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Delegations will find attached Commission document SWD(2012) 29 final.

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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

Proposal for a
DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of the public health insurance systems

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1. INTRODUCTION

The pharmaceutical market is characterised by its specific structure and by a high degree of public regulation. On the one hand, EU legislation provides harmonised rules to ensure the quality, safety and efficacy of medicinal products. Medicines can be placed on the market in the European Union only if they have received a marketing authorisation from the European Commission or from the competent national authorities. On the other hand, pharmaceutical expenditure is largely subsidised by national health systems in order to ensure the adequate provision of medicines to all citizens. In this context, Member States adopt measures to regulate the prices of medicines and the conditions of their public funding. Such measures influence the prescription and utilisation of medicines in each country. They may create barriers to pharmaceutical trade within the EU because they affect the capacity of pharmaceutical companies to sell their products in domestic markets.

Directive 89/105/EEC was adopted in the late 1980s to enable market operators to verify that national measures do not create barriers to trade incompatible with the provisions of the Treaty governing the free movement of goods. The directive lays down minimal procedural requirements to ensure the transparency of national pricing and reimbursement measures (for this reason, it is commonly referred to as the Transparency Directive). In accordance with provisions of the Treaty, the directive does not affect national pricing decisions and social security policies. Member States are free to adopt their own pricing and reimbursement decisions, as long as these comply with the procedural obligations of the directive. These obligations include specific time-limits for individual pricing and reimbursement decisions (90 days for pricing, 90 days for reimbursement or 180 days for combined decisions). The directive also requires the competent national authorities to issue a statement of reasons for each of their decisions, based on objective and verifiable criteria, and to provide appropriate legal remedies to the applicant companies.

This impact assessment examines the need to update Directive 89/105/EEC more than twenty years after its entry into force. It focuses on the fundamental objectives of the directive, without putting into question the responsibilities of the Member States for the organisation and financing of their health insurance systems.

2. PROBLEM DEFINITION

Since the early 1990s, Directive 89/105/EEC has played an important role in promoting the transparency of national pricing and reimbursement measures and facilitating the internal market in medicinal products. However, the evolution of the pharmaceutical market has created a gap between the procedural rules laid down in the directive and the national measures it intends to address. In particular, the market structure has fundamentally changed,for instance with the emergence of generic medicines or the development of highly innovative research-based medicinal products. Furthermore, Member States have been devising increasingly complex and innovative pricing and reimbursement policies in order to contain rising pharmaceutical expenditure.

The main problems observed are summarised below.

(1) Delays in time to market medicinal products

The Pharmaceutical sector inquiry carried out by the European Commission (2008-2009) highlighted frequent delays in pricing and reimbursement decisions by Member States, both with respect to innovative (originator) medicines and to generic medicines. These delays contribute to postponing the entry of medicines in national markets after the granting of a marketing authorisation.

For originator medicines, the time-limits of 90/180 days laid down in Directive 89/105/EEC are not always complied with by the competent authorities due to procedural or technical delays. This situation affects patients, by delaying the availability of authorised treatments, as well as pharmaceutical companies, which benefit from a limited period of time (the patent and data protection periods) to recoup their extensive research and development costs and to generate profits.

As regards generic medicines, it takes on average 140 days in EU countries to obtain a pricing and reimbursement decision. However, the Pharmaceutical sector inquiry demonstrated that national procedures could be much shorter because generics contain the same, well-known active ingredients as the reference (originator) product and the latter is generally already reimbursed at a higher price than its generic versions. In addition, the sector inquiry reported specific regulatory approaches or administrative practices which unnecessarily delay pricing and reimbursement decisions for generic medicines. These practices include the re-evaluation of safety features already assessed during the marketing authorisation process and attempts to delay pricing and reimbursement procedures on the basis of arguments relating to intellectual property rights (patent linkage). Unnecessary delays in the pricing and reimbursement of generic medicines affect healthcare budgets (lost saving opportunities due to postponed price competition), generic companies (reduced prospects of return on investment) and patients (deferred access to cheaper medicines).

