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REVISION OF THE RULES ON PRICING AND REIMBURSEMENT OF MEDICINES (THE "TRANSPARENCY DIRECTIVE") IN THE EUROPEAN UNION

Today the European Commission published its long awaited proposal for the revision of the so-called Transparency Directive. The Directive lays down procedural guarantees for the systems that regulate the pricing and reimbursement ("P&R") of medicines in the thirty EU and EEA Member States. The revision aims at modernizing the current rules, which date back to 1989 and no longer reflect the practical realities of the national schemes.

The proposal will now be reviewed by the European Parliament (EP) and the Council, the body grouping the Member States. It is likely that it will be significantly amended before it is finally adopted. Adoption is foreseen during the course of 2013 or in early 2014 and the new rules may take effect one year later.

NO FUNDAMENTAL REVISION

The proposed Directive does not set out a radically different system. Rather, it mainly clarifies controversial issues and introduces new tools for better enforcement and enhanced transparency.

- **A Procedural Directive.** The proposed Directive sets out procedural requirements but does not harmonize national pricing and reimbursement measures. Nor does it identify substantive criteria on which Member States must base their P&R decisions. This is in line with the limited competence of the EU in the field of management of healthcare resources and the principle of minimum interference in the organization by Member States of their domestic social security policies.

- **No Change of Basic Principles.** The basic requirements of the 1989 Directive are fundamentally unchanged. These remain time limits for P&R decisions, statement of reasons based on objective and verifiable criteria, and availability of appropriate legal remedies.

- **Clarification of the Scope.** The proposed Directive now explicitly applies to all official P&R measures, as well as all procedural steps leading to the P&R decision. This includes demand-side measures to control or promote the prescription of specific medicines, grouping of medicines for reimbursement purposes, and Health Technology Assessments (HTA). Public procurement or voluntary contractual agreements are not included in the scope of the Directive. Medical devices, including companion diagnostics, remain outside the scope of the Directive.

TIME LIMITS

The proposal reduces the time limits for both innovative and generic medicines. Other possible tools to ensure quicker patient access, such as automatic reimbursement or filing of the P&R dossier after scientific opinion, are not included.

- **Shorter and Differentiated Time Limits.** New and differentiated time limits apply for Member States to make their P&R decisions. For innovative medicines, the time-limits decrease from 180 days (90 days for pricing and 90 days for reimbursement) to 120 days (60 days for

pricing and 60 days for reimbursement). For generic medicines, the time limits decrease from 180 days (90 days for pricing and 90 days for reimbursement) to 30 days (15 days for pricing and 15 days for reimbursement), provided that the price of the reference product has already been approved or has already been included in the public health insurance system. Importantly, the time limits remain 90/180 days in cases where Member States subject medicines to HTA procedures.

Products approved on the basis of a so-called hybrid application (which contains bridging data to cover a difference in active ingredient, strength or therapeutic indication) do not qualify as generics for purposes of the shorter time limit.

- **Real Time Limits.** The proposal contains an express provision that the time limits cover the period between the application and the effective entry into force of the P&R decision. Currently, the time limits are sometimes respected with regard to the decision but not with regard to its publication and entry into effect.

- **No Automatic Reimbursement.** Contrary to the preference of the industry, the proposed Directive does not embrace the practice in some European Member States granting automatic reimbursement of a medicine when a Member State has not made a decision within the time limits.

- **No Express Possibility to Submit P&R Dossier before the Marketing Authorization.** The proposal does not explicitly permit pharmaceutical companies to submit their P&R dossier as soon as the opinion of the CHMP or national agency is issued (i.e., before the marketing authorization). Had it been done, this may have expedited the P&R process.

NEW ENFORCEMENT AND TRANSPARENCY TOOLS

New tools are put in place to increase transparency of the measures and consultation of interested parties, as well as to ensure better enforcement.

- **Notification of Draft P&R Measures.** All draft P&R measures must be notified to the Commission, together with the reasoning on which they are based. The Commission has three months to make observations, which the Member State shall take into account when adopting the final measure.

- **Consultation of Interested Parties.** The proposed Directive requires Member States to open consultation with interested parties on any draft P&R measures at national level.

- **Biannual Reporting by Member States.** Twice a year, Member States must report to the Commission on the number of applications received and on the timing of decisions, with an analysis of the main reasons for delays. The information must also be published.

- **National Enforcement Bodies.** Each Member State must establish an independent judicial or quasi-judicial body that can enforce the time limits for the reimbursement decision. The body can order interim measures, impose penalties and award damages.

FOCUS ON SPECIFIC ISSUES

- **No Patent Linkage.** In line with the current rules on marketing authorization, the proposed Directive clarifies that the protection of intellectual property rights cannot be a valid ground to refuse, suspend or revoke P&R decisions. It is, however, specifically stated that this does not affect the EU and national legislation on the protection of IP rights.

- **No Reassessment of a Medicine.** Issues assessed during the marketing authorization procedure (quality, safety and efficacy or bioequivalence) may not be reassessed during P&R procedures.

- **Health Technology Assessment.** HTA is defined as *"an assessment of the relative efficacy or of the short- and long-term effectiveness of the medicinal product compared to other health technologies in use for treating the associated condition"*. Due to the impact on time limits of HTA procedures, it will be particularly important to monitor how Member States understand and intend to conduct HTAs.

NEXT STEPS

The proposal will now be debated within the European Parliament and the Council and there will most likely be significant amendments.

- **In the European Parliament.** The first step will be to identify the Parliamentary committee or committees responsible for reviewing the proposal. Importantly, under recent procedural rules, it is possible for the Parliament to appoint more than one lead committee -- creating both challenges and opportunities for those engaged in advocacy on the proposal. The Parliament must also appoint a member as "rapporteur", who will lead negotiations on the proposal. The choice of committees and of rapporteur(s) will play a significant role in the course of the legislation, influencing what amendments to the proposal are tabled and adopted, but also how negotiations with the Council over the proposal proceed.

- **In the Council**. The initial analysis of the proposal will be performed by a working group staffed by national officials and experts. The working group will collaborate closely with the relevant Ministries in each of the Member States on both the political and technical dimensions of the proposal. Given the strong national nature of the dossier and significantly increased requirements on Member States, we can expect the Council to be particularly active during the revision.

Interested companies can be engaged in this process. In December 2011, the Commission also proposed a new Directive on public procurement, which will also affect the pharmaceutical industry. The proposal is now also under review by the European Parliament and the Council.

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