Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2012/0035(COD)
Medicinal products for human use: transparency of measures regulating the prices and their inclusion in the scope of public health insurance systems Subject 2.10 Free movement of goods 2.60.03 State aids and interventions 4.20.04 Pharmaceutical products and industry 4.20.06 Health services, medical institutions 4.60.06 Consumers' economic and legal interests 8.50.01 Implementation of EU law	Procedure lapsed or withdrawn

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety		19/04/2012
	ALDE PARVANOVA Antonyia	
	Shadow rapporteur	
	PPE MAZEJ KUKOVIČ Zofija	
	S&D CHILDERS Nessa	
	Verts/ALE RIVASI Michèle	
	ECR CABRNOCH Milan	
	EFD CYMAŃSKI Tadeusz	
Former committee responsible		
ENVI Environment, Public Health and Food Safety		
ENVI Environment, Public Health and Food Safety		23/10/2014
	FARIA José Inácio	

Committee for opinion	Rapporteur for opinion	Appointed
EMPL Employment and Social Affairs	The committee decided not to give an opinion.	
ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
IMCO Internal Market and Consumer Protection		20/03/2012
	ALDE BUŞOI Cristian-Silviu	
JURI Legal Affairs	The committee decided not to give an opinion.	
Former committee for opinion		
EMPL Employment and Social Affairs		
EMPL Employment and Social Affairs	The committee decided not to give an opinion.	

	ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
	ITRE Industry, Research and Energy		
	IMCO Internal Market and Consumer Protection		
	IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
	JURI Legal Affairs		
	JURI Legal Affairs	The committee decided not to give an opinion.	
	Committee for opinion on the legal basis	Rapporteur for opinion	Appointed
	JURI Legal Affairs	EFD SPERONI Francesco Enrico	09/01/2013
Council of the European Union	Council configuration	Meeting	Date
	Employment, Social Policy, Health and Consumer Affairs	3206	06/12/2012
European Commission	Commission DG	Commissioner	
	Internal Market, Industry, Entrepreneurship and SMEs	TAJANI Antonio	
European Economic and Social Committee			

Key events

01/03/2012	Legislative proposal published	COM(2012)0084	Summary
13/03/2012	Committee referral announced in Parliament, 1st reading		
06/12/2012	Debate in Council	3206	
18/12/2012	Vote in committee, 1st reading		
25/01/2013	Committee report tabled for plenary, 1st reading	A7-0015/2013	Summary
04/02/2013	Debate in Parliament		
06/02/2013	Results of vote in Parliament		
06/02/2013	Decision by Parliament, 1st reading	T7-0039/2013	Summary
18/03/2013	Amended legislative proposal for reconsultation published	COM(2013)0168	Summary
21/03/2013	Formal reconsultation of Parliament		
07/03/2015	Proposal withdrawn by Commission		

Technical information

Procedure reference	2012/0035(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive

Legal basis	Treaty on the Functioning of the EU TFEU 114-p1
Other legal basis	Rules of Procedure EP 159
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Procedure lapsed or withdrawn
Committee dossier	ENVI/8/00115; ENVI/7/08978

Documentation gateway

Legislative proposal		COM(2012)0084	01/03/2012	EC	Summary
Document attached to the procedure		SWD(2012)0029	01/03/2012	EC	
Document attached to the procedure		SWD(2012)0030	01/03/2012	EC	
Economic and Social Committee: opinion, report		CES1573/2012	12/07/2012	ESC	
Committee draft report		PE491.292	21/09/2012	EP	
Amendments tabled in committee		PE497.983	22/10/2012	EP	
Amendments tabled in committee		PE498.042	25/10/2012	EP	
Committee opinion	IMCO	PE494.638	09/11/2012	EP	
Amendments tabled in committee		PE498.122	11/12/2012	EP	
Specific opinion	JURI	PE504.108	23/01/2013	EP	
Committee report tabled for plenary, 1st reading/single reading		A7-0015/2013	25/01/2013	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0039/2013	06/02/2013	EP	Summary
Amended legislative proposal for reconsultation		COM(2013)0168	18/03/2013	EC	Summary
Commission response to text adopted in plenary		SP(2013)239	04/04/2013	EC	
Economic and Social Committee: opinion, report		CES3335/2013	22/05/2013	ESC	
Document attached to the procedure		N7-0071/2014 OJ C 032 04.02.2014, p. 0017	30/05/2013	EDPS	Summary

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Medicinal products for human use: transparency of measures regulating the prices and their inclusion in the scope of public health insurance systems

PURPOSE: to improve the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems.

