

## ROADMAP

Title of the initiative: **Review of Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems**

Type of initiative (CWP/Catalogue/Comitology):CWP

Lead DG/contact person/details:DG ENTR

Expected date of adoption of the initiative (month/year): December 2011

Date of modification:

Version No:

### Initial IA screening & planning of further work

#### A. Context and problem definition

(i) What is the political context of the initiative? (ii) How does this initiative relate to past and possible future initiatives, and to other EU policies?

European Community legislation provides a harmonised framework for the authorisation of medicinal products. It is designed to ensure the highest level of safety for patients, while guaranteeing the free movement of medicines throughout the European Union. This common regulatory framework has made a major contribution to the development of a single European market for medicines and to the competitiveness of the pharmaceutical industry. At the same time, national policies continue to play an important role in the provision and dispensation of medicines.

Member States are responsible for the definition of health policies and for the organisation and delivery of health services and medical care (Article 168(7) TFEU). In this context, the national authorities are free to regulate the prices of medicinal products and to determine the conditions of their reimbursement in the framework of their health insurance system. Pricing and reimbursement decisions are therefore subject to complex array of national legislations and national policies in this field vary significantly within the EU.

In order to mitigate the potential impact of national pricing and reimbursement measures on the functioning of the internal market, basic rules have been established at European level. Directive 89/105/EEC lays down a series of procedural requirements to ensure the transparency of national pricing and reimbursement systems. The objective of the directive is to avoid that national measures to determine the prices and reimbursement conditions of medicines create barriers to trade prohibited by the Treaty rules on free movement of goods (Article 34 TFEU). The directive is built on the principle of minimum interference in the organisation of national social security systems.

The possible review of the directive relates to several Commission initiatives which examined issues faced by the pharmaceutical sector: the Pharmaceutical Forum (October 2008), the Commission Communication on the future of the pharmaceutical sector (December 2008), the Pharmaceutical Sector Inquiry (July 2009) and the on-going market monitoring exercise.

What are the main problems identified?

Directive 89/105/EEC was adopted in 1989 and market conditions for medicinal products have considerably changed since it came into force. This evolution concerns not only the EU regulatory framework for marketing medicines, but also Member States' policies to control the cost of medicines and their impact on national budgets. Nowadays, national policies and related cost-containment measures are much more varied and complex than they were twenty years ago. Many new forms of price or reimbursement control mechanisms are not clearly apprehended by the directive. This has created uncertainties regarding the exact legal scope of EU legislation and difficulties in the practical implementation of some of the procedural requirements. The case-law of the European Court of Justice recognises the necessity of an extensive interpretation of the

provisions of the directive in order to ensure that its core objectives are not jeopardised by national systems and policies.

In addition, the wide variety of pricing and reimbursement procedures which can be observed across Member States has an important impact on intra-Community trade, on the activities of pharmaceutical companies and on the availability and affordability of medicines for European citizens/patients. One of the main impacts of pricing and reimbursement regulation relates to the delayed entry of medicines on the market of individual Member States.

The Pharmaceutical Sector Enquiry has shown significant disparities in time to market for medicinal products in the EU. This situation is explained not only by the pharmaceutical companies' strategies, but also by important differences between Member States in processing pricing and reimbursement applications. Some progress has been made but it remains slow and unequal between Member States, in spite of increased cooperation in this area under the auspices of the Commission (Pharmaceutical Forum, Transparency Committee, Network of competent authorities responsible for pricing and reimbursement). The problem of delayed entry in the market affects both innovative and generic medicines and the Pharmaceutical sector enquiry indicated that the competitive environment for generic products is particularly affected by national pricing and reimbursement systems.

Who is affected?

The situation mainly affects:

- Pharmaceutical companies, including the innovative industry and the generic industry. Access to market is indeed essential to ensure the competitiveness and profitability of the industry.
- European Citizens and patients, who do not have equal access to treatments across the EU.
- Public health budgets, as pricing and reimbursement systems influence the uptake of medicines and the potential savings to be realised by the social security systems.

(i) Is EU action justified on grounds of subsidiarity? (ii) Why can the objectives of the proposed action not be achieved sufficiently by Member States (necessity test)? (iii) As a result of this, can objectives be better achieved by action by the Community (test of EU Value Added)?

The overall objective of this initiative is to ensure that the national measures on pricing and reimbursement of medicinal products do not hinder intra-Community trade and do not prevent, restrict or distort competition within the common market. These objectives cannot be sufficiently achieved by Member States: the diversity of national policies makes it necessary to achieve a minimum level of procedural convergence at European level in order to create a level playing field for pharmaceutical companies and ensure timely access to medicines for all citizens. EU action is therefore justified and in line with the principle of subsidiarity.