(2) Adequacy and effectiveness of the directive in a changing context

Directive 89/105/EEC was adopted at the end of the 1980s in consideration of the market conditions and national policies which prevailed at the time. The pharmaceutical market as well as pricing and reimbursement policies have tremendously evolved since then. The following problems have arisen in this context:

(a) Issues of legal interpretation, implementation and enforcement

Directive 89/105/EEC has frequently given rise to interpretation controversies, for instance during infringement investigations initiated by the Commission and in the framework of cases submitted to the Court of Justice of the European Union (CJEU). Different factors account for these recurrent interpretation debates: firstly, the increasing complexity of the pricing and reimbursement mechanisms introduced by Member States means that national measures do not necessarily match the processes described in the directive; secondly, cost-control policies now extend beyond pricing and reimbursement (supply-side measures) to include measures targeted at health professionals, pharmacists and patients (demand-side measures); thirdly, several provisions of the directive are drafted in such a way that they often trigger divergent interpretations.

The CJEU has consistently interpreted Directive 89/105/EEC in an extensive manner, on the basis of its general objectives, in order to ensure its effectiveness. However, Member States tend to advocate a restrictive interpretation of the directive and regularly dismiss the application of its requirements to their pricing and reimbursement measures. Implementation issues also arise when Member States fail to see concretely how the directive should be applied to their specific national systems. Finally, the frequent administrative or regulatory changes introduced by national authorities in all countries have created additional enforcement difficulties.

(b) *Relationship with innovative pricing and reimbursement mechanisms*

In response to the evolution of pharmaceutical expenditure, Member States have developed alternative pricing and reimbursement mechanisms which fundamentally differ from the procedural approaches envisaged by Directive 89/105/EEC. Innovative instruments include contractual agreements designed to facilitate access to new medicines under specific conditions agreed with individual pharmaceutical companies (managed entry agreements) and tendering procedures used by the social security institutions to determine the prices and reimbursement conditions of specific categories of medicinal products. These mechanisms do not respond to the administrative logic of Directive 89/105/EEC and are also covered by specific rules such as legislation on public procurement and administrative or contract law. This leads to uncertainty as regards the legal relationship between these innovative practices and the directive.

(c) *Adequacy to address medical developments*

The development of new therapeutic approaches based on patient-specific information (e.g. genetic profile) may create further challenges for the internal market in the context of pricing and reimbursement decisions. In particular, "personalised medicines" closely associate medicinal products with medical devices, such as in-vitro diagnostic tests. This feature implies that disconnections between pricing and reimbursement decisions for the medicinal product and for the associated diagnostic/medical device might result in trade barriers and market access delays. This particular situation was not foreseen by the current directive.

(3) Transparency of pricing and reimbursement procedures for medical devices

Directive 89/105/EEC only applies to medicinal products. Medical devices are currently excluded from the scope of the directive. Despite the specificity of the medical devices market, including major differences with the pharmaceutical sector in terms of pricing and coverage by health insurance systems, some medical devices can be subject to price regulation and administrative reimbursement decisions. The relevance of Directive 89/105/EEC to these products therefore requires examination.

3. ANALYSIS OF SUBSIDIARITY

Pursuant to Article 168(7) of the Treaty on the Functioning of the European Union (TFEU), Member States are responsible for the definition of their health policy and the organisation of their healthcare system, including the allocation of resources assigned to health services and medical care. Directive 89/105/EEC is based on Article 114 TFEU, which foresees the

adoption of measures for the establishment and functioning of the internal market. Its provisions provide for minimal harmonisation: they do not affect national policies on price setting and reimbursement, except as far as necessary to ensure procedural transparency.

The proper functioning of the internal market requires timely and transparent decisions on the pricing and reimbursement of medicines. Despite the extensive interpretation of the directive by the Court of Justice, the notion of procedural transparency is understood differently in each Member State, so that action by individual Member States would not provide sufficient guarantees of procedural transparency for economic operators. Nevertheless, this initiative shall take into account the responsibilities of the Member States for the organisation and financing of their health insurance system. It should therefore focus on the possible clarification of the general procedural rules framing pharmaceutical pricing and reimbursement. Issues of substance – such as the content of national policies or the challenges linked to differences in the prices, availability and affordability of medicines across Europe – are linked to the exercise of national competences and therefore remain outside the scope of the analysis.