PROPOSED ACT: Directive of the European Parliament and of the Council.

BACKGROUND: Council Directive 89/105/EEC 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 was adopted so as to remove distortions to intra-Community

trade in medicinal products. Directive 89/105/EEC has never been amended since its adoption. Its provisions reflect the pharmaceutical market conditions which prevailed more than twenty years ago. However, these conditions have fundamentally changed, for instance with the emergence of generic medicines providing cheaper versions of existing products or the development of increasingly innovative (yet often expensive) research-based medicinal products. In parallel, the constant rise in public expenditure on pharmaceuticals in the last decades has encouraged Member States to devise more complex and innovative pricing and reimbursement systems over time.

Despite the historically positive impact of Directive 89/105/EEC on the internal market for medicines, there is evidence that it does not fully achieve its objectives in the present context:

(1) A gap has emerged between the provisions of the Directive, which describe the main types of pricing and reimbursement procedures established in the 1980s, and the much wider range of cost-containment measures adopted nowadays by Member States. Despite the extensive interpretation of the Directive by the Court of Justice, the implementation of its provisions in national law and the effective enforcement of its principles, in particular by the Commission, have become particularly challenging. This situation not only results in legal uncertainties but also in a reduced transparency of national pricing and reimbursement measures, which negatively affects the smooth functioning of the internal market to the detriment of European patients and pharmaceutical companies.

(2) The time limits for pricing and reimbursement decisions established by Directive 89/105/EEC are regularly exceeded by Member States. This leads to delays in the marketing of medicinal products, which in turn slows down the availability of valuable treatments for patients.

In order to take into account the evolution of the pharmaceutical market and of national policies to control public expenditure on medicines, substantive changes are necessary to all major provisions of Directive 89/105/EEC. Therefore, in the interest of clarity, Directive 89/105/EEC should be replaced. The fundamental objectives and principles of Directive 89/105/EEC remain fully valid in the present context.

IMPACT ASSESSMENT: the proposal to revise the Directive is based on the combination of options recommended in the framework of the impact assessment, namely:

- to ensure timely pricing and reimbursement decisions: options A.3/c (regular reports on pricing and reimbursement approval times), A.4/a (shorter time-limits for pricing and reimbursement decisions concerning generic medicinal products) and A.4/b (prohibition of patent linkage and re-assessment of safety features);
- to ensure the adequacy and effectiveness of the Directive in the current context: options B.3/b (extensive revision of the Directive to clarify its scope and wording) and B.4 (notification of draft national measures to facilitate enforcement).

The possible extension of the Directive to include medical devices was examined in the impact assessment but discarded due to the specificities of this market.

Furthermore, in spite of the difficulty to conclude on the overall cost-benefit balance of reducing the time limits with respect to originator medicines, a reduction from the current 90/180 days to 60/120 days is proposed in light of the positive impact it would have on the swift availability of innovative medicines to patients and on rewarding pharmaceutical innovation when medicines are approved for reimbursement.

LEGAL BASIS: Article 114 of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: the overall objective of the proposal is to clarify the procedural obligations incumbent upon Member State and to ensure the effectiveness of the Directive, both in avoiding delays in pricing and reimbursement decisions and in preventing barriers to pharmaceutical trade. This shall be done without affecting national social security policies, except as far as it is necessary to achieve the transparency of national procedures and the effectiveness of the internal market legislation.

The proposal maintains the core principles of the existing Directive but also puts forward a comprehensive adaptation of its legal provisions based on the following key elements:

Clarification of the scope of the Directive: the transparency requirements apply to all pricing and reimbursement measures understood in a broad sense, including demand side measures to control or promote the prescription of specific medicines. Nevertheless, measures involving public procurement and voluntary contractual agreements with individual companies are excluded from the scope of the Directive in order to avoid interference with other bodies of law.

Comprehensive coverage of national measures and legal clarity: the provisions of the Directive are reworded in accordance with general principles (rather than on the basis of specific national procedures) and incorporate the case-law of the Court of Justice. Several key provisions are clarified and updated to avoid interpretation controversies. In particular, it is made clear that the time limits for pricing and reimbursement decisions include all procedural steps leading to the decision, including health technology assessments where applicable.

Adaptation of the time limits for pricing and reimbursement decisions: the time limits applicable to generic medicines are reduced to 15/30 days when the reference product has already been priced and included in the health insurance system. The time limits applicable to all other medicinal products are reduced to 60/120 days.

