EUROPEAN PARLIAMENT

2009 - 2014

Plenary sitting

A7-0015/2013

24.1.2013

***I
REPORT

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
(COM(2012)0084 – C7-0056/2012 – 2012/0035(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Antonyia Parvanova

PR_COD_1amCom

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

In amendments by Parliament, amendments to draft acts are highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the draft act which may require correction when the final text is prepared – for instance, obvious errors or omissions in a language version. Suggested corrections of this kind are subject to the agreement of the departments concerned.

The heading for any amendment to an existing act that the draft act seeks to amend includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend. Passages in an existing act that Parliament wishes to amend, but that the draft act has left unchanged, are highlighted in **bold**. Any deletions that Parliament wishes to make in such passages are indicated thus: **[...]**.

CONTENTS

Page

DRAFT EUROPEAN PARLIAMENT 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 (COM(2012)0084 – C7-0056/2012 – 2012/0035(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2012)0084),

– having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0056/2012),

– having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Austrian National Council and by the Luxembourg Chamber of Deputies, asserting that the draft legislative act does not comply with the principle of subsidiarity,

– having regard to the opinion of the European Economic and Social Committee of 12 July 2012[1],

– having regard to Rules 55 and 37 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on the Internal Market and Consumer Protection (A7-0015/2013) ,

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1

[1] OJ C 299, 4.10.2012, p. 83.

Proposal for a directive
Citation 1

Text proposed by the Commission	*Amendment*
Having regard to the Treaty on the Functioning of the European Union, and in particular ***Article 114*** thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular ***Articles 114 and 168*** thereof,

Justification

This proposal does not relate to the free movement of just any type of goods, but deals with the free movement of medicinal products and the pricing thereof, and the latter 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.

Amendment 2

Proposal for a directive
Recital 2

Text proposed by the Commission	*Amendment*
(2) 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.	(2) In order to take into account the evolution of the pharmaceutical market and of national policies to control public expenditure on ***medicinal products***, 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.

Amendment 3

Proposal for a directive
Recital 4

Text proposed by the Commission	*Amendment*
(4) Member States have been confronted to a steady rise in pharmaceutical expenditure over the last decades, leading to the adoption of increasingly innovative and complex policies to manage the consumption of ***medicines*** in the framework of their public health insurance	(4) Member States have been confronted *with* a steady rise in pharmaceutical expenditure over the last decades, leading to the adoption of increasingly innovative and complex policies to manage the consumption of ***medicinal products*** in the framework of their public health insurance

systems. In particular, Member States' authorities have implemented a broad range of measures to control the prescription of ***medicines***, to regulate their prices or to establish the conditions of their public funding. Such measures mainly aim at promoting public health by ensuring the availability of adequate supplies of medicinal products at reasonable costs, while ensuring ***the financial stability of public health insurance systems***.	systems. In particular, Member State authorities have implemented a broad range of measures to control the prescription of ***medicinal products***, to regulate their prices or to establish the conditions of their public funding. Such measures mainly aim at promoting public health ***for all citizens*** by ensuring the availability of adequate supplies of ***effective*** medicinal products ***on equal terms to all citizens of the Union*** at reasonable costs, while ensuring ***equal access to high-quality healthcare for all***. ***Those measures should also aim to promote research and development of new medicinal products and to promote medical innovation. Medicines classed as essential on the WHO list should be available to patients in all Member States, irrespectively of the size of the market.***

Justification

Innovation in the field of healthcare brings considerable advantages for patients and makes healthcare systems more efficient and durable.

Amendment 4

Proposal for a directive
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) Ensuring patients' access to medicinal products throughout the Union and effective free movement of goods requires that Member States make a reasonable use of external reference pricing, namely by reference to Member States with a comparable income level. The unconditional use of external reference pricing has been proven to reduce the availability of medicinal products by encouraging shortages in Member States with lower price levels.

Justification

Member States should be encouraged to adopt a reasonable approach to the use of external reference pricing by including in their referencing system Member States with a comparable purchasing power. Otherwise producers would be reluctant at putting their products on the market of Member States where prices are lower, just to avoid a downward pressure on prices across the EU as a whole.

Amendment 5

Proposal for a directive
Recital 6

Text proposed by the Commission	*Amendment*
(6) In order to reduce the effects of the disparities on the internal market, national measures should comply with minimum procedural requirements enabling the parties concerned to verify that those measures do not constitute quantitative restrictions on imports or exports or measures having equivalent effect thereto. However, those requirements should not affect the policies of those Member States which rely primarily upon free competition to determine the price of medicinal products. They also should not affect national policies on price setting and on the determination of social security schemes, except as far as it is necessary to attain transparency within the meaning of this Directive and to ensure the functioning of the internal market.	(6) In order to reduce the effects of the disparities on the internal market, national measures should comply with minimum procedural requirements enabling the parties concerned to verify that those measures do not constitute quantitative restrictions on imports or exports or measures having equivalent effect thereto. ***Those minimum procedural requirements should also ensure legal certainty and transparency for the competent authorities when adopting decisions relating to the pricing and coverage of medicinal products by public 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.*** However, those requirements should not affect the policies of those Member States which rely primarily upon free competition to determine the price of medicinal products. They also should not affect national policies on price setting and on the determination of social security schemes, except as far as it is necessary to attain transparency within the meaning of this Directive and to ensure the functioning of the internal market.

Amendment 6

Proposal for a directive
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) 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. The delay in defining the terms and conditions of such contractual agreements often exceeds the time limits set and justifies the exclusion of such agreements from the scope of this Directive. Those agreements should be limited to therapeutic areas where their conclusion would effectively facilitate or enable patients' access to innovative medicinal products, would remain voluntary and would not affect the right of the marketing authorisation holder to submit an application in compliance with this Directive.

Amendment 7

Proposal for a directive
Recital 9

Text proposed by the Commission	*Amendment*
(9) Any measure to regulate, either directly or indirectly, the prices of medicinal products, as well as any measure to determine their coverage by public health insurance systems should be based on objective and verifiable criteria that are	(9) Any measure to regulate, either directly or indirectly, the prices of medicinal products, as well as any measure***,*** ***including recommendations that may be required,*** to determine their coverage by public health insurance systems should be

independent from the origin of the product and should provide adequate legal remedies, including judicial remedies, to affected companies. These requirements should equally apply to national, regional or local measures to control or promote the prescription of specific medicinal products as such measures also determine their effective coverage by health insurance systems.	based on ***transparent,*** objective and verifiable criteria that are independent from the origin of the product and should provide adequate legal remedies***, in accordance with national procedures***, to affected companies. These requirements should equally apply to national, regional or local measures to control or promote the prescription of specific medicinal products as such measures also determine their effective coverage by health insurance systems.

Amendment 8

Proposal for a directive
Recital 9 a (new)

Text proposed by the Commission	*Amendment*
	(9a) 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, as laid down in the opinion of the European Economic and Social Committee of 12 July 2012 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[1]. Such criteria should also include the protection of the most vulnerable groups of the population.
	[1] OJ C 299, 4.10.2012, p. 83.

Amendment 9

Proposal for a directive
Recital 10

Text proposed by the Commission	*Amendment*
(10) Applications to approve the price of a medicinal product or to determine its coverage by the health insurance system should not delay the placing on the market of that product beyond what is necessary. It is therefore desirable that this Directive sets out mandatory time limits within which national decisions should be made. In order to be effective, the prescribed time periods should run from the receipt of an application until the entry into force of the corresponding decision. They should include all expert evaluations, including health technology assessments where applicable, and all administrative steps required for the decision to be adopted and take legal effect.	(10) Applications to approve the price of a medicinal product or to determine its coverage by the health insurance system should not delay the placing on the market of that product beyond what is necessary. It is therefore desirable that this Directive sets out mandatory time limits within which national decisions should be made. In order to be effective, the prescribed time periods should run from the receipt of an application until the entry into force of the corresponding decision. They should include all ***recommendations and*** expert evaluations, including health technology assessments where applicable, and all administrative steps required for the decision to be adopted and take legal effect.

Amendment 10

Proposal for a directive
Recital 10 a (new)

Text proposed by the Commission	*Amendment*
	(10a) In order to facilitate compliance with those time limits, it may be useful for applicants to start procedures for price approval or for inclusion of a medicinal product in the public health insurance systems already before the marketing authorisation is formally granted. To this end, Member States may allow applicants to submit an application as soon as a positive opinion on the granting of the marketing authorisation for the medicinal product concerned has been issued by the Committee for Medicinal Products for Human Use or by the national competent authority in charge of the marketing authorisation procedure, as appropriate.

In such cases the time limits should run from the formal receipt of the marketing authorisation.

Amendment 11

Proposal for a directive
Recital 10 b (new)

Text proposed by the Commission	*Amendment*
	(10b) The Union's support for cooperation on health technology assessment (HTA) in accordance with Article 15 of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare[1] aims to optimise and coordinate HTA methodologies which should ultimately also reduce delays in pricing and reimbursement processes of medicinal products for which Member States use HTA as part of their decision-making process. HTA includes, in particular, information on the relative efficacy as well as on the short- and long-term effectiveness, where appropriate, of health technologies, also taking into account broader economic and social benefits or cost-effectiveness of the assessed medicinal product, in accordance with the methodology of the competent authorities. HTA is a multidisciplinary process that summarises information about the medical, social, economic and ethical aspects relating to the use of health technology in a systematic, transparent, unbiased and robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient-focused and that seek to achieve best value.

[1] OJ L 88, 4.4.2011, p. 45.

Amendment 12

Proposal for a directive
Recital 12

Text proposed by the Commission	*Amendment*
(12) In its Communication 'Executive Summary of the Pharmaceutical Sector Inquiry Report' the Commission demonstrated that pricing and reimbursement procedures often unnecessarily delay the launch of generic ***medicines*** in Union markets. Approving the price of generic medicinal products and their coverage by the health insurance system should not require any new or detailed assessment when the reference product has already been priced and included in the health insurance system. It is therefore appropriate to lay down shorter time limits for generic medicinal products in those cases.	(12) In its Communication 'Executive Summary of the Pharmaceutical Sector Inquiry Report' the Commission demonstrated that pricing and reimbursement procedures often unnecessarily delay the launch of generic ***or biosimilar medicinal products*** in Union markets. Approving the price of generic ***or biosimilar*** medicinal products and their coverage by the health insurance system should not require any new or detailed assessment when the reference product has already been priced and included in the health insurance system. It is therefore appropriate to lay down shorter time limits for generic ***or biosimilar*** medicinal products in those cases.

Amendment 13

Proposal for a directive
Recital 13

Text proposed by the Commission	*Amendment*
(13) The judicial remedies available in the Member States have played a limited role in ensuring compliance with the time limits due to the often lengthy procedures in national jurisdictions, ***which deter affected companies from initiating legal action.*** Therefore, effective mechanisms are necessary to control and enforce compliance with the time limits for pricing and reimbursement decisions.	(13) The judicial remedies available in the Member States have played a limited role in ensuring compliance with the time limits due to the often lengthy procedures in national jurisdictions. Therefore, effective mechanisms are necessary to ***ensure swift infringement resolution by means of administrative mediation in advance of judicial proceedings, as well as to*** control and enforce compliance with the time limits for pricing and reimbursement decisions. ***To this end, Member States might designate an administrative body,***

which may be an existing one.