4. OBJECTIVES

The overall objective of this initiative is to ensure the transparency of national measures intended to regulate the prices of medicinal products, to manage their consumption or to establish the conditions of their public funding in order to avoid obstacles to pharmaceutical trade prohibited by the Treaty.

In light of the situation described in Section 2, any policy initiative relating to Directive 89/105/EEC should specifically aim at:

(1) Ensuring timely pricing and reimbursement decisions for medicinal products (Objective A);

(2) Ensuring the adequacy and effectiveness of the directive in a changing context (Objective B);

(3) Examining the relevance of the directive to the medical devices market (Objective C).

5. POLICY OPTIONS

Two extreme policy options were discarded at an early stage, namely:

– the full harmonisation of pricing and reimbursement measures, which would be incompatible with the rules of the Treaty recognising the competence of Member States for the definition and financing of their health policies;

– the mere repeal of Directive 89/105/EEC, which would represent a step backward in the operation of the single market.

Besides the baseline scenario (options A.1, B.1 and C.1), the following options were examined in relation to each of the specific objectives outlined above:

(1) Objective A: Ensure timely pricing and reimbursement decisions for medicinal products

- Option A.2: soft law
- Option A.3: revision of the directive to improve the enforcement of the time-limits
  - Option A.3/a: financial penalties by national judges
  - Option A.3/b: automatic inclusion of individual products in the health insurance system after expiry of the deadlines and until a decision is adopted
  - Option A.3/c: obligation to communicate and publish reports on pricing and reimbursement approval times
- Option A.4: revision of the directive to avoid unnecessary delays for generic medicines
  - Option A.4/a: shorter time-limits for pricing and reimbursement decisions concerning generic products
  - Option A.4/b: prohibition of patent linkage and of the duplication of assessments carried out during the marketing authorisation phase
- Option A.5: shorter time-limits for pricing and reimbursement decisions concerning originator medicines

(2) Objective B: Ensure the adequacy and effectiveness of the directive in a changing context

- Option B.2: soft law
- Option B.3: revision of the directive to align its provisions with major developments in the pharmaceutical market
  - Option B.3/a: minimal revision of the directive to reflect the case-law of the Court of Justice
  - Option B.3/b: extensive revision of the directive to bring it into line with the current pharmaceutical environment
- Option B.4: notification of draft national measures to facilitate the enforcement of the directive

(3) Objective C: Possible extension of the scope of the directive to cover medical devices

The extension of the directive to the medical devices market as a whole was discarded at an early stage. Indeed, many medical devices are not reimbursed as such to the patients: they are instead covered by health insurance systems as part of the global health interventions practised by health professionals. One option was therefore examined in addition to the status quo:

– Option C.2: partial extension of the directive to cover medical devices subject to pricing and inclusion in reimbursement lists.

6. ASSESSMENT OF IMPACTS

Given the merely procedural nature of Directive 89/105/EEC, no environmental impact has been identified for the analysed options. Economic and social impacts are summarised below.

(1) Objective A: Ensure timely pricing and reimbursement decisions for medicinal products