However, in cases where national authorities subject medicinal products to health technology assessment procedures in order to assess the relative efficacy or the short- and long-term effectiveness, as an integral part of their decision-making process, the time-limits shall be 90/180 days.

Non-interference of patent and safety issues with pricing and reimbursement procedures: the proposal clarifies that intellectual property rights should not interfere with pricing and reimbursement procedures, as is already the case for marketing authorisation procedures. In addition, elements already assessed in the framework of the marketing authorisation process (quality, safety and efficacy, including bioequivalence) may not be reassessed in the framework of pricing and reimbursement procedures.

Dialogue and enforcement tools: different instruments are put in place to facilitate dialogue on the implementation of the Directive and to ensure its effective enforcement (consultation on draft measures at national level and pre-notification to the Commission, the creation of a remedies procedure in case of non-compliance with the time-limits related to the inclusion of medicinal products in health insurance systems).

BUDGETARY IMPLICATION: the Commission's proposal has no impact on the European Union budget beyond what is already foreseen for the years to come in the Multiannual Financial Framework. Total appropriations under headings 1 to 5 of the multiannual financial framework are estimated at EUR 0.859 million (2014); EUR 1.293 million (2015); EUR 1.143 million (2016-2017); EUR 1.093 (2018 action continued).

Medicinal products for human use: transparency of measures regulating the prices and their inclusion in the scope of public health insurance systems

The Committee on the Environment, Public Health and Food Safety adopted the report by Antonyia PARVANOVA (ALDE, BG) on the 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 public health insurance systems.

It recommends that the European Parliaments position at first reading, under the ordinary legislative procedure, should amend the Commissions proposal as follows:

Legal base: Members consider that because this proposal deals specifically with the free movement of medicinal products and the pricing thereof (a matter that falls within the competence of Member States in the field of public health), Article 168 of the TFEU should therefore be added to the legal basis.

Scope: this Directive may not call into question a marketing authorisation relating to a medicinal product granted in accordance with the procedure referred to in Directive 2001/83/EC.

Definitions: Members define a voluntary contractual agreement as an agreement concluded between public authorities and the marketing authorisation holder for a medicinal product which is neither mandatory nor required by law, nor the only alternative to being included in the national pricing and reimbursement scheme to ensure that agreements are not used as a loophole to avoid the applicability of the Directive. A biosimilar medicinal product means a similar biological medicinal product approved in accordance with Directive 2001/83/EC. Health technology assessment (HTA) means an assessment which as a minimum includes the relative efficacy or the short- and long-term effectiveness of the medicinal product compared to other health technologies or interventions in use for treating the associated condition.

Innovative treatments: competent authorities and marketing authorisation holders increasingly engage in contractual agreements to provide patients with access to innovative treatments by including a medicinal product in the scope of public health insurance systems whilst monitoring elements agreed upfront and for a defined period of time in order, in particular, to address evidentiary uncertainties relating to the effectiveness and/or relative efficacy or the appropriate use of a specific medicinal product.

Criteria underlying decisions regulating prices of medicinal products: the criteria underlying any decision directly or indirectly regulating the prices of medicinal products, as well as any measure determining the extent to which they shall be covered by public health insurance systems, should include the assessment of unmet medical needs, clinical and societal benefits and innovation. Such criteria should also include the protection of the most vulnerable groups of the population.

Members consider that in the framework of pricing and reimbursement decisions, the competent authorities responsible for these decisions should not reassess the essential elements on which the marketing authorisation is based, including the quality, safety, efficacy, bioequivalence or biosimilarity of the medicinal product.

Time-periods: the Committee extended a number of the deadlines in the Commissions proposal. For example, Member States shall ensure that a decision on the price which may be charged for the medicinal product concerned is adopted and communicated to the applicant within 90 days (60 days in Commission proposal) of the receipt of an application submitted. Members recommended a 60-day time limit to decide on the pricing and reimbursement of generic medicines.

Transparency of decision-making bodies and prices: Member States shall ensure that the competent authorities controlling the prices of medicinal products or determining the coverage of medicinal products by public health insurance systems make publicly available a regularly updated list of the members of their decision-making bodies, together with their declarations of interest. These authorities shall also publish and communicate to the Commission, at least once a year, a complete list of the medicinal products covered by their public health insurance systems and the prices which have been set during the relevant period. Any decision to exclude a medicinal product or a category of medicinal products from the scope of the public health insurance system shall be made publicly available, together with a summary of the statement of reasons.