Amendment 14

Proposal for a directive
Recital 14

Text proposed by the Commission	*Amendment*
(14) The quality, safety and efficacy of medicinal products, including the bioequivalence of generic medicinal products with the reference product, are ascertained in the framework of marketing authorisation procedures. In the framework of pricing and reimbursement ***procedures***, ***Member States*** should therefore not re-assess the elements on which the marketing authorisation is based, including the quality, safety, efficacy ***or*** bioequivalence of the medicinal product.	(14) The quality, safety and efficacy of medicinal products, including the bioequivalence of generic ***or the biosimilarity of biosimilar*** medicinal products with the reference product, are ascertained in the framework of marketing authorisation procedures. In the framework of pricing and reimbursement ***decisions***, ***the competent authorities responsible for these decisions*** should therefore not re-assess the ***essential*** elements on which the marketing authorisation is based, including the quality, safety, efficacy, bioequivalence ***or biosimilarity*** of the medicinal product. ***Similarly, in the case of orphan drugs, the competent authorities should not re-assess the criteria of the orphan designation. However, competent authorities should have full access to the data used by the authorities responsible for granting the marketing authorisation of a medicinal product as well as the possibility of including or generating additional relevant data for the purpose of assessing a medicinal product in the context of its inclusion in the scope of the public health insurance system.***

Amendment 15

Proposal for a directive
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) The non re-assessment of the elements on which the marketing

	authorisation is based within the framework of pricing and reimbursement procedures should not, however, prevent the competent authorities from requesting, accessing and using data generated during the marketing authorisation process for the purpose of evaluation and HTA. Data sharing between the competent authorities responsible for marketing authorisation and for pricing and reimbursement should be possible at national level if such sharing exists. The competent authorities should also be able to include or generate additional relevant data for evaluation and HTA purposes.

Amendment 16

Proposal for a directive
Recital 15

Text proposed by the Commission	*Amendment*
(15) In accordance with Directive 2001/83/EC, intellectual property rights do not provide a valid ground to refuse, suspend or revoke a marketing authorisation. By the same token, applications, decision-making procedures and decisions to regulate the prices of medicinal products or to determine their coverage by health insurance systems should be considered administrative procedures which, as such, are independent from the enforcement of intellectual property rights. The national authorities in charge of those procedures, when examining an application with respect to a generic medicinal product, should not request information concerning the patent status of the reference medicinal product ***and*** should ***not*** examine the validity of an alleged violation of intellectual property rights should the generic medicinal product be manufactured or placed on the market subsequently to their decision.	(15) In accordance with Directive 2001/83/EC, intellectual property rights do not provide a valid ground to refuse, suspend or revoke a marketing authorisation. By the same token, applications, decision-making procedures and decisions to regulate the prices of medicinal products or to determine their coverage by health insurance systems should be considered administrative procedures which, as such, are independent from the enforcement of intellectual property rights. The national authorities in charge of those procedures, when examining an application with respect to a ***bioequivalent*** generic ***or biosimilar*** medicinal product, should not request information concerning the patent status of the reference medicinal product***, but they*** should ***be allowed to*** examine the validity of an alleged violation of intellectual property rights should the generic ***or biosimilar*** medicinal product be

Consequently, intellectual property issues should neither interfere with nor delay pricing and reimbursement ***procedures*** in the Member States.	manufactured or placed on the market subsequently to their decision. ***That competence should remain with Member States. Without prejudice to the responsibility of Member States to examine information,*** intellectual property issues should neither interfere with nor delay pricing and ***procedures for*** reimbursement ***of generic medicines*** in the Member States.

Justification

Clarification that this procedure refers only to generic medicines.

Amendment 17

Proposal for a directive
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) Member States should ensure the public availability of documents and information in an appropriate publication, in accordance with national practice, which could include electronic and online format. They should also ensure that the information delivered is understandable and supplied in a reasonable quantity. The Commission and the Member States should also examine how to continue to co-operate on the functioning of the EURIPID price information database, which provides EU-wide added value in terms of price transparency.

Amendment 18

Proposal for a directive
Recital 15 b (new)

Text proposed by the Commission	*Amendment*
	(15b) The principle of transparency,

	integrity and independence of the decision-making process within the national competent authorities should be ensured by the public disclosure of the names of experts participating in the bodies responsible for pricing and reimbursement decisions, together with their declarations of interest and the procedural steps leading to pricing and reimbursement decisions.

Amendment 19

Proposal for a directive
Recital 16

Text proposed by the Commission	*Amendment*
(16) Member States have frequently amended their health insurance schemes or adopted new measures falling within the scope of Directive 89/105/EEC. It is therefore necessary to establish information ***mechanisms*** intended***, on the one hand,*** to ensure the consultation of interested stakeholders ***and, on the other hand, to facilitate preventive dialogue with the Commission as regards the application of this Directive***.	(16) Member States have frequently amended their health insurance schemes or adopted new measures falling within the scope of Directive 89/105/EEC. It is therefore necessary to establish ***an*** information ***mechanism*** intended to ensure the consultation of ***all*** interested stakeholders ***including civil society organisations***.

Amendment 20

Proposal for a directive
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that any national, regional or local measure, whether laid down by law, regulation or administrative action, to control the prices of medicinal products for human use or to determine the range of medicinal products covered by public health insurance systems, including the extent and conditions of their coverage, complies with	1. Member States shall ensure that any national, regional or local measure, whether laid down by law, regulation or administrative action, to control the prices of medicinal products for human use or to determine the range of medicinal products covered by public health insurance systems, including the extent and conditions of their coverage, complies with

the requirements of this Directive.	the requirements of this Directive. ***Member States shall ensure that those measures are not duplicated at regional or local level in their respective territories.***

Justification

In certain Member States, healthcare is managed simultaneously at national level and local level. So as to avoid creating unnecessary rises in waiting time and extra red tape, the Directive must ensure that there is no overlap in procedures at national, regional or local level.

Amendment 21

Proposal for a directive
Article 1 – paragraph 2 – first subparagraph – point a

Text proposed by the Commission	*Amendment*
(a) ***voluntary*** contractual agreements concluded between public authorities and the holder of a marketing authorisation ***for a medicinal product*** that have as their object to ***enable*** the effective provision of ***this*** medicine to patients under specific conditions;	(a) contractual agreements concluded ***voluntarily*** between public authorities and the holder of a marketing authorisation, that have as their object to ***include a medicinal product under the scope of a health insurance system while monitoring elements agreed upfront among both parties relating to the effectiveness and/or relative efficacy or the appropriate use of the given medicinal product, and with a view to enabling*** the effective provision of ***that*** medicine to patients under specific conditions ***and during an agreed period of time***;

Justification

Exclusion from the scope of this Directive should be limited to voluntary contractual agreements for which the definition of monitoring and outcome criteria would require additional time for competent authorities and marketing authorisation holders to agree on, with an ultimate goal of enabling the effective provision of this medicine to patients under specific conditions.

Amendment 22

Proposal for a directive
Article 1 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
The provisions of this Directive shall apply to measures intended to determine which medicinal products may be included in contractual agreements or public procurement procedures.	The provisions of this Directive shall apply to measures intended to determine which medicinal products may be included in contractual agreements or public procurement procedures. ***In accordance with Union and national law regarding business confidentiality, basic information regarding medicinal products included in contractual agreements or public procurement procedures, such as the name of the product and the name of the marketing authorisation holder, shall be made publicly available once agreements or procedures are concluded.***

Justification

Minimum transparency and public disclosure requirements should apply to medicinal products covered by public health insurance systems through a particular contractual agreement or a public procurement procedure.

Amendment 23

Proposal for a directive
Article 1 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. This Directive may not call into question a marketing authorisation relating to a medicinal product granted in accordance with the procedure referred to in Article 6 of Directive 2001/83/EC.

Justification

The Directive should govern decision-making procedures in respect of pricing and reimbursement of pharmaceutical products and not redefine processes for granting marketing authorisations. Marketing authorisations are governed by Directive 2001/83/EC, which lists the criteria applicable to the quality, safety and efficacy of a product.

Amendment 24

Proposal for a directive
Article 2 – point 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) "biosimilar medicinal product" means a similar biological medicinal product approved in accordance with Article 10(4) of Directive 2001/83/EC;

Amendment 25

Proposal for a directive
Article 2 – point 5

Text proposed by the Commission	*Amendment*
(5) "health technology assessment" means 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.	(5) "health technology assessment" means an assessment ***which as a minimum includes*** 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,

Justification

Without prejudice to additional assessment methodologies applied by competent authorities at national level, a common definition of health technology assessment (HTA) is necessary to ensure legal certainty and consistency for national competent authorities when applying the provisions set out by this Directive.

Amendment 26

Proposal for a directive
Article 2 – point 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) "voluntary contractual agreement" means 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.

Justification

The scope of the Directive needs to be clarified to be non-ambiguous. Although the term "agreement" implies that the parties freely accepted their contractual obligations, there may be cases where marketing authorisation holders are at least factually forced to enter into an agreement in order to have access to the market. In such cases, the marketing authorisation holder's only other option would be to refrain from concluding the agreement and to accept to be barred from the market. In order to ensure that agreements are not used as a loophole to avoid the applicability of the Directive, a definition of "voluntary contractual agreements" should be included.

Amendment 27

Proposal for a directive
Article 2 – point 5 b (new)

Text proposed by the Commission	*Amendment*
	(5b) "vulnerable groups" means those groups of the population most sensitive to measures determining the extent to which medicinal products are covered by public health insurance systems, such as children, pensioners, the unemployed, those reliant on orphan drugs, the chronically ill.

Amendment 28

Proposal for a directive
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that an application to approve the price of the product can be introduced by the marketing authorisation holder ***at any point in time***. The competent authorities shall provide the applicant with an official acknowledgement of receipt.	2. Member States shall ensure that an application to approve the price of the product can be introduced by the marketing authorisation holder ***once the marketing authorisation of the product has been granted. Member States may also provide the possibility for the applicant of a***

	marketing authorisation to submit such a price approval application once the Committee for Medicinal Products for Human Use established by Regulation (EC) No 726/2004 or the national competent authority has issued a positive opinion on the granting of a marketing authorisation for the medicinal product concerned. The competent authorities shall provide the applicant with an official acknowledgement of receipt ***within 10 days of receipt of the application.***

Amendment 29

Proposal for a directive
Article 3 – paragraph 3

Text proposed by the Commission	*Amendment*
3. 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 ***60*** days of the receipt of an application submitted, in accordance with the requirements laid down in the Member State concerned, by the holder of a marketing authorisation. ***However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days.*** With respect to generic medicinal products, that time limit shall be ***15*** days, provided that the price of the reference medicinal product has been approved by the competent authorities.	3. 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 of the receipt of an application submitted, in accordance with the requirements laid down in the Member State concerned, by the holder of a marketing authorisation. With respect to generic medicinal products, that time limit shall be ***30*** days, provided that the price of 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.***

Amendment 30

Proposal for a directive
Article 3 – paragraph 5

Text proposed by the Commission	*Amendment*
5. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within ***60 days*** of receipt of this additional information. ***However, with respect to medicines for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days.*** With respect to generic medicinal products, that time limit shall be in all events ***15 days***, provided that the price of the reference medicinal product has been approved by the competent authorities. ***Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.***	5. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within ***90 days*** of receipt of this additional information. With respect to generic medicinal products, that time limit shall be in all events ***30 days***, provided that the price of the reference medicinal product has been approved by the competent authorities.