Option A.1: **Status quo (baseline scenario)**	Delays for originator medicines • Originator companies: lost revenues linked to delayed market entry (estimate: 35 to 100 million EUR per medicine), reduced capacity to invest in R&D, viability of SMEs at stake. • Patients: welfare losses due to the delayed availability of medicines (order of magnitude in monetary value: up to 970 million EUR/country/year). • Member States: pricing and reimbursement delays do not necessarily represent a budgetary gain (the reduction in non-pharmaceutical spending resulting from the introduction of a new medicine may be higher than the cost induced by the prescription of that medicine). Delays for generic medicines • Generic companies: lost return on investment and revenues linked to delayed market entry. • Member States: lost savings (estimate: 3 billion EUR for the period 2000-2007 based on a sample of medicines in 17 EU countries). • Patients: additional costs in case of co-payment (depends on the national system).
Option A.2: **Soft Law**	• Stronger basis for the enforcement of existing time-limits but legal certainty will not significantly improve. • Possibly effective to reduce delays for originator products (based on collaborative actions such as EUNetHTA) but success depends on Member States' cooperation. Unlikely to be successful for generics: guidance provided by the Pharmaceutical sector inquiry has not reduced unnecessary delays in all EU countries.
Option A.3/a: **Financial penalties by national judges**	• Compensation of economic damage for pharmaceutical companies. • Budgetary impact for national authorities depends on their capacity to comply with the time-limits. • Incentive for Member States to comply with the time-limits but effectiveness will depend on the willingness of economic operators to enforce their rights and on the level of sanctions decided by national judges. • Problem of delayed access to medicines for patients is not addressed. Patients even pay twice, first due to delayed access and second due to financial compensations paid by taxpayers' money.
Option A.3/b: **Automatic inclusion in reimbursement after expiration of the time-limits and until a decision is adopted**	• Pharmaceutical companies: improved market access and additional predictability in the absence of unjustified delays. • Member States: incentive to comply with the time-limits but some Member States may need to streamline or improve the efficiency of HTA procedures. Potentially significant impact on public health budgets (budgetary impact proportionate to the level of non-compliance with the time-limits) but mitigated by specific safeguards (ability to stop the clock) and Member States' capacity to make the final decision. • Patients: quicker access to medicines in the absence of decision by the competent authorities. • Potential unintended effects: insecurity for patients and companies if the decision issued beyond the time-limits is negative.

Option A.3/c: **Benchmarking reports**	• Public pressure on Member States: facilitates monitoring of compliance with the time-limits and provides a basis for dialogue with competent authorities. • Only effective if Member States provide accurate data and are willing to draw lessons from poor compliance. • Additional compliance costs for public authorities, although very limited if reporting takes place no more than once per year.
Options A.4/a and A.4/b: **- Shorter time-limits for generics** **- Prohibition of patent linkage and duplication of assessments**	• Originator companies: short-term losses due to earlier competition but encourages the pursuit of innovation. • Generic companies: quicker return on investment and profits due to earlier market entry. • Member States: significant savings for public health budgets (order of magnitude: several hundred million EUR/country if time-limits for the pricing and reimbursement of generics are reduced to 30 days). One-off adjustment costs for public authorities, in particular Member States will long decision-making timeframe for generics, but unlikely to offset long-term savings resulting from earlier price competition. • Patients: possible savings in case of co-payment (depends on national system).
Option 5: **Revision of the directive to improve market access delays for originator products**	• Originator companies: earlier return on investment with potentially positive effects on research and innovation. • Public authorities: significant adjustment costs due to the necessity to streamline and improve pricing and reimbursement procedures. • Patients: earlier access to medicines with associated welfare gains. • Possible unintended effects: non-inclusion of medicinal products into reimbursement in order to respect the shorter time-limits imposed by the directive.

(2) Objective B: Ensure the adequacy and effectiveness of the directive in a changing context

Option B.1: **Status quo (baseline scenario)**	• Discrepancy between the provisions of the directive and the current pharmaceutical market will remain, leading to persistent problems of legal interpretation, implementation and enforcement. • Pharmaceutical companies: legal uncertainty and lack of business predictability; lack of level playing field with potential effects on competitiveness (reduced pharmaceutical sales, R&D and employment). • Patients: potentially unjustified limitations in terms of access to medicines, with consequences on health and well-being.
Option B.2: **Soft Law**	• Stronger basis for the enforcement of existing obligations but legal certainty would not significantly improve: this option is unlikely to address the persistent issues of enforcement if Member States continue to advocate a restrictive interpretation of the directive. • Important resources required to draft guidelines (e.g. regular cooperation between the Commission and Member States).
Option B.3/a: **Minimal revision to reflect case-law**	• Implementation of the directive by Member States and verification of compliance by the Commission would be facilitated. • Limited improvement in legal clarity and predictability: the variety of pricing and reimbursement policies would not be addressed (e.g. uncertainties regarding tendering procedures and contractual agreements would remain). • Limited flexibility to adjust reegulatory framework over time.
Option B.3/b: **Extensive revision to align with the current pharmaceutical environment**	• Improvement in legal clarity and effectiveness of the directive: unjustified barriers to trade could be more easily detected and deterred or sanctioned. Directive drafted on the basis of general principles would be more 'future proof'. • Better regulation: clear delimitation between the directive and other relevant legal instruments (e.g. public procurement law, contract law). • Potential delays in pricing and reimbursement procedures relating to personalised medicines could be avoided through better coordination within the competent authorities but approach abandoned because it raises subsidiarity issues and it gathered weak support in the public consultation. • Limited flexibility to adjust regulatory framework over time.