Report: Members consider that a yearly report collecting Member States data and information would be more appropriate than a six-monthly report, as proposed by the Commission, in order to allow an accurate overview and relevant trends analysis on the implementation of time limits.

Medicinal products for human use: transparency of measures regulating the prices and their inclusion in the scope of public health insurance systems

The European Parliament adopted by 559 votes to 54, with 72 abstentions, a legislative resolution on the 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 public health insurance systems.

Parliament adopted its position at first reading under the ordinary legislative procedure. Its amendments are as follows:

Scope: this Directive may not call into question a marketing authorisation relating to a medicinal product granted in accordance with the procedure referred to in Directive 2001/83/EC.

Definitions: Parliament defines a voluntary contractual agreement as an agreement concluded between public authorities and the marketing authorisation holder for a medicinal product which is neither mandatory nor required by law, nor the only alternative to being included in the national pricing and reimbursement scheme to ensure that agreements are not used as a loophole to avoid the applicability of the Directive. A biosimilar medicinal product means a similar biological medicinal product approved in accordance with Directive 2001/83/EC. Health technology assessment (HTA) means an assessment which as a minimum includes the relative efficacy or the short- and long-term effectiveness of the medicinal product compared to other health technologies or interventions in use for treating the associated condition.

Criteria underlying decisions regulating prices of medicinal products: Parliament introduces a new recital requiring that the criteria underlying any decision directly or indirectly regulating the prices of medicinal products, as well as any measure determining the extent to which they shall

be covered by public health insurance systems, include the assessment of unmet medical needs, clinical and societal benefits and innovation. Such criteria should also include the protection of the most vulnerable groups of the population.

These criteria, as well as the information concerning the decision-making bodies at national or regional level, should be made publicly available.

Deadlines: Parliament proposes extending a number of the deadlines in the Commissions proposal. Member States shall ensure that a decision on the price which may be charged for a medicinal product concerned is adopted and communicated to the applicant within 90 days of the receipt of an application submitted. With respect to generic medicinal products, that time limit shall be 30 days, provided that the reference medicinal product has been approved by the competent authorities. Where appropriate, Member States shall use health technology assessment as part of their decision-making process on the pricing of medicinal products.

In regard to a decision on the inclusion of a medicinal product in the scope of the public health insurance scheme, a decision shall be adopted and communicated to the applicant within 90 days of its receipt. With respect to generic medicinal products, that time limit shall be 30 days, provided that the reference medicinal product has already been included in the public health insurance system.

Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure and the price approval procedure does not exceed 180 days. With respect to generic medicinal products, that time limit shall not exceed 60 days, provided that the reference medicinal product has already been included in the public health insurance system.

Mediation and remedies procedures: Parliament amended the Commissions proposal requiring Member States to ensure that effective and rapid mediation or remedies procedures are available to the applicant in case of unjustified delays or non-compliance with the time limits set in the Directive, and in accordance with their national law.

Transparency of decision-making bodies and prices: Member States shall ensure that the competent authorities controlling the prices of medicinal products or determining the coverage of medicinal products by public health insurance systems make publicly available a regularly updated list of the members of their decision-making bodies, together with their declarations of interest. These authorities shall also publish and communicate to the Commission, at least once a year, a complete list of the medicinal products covered by their public health insurance systems and the prices which have been set during the relevant period. Any decision to exclude a medicinal product or a category of medicinal products from the scope of the public health insurance system shall be made publicly available, together with a summary of the statement of reasons.

Report: Parliament considers that a yearly report collecting Member States data and information would be more appropriate than a six-monthly report, as proposed by the Commission, in order to allow an accurate overview and relevant trends analysis on the implementation of time limits.

Medicinal products for human use: transparency of measures regulating the prices and their inclusion in the scope of public health insurance systems

The Commission presents an amended proposal for the Directive on the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems. The European Parliament will be consulted again on this proposal.

Background: the Commission presented its initial legislative proposal on 1st March 2012 (please refer to the summary of the same date). Negotiations in the Council Working Party on Pharmaceuticals and Medical Devices proved to be difficult. The main concerns of Member States were related to: (i) the principle of subsidiarity; (ii) the remedies procedure; (iii) the creation of a system of pre-notification of draft national measures to the Commission; (iv) the shortening of the time limits for taking decisions on pricing of medicines and their inclusion in the scope of health insurance systems; (v) the distinction between originator medicinal products subject to health technology assessment (HTA) and those not subject to HTA; (vi) the obligation to consult the interested parties.