Given the internal market objective of the directive, this proposal should be adopted on the basis of Article 114 TFEU (ex Article 95 EC). This Directive has as its underlying principle the idea of minimum interference in the organization of national health systems. Article 168 (7) TFEU (ex Article 152(5) EC Treaty) acknowledges the Member States' responsibilities in the field of healthcare. The main aim of this initiative is to reinforce the internal market for pharmaceuticals, while at the same time respecting Member States' competences to organise their national health insurance system.

## **B. Objectives of EU initiative**

What are the main policy objectives?

The underlying policy objective is to improve the functioning of the internal market for medicines. The aim of the review is therefore to look at the opportunity to update a directive dating back from 1989, taking into account the case-law developed by the European Court of Justice, the outcomes

of the Pharmaceutical Sector Enquiry and of the market monitoring as well as developments in the market and in national pricing and reimbursement regulations.

Do the objectives imply developing EU policy in new areas or in areas of strategic importance?

No.

### **C. Options**

(i) What are the policy options? (ii) What legislative or 'soft law' instruments could be considered? (iii) Would any legislative initiatives go beyond routine up-date of existing legislation?

The review will look at adequate regulatory and non-regulatory options, taking into account stakeholders' contributions and the Treaty obligation to preserve the competence of Member States' for the organisation of their health insurance systems. Broad policy options include:

- No regulatory/policy change;
- Soft-law instruments such as the identification of best practices, the development of guidelines for the implementation of the existing directive or an interpretative Communication on the implementation of the directive;
- Updating of the current directive to clarify its scope and improve the effectiveness of its provisions.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

The proposed review has a cross-cutting policy impact insofar as it:

- Constitutes a follow-up to the outcomes and recommendations of the Pharmaceutical Sector Enquiry;
- Concerns the completion of the internal market for goods;
- Relates to the overall Community objective to improve the health of European citizens.

Explain how the options respect the proportionality principle

Given the responsibility of Member States for the organisation of national healthcare systems, the review will examine the procedural framework for pricing and reimbursement decisions, but it will not address the structure or substance of national health insurance schemes. The current directive is based on the principle of minimal interference in the organisation of national social security systems, so that recourse to soft-law instruments or the absence of policy change would fully respect the proportionality principle. Similarly, any proposal to update the current directive would not go beyond what is necessary to achieve the transparency of decision-making procedures and thereby avoid unjustified obstacles to the internal market.

### **D. Initial assessment of impacts**

What are the significant impacts likely to result from each policy option (cf. list of impacts in the Impact Assessment Guidelines pages 32-37), even if these impacts would materialise only after subsequent Commission initiatives?

- The absence of policy change would maintain and maybe even increase the discrepancies in time to market medicines in the EU. This could have negative impacts on the functioning of the internal market, the competitiveness of the pharmaceutical industry and its capacity to develop new innovative treatments, healthcare budget savings and the health of citizens.

- The impact of soft-law instruments in the above-mentioned areas would essentially depend on the willingness of Member States to follow the guidance proposed. Experience of discussions within the Pharmaceutical Forum, the Transparency Committee and the Network of competent authorities for pricing and reimbursement will be taken into account in order to assess the impact of voluntary or soft-law instruments.

- The potential impacts of a revision of Directive 89/105/EEC remain to be examined in light of the scope and nature of the legal adaptations.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation? No.

Could the options have significant impacts on (i) simplification, (ii) administrative burden or on (iii) relations with third countries?

No significant impact expected. However, specific provisions for SMEs will be examined. In addition, the Transparency Directive has positive ramifications for the Commission's trade policy since it sets an example of how to establish and enforce minimum procedural requirements on public bodies engaged in decisions on pricing/reimbursement. As many emerging economies run public healthcare insurance programmes and European companies often criticise the non-transparent nature of decisions and procedures (which in their view tend to favour local manufacturers) the reference to the existing European provisions has proven to be a good instrument to ensure certain minimum standards.

## **E. Planning of further impact assessment work**

When will the impact assessment work start?

An external study is foreseen as basis for the impact assessment. The study will be commissioned by the Summer 2010. Work on the impact assessment will therefore begin in the second quarter 2010.

(i) What information and data are already available? (ii) Will this impact assessment build on already existing impact assessment work or evaluations carried out? (iii) What further information needs to be gathered? (iv) How will this be done (e.g. internally or by an external contractor) and by when?

(v) What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

The following information and data are already available:

- Commission Communication and final report on the Pharmaceutical Sector Enquiry;
- Market Monitoring exercise;
- Case-law of the European Court of Justice.

It will be necessary to commission an external study in order to gather additional information on relevant policy and market developments.

Which stakeholders & experts have been/will be consulted, how and at what stage?

- Initial consultation of Member States and stakeholders: in the second half of 2010, in the framework of the Network of competent authorities for pricing and reimbursement and of a possible stakeholder forum. Targeted consultation will be carried out in the framework of the foreseen external study.

- Open public consultation in 2011.