Option B.4: **Notification of draft national measures**	• Preventive dialogue and improved enforcement • Compliance costs for public authorities and risk of financial costs linked to the delayed adoption of national measures (no impact on individual pricing and reimbursement decisions addressed to companies).

(3) Objective C: Possible extension of the scope of the directive to cover medical devices

Option C.1: **Status quo (baseline scenario)**	• Strong support from Member States and industry for this option. • Maintenance of the regulatory delimitation between medicines and medical devices. • No fundamental impact on the medical devices market: approximately 85% of the medical devices sold in the EU (in value) are not subject to price regulation and to mechanisms of inclusion in reimbursement. Transparency issues in the medical devices sector mostly relate to public procurement (purchasing by hospitals) and can be addressed via other legal instruments. • The segment of the medical devices market subject to pricing and reimbursement decisions is small (15%) and decreasing. • Medical devices are covered by the obligations of the Treaty governing the free movement of goods.
Option C.2: **Partial extension of the directive to cover a specific segment of the medical devices market**	• Early market access for medical devices subject to price regulation and inclusion in reimbursement lists (application of time-limits): benefits for companies in terms of return on investment and for patients due to swift access to health technologies. However, no industry support for this option. • Legal and technical complexity. Increased market fragmentation due to the differentiated treatment of similar products depending on the national rules governing their pricing and reimbursement. • Additional burden/costs for some Member States.

7. COMPARISON OF OPTIONS

The options relating to medicinal products have been compared against the main criteria of effectiveness to achieve the objectives pursued, efficiency (taking into account the burden and costs on Member States), legal certainty and enforcement.

On this basis, the preferred options are:

– Options A.3/b, A.3/c, as well as options A.4/a and A.4/b, to ensure timely pricing and reimbursement decisions;

– Options B.3/b and B.4 to ensure the adequacy and effectiveness of the directive in a changing context.

Performance of options against key criteria – Objective A

Objective A: Ensure timely pricing and reimbursement decisions	**Effectiveness**	**Efficiency = Effectiveness vs. burden/costs for Member States**	**Legal certainty**	**Enforcement**
Option A.1: Status quo (baseline scenario)	-	-	-	-
Option A.2: Soft Law	±	+	±	±
Option A.3/a: Financial penalties by national judges	±	+	+	±
Option A.3/b: Automatic inclusion in reimbursement after expiry of the time-limits and until decision	+ +	±	+	+
Option A.3/c: Benchmarking reports	+	+	+	±
Option A.4/a: Shorter time-limits for generics	+ +	+	+	×
Option A.4/b: Prohibition of patent linkage and	+ +	+ +	+ +	×

duplication of assessments				
Option 5: Shorter time-limits for originator medicines	+	-	+	×

Performance of options against key criteria – Objective B

Objective B: Ensure the adequacy and effectiveness of the directive in a changing context	Effectiveness	Efficiency = Effectiveness vs. burden/costs for Member States	Legal certainty	Enforcement
Option B.1: Status quo (baseline scenario)	-	-	-	-
Option B.2: Soft Law	±	+	±	±
Option B.3/a: Minimal revision to reflect case-law	±	±	+	+
Option B.3/b: Extensive revision to align with the current pharmaceutical environment	+	+	+ +	±
Option B.4: Notification of draft national measures	+	±	+	+ +

Performance levels: + + Very high + High ± Moderate - Negative × No impact
□□□□ : Preferred options

The options relating to the possible extension of the directive to medical devices have mainly been compared in terms of general benefits and drawbacks. The conclusion is that the benefits of extending the directive to the small share of the medical devices market subject to pricing and inclusion in reimbursement lists do not counterbalance the drawbacks, in particular the legal and technical complexities of such an extension as well as the risk of further market fragmentation.