As the result of the European Parliaments position in 1st reading on 6 February 2013 (please refer to the summary of that date) and taking into consideration the position of Member States in the Council, the Commission decided to amend its proposal.

It took into account the amendments of the European Parliament voted in plenary: 50 were acceptable (16 as such and 34 acceptable in principle, even if, a few of them were acceptable only in part) and only 7 were unacceptable.

The main amendments to the initial proposal are as follows:

Minimum procedural requirements: these should ensure legal certainty and transparency for all the parties involved in the process of pricing of medicinal products and inclusion in the health insurance systems, while promoting the production of medicinal products, accelerating the entry into the market of generic medicinal products and encouraging research and development of new medicinal products.

Definitions: the amended proposal inserted a definition for biosimilar medicinal product which means a biological medicinal product that is similar to a reference biological medicinal product.

The concept of health technology assessment is clarified: it means an assessment which as a minimum includes the assessment of the relative efficacy or of the short- and long-term effectiveness of the medicinal product compared to other health technologies or interventions in use for treating the associated condition.

Price approval: a decision on the price which may be charged for the medicinal product concerned is adopted and communicated to the applicant within 90 days (rather than 60 days as stated in the initial proposal) of the receipt of an application submitted. With respect to generic medicinal products, that time limit shall be 30 days (15 days in the initial proposal), provided that the price of the reference medicinal product has been approved by the competent authorities.

Where Member States decide to include health technology assessment as part of their decision-making process on the pricing of medicinal products, such assessment shall be carried out within these time limits.

Price increase: a decision to approve or reject on an application to increase the price of a medicinal product must be adopted and communicated to the applicant within 90 days of its receipt.

Price freeze and price reduction: once a year Member States shall assess whether the price freeze or the price reduction is still justified taking into account the macro-economic conditions and adopt necessary changes where appropriate.

Inclusion of medicinal products in health insurance systems: the amended proposal states that a decision must be adopted and communicated to the applicant within 90 days of its receipt. With respect to generic medicinal products, that time limit shall be 30 days, provided that the reference medicinal product has already been included in the public health insurance system.

Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure and the price approval procedure does not exceed 180 days. With respect to generic medicinal products, that time limit shall not exceed 60 days, provided that the reference medicinal product has already been included in the public health insurance system.

Furthermore, information on information on the criteria which the competent authorities must take into account when deciding whether or not to include medicinal products within the scope of the public health insurance system must be made public, as must information regarding decision-making bodies at national or regional level.

Additional proof of quality, safety, efficacy or bioequivalence: in the framework of pricing and reimbursement decisions, Member States shall not re-assess the elements on which the marketing authorisation is based, including the quality, safety, efficacy, or bioequivalence, or biosimilarity of the medicinal product or the criteria for orphan designation which have already been assessed during the marketing authorisation procedure.

Consultation of interested parties: where a Member State intends to adopt or amend any legislative measure falling within the scope of the Directive, it shall give civil society organisations, including patient and consumer groups, and other interested parties, the opportunity to comment on the draft measure within a reasonable period.

Medicinal products for human use: transparency of measures regulating the prices and their inclusion in the scope of public health insurance systems

Opinion of the European Data Protection Supervisor on the amended Commission proposal for a directive on the transparency of measures regulating the prices of

medicinal products for human use and their inclusion in the scope of public health insurance systems.

The opinion focuses on the following aspects of the proposed directive relating to personal data protection:

Applicability of the data protection legislation: a reference should provide as a general rule that Directive 95/46/EC and Regulation (EC) No 45/2001 apply to the processing of personal data within the framework of the proposed directive;

Publication of data concerning experts and members of certain organisations: subject to the outcome of a proportionality test, the publication obligation should in any event be supported by adequate safeguards to ensure respect of the rights of the persons concerned to object, the security/accuracy of the data and their deletion after an adequate period of time;:

Potential processing of data concerning the health of patients due to access to data regarding market authorisation data: new provisions should be introduced in order to:

- clearly define in which situations and subject to what safeguards information containing patient health data will be processed, as well as safeguards in this regard;
- provide for a requirement to fully anonymise any patient data included in the market authorisation data before this data is transferred to the competent authority for any further processing for purposes of pricing and reimbursement decisions.

Creation of databases at EU.Member State levels: a data protection impact assessment should be carried out in advance, before any further action is undertaken with a view to launching any new database.