "Directive"), which is set to replace the current Transparency Directive 89/105/EEC in place since 1989. The Transparency Directive sets the framework for national authorities in EU Member States' pricing and reimbursement ("P&R") decisions for pharmaceuticals and has in the past proven to be an important tool to support transparent market access rules in the EU.

I. The Commission's Proposal

The proposal's draft Directive maintains the Directive's core principles: The draft Directive still lays down a number of procedural safeguards for pharmaceutical companies to ensure transparency and due process in national P&R procedures of EU Member States (e.g. specific time limits for Member States to decide on reimbursement and mandatory statement of reasons based on objective and verifiable criteria for each P&R decision, cf. Art. 3-7).[1] Following a stakeholder consultation in early 2011 ("Consultation"), the Commission's draft overhauls a number of the Directive's provisions, and clarifies its scope in line with case law of the Court of Justice of the European Union ("Court of Justice").

The most important aspects of the proposal can be summarized as follows:

- **Extended scope of the Transparency Directive:** The Commission proposes to explicitly extend the scope of the Directive to:

  – so-called "demand side related measures" such as financial incentive schemes of public payers to influence the prescription behavior of physicians, e.g. towards the prescription of generic substances (Art. 11 of the draft Directive, cf. Court of Justice, case C-62/09, ABPI); and

  – national Health Technology Assessment ("HTA") procedures as part of reimbursement procedures (e.g. by NICE in the U.K., or by the German Institute for Quality and Efficiency in Healthcare (IQWiG) in the recently established mandatory "early benefit assessment" for innovative products in Germany) (Art. 7(5) and 12).

- **No mandatory EU price list:** The Commission has not installed a mandatory EU price list to compare listed/discounted prices for pharmaceuticals across Member States. However, Member States remain free to compare prices and to maintain reference pricing systems (which are in place in almost all Member States).
- **No application to managed entry agreements or similar individual P&R agreements:** Managed entry agreements and other individual agreements with public payers remain excluded from the scope of the Directive (Art. 1 (2) (a)). EU law would thus not require disclosure of prices (rebates) agreed in such contracts.
- **Shorter periods for Member States to decide on reimbursement (Art. 3 (3) and 7(4)):** To speed up market access, the draft proposes to considerably reduce time limits for Member States to make decisions on pricing and reimbursement (including any HTA proceedings) from currently 180 days to 120 days for innovative products (except for more complex procedures, where the 180 day-limit continues to apply) and to 30 days instead of 180 days for generic medicinal products (when the reference product is already included in the national health insurance system).
- **Sanctions for non-compliance with time limits:** To increase the effectiveness of the Directive, the Commission proposes strong enforcement measures (Art. 8). In case of non-compliance with the time limits for pricing and reimbursement decisions, a Member State has to designate a body entrusted with the powers to take rapid measures, such as:

  – adopting interim measures with the aim of correcting the alleged infringement or preventing further damage to the interests concerned;

  – awarding damages to the applicant; and

  – imposing a penalty payment, calculated by day of delay.

- **Extended powers of the Commission to monitor adherence to the Directive:** The draft contains new procedures to monitor Member States' adherence to its provisions and requires Member States to submit national pricing and reimbursement measures at draft stage (such as laws implementing the Directive at the national level) to the EU Commission for review prior to their adoption (Art. 16).
- **No reassessment of results of marketing authorization procedures in national HTA proceedings:** Member States shall not reassess the elements on which the marketing authorization is based, including the quality, safety, efficacy or bioequivalence of the medicinal product (Art. 13).
- **No application to medical devices and personalized medicines:** National reimbursement decisions for medical devices remain outside the scope of the Transparency Directive. The same applies to personalized medicines (diagnostic testing and medicines specifically adapted to the patient's needs).

II. Preliminary Assessment

Following its decision to redraft the Directive, the Commission now presents a cautious approach to updating the Transparency Directive and provides a number of helpful clarifications to ensure timely and transparent market access for pharmaceuticals in the EU.

The Commission's proposals for a tighter and more effective enforcement of the Directive are to be welcomed, in particular the proposal of short-term remedies for pharmaceutical companies in case of deviations from the Directive's time limits for national P&R decisions (deviations from the obligations of Member States under the Transparency Directive can currently only be dealt with in

lengthy infringement procedures). The obligation of Member States to notify national pricing and reimbursement measures at draft stage, allowing the Commission to monitor compliance with the Directive's transparency requirements, is a welcomed "fix it first" approach and will likely improve the transparency of national P&R procedures.

The draft furthermore includes the helpful clarification that national HTA proceedings are part of P&R decisions and are therefore covered by the Directive's transparency obligations and its strict timeframes for a decision by national regulators. This is significant since HTA proceedings increasingly become a "fourth hurdle" for market access in the EU, requiring companies to prove an added therapeutic benefit of their new products over existing therapies to obtain reimbursement/favorable pricing. For instance, a new French law passed in December 2011 principally links reimbursement eligibility in France to the submission of comparative clinical trial data against reference therapies.

Furthermore, it is to be welcomed that the draft does not foresee the disclosure of contractual rebates and reimbursement agreements with public payers (managed entry agreements and other individual agreements on pricing and reimbursement are excluded from the Directive's scope). However, Member States remain free to bypass confidentiality and demand disclosure of such confidential rebates for use in their reference pricing systems, which potentially could lead to a downward trend of prices in the EU. This is an issue e.g. in Germany under the new value-based pricing regime introduced by the major 2010 German pharmaceutical pricing reform (AMNOG).

The proposed extended monitoring powers of the Commission and remedies for applicants in case of non-compliance with the Directive's time limits as well as the application of the Directive to national HTA proceedings and the issue of an EU price list/disclosure of contractual rebates are likely to be intensively discussed in the upcoming legislative process on the Directive. Since these questions are important for market access and pricing strategies in the European Union, further developments on the Commission's proposal should be closely monitored.

III. Next Steps

The Commission's proposal will be debated in the European Parliament and the Council in the coming months. A new Transparency Directive is currently expected to be passed before the end of 2012. The proposal foresees that Member States have to adapt their national laws to the new Directive within 12 months, i.e. in 2013/2014.

---

[1] The Directive does not contain the substantive criteria on P&R for pharmaceuticals in national public health care systems, which are a national competence (each of the 27 EU Member States has its own specific P&R system).

Verfasser

Prof. Dr. Hans-Georg Kamann

PARTNER

Vice Chair, Antitrust and Competition Practice

hans-georg.kamann@wilmerhale.com

+49 69 27 10 78 204

Dr. Peter Gey, LLM

SPECIAL COUNSEL

peter.gey@wilmerhale.com

+49 69 27 10 78 204