Performance of options against key criteria – Objective C

Objective C: Possible extension of Directive 89/105/EEC to medical devices	Effectiveness (impact on transparency of the market)	Efficiency = Effectiveness vs. burden/costs for Member States	Legal certainty
Option C.1: Status quo	±	+	+
Option C.2: Partial extension to a specific segment of the medical devices market	±	-	-

Synergies exist between the preferred options. For instance, the objective of scrapping unnecessary pricing and reimbursement delays for generic medicines will be more effectively achieved by combining different options. However, synergies could not be quantified as they essentially lie in the mutually reinforcing legal effects of the recommended options.

The main implications of the proposed set of policy options for each of the main stakeholders are presented below.

	Advantages/Benefits	Disadvantages/Costs
Member States	• Increased legal clarity and easier implementation of the procedural requirements. • Potential cost savings linked to quicker pricing and reimbursement for generics. • No interference of intellectual and industrial property rights with day-to-day pricing and reimbursement activities.	• Stronger enforcement instruments requiring more systematic compliance. Potential impact on public health budgets in case of non-compliance with the time-limits. • Need to improve or streamline pricing and reimbursement processes (including expert assessments such as HTA). • Shorter time-limits for generics may entail initial compliance costs if national procedures need to be adapted. • Limited administrative costs linked to reporting obligations and notification of draft national measures.
Originator companies	• Increased legal clarity, stronger enforcement instruments and more 'future proof' legislation will: - bring additional business predictability; - improve market access; - improve competitiveness and foster innovation. • Earlier competition with generics will encourage the pursuit of innovation.	• Automatic inclusion in case of non-compliance with the time-limits may have the side effect of encouraging Member States to issues negative decisions within the deadlines. • Should automatic inclusion occur in practice, potential insecurity if the decision eventually issued by the competent authorities beyond the time-limits is negative.
Generic companies	• Increased legal clarity, stronger enforcement instruments and more 'future proof' legislation will: - bring additional business predictability; - improve market access; - improve competitiveness and foster innovation. • Shorter time-limits for pricing and reimbursement decisions and clarification of the non-interference of safety and IPR issues with pricing and reimbursement procedures will ensure earlier market entry and more effective competition in off-patent markets.	• Should automatic inclusion occur in practice, potential insecurity if the decision eventually issued beyond the time-limits by the competent authorities is negative.
Patients	• Access to medicines not hampered by delays in pricing and reimbursement decisions. • Cost savings linked to earlier generic entry and price competition in off-patent markets (in case of co-payment).	• Should automatic inclusion occur in practice, potential insecurity or even health impact if the decision eventually issued beyond the time-limits by the competent authorities is negative and patients have to switch their treatment.

8. MONITORING AND EVALUATION

The monitoring and implementation plans will mainly rely on:

– Cooperation between the Commission and the Member States in the framework of the Transparency Committee established by the directive. The Committee will meet on a regular basis during the transposition phase to monitor and facilitate transposition by the Member States.

– The proposed pre-notification mechanism to monitor the adequate implementation of the directive and enable bilateral dialogue with the Member States.

– Implementation reports to be communicated by Member States within three years after the entry into force of the directive, followed by an assessment of the operation of the directive by the Commission within three years after the date of entry into force.

The core progress indicators and monitoring instruments which will be used to assess whether the new directive is meeting its objectives are presented below.

Objectives	Progress indicators	Monitoring instruments
A. Timely pricing and reimbursement decisions: compliance with the time-limits	Observed timing for pricing and reimbursement decisions in the Member States	Annual mandatory reporting on the actual time taken for individual pricing and reimbursement decisions.
B. Adequacy and effectiveness: legal clarity and enforcement	a) Changes in national measures and compliance of notified drafts with the directive (compliance rate based on pre-notification system) b) Complaints filed and investigated by the Commission, Commission referrals to the Court of Justice of the European Union	Notification of draft national measures to the Commission Infringement statistics