Amendment 31

Proposal for a directive
Article 3 – paragraph 8

Text proposed by the Commission	*Amendment*
8. Member States shall ***publish in an appropriate publication and*** communicate to the Commission the criteria which the competent authorities must take into account when approving the prices of medicinal products.	8. Member States shall communicate to the Commission the criteria which the competent authorities must take into account when approving the prices of medicinal products. ***Those criteria and information about the decision-making bodies at national or regional level shall be made publicly available.***

Amendment 32

Proposal for a directive
Article 3 – paragraph 9

Text proposed by the Commission	*Amendment*
9. If the competent authorities decide to reduce the price of a specific named medicinal product on their own initiative, the decision shall contain a statement of reasons based on objective and verifiable criteria***, including any evaluation, expert opinion or recommendation on which it is based***. The decision shall be communicated to the holder of the marketing authorisation, who shall be informed of all remedies available, including judicial remedies, and of the time limits for applying for such remedies.	9. If the competent authorities decide to reduce the price of a specific named medicinal product on their own initiative, the decision shall contain a statement of reasons based on objective and verifiable criteria. The decision shall be communicated to the holder of the marketing authorisation, who shall be informed of all remedies available, including judicial remedies, and of the time limits for applying for such remedies. ***The decision and summary of the statement of reasons shall be made publicly available without delay.***

Amendment 33

Proposal for a directive
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that an application to increase the price of the product can be submitted by the marketing authorisation holder ***at any point in time***. The competent authorities shall provide the applicant with an official acknowledgement of receipt.	2. Member States shall ensure that an application to increase the price of the product can be submitted by the marketing authorisation holder ***in accordance with national law***. The competent authorities shall provide the applicant with an official acknowledgement of receipt ***within 10 days of receipt of the application.***

Amendment 34

Proposal for a directive
Article 4 – paragraph 3 – first subparagraph

Text proposed by the Commission	*Amendment*
3. Member States shall ensure that a decision ***on*** an application submitted in accordance with the requirements laid down in the Member State concerned, by a marketing authorisation holder to increase	3. Member States shall ensure that a decision ***to approve or reject*** an application submitted in accordance with the requirements laid down in the Member State concerned, by a marketing

the price of a medicinal product is adopted and communicated to the applicant within ***60*** days of its receipt.	authorisation holder to increase the price of a medicinal product is adopted and communicated to the applicant within ***90*** days of its receipt.

Amendment 35

Proposal for a directive
Article 4 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
The applicant shall furnish the competent authorities with adequate information, including details of those events intervening since the price of the medicinal product was last determined which in his opinion justify the price increase requested. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within ***60 days*** of receipt of this additional information. ***Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.***	The applicant shall furnish the competent authorities with adequate information, including details of those events intervening since the price of the medicinal product was last determined which in his opinion justify the price increase requested. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within ***90 days*** of receipt of this additional information.

Amendment 36

Proposal for a directive
Article 4 – paragraph 5

Text proposed by the Commission	*Amendment*
5. In the absence of a decision within the relevant time limit referred to in paragraphs 3 and 4, the applicant shall be entitled to apply the price increase requested.	***deleted***

Justification

This provision goes well beyond the aim of the proposal, namely that of ensuring the prompt

availability of new medicinal products, and is neither proportionate nor consistent with the subsidiarity principle. What is more, such a measure could undermine even further the already shaky budgetary situation of public health insurance systems.

Amendment 37

Proposal for a directive
Article 5 – paragraph 1

Text proposed by the Commission	*Amendment*
1. In the event of a price freeze or price reduction imposed on all medicinal products or on certain categories of medicinal products by the competent authorities of a Member State, that Member State shall publish a statement of reasons for its decision based on objective and verifiable criteria, including, if applicable, a justification of the categories of products subject to the price freeze or price reduction.	1. In the event of a price freeze or price reduction imposed on all medicinal products or on certain categories of medicinal products by the competent authorities of a Member State, that Member State shall publish a statement of reasons for its decision based on objective and verifiable criteria, including, if applicable, a justification of the categories of products subject to the price freeze or price reduction. ***Member States shall carry out an annual review.***

Amendment 38

Proposal for a directive
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Marketing authorisation holders may apply for a derogation from a price freeze or price reduction if this is justified by particular reasons. The application shall contain an adequate statement of reasons. Member States shall ensure that applications for a derogation can be introduced by the marketing authorisation holder at any point in time. The competent authorities shall provide the applicant with an official acknowledgement of receipt.	2. Marketing authorisation holders may apply for a derogation from a price freeze or price reduction if this is justified by particular reasons. The application shall contain an adequate statement of reasons. Member States shall ensure that applications for a derogation can be introduced by the marketing authorisation holder at any point in time. The competent authorities shall provide the applicant with an official acknowledgement of receipt ***within 10 days of receipt of the application.***

Amendment 39

Proposal for a directive
Article 5 – paragraph 3 – first subparagraph

Text proposed by the Commission	*Amendment*
3. Member States shall ensure that a reasoned decision on an application referred to in paragraph 2 is adopted and communicated to the applicant within ***60*** days of the receipt of the application. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within ***60*** days of receipt of this additional information. If the derogation is granted, the competent authorities shall forthwith publish an announcement of the price increase allowed.	3. Member States shall ensure that a reasoned decision on an application referred to in paragraph 2 is adopted and communicated to the applicant within ***90*** days of the receipt of the application. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within ***90*** days of receipt of this additional information. If the derogation is granted, the competent authorities shall forthwith publish an announcement of the price increase allowed.

Amendment 40

Proposal for a directive
Article 7 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that an application to include a medicinal product in the scope of the public health insurance system can be introduced by the marketing authorisation holder ***at any point in time***. ***If the public health insurance system comprises several schemes or categories of coverage, the marketing authorisation holder shall be entitled to apply for the inclusion of its product in the scheme or category of its choice.*** The competent authorities shall provide the applicant with an official acknowledgement of receipt.	2. Member States shall ensure that an application to include a medicinal product in the scope of the public health insurance system can be introduced by the marketing authorisation holder ***once the marketing authorisation of the product has been granted. Member States may also provide the possibility for the applicant of a marketing authorisation to submit such an inclusion application once the Committee for Medicinal Products for Human Use established by Regulation (EC) No 726/2004 or the national competent authority has issued a positive opinion on the granting of the marketing authorisation for the medicinal product***

concerned. The competent authorities shall provide the applicant with an official acknowledgement of receipt ***within 10 days of receipt of the application.***

Amendment 41

Proposal for a directive
Article 7 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within ***60*** days of its receipt. ***However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days.*** With respect to generic medicinal products, that time limit shall be ***15*** days, provided that the reference medicinal product has already been included in the public health insurance system.	4. Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is 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. ***Where appropriate, Member States shall use health technology assessment as part of their decision-making process on the inclusion of medicinal products in the scope of the public health insurance system.***

Amendment 42

Proposal for a directive
Article 7 – paragraph 5

Text proposed by the Commission	*Amendment*
5. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within ***60*** days of receipt of this	5. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within ***90*** days of receipt of this

additional information. ***However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days.*** With respect to generic medicinal products, that time limit shall be ***15*** days, provided that the reference medicinal product has already been included in the public health insurance system. ***Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.***	additional information. 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.

Amendment 43

Proposal for a directive
Article 7 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed ***120*** days. ***However, with respect to the medicinal products for which Member States use health technology assessment as part of their decision-making process, the time limit shall not exceed 180 days.*** With respect to generic medicinal products, that time limit shall not exceed ***30*** days, provided that the reference medicinal product has already been included in the public health insurance system. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5).	6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 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. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5).

Amendment 44

Proposal for a directive
Article 7 – paragraph 7 – subparagraph 2 and 2 a (new)

Text proposed by the Commission	*Amendment*
The decisions referred to in this paragraph shall also include any evaluation, expert opinion or recommendation on which they are based. The applicant shall be informed of all remedies available, ***including judicial remedies, and the remedies procedure set out Article 8,*** of the time limits ***for applying for such remedies.***	The decisions referred to in this paragraph shall also include any evaluation, expert opinion or recommendation on which they are based. The applicant shall be informed of all ***mediation and*** remedies ***procedures*** available ***and*** of the time limits ***applicable to those procedures.*** ***The criteria governing the decisions referred to in the first subparagraph shall include assessments of unmet medical needs and of the clinical and societal benefits, innovation and the protection of the most vulnerable groups of the population.***

Amendment 45

Proposal for a directive
Article 7 – paragraph 8

Text proposed by the Commission	*Amendment*
8. Member States shall ***publish in an appropriate publication and*** communicate to the Commission 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.	8. Member States shall communicate to the Commission 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. ***Those criteria and information about the decision-making bodies at national or regional level shall be made publicly available.***

Amendment 46

Proposal for a directive
Article 8

Text proposed by the Commission	*Amendment*
Remedies ***procedure in case of non-compliance with the time limits related to the inclusion of medicinal products in***	***Mediation and*** remedies ***procedures***

health insurance systems

1. Member States shall ensure that effective and rapid remedies are available to the applicant in case of non-compliance with the time limits set in Article 7.	1. Member States shall 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 Article 7, ***and in accordance with their national law.***
2***.*** For the purposes of the remedies ***procedure*** Member States ***shall*** designate ***a*** body and entrust it with the powers to***:***	2. For the purposes of the ***mediation or*** remedies ***procedures*** Member States ***may*** designate ***an administrative*** body and entrust it with the powers to take, at the earliest opportunity and by way of interlocutory procedures, interim measures with the aim of correcting the alleged infringement or preventing further damage to the interests concerned.
(a) take, at the earliest opportunity and by way of interlocutory procedures, interim measures with the aim of correcting the alleged infringement or preventing further damage to the interests concerned;	
(b) award damages to the applicant in case of non-compliance with time limits set in Article 7 where damages are claimed, unless the competent authority may prove that the delay is not imputable to it;	
(c) impose a penalty payment, calculated by day of delay.	
For the purposes of point (c), the penalty payment shall be calculated depending on the seriousness of the infringement, its duration, *and* ***the need to ensure that the penalty itself is a deterrent to further infringements.***	
Member States may provide that the body referred to in the first subparagraph may take into account the probable consequences of potential measures taken under the present paragraph for all interests likely to be harmed, as well as the public interest, and may decide not to take such measures when their negative	

consequences could exceed their benefits.

3. A decision not to grant interim measure shall not prejudice any other claim of the applicant seeking such measures.

4. Member States shall ensure that decisions taken by bodies responsible for remedies procedures can be effectively enforced.

5. The body referred to in paragraph 2 shall be independent of the competent authorities in charge of controlling the prices of medicinal products for human use or in charge of determining the range of medicinal products covered by health insurance systems.

6. The body referred to in paragraph 2 shall state reasons for its decision. Furthermore, where that body is not judicial in character, provision must be made to guarantee procedures whereby any allegedly illegal measure taken by the independent body or any alleged defect in the exercise of powers conferred on it can be subject to judicial review or review by another body which is a court or tribunal within the meaning of Article 267 of the Treaty on the Functioning of the European Union and independent of both the competent authority and the body referred to in paragraph 2.

The members of the body referred to in paragraph 2 shall be appointed and leave office under the same conditions as members of the judiciary as regards the authority responsible for their appointment, their period of office, and their removal. At least the president of that body shall have the same legal and professional qualifications as members of the judiciary. That body shall take its decisions following a procedure in which both sides are heard, and these decisions shall, by means determined by each Member State, be legally binding.

Amendment 47

Proposal for a directive
Article 9 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Any decision to exclude a medicinal product from the scope of the public health insurance system, or to modify the extent or the conditions of coverage of the product concerned, shall contain a statement of reasons based on objective and verifiable criteria. Such decisions shall include any evaluation, expert opinion or recommendation on which they are based. The applicant shall be informed of all remedies available, including judicial remedies, and of the time limits for applying for such remedies.	1. Any decision to exclude a medicinal product from the scope of the public health insurance system, or to modify the extent or the conditions of coverage of the product concerned, shall contain a statement of reasons based on objective and verifiable criteria. Such decisions shall include ***assessments of unmet medical needs, the clinical impact and social costs, the protection of the most vulnerable groups of the population and*** any evaluation, expert opinion or recommendation on which they are based. The applicant shall be informed of all remedies available, including judicial remedies, and of the time limits for applying for such remedies.

Amendment 48

Proposal for a directive
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Any decision to exclude a category of medicinal products from the scope of the public health insurance system, or to modify the extent or the conditions of coverage of the category concerned, shall contain a statement of reasons based on objective and verifiable criteria ***and be published in an appropriate publication***.	2. Any decision to exclude a category of medicinal products from the scope of the public health insurance system, or to modify the extent or the conditions of coverage of the category concerned, shall contain a statement of reasons based on objective and verifiable criteria.

Amendment 49

Proposal for a directive
Article 9 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. 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.

Amendment 50

Proposal for a directive
Article 11 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Paragraphs 2, 3 and 4 shall apply where a Member State adopts measures intended to control or promote the prescription of specific named medicinal products.	1. Paragraphs 2, 3 and 4 shall apply where a Member State adopts measures intended to control or promote the prescription of specific named medicinal products ***or of a category of medicinal products.***

Justification

Transparency should apply also to measures intended to promote the prescription of categories of medicinal products, not only to the prescription of specific named ones.

Amendment 51

Proposal for a directive
Article 11 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Measures referred to in paragraph 1, including any evaluation, expert opinion or recommendation on which they are based, shall be published in an appropriate publication.	3. Measures referred to in paragraph 1, including any evaluation, expert opinion or recommendation on which they are based, shall be published in an appropriate publication ***and made available to the public***.

Amendment 52

Proposal for a directive
Article 12 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. With respect to generic medicinal products, a certain period for submitting an application and a certain period for the effective entry into force of the corresponding decision shall, however, not be included in the time limits, provided that neither of those periods exceeds one calendar month each and that those periods are explicitly regulated by national legislation or administrative guidelines.

Amendment 53

Proposal for a directive
Article 12 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. If a decision-making process involving negotiations between the marketing authorisation holder and the competent authority is required, the time limits laid down in Articles 3, 4, 5 and 7 shall be suspended from the time the competent authority communicates its proposals to the marketing authorisation holder until it receives the marketing authorisation holder's response to its proposals.

Amendment 54

Proposal for a directive
Article 13

Text proposed by the Commission	*Amendment*
Additional proof of quality, safety, efficacy or bioequivalence	***Non- reassessment of essential marketing authorisation elements***

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 of the medicinal product.	***1.*** In the framework of pricing and reimbursement decisions, ***the competent authorities*** shall not re-assess the ***essential*** elements on which the marketing authorisation is based ***such as quality, safety, efficacy, bioequivalence, biosimilarity or criteria for orphan designation***. ***1a. Paragraph 1 shall be without prejudice to the right of the competent authorities to request and have full access to data generated during the marketing authorisation process for the purpose of evaluation and health technology assessment, so that they can assess the relative efficacy as well as the short- and long-term effectiveness, where appropriate, of a medicinal product in the context of its inclusion in the scope of the public health insurance system.*** ***1b. The competent authorities shall also be able to include or generate additional relevant data for the purpose of assessing medicinal products.***

Amendment 55

Proposal for a directive
Article 15

Text proposed by the Commission	*Amendment*
Where a Member State intends to adopt or amend any measure falling within the scope of this Directive, it shall give interested parties the opportunity to comment on the draft measure within a reasonable period. The competent authorities shall publish the rules applicable to consultations. The results of consultations shall be made publicly available, with the exception of confidential information in accordance with Union and national legislation regarding business confidentiality.	Where a Member State intends to adopt or amend any ***legislative*** measure falling within the scope of this Directive, it shall give interested parties***, including civil society organisations such as patient and consumer groups,*** the opportunity to comment on the draft measure within a reasonable period. The competent authorities shall publish the rules applicable to consultations. The results of consultations shall be made publicly available, with the exception of confidential information in accordance with Union and national legislation

regarding business confidentiality.

Justification

Civil society organisations, and notably patients and consumers groups should be involved in any consultation process prior to the adoption or amendment of a legislative measure falling within the scope of this Directive.

Amendment 56

Proposal for a directive
Article 15 a (new)

Text proposed by the Commission	*Amendment*
	Article 15a
	Transparency of decision-making bodies and prices
	1. 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.
	2. Paragraph 1 shall also apply to the administrative body referred to in Article 8(2).
	3. The competent authorities shall publish in an appropriate publication 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.

Amendment 57

Proposal for a directive
Article 16

Text proposed by the Commission	*Amendment*
Article 16	***deleted***
Notification of draft national measures	
1. Where Member States intend to adopt or amend any measure falling within the scope of this Directive, they shall immediately communicate to the Commission the draft measure envisaged, together with the reasoning on which the measure is based.	
2. Where appropriate, Member States shall simultaneously communicate the texts of the basic legislative or regulatory provisions principally and directly concerned, if knowledge of such texts is necessary to assess the implications of the measure proposed.	
3. Member States shall communicate the draft measure referred to in paragraph 1 again if they make changes to the draft that have the effect of significantly altering its scope or substance, or shortening the timetable originally envisaged for implementation.	
4. The Commission may send its observations to the Member State which has communicated the draft measure within three months.	
The observations of the Commission shall be taken into account as far as possible by the Member State concerned, in particular if the observations indicate that the draft measure may be incompatible with Union law.	
5. When the Member State concerned definitively adopts the draft measure, it shall communicate the final text to the Commission without delay. If observations have been made by the	

Commission in accordance with paragraph 4, this communication shall be accompanied by a report on the actions taken in response to the observations of the Commission.

Justification

The measures and provisions foreseen in Article 16 do not appear as proportionate to the objectives and means of this Directive. Transposition provisions as set out in Art 18 (2) should already provide the European Commission with sufficient information to monitor the legislative implementation of this Directive.

Amendment 58

Proposal for a directive
Article 17 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. By 31 January of […] [*insert a date - the year following the date referred to in the first subparagraph of Article 18(1)*], and by 31 January ***and 1 July*** of every year thereafter, Member States shall communicate to the Commission and publish in an appropriate publication a detailed report providing the following information:	1. By 31 January of […] [*insert a date - the year following the date referred to in the first subparagraph of Article 18(1)*], and by 31 January of every year thereafter, Member States shall communicate to the Commission and publish in an appropriate publication a detailed report providing the following information:

Justification

A yearly report collecting the requested data and information would be more appropriate in order to allow an accurate overview and relevant trends analysis on the implementation of time limits.

Amendment 59

Proposal for a directive
Article 17 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission shall publish every ***six months*** a report on the information submitted by Member States according to	2. The Commission shall publish every ***year*** a report on the information submitted by Member States according to paragraph

paragraph 1. 1.

Justification

A yearly report collecting the requested data and information would be more appropriate in order to allow an accurate overview and relevant trends analysis on the implementation of time limits.

EXPLANATORY STATEMENT

The rapporteur welcomes the Commission's proposal and its main provisions, based on an accurate analysis of the current conditions of the pharmaceutical markets as well as of the current context and constraints, notably financial, under which competent authorities have to decide on the pricing and reimbursement of medicinal products. The rapporteur shares the view that the overall objective of this proposal, should be to update the existing legislative framework in order to clarify the procedural obligations incumbent to Member States and to ensure the good functioning of the Single Market and the effectiveness of the internal market legislation, both in avoiding delays in pricing and reimbursement decisions, and in preventing barriers to pharmaceutical trade.

While respecting the exclusive competence of Member States in deciding on the pricing and reimbursement of medicinal products, minimum procedural requirements should also ensure legal certainty and transparency for national competent authorities, promote the production of medicinal products and the entry on the market of generic medicinal products, and encourage research and development of new medicinal products, with the ultimate goal of facilitating the access to affordable treatment for all patients in Europe.

The rapporteur fully supports the approach proposed by the European Commission regarding dual and differentiated timelines for the pricing and reimbursement of medicinal products, providing an extended timeline for which Member States using health technology assessment as part of their decision-making process. Directive 2011/24/EU on the application of patients' rights in cross-border healthcare already set out the basis for a European cooperation on health technology assessment, which should ultimately also reduce existing delays. It is however essential to include a common definition of health technology assessment (HTA), without prejudice to additional assessment methodologies applied at national level, in order to ensure legal certainty and consistency for competent authorities when applying the provisions set out by this Directive. The incentive given to the application of health technology assessment should inform the formulation of safe and effective health policies that are patient focused and seek to achieve best value.

As a priority, the rapporteur would like to insist on the need to strengthen the provisions related to the transparency of the decision making-process and decisions taken, which represents a growing societal demand, in particular when it comes to the pricing and reimbursement of pharmaceutical products. The rapporteur therefore suggests a series of additional measures, notably with the obligation for competent authorities to disclose the names and the declarations of interest of experts members of their decision-making bodies. Such provisions, as well as an increased public availability of documents and information, should aim at reinforcing the transparency, integrity and independence of the decisions taken, and should ultimately reinforce the trust and confidence in responsible public authorities at national level.

Key provisions have been proposed by the European Commission, notably in order to translate through this updated legislative framework the conclusion of the 2009 pharmaceutical sector enquiry with regards to unnecessary delays for the launch of generic medicines in Union markets. Such provisions, and in particular the non-reassessment of the

elements on which the marketing authorisation is based and the non interference of intellectual property rights shall be maintained, but shall also take into account new developments in the pharmaceutical market such as the growing number of biosimilar medicinal products now being authorised. While shortened time limits for generic medicinal products are fully justified and would be beneficial to both public health insurance systems and patients, they should however take into account and allow national competent authorities considerations and specific measures when deciding on pricing and reimbursement of generic medicinal products.

In line with the proposed extension of time limits for generic medicinal products, the rapporteur indeed believes that the Commission's proposal should be amended in order to guarantee a practical and effective implementation of the provisions foreseen, and provide national competent authorities with the necessary level of flexibility and autonomy to comply with the requirement of this Directive. In this regard, the remedies procedure in case of non-compliance with the time limits related to the inclusion of medicinal products in health insurance systems should remain administrative and, in case of unjustified delays, be referred to the relevant administrative or judicial body in accordance with national law.

Proportionality is also essential to ensure a practicable and reasonable implementation of the measures foreseen by this Directive. The rapporteur believes that the provisions of Article 16 on the notification of draft national measure do not meet this principle and go beyond the objectives as set out by the Commission. Furthermore, transposition provisions in Art 18 (2) should already provide with sufficient information to monitor the good legislative implementation of this Directive.

Acknowledgement and legislative footprint

The rapporteur would like to thank the European Commission and the Cyprus Presidency of the Council of the European Union for their complete and fruitful cooperation during the drafting process of this report.

The rapporteur would also like to thank for their valuable contributions the following non-institutional stakeholders who have communicated their positions and views on the proposed Directive: The European Patients Forum (EPF), the European Organisation for Rare Diseases (EURORODIS), the European Federation of Pharmaceutical Industry Associations (EFPIA), the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), the European Generic Medicines Association (EGA), GlaxoSmithKline, Celgene, the European Social Insurers Platform (ESIP), the Représentation des institutions françaises de sécurité sociale auprès de l'UE, The Alliance for cost-efficiency in healthcare (COSTEFF), Prescrire and Health Action International - Europe.

OPINION OF THE COMMITTEE ON LEGAL AFFAIRS ON THE LEGAL BASIS

Mr Matthias Groote
Chair
Committee on the Environment, Public Health and Food Safety
BRUSSELS

Subject: Opinion on the legal basis for 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 (COM(2012)0084 – C7-0056/2012 – 2012/0035(COD))

Dear Mr Chair,

By letter of 8 January 2013, you asked the Committee on Legal Affairs, pursuant to Rule 37 of the Rules of Procedure, to give its opinion on the appropriateness of adding Article 168 to Article 114 TFEU as the legal basis for 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.

The proposal (COM(2012)0084) was presented by the Commission on the basis of Article 114 TFEU. Parliament's Legal Service has stated in a note dated 15 January 2013 that the appropriate legal basis for the proposed Directive is Article 114 TFEU alone.

Background

1. The proposal

The proposal is aimed at replacing the existing Directive 89/105/EEC[1] by adapting it to the current pharmaceutical environment while preserving its system in general. As, pursuant to Article 168(7) TFEU, Member States are responsible for the organisation of their healthcare system and for the delivery of health services and medical care, each Member State can take measures to manage the consumption of medicines, regulate their prices or establish the conditions of their public funding. Directive 89/105/EEC codifies the minimum requirements in order to ensure that those national measures, in particular those regulating the pricing and reimbursement of medicines, do not contravene the principle of the free movement of goods. To this end, Directive 89/105/EEC lays down a number of procedural requirements to ensure

[1] 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 (OJ L 40, 11.2.1989, p. 8).

the transparency of pricing and reimbursement measures adopted by Member States, including specific time limits for the relevant decisions or an obligation for competent national authorities to provide a statement of reasons for each of their decisions and also to provide appropriate legal remedies to the applicant companies.

The present proposal maintains the core principles of the existing Directive but suggests the following main adaptations: clarification of the scope and of several key provisions; adaptation of the time limits for pricing and reimbursement decisions; clarification of the relationship of pricing and reimbursement procedures with intellectual property rights and the marketing authorisation process; setting up of a number of instruments to facilitate dialogue and the implementation of the Directive and to ensure its effective enforcement.

2. The report adopted in ENVI

The report adopted in ENVI appears to maintain the broad lines of the Commission proposal[1], but introduces a number of changes. The main changes are the following:

– Some adjustments and clarifications have been made to the scope (AMs 21, 22, 26).

– The relationship between pricing decisions and marketing authorisation has been further clarified (AMs 23, 28, 40, 54).

– Some adjustments and additions have been made to the provisions on time limits proposed by the Commission (AMs 30, 35, 41, 42, 43, 52, 53).

– Additional requirements ensuring further transparency have been introduced, e.g. public availability of information and documentation (AMs 31, 32, 45, 49, 51, 56), introduction of time limits for providing acknowledgement of receipt (AMs 33, 38)

– Some decision criteria have been explicitly specified (AMs 41, 44, 47).

– A mediation procedure has been introduced and changes have been made to the remedy procedure (AM 46).

– Article 16 on the notification of draft national measures has been deleted (AM 57).

3. The legal bases in question

a. Legal basis of the proposal

The proposal is based on Article 114 TFEU, which reads as follows:

"Article 114

1. Save where otherwise provided in the Treaties, the following provisions shall apply for the achievement of the objectives set out in Article 26. The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

2. [...]

3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.

[1] See also the explanatory memorandum to the report, p. 40.

Within their respective powers, the European Parliament and the Council will also seek to achieve this objective."

Article 26 TFEU, which is referred to in Article 114 TFEU, reads:

"1. The Union shall adopt measures with the aim of establishing or ensuring the functioning of the internal market, in accordance with the relevant provisions of the Treaties.

2. The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaties."

b. Proposed change of the legal basis

ENVI has requested the opinion of the Legal Affairs Committee on the appropriateness of adding Article 168 TFEU to Article 114 TFEU, given that an amendment (AM 1) adding Article 168 TFEU to the legal basis was adopted in ENVI.

Article 168 TFEU reads as follows:

"1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.

The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

[...]

4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) measures setting high standards of quality and safety for medicinal products and devices

for medical use.

5. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.

[...]

7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood."

Analysis

Certain principles emerge from the case law of the Court as regards the choice of legal basis. First, in view of the consequences of the legal basis in terms of substantive competence and procedure, the choice of the correct legal basis is of constitutional importance[1]. Secondly, under Article 13(2) TEU, each institution is to act within the limits of the powers conferred upon it by the Treaty[2]. Thirdly, according to the case-law of the Court of Justice, "the choice of legal basis for a Community measure must rest on objective factors amenable to judicial review, including in particular the aim and the content of the measure"[3]. Finally, as regards multiple legal bases, if examination of a EU measure reveals that it pursues a twofold purpose or that it has a twofold component and if one of those is identifiable as the main or predominant purpose or component, whereas the other is merely incidental, the act must be based on a single legal basis, namely that required by the main or predominant purpose or component[4]. On the other hand, where a measure has several contemporaneous objectives or components which are indissolubly linked with each other without one being secondary and indirect in respect of the others, the measure must be based on the various relevant Treaty provisions[5].

1. Article 114 TFEU

[1] Opinion 2/00 *Carthagna Protocol* [2001] E.C.R. I-9713, para. 5; Case C-370/07 *Commission v Council* [2009] E.C.R. I-8917, paras 46-49; Opinion 1/08, *General Agreement on Trade in Services* [2009] ECR I-11129, para. 110.
[2] Case C-403/05 *Parliament v Commission* [2007] E.C.R. I-9045, para. 49, and the case-law cited therein.
[3] See most recently Case C-411/06 *Commission v Parliament and Council* [2009] E.C.R. I-7585.
[4] Case C-42/97 *Parliament v Council* [1999] E.C.R. I-868, paras 39-40; Case-C 36/98 *Spain v Council* [2001] E.C.R. I-779, para. 59; Case C-211/01 Commission v Council [2003] E.C.R. I-8913, para. 39.
[5] Case C-165/87 *Commission v Council* [1988] E.C.R. 5545, para. 11; Case C-178/03 *Commission v. European Parliament and Council* [2006] E.C.R. I-107, paras. 43-56.

Article 114 TFEU provides the legal basis for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and the functioning of the internal market. In the judgment by which the Court of Justice annulled the tobacco advertising directive[1], it held that the then Article 100a EC (now Article 114 TFEU) does not "vest in the Community legislature a general power to regulate the internal market"[2]. It further held that "a measure adopted on the basis of Article 100a of the Treaty must genuinely have as its object the improvement of the conditions for the establishment and the functioning of the internal market"[3].

When explaining its choice of Article 114 TFEU as legal basis, the Commission refers to the main objective of Directive 89/105/EEC which "is to facilitate the functioning of the internal market for medicinal products"[4]. Directive 89/105/EEC is based on Article 100a of the Treaty establishing the European Economic Community (now Article 114 TFEU). Recital 5 of the now proposed Directive explains that "disparities in national measures may hinder or distort intra-Union trade in medicinal products and distort competition, thereby directly affecting the functioning of the internal market in medicinal products". Recital 6 expands on this by stating that "in order to reduce the effects of the disparities on the internal market, national measures should comply with minimum procedural requirements [...]. However, those requirements [...] should not affect national policies on price setting and on the determination of social security schemes, except as far as it is necessary to attain transparency within the meaning of this Directive and to ensure the functioning of the internal market." The Commission further explains that, in order to achieve this aim, the proposal is drafted to apply to "all medicinal products for human use" (Recital 7) and to "all types of measures devised by Member States and susceptible to impact the internal market" (Recital 8).

The Commission has mainly proposed procedural provisions to ensure the transparency of Member States' measures, with the objective of improving the functioning of the internal market through verifiable and swift decision-making on prices and reimbursement within Member States. The proposed measures can therefore be based on Article 114 TFEU.

2. Article 168 TFEU

The question is, now, whether there is room for the addition of Article 168 TFEU to the legal basis. Article 168 TFEU relates to public health.

The ENVI amendment which adds Article 168 TFEU to the legal basis justifies this as follows: "This proposal does not relate to the free movement of just any type of goods, but deals with the free movement of medicinal products and the pricing thereof, and the latter 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."

Article 168(1) TFEU lays down the general objective that the Union should ensure a "high level of human health protection"; Union action is presented as complementing national policies and as directed towards improving public health, preventing physical and mental

[1] Case C-376/98 *Germany v European Parliament and Council* [2000] E.C.R. I-8419.
[2] Case C-376/98 *Germany v European Parliament and Council* [2000] E.C.R. I-8419, para. 83.
[3] Case C-376/98 *Germany v European Parliament and Council* [2000] E.C.R. I-8419, para. 84.
[4] Explanatory memorandum, p. 5.

illness and diseases, and obviating sources of danger to physical and mental health. Whereas paragraphs 2 and 3 of Article 168 deal with cooperation and coordination between Member States and with third countries, paragraphs 4 and 5 provide for specific measures to be adopted by the European Parliament and Council under the ordinary legislative procedure, i.e. harmonisation measures in order to meet common safety concerns (Article 168(4) TFEU) and "incentive measures designed to protect and improve human health" (Article 168(5) TFEU). Article 168(7) TFEU states that the Union must fully respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care.

It is recalled that public health is included in Article 6(a) TFEU among the areas where the Union has competence only to carry out actions to support, coordinate or supplement the actions of the Member States; however, "common safety concerns in public health matters" are, as far as the aspects defined by the TFEU are concerned, included within the Union's shared competences (Article 4(2)(k) TFEU).

The proposal under examination does not put forward any specific measures which could be identified as falling under Article 168(4) or (5) TFEU. On the contrary, it refrains from harmonising national pricing and reimbursement measures. It is thus designed to respect Member States' responsibility for health policy under Article 168(7) TFEU, while restating the framework for Member States' measures according to the settled case law of the Court[1], i.e. that Member States' measures in this area must comply with Union law, in particular the provisions of the Treaty on the freedoms of movement which prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of those freedoms in the health care sector.

As stated above, the objective of the proposal is to eliminate obstacles to the functioning of the internal market and to improve its functioning. Given that a dual legal base is only admitted by the Court in situations where two separate, equivalent objectives are identifiable within a given piece of legislation, there does not appear to be any reason for adding Article 168 TFEU to Article 114 TFEU as the legal basis in this case. It is, however, not excluded, that regard may also be had – in the context of the proposed internal market legislation – to the protection of public health: Article 168(1) TFEU subjects all Union policies and activities to ensuring a high level of protection of human health. This is further confirmed by Article 114(3) TFEU, which contains a commitment for the Commission, when it proposes measures concerning, inter alia, health, to take as its base "a high level of protection, taking account of any new development based on scientific facts".

Finally, the amendments to the Commission proposal as adopted in ENVI do not require any addition of Article 168 TFEU: the approach underlying the Commission proposal has not been changed, and no specific health policy dimension has been added to the text. In particular, the mere specification of some applicable assessment criteria (AM 41, 44, 47) could not be seen as adding a health policy objective.

In the final analysis, it is therefore considered that it is unnecessary for Article 168 TFEU to

[1] Case C-372/04 *Watts* [2006], E.C.R I-4325, paras 92 and 146; Case C-531/06 *Commission* v *Italy* [2009] E. C.R. I-4103, paras 35 and 36.

be included in a citation as forming part of the legal basis.

Recommendation of the Committee on Legal Affairs

The committee considered the above question at its meeting of 22 January 2013. At this meeting, it accordingly unanimously decided[1] to recommend that the appropriate legal basis for 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 is Article 114 TFEU alone.

Yours sincerely,

Klaus-Heiner Lehne

[1] The following were present for the final vote: Raffaele Baldassarre (Vice-Chair), Luigi Berlinguer, Sebastian Valentin Bodu (Vice-Chair), Piotr Borys, Françoise Castex (Vice-Chair), Christian Engström, Giuseppe Gargani, Lidia Joanna Geringer de Oedenberg, Sajjad Karim, Vytautas Landsbergis, Eva Lichtenberger, Antonio Masip Hidalgo, Jiří Maštálka, Evelyn Regner (Vice-Chair), Dagmar Roth-Behrendt, Francesco Enrico Speroni (rapporteur), Dimitar Stoyanov, József Szájer, Rebecca Taylor, Axel Voss, Rainer Wieland, Cecilia Wikström, Tadeusz Zwiefka.

9.11.2012

OPINION OF THE COMMITTEE ON THE INTERNAL MARKET AND CONSUMER PROTECTION

for the Committee on the Environment, Public Health and Food Safety

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
(COM(2012)0084 – C7-0056/2012 – 2012/0035(COD))

Rapporteur: Cristian Silviu Buşoi

AMENDMENTS

The Committee on the Internal Market and Consumer Protection calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a directive
Citation 1

Text proposed by the Commission	*Amendment*
Having regard to the Treaty on the Functioning of the European Union, and in particular ***Article*** 114 thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular ***Articles*** 114 ***and 168*** thereof,

Justification

This proposal does not relate to the free movement of just any type of goods, but deals with the free movement of medicinal products and the pricing thereof, and the latter 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.

Amendment 2

Proposal for a directive
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4 a) Ensuring patients' access to medicinal products throughout the Union and effective free movement of goods requires that Member States make a reasonable use of external reference pricing, namely by referring to Member States with a comparable income level. The unconditional use of external reference pricing has been proven to reduce the availability of medicinal products by encouraging shortages in low-price Member States.

Justification

Member States should be encouraged to adopt a reasonable approach to the use of external reference pricing by including in their referencing system Member States with a comparable purchasing power. Otherwise producers would be reluctant at putting their products on the market of Member States where prices are lower, just to avoid a downward pressure on prices across the EU as a whole.

Amendment 3

Proposal for a directive
Recital 5

Text proposed by the Commission	*Amendment*
(5) Disparities in national measures may hinder or distort intra-Union trade in medicinal products ***and distort competition***, thereby directly affecting the functioning of the internal market in	(5) Disparities in national measures may hinder or distort intra-Union trade in medicinal products, thereby directly affecting the functioning of the internal

medicinal products.	market in medicinal products.

Amendment 4

Proposal for a directive
Recital 6

Text proposed by the Commission	*Amendment*
(6) In order to reduce the effects of the disparities on the internal market, national measures should comply with minimum procedural requirements enabling the parties concerned to verify that those measures do not constitute quantitative restrictions on imports or exports or measures having equivalent effect thereto. However, those requirements should not affect the policies of those Member States which rely primarily upon free competition to determine the price of medicinal products. They also should not affect national policies on price setting and on the determination of social security schemes, except as far as it is necessary to attain transparency within the meaning of this Directive and to ensure the functioning of the internal market.	(6) In order to reduce the effects of the disparities on the internal market, national measures should comply with minimum procedural requirements enabling the parties concerned to verify that those measures do not constitute quantitative restrictions on imports or exports or measures having equivalent effect thereto. ***Those requirements are also intended to ensure more predictability, transparency, fairness and legal certainty to producers of pharmaceutical products, to contribute to encouraging research and development and the placing on the market of innovative medicinal products to the benefit of patients and to increase patient accessibility to medicinal products across the board in general.*** However, those requirements should not affect the policies of those Member States which rely primarily upon free competition to determine the price of medicinal products. They also should not affect national policies on price setting and on the determination of social security schemes, except as far as it is necessary to attain transparency within the meaning of this Directive and to ensure the functioning of the internal market.

Amendment 5

Proposal for a directive
Recital 8

Text proposed by the Commission	*Amendment*
(8) Due to diversity of national measures managing the consumption of medicines, regulating their prices or establishing the conditions of their public funding it is necessary to clarify Directive 89/105/EEC. In particular this Directive should cover all types of measures devised by Member States and susceptible to impact the internal market. Since the adoption of Directive 89/105/EEC, the pricing and reimbursement procedures have evolved and have become more complex. While some Member States have interpreted the scope of Directive 89/105/EEC restrictively, the Court of Justice ruled that those pricing and reimbursement procedures fall within the scope of Directive 89/105/EEC given the objectives of that Directive and the need to ensure its effectiveness. Therefore, this Directive should reflect the developments in national pricing and reimbursement policies. Given that specific rules and procedures exist in the area of public procurement ***and voluntary contractual agreements***, national measures involving public procurement ***and voluntary contractual agreements*** should be excluded from the scope of this Directive.	(8) Due to diversity of national measures managing the consumption of medicines, regulating their prices or establishing the conditions of their public funding it is necessary to clarify Directive 89/105/EEC. In particular this Directive should cover all types of measures devised by Member States and susceptible to impact the internal market. Since the adoption of Directive 89/105/EEC, the pricing and reimbursement procedures have evolved and have become more complex. While some Member States have interpreted the scope of Directive 89/105/EEC restrictively, the Court of Justice ruled that those pricing and reimbursement procedures fall within the scope of Directive 89/105/EEC given the objectives of that Directive and the need to ensure its effectiveness. Therefore, this Directive should reflect the developments in national pricing and reimbursement policies. Given that specific rules and procedures exist in the area of public procurement, national measures involving public procurement should be excluded from the scope of this Directive.

Amendment 6

Proposal for a directive
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) In addition to conventional measures laid down by law, regulation or administrative action to regulate the conditions of public funding of medicinal products, public authorities are increasingly engaging in agreements which aim at providing patient access to

innovative treatments by including a medicinal product in the scope of the public health insurance system whilst monitoring elements agreed upfront with the marketing authorisation holder. Such monitoring aims at addressing evidentiary uncertainties related to the effectiveness and appropriate use of the medicinal product in clinical practice over time. The level of coverage of the medicinal product subject to such agreement is dependent on the output of monitoring and is unknown upfront. The terms and conditions of such agreements are governed by contracts concluded between the public authority and the holder of a marketing authorisation concerned. Where public authorities make the decision on including a medicinal product in the scope of the public health insurance system conditional upon the entry into such agreement, the agreement should not be considered to have been concluded at the request of the holder of the marketing authorisation.

Justification

When standard coverage/reimbursement mechanisms are not deemed appropriate, in particular where higher than normal levels of uncertainty exist as regards the effect of a medicine on patients and society, the reimbursement authority and the manufacturer can agree on specific conditions regulated in contracts to ensure patient access to innovative medicines. These agreements, which deviate from standard administrative practices, operate outside of the scope of this Directive, provided that they are not imposed on the applicant.

Amendment 7

Proposal for a directive
Recital 10 a (new)

Text proposed by the Commission	*Amendment*
	(10a) In order to facilitate compliance with these time limits, it may be useful for applicants to start procedures for price approval or for inclusion of a medicinal product in the health insurance systems

	already before the marketing authorisation is formally granted. To this end, Member States may give applicants the possibility to submit an application as soon as a positive opinion has been issued, upon the case, by the Committee for Medicinal Products for Human Use or by the national authority in charge of the marketing authorisation procedure. In such cases the time limits should run from the formal receipt of the marketing authorisation.

Amendment 8

Proposal for a directive
Recital 13

Text proposed by the Commission	*Amendment*
(13) The judicial remedies available in the Member States have played a limited role in ensuring compliance with the time limits due to the often lengthy procedures in national jurisdictions, which deter affected companies from initiating legal action. Therefore, effective mechanisms are necessary to control and enforce compliance with the time limits for pricing and reimbursement decisions.	(13) The judicial remedies available in the Member States have played a limited role in ensuring compliance with the time limits due to the often lengthy procedures in national jurisdictions, which deter affected companies from initiating legal action. Therefore, effective mechanisms are necessary to control and enforce compliance with the time limits for pricing and reimbursement decisions. ***To this end, Member States shall designate a body, which may be an existing one, entrusted with the power to impose the remedies provided in this Directive.***

Amendment 9

Proposal for a directive
Recital 14

Text proposed by the Commission	*Amendment*
(14) The quality, safety and efficacy of medicinal products, including the bioequivalence of generic medicinal products with the reference product, are	(14) The quality, safety and efficacy of medicinal products, including the bioequivalence of generic medicinal products ***and the similarity of biosimilar***

ascertained in the framework of marketing authorisation procedures. In the framework of pricing and reimbursement procedures, Member States should therefore not re-assess the elements on which the marketing authorisation is based, including the quality, safety, efficacy ***or bioequivalence*** of the medicinal product.

products with the reference product, are ascertained in the framework of marketing authorisation procedures. In the framework of pricing and reimbursement procedures, Member States should therefore not re-assess the elements on which the marketing authorisation is based, including the quality, safety, efficacy***, bioequivalence or biosimilarity*** of the medicinal product. ***The marketing authorisation of an orphan medicinal product is also based on the evaluation of several criteria, including the significant benefit of the product over any available existing alternatives in the Union, in accordance with Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[1], which should not be re-assessed in the framework of pricing and reimbursement procedures.***

Similarly, in the case of orphan drugs, Member States shall not re-assess the criteria of the orphan designation, including the significant benefit. However, if necessary for the pricing and reimbursement decision, including for health technology assessment or pharmaco-economic evaluation purposes, Member States may take into account data on the assessment of these elements during the marketing authorisation procedure.

---

[1] OJ L 18, 22.1.2000, p. 1.

Amendment 10

Proposal for a directive
Recital 15

Text proposed by the Commission	*Amendment*
(15) In accordance with Directive 2001/83/EC, intellectual property rights do	(15) In accordance with Directive 2001/83/EC, intellectual property rights do

not provide a valid ground to refuse, suspend or revoke a marketing authorisation. By the same token, applications, decision-making procedures and decisions to regulate the prices of medicinal products or to determine their coverage by health insurance systems should be considered administrative procedures which, as such, are independent from the enforcement of intellectual property rights. The national authorities in charge of those procedures, when examining an application with respect to a generic medicinal product, should not request information concerning the patent status of the reference medicinal product and should not examine the validity of an alleged violation of intellectual property rights should the generic medicinal product be manufactured or placed on the market subsequently to their decision. Consequently, intellectual property issues should neither interfere with nor delay pricing and reimbursement procedures in the Member States.

not provide a valid ground to refuse, suspend or revoke a marketing authorisation. By the same token, applications, decision-making procedures and decisions to regulate the prices of medicinal products or to determine their coverage by health insurance systems should be considered administrative procedures which, as such, are independent from the enforcement of intellectual property rights. The national authorities in charge of those procedures, when examining an application with respect to a generic ***or biosimilar*** medicinal product, should not request information concerning the patent status of the reference medicinal product and should not examine the validity of an alleged violation of intellectual property rights should the generic ***or biosimilar*** medicinal product be manufactured or placed on the market subsequently to their decision. Consequently, intellectual property issues should neither interfere with nor delay pricing and reimbursement procedures in the Member States.

Amendment 11

Proposal for a directive
Article 1 – paragraph 2 – subparagraph -1 (new)

Text proposed by the Commission	*Amendment*
	This Directive shall apply to measures intended to determine which medicinal products may be included in contractual agreements or public procurement procedures.

Justification

When standard coverage/reimbursement mechanisms are not deemed appropriate, in particular where higher than normal levels of uncertainty exist as regards the effect of a medicine on patients and society, the reimbursement authority and the manufacturer can agree on specific conditions regulated in contracts to ensure patient access to innovative medicines. These agreements, which deviate from standard administrative practices, operate

outside of the scope of this Directive, provided that they are not imposed on the applicant.

Amendment 12

Proposal for a directive
Article 1 – paragraph 2 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) ***voluntary contractual*** agreements concluded ***between public authorities and*** the holder of a marketing authorisation ***for*** a medicinal product ***that have as their object to enable the effective provision of this medicine to patients under specific conditions***;	(a) agreements concluded ***at the written request of*** the holder of a marketing authorisation ***with public authorities which aim at including*** a medicinal product ***in the scope of the public health insurance system whilst monitoring elements agreed upfront with the holder of a marketing authorisation to address evidentiary uncertainties related to the effectiveness and appropriate use of the given medicinal product over time***;

Justification

When standard coverage/reimbursement mechanisms are not deemed appropriate, in particular where higher than normal levels of uncertainty exist as regards the effect of a medicine on patients and society, the reimbursement authority and the manufacturer can agree on specific conditions regulated in contracts to ensure patient access to innovative medicines. These agreements, which deviate from standard administrative practices, operate outside of the scope of this Directive, provided that they are not imposed on the applicant.

Amendment 13

Proposal for a directive
Article 1 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
The provisions of this Directive shall apply to measures intended to determine which medicinal products may be included in contractual agreements or public procurement procedures.	***deleted***

Justification

When standard coverage/reimbursement mechanisms are not deemed appropriate, in

particular where higher than normal levels of uncertainty exist as regards the effect of a medicine on patients and society, the reimbursement authority and the manufacturer can agree on specific conditions regulated in contracts to ensure patient access to innovative medicines. These agreements, which deviate from standard administrative practices, operate outside of the scope of this Directive, provided that they are not imposed on the applicant.

Amendment 14

Proposal for a directive
Article 2 – point 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) "biosimilar medicinal product" means a similar biological medicinal product approved in accordance with Article 10(4) of Directive 2001/83/EC;

Justification

The introduction of specific provisions for generic medicinal products is what provides the main 'added value' of this recast. However, in order to cover all generic medicinal products, including biotherapies, it is necessary to introduce the concept of biosimilarity in addition to bioequivalence.

Amendment 15

Proposal for a directive
Article 2 – point 5

Text proposed by the Commission	*Amendment*
(5) "health technology assessment" means 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.***	(5) "health technology assessment" means an assessment of ***the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner. Its aim is to inform the formulation of safe, effective health policies that are patient focused and seek to achieve best value.***

Justification

The definition of HTA provided for in this Directive should be in line with the one by national HTA agencies cooperating within EUnetHTA.

Amendment 16

Proposal for a directive
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that an application to approve the price of the product can be introduced by the marketing authorisation holder at any point in time. The competent authorities shall provide the applicant with an official acknowledgement of receipt.	2. Member States shall ensure that an application to approve the price of the product can be introduced by the marketing authorisation holder at any point in time. ***Member States may also provide the possibility for marketing authorisation holders to submit such requests once the Committee for Medicinal Products for Human Use established by Regulation (EC) No 726/2004 or the national competent authority has issued a positive opinion.*** The competent authorities shall provide the applicant with an official acknowledgement of receipt ***within 10 days***.

Justification

In order to ensure the effectiveness of this procedure, it would be useful to have a clearly established time limit for the acknowledgement of receipt. The purpose is to avoid any undue delay in the acknowledgement of receipt. In order to help Member States in respecting the deadlines, it can be useful to have applications submitted at an earlier stage, immediately after a positive opinion of the CHMP or the national authority in charge of the marketing authorisation procedure has issued a positive opinion.

Amendment 17

Proposal for a directive
Article 3 – paragraph 3

Text proposed by the Commission	*Amendment*
3. 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 60 days of the receipt of an application submitted, in accordance	3. Member States shall ensure that a ***reasoned and objectively justified*** decision on the price which may be charged for the medicinal product concerned is adopted and communicated to the applicant within 60 days of the receipt of an application

with the requirements laid down in the Member State concerned, by the holder of a marketing authorisation. However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. With respect to generic medicinal products, that time limit shall be ***15*** days, provided that the price of the reference medicinal product has been approved by the competent authorities.	submitted ***or, where appropriate, of the formal receipt of the marketing authorisation,*** in accordance with the requirements laid down in the Member State concerned, by the holder of a marketing authorisation. However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. With respect to generic medicinal products, that time limit shall be ***30*** days, provided that the price of the reference medicinal product has been approved by the competent authorities.

Justification

In order to help Member States in respecting the time limits, it can be useful to have applications submitted at an earlier stage, immediately after a positive opinion of the CHMP or the national authority in charge of the marketing authorisation procedure has issued a positive opinion. However in such cases the time limits shall run only from the formal receipt of the marketing authorisation, which would give national authorities some extra time to process the application.

Amendment 18

Proposal for a directive
Article 3 – paragraph 5

Text proposed by the Commission	*Amendment*
5. If the information supporting the application is inadequate, the competent authorities shall ***forthwith*** notify the applicant of the detailed additional information required and take their final decision within 60 days of receipt of this additional information. However, with respect to medicines for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. With respect to generic medicinal products, that time limit shall be in all events ***15*** days, provided that the price of the reference medicinal product has been approved by the	5. If the information supporting the application is inadequate, the competent authorities shall notify the applicant ***within 10 days*** of the detailed additional information required and take their final decision within 60 days of receipt of this additional information. However, with respect to medicines for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. With respect to generic medicinal products, that time limit shall be in all events ***30*** days, provided that the price of the reference medicinal product has been approved by the

competent authorities. Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.	competent authorities. Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.

Justification

In order to ensure the effectiveness of this procedure, it would be useful to have a clearly established time limit for the acknowledgement of receipt. The purpose is to avoid any undue delay in the acknowledgement of receipt.

Amendment 19

Proposal for a directive
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that an application to increase the price of the product can be submitted by the marketing authorisation holder at any point in time. The competent authorities shall provide the applicant with an official acknowledgement of receipt.	2. Member States shall ensure that an application to increase the price of the product can be introduced by the marketing authorisation holder at any point in time. The competent authorities shall provide the applicant with an official acknowledgement of receipt ***within 10 days.***

Justification

In order to ensure the effectiveness of this procedure, it would be useful to have a clearly established time limit for the acknowledgement of receipt. The purpose is to avoid any undue delay in the acknowledgement of receipt.

Amendment 20

Proposal for a directive
Article 4 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall establish in detail the particulars and documents to be submitted by the applicant.	4. Member States shall establish in detail ***and publish in an appropriate publication*** the particulars and documents to be submitted by the applicant.
The applicant shall furnish the competent	The applicant shall furnish the competent

authorities with adequate information, including details of those events intervening since the price of the medicinal product was last determined which in his opinion justify the price increase requested. If the information supporting the application is inadequate, the competent authorities shall ***forthwith*** notify the applicant of the detailed additional information required and take their final decision within 60 days of receipt of this additional information. Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.	authorities with adequate information, including details of those events intervening since the price of the medicinal product was last determined which in his opinion justify the price increase requested. If the information supporting the application is inadequate, the competent authorities shall notify the applicant ***within 10 days*** of the detailed additional information required and take their final decision within 60 days of receipt of this additional information. Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.

Justification

For transparency reasons, the criteria to be taken into account and the documents required for the approval of a price increase should be published din an appropriate publication as are the criteria for price approval. In order to ensure the effectiveness of this procedure, it would be useful to have a clearly established time limit for the acknowledgement of receipt. The purpose is to avoid any undue delay in the acknowledgement of receipt.

Amendment 21

Proposal for a directive
Article 5 – paragraph 1

Text proposed by the Commission	*Amendment*
1. In the event of a price freeze or price reduction imposed on all medicinal products or on certain categories of medicinal products by the competent authorities of a Member State, that Member State shall publish a statement of reasons for its decision based on objective and verifiable criteria, including, if applicable, a justification of the categories of products subject to the price freeze or price reduction.	1. In the event of a ***temporary*** price freeze or price reduction imposed on all medicinal products or on certain categories of medicinal products by the competent authorities of a Member State, that Member State shall publish a statement of reasons for its decision based on objective and verifiable criteria, including, if applicable, a justification of the categories of products subject to the price freeze or price reduction. ***Furthermore, at least once a year, that Member State shall carry out a review to ascertain whether the macro-economic conditions justify that the freeze be***

continued unchanged.

Justification

In order to ensure the effectiveness of this procedure, it would be useful to have a clearly established time limit for the acknowledgement of receipt. The purpose is to avoid any undue delay in the acknowledgement of receipt.

Amendment 22

Proposal for a directive
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Marketing authorisation holders may apply for a derogation from a price freeze or price reduction if this is justified by particular reasons. The application shall contain an adequate statement of reasons. Member States shall ensure that applications for a derogation can be introduced by the marketing authorisation holder at any point in time. The competent authorities shall provide the applicant with an official acknowledgement of receipt.	2. Marketing authorisation holders may apply for a derogation from a price freeze or price reduction if this is justified by particular reasons. The application shall contain an adequate statement of reasons. Member States shall ensure that applications for a derogation can be introduced by the marketing authorisation holder at any point in time. The competent authorities shall provide the applicant with an official acknowledgement of receipt ***within 10 days.***

Justification

In order to ensure the effectiveness of this procedure, it would be useful to have a clearly established time limit for the acknowledgement of receipt. The purpose is to avoid any undue delay in the acknowledgement of receipt.

Amendment 23

Proposal for a directive
Article 5 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall ensure that a reasoned decision on an application referred to in paragraph 2 is adopted and communicated to the applicant within 60 days of the receipt of the application. If the	3. Member States shall ensure that a reasoned decision on an application referred to in paragraph 2 is adopted and communicated to the applicant within 60 days of the receipt of the application. If the

information supporting the application is inadequate, the competent authorities shall ***forthwith*** notify the applicant of the detailed additional information required and take their final decision within 60 days of receipt of this additional information. If the derogation is granted, the competent authorities shall forthwith publish an announcement of the price increase allowed.	information supporting the application is inadequate, the competent authorities shall notify the applicant ***within 10 days*** of the detailed additional information required and take their final decision within 60 days of receipt of this additional information. If the derogation is granted, the competent authorities shall forthwith publish an announcement of the price increase allowed.

Justification

In order to ensure the effectiveness of this procedure, it would be useful to have a clearly established time limit for the acknowledgement of receipt. The purpose is to avoid any undue delay in the acknowledgement of receipt.

Amendment 24

Proposal for a directive
Article 5 – paragraph 3 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	Member States shall ensure that dispensaries possess information about the actual price of the medicinal product in order to prevent possible distorting effects caused by a lack of transparency in prices displayed on the market.

Justification

There has been an increase in the number of voluntary agreements such as discount contracts between pharmaceutical manufacturers and health insurance funds. As a result, the actual price of the medicinal product is not clear to doctors and pharmacists and the patient is not always prescribed the least expensive and therefore the most economical medicine.

Amendment 25

Proposal for a directive
Article 7 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that an application to include a medicinal product	2. Member States shall ensure that an application to include a medicinal product

in the scope of the public health insurance system can be introduced by the marketing authorisation holder at any point in time. If the public health insurance system comprises several schemes or categories of coverage, the marketing authorisation holder shall be entitled to apply for the inclusion of its product in the scheme or category of its choice. The competent authorities shall provide the applicant with an official acknowledgement of receipt.	in the scope of the public health insurance system can be introduced by the marketing authorisation holder at any point in time. ***Member States may also provide the possibility for marketing authorisation holders to submit such requests once the Committee for Medicinal Products for Human Use established by Regulation (EC) No 726/2004 or the national competent authority has issued a positive opinion.*** If the public health insurance system comprises several schemes or categories of coverage, the marketing authorisation holder shall be entitled to apply for the inclusion of its product in the scheme or category of its choice. The competent authorities shall provide the applicant with an official acknowledgement of receipt ***within 10 days***.

Justification

In order to ensure the effectiveness of this procedure, it would be useful to have a clearly established time limit for the acknowledgement of receipt. The purpose is to avoid any undue delay in the acknowledgement of receipt. In order to help Member States in respecting the deadlines, it can be useful to have applications submitted at an earlier stage, immediately after a positive opinion of the CHMP or the national authority in charge of the marketing authorisation procedure has issued a positive opinion.

Amendment 26

Proposal for a directive
Article 7 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within 60 days of its receipt. However, with respect to medicinal products for	4. Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within 60 days of its receipt ***or, where appropriate, of the formal receipt of the***

which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. With respect to generic medicinal products, that time limit shall be ***15*** days, provided that the reference medicinal product has already been included in the public health insurance system.

marketing authorisation. However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. 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.

Justification

In order to help Member States in respecting the time limits, it can be useful to have applications submitted at an earlier stage, immediately after a positive opinion of the CHMP or the national authority in charge of the marketing authorisation procedure has issued a positive opinion. In such cases, however, the time limits shall run only from the formal receipt of the marketing authorisation, which would give national authorities some extra time to process the application.

Amendment 27

Proposal for a directive
Article 7 – paragraph 5

Text proposed by the Commission

5. If the information supporting the application is inadequate, the competent authorities shall ***forthwith*** notify the applicant of the detailed additional information required and take their final decision within 60 days of receipt of this additional information. However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. With respect to generic medicinal products, that time limit shall be ***15*** days, provided that the reference medicinal product has already been included in the public health insurance system. Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.

Amendment

5. If the information supporting the application is inadequate, the competent authorities shall notify the applicant ***within 10 days*** of the detailed additional information required and take their final decision within 60 days of receipt of this additional information. However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. 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. Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.

Justification

In order to ensure the effectiveness of this procedure, it would be useful to have a clearly established time limit for the acknowledgement of receipt. The purpose is to avoid any undue delay in the acknowledgement of receipt.

Amendment 28

Proposal for a directive
Article 7 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed 120 days. However, with respect to the medicinal products for which Member States use health technology assessment as part of their decision-making process, the time limit shall not exceed 180 days. With respect to generic medicinal products, that time limit shall not exceed ***30*** days, provided that the reference medicinal product has already been included in the public health insurance system. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5).	6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed 120 days. However, with respect to the medicinal products for which Member States use health technology assessment as part of their decision-making process, the time limit shall 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. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5).

Amendment 29

Proposal for a directive
Article 7 – paragraph 8

Text proposed by the Commission	*Amendment*
8. Member States shall publish in an appropriate publication and communicate to the Commission the criteria which the competent authorities must take into account when deciding whether or not to include medicinal products within the	8. Member States shall publish in an appropriate publication and communicate to the Commission 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.

scope of the public health insurance system. ***The identity and statements of interest of the experts involved in the decision-making process shall also be published.***

Amendment 30

Proposal for a directive
Article 8 – paragraph 2

Text proposed by the Commission	*Amendment*
2. For the purposes of the remedies procedure Member States shall designate a body and entrust it with the powers to:	2. For the purposes of the remedies procedure Member States shall designate a body and entrust it with the powers to:
(a) take, at the earliest opportunity and by way of interlocutory procedures, interim measures with the aim of correcting the alleged infringement or preventing further damage to the interests concerned;	(a) take, at the earliest opportunity and by way of interlocutory procedures, interim measures with the aim of correcting the alleged infringement or preventing further damage to the interests concerned;
(b) award damages to the applicant in case of non-compliance with time limits set in Article 7 where damages are claimed, unless the competent authority may prove that the delay is not imputable to it;	
(c) impose a penalty payment, calculated by day of delay.	
For the purposes of point (c), the penalty payment shall be calculated depending on the seriousness of the infringement, its duration, the need to ensure that the penalty itself is a deterrent to further infringements.	
Member States may provide that the body referred to in the first subparagraph may take into account the probable consequences of potential measures taken under the present paragraph for all interests likely to be harmed, as well as the public interest, and may decide not to take such measures when their negative consequences could exceed their benefits.	Member States may provide that the body referred to in the first subparagraph may take into account the probable consequences of potential measures taken under the present paragraph for all interests likely to be harmed, as well as the public interest, and may decide not to take such measures when their negative consequences could exceed their benefits.

Justification

Even if they may have a deterrent effect and prompt national pricing and reimbursement authorities to keep the deadlines, penalty payments may also have a negative side effect, namely, that authorities may prefer to reject the application rather than taking the risk of paying such penalties.

Amendment 31

Proposal for a directive
Article 8 – paragraph 2 – subparagraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) refer any instances of non-compliance with time limits set in Article 7 to the relevant body, in accordance with national law, should the competent authority have been unable to prove that the delay is not imputable to it.

Amendment 32

Proposal for a directive
Article 8 – paragraph 2 – subparagraph 3

Text proposed by the Commission	*Amendment*
Member States may provide that the body referred to in the first subparagraph may take into account the probable consequences of potential measures taken under the present paragraph for all interests likely to be harmed, as well as the public interest, and may decide not to take such measures when their negative consequences could exceed their benefits.	***deleted***

Amendment 33

Proposal for a directive
Article 8 – paragraph 6 – subparagraph 1

Text proposed by the Commission	*Amendment*
The body referred to in paragraph 2 shall state reasons for its decision. Furthermore, where that body ***is not judicial in character***, provision must be made to guarantee procedures whereby any allegedly illegal measure taken by the independent body or any alleged defect in the exercise of powers conferred on it can be subject to judicial review or review by another body which is a court or tribunal within the meaning of Article 267 of the Treaty on the Functioning of the European Union and independent of both the competent authority and the body referred to in paragraph 2.	The body referred to in paragraph 2 shall state reasons for its decision. Furthermore, where that body ***does not have judicial authority***, provision must be made to guarantee procedures whereby any allegedly illegal measure taken by the independent body or any alleged defect in the exercise of powers conferred on it can be subject to judicial review or review by another body which is a court or tribunal within the meaning of Article 267 of the Treaty on the Functioning of the European Union and independent of both the competent authority and the body referred to in paragraph 2.

Amendment 34

Proposal for a directive
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Any decision to exclude a category of medicinal products from the scope of the public health insurance system, or to modify the extent or the conditions of coverage of the category concerned, shall contain a statement of reasons based on objective and verifiable criteria and be ***published in an appropriate publication***.	2. Any decision to exclude a category of medicinal products from the scope of the public health insurance system, or to modify the extent or the conditions of coverage of the category concerned, shall contain a statement of reasons based on objective and verifiable criteria and be ***made publicly available***.

Amendment 35

Proposal for a directive
Article 10 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ***publish in an appropriate publication*** and communicate to the Commission the objective and verifiable criteria according to which	2. Member States shall ***make publicly available*** and communicate to the Commission the objective and verifiable criteria according to which medicinal

medicinal products are classified in view of their inclusion in the public health insurance system.	products are classified in view of their inclusion in the public health insurance system.

Amendment 36

Proposal for a directive
Article 10 – paragraph 3

Text proposed by the Commission	*Amendment*
3. For the medicinal products subject to such grouping or classification, Member States shall ***publish in an appropriate publication*** and communicate to the Commission the methodologies used to determine the extent or conditions of their inclusion in the public health insurance system.	3. For the medicinal products subject to such grouping or classification, Member States shall ***make publicly available*** and communicate to the Commission the methodologies used to determine the extent or conditions of their inclusion in the public health insurance system.

Amendment 37

Proposal for a directive
Article 11 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Paragraphs 2, 3 and 4 shall apply where a Member State adopts measures intended to control or promote the prescription of specific named medicinal products.	1. Paragraphs 2, 3 and 4 shall apply where a Member State adopts measures intended to control or promote the prescription of specific named medicinal products ***or of a category of medicinal products.***

Justification

Transparency should apply also to measures intended to promote the prescription of categories of medicinal products, not only to the prescription of specific named ones.

Amendment 38

Proposal for a directive
Article 11 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Measures referred to in paragraph 1, including any evaluation, expert opinion or recommendation on which they are based, shall be ***published in an appropriate publication***.	3. Measures referred to in paragraph 1, including any evaluation, expert opinion or recommendation on which they are based, shall be ***made publicly available***.

Amendment 39

Proposal for a directive
Article 13 – title

Text proposed by the Commission	*Amendment*
Additional proof of quality, safety, efficacy or bioequivalence	***Non-reassessment of elements underpinning the market authorisation***

Justification

The title should remain general and not be a list of everything that should not be subject to reassessment.

Amendment 40

Proposal for a directive
Article 13

Text proposed by the Commission	*Amendment*
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 of the medicinal product.	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***, where appropriate, the*** bioequivalence ***or biosimilarity*** of the medicinal product ***or the criteria for orphan designation***. ***However, this Directive shall not prevent Member States from using the data generated in the marketing authorisation process for health technology assessment or pharmaco-economic evaluation purposes.***

Justification

Adjustment of Amendment 19 to include also biosimilarity which is established by EMA at the marketing authorization stage.

Amendment 41

Proposal for a directive
Article 16 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where Member States intend to adopt or amend any measure falling within the scope of this Directive, they ***shall immediately*** communicate to the Commission the draft measure envisaged, together with the reasoning on which the measure is based.	1. Where Member States intend to adopt or amend any measure falling within the scope of this Directive, they ***should*** communicate to the Commission the draft measure envisaged, together with the reasoning on which the measure is based.

Amendment 42

Proposal for a directive
Article 16 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where appropriate, Member States ***shall*** simultaneously communicate the texts of the basic legislative or regulatory provisions principally and directly concerned, if knowledge of such texts is necessary to assess the implications of the measure proposed.	2. Where appropriate, Member States ***should*** simultaneously communicate the texts of the basic legislative or regulatory provisions principally and directly concerned, if knowledge of such texts is necessary to assess the implications of the measure proposed.

Amendment 43

Proposal for a directive
Article 16 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
4. The Commission may send its observations to the Member State which has communicated the draft measure	4. The Commission may send its observations to the Member State which has communicated the draft measure

within three months.	***before the definitive adoption by the Member State***.

Justification

Clarification that the possibility for the Commission to submit comments on the draft measure does not suspend the procedure at national level, which would generate undue delays.

Amendment 44

Proposal for a directive
Article 16 – paragraph 5

Text proposed by the Commission	*Amendment*
5. When the Member State concerned definitively adopts the draft measure, it shall communicate the final text to the Commission without delay***. If observations have been made by the Commission in accordance with paragraph 4, this communication shall be accompanied by a report on the actions taken in response to the observations of the Commission.***	5. When the Member State concerned definitively adopts the draft measure, it shall communicate the final text to the Commission without delay***, which shall publish it in the form of a public on-line database***.

Justification

The amendment aims at simplifying the notification procedure in order to make it less burdensome for the Member States. This would not prevent the Commission from asking national authorities to provide such information where doubts about conflicts with EU law arise. However, a systematic report from the Member State concerned could place too much administrative burden on national authorities, which should be avoided.

Amendment 45

Proposal for a directive
Article 17 a (new)

Text proposed by the Commission	*Amendment*
	Article 17 a
	The Commission shall establish and maintain a publicly accessible on-line database containing comparative information on procurement prices for all

medicines purchased by Member States.

Amendment 46

Proposal for a directive
Article 17 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
1. By ***31 January*** of […] [*insert a date - the year following the date referred to in the first subparagraph of Article 18(1)*], and by ***31 January and*** 1 July of every year thereafter, Member States shall communicate to the Commission and publish in an appropriate publication a detailed report providing the following information:	1. By ***1 July*** of […] [*insert a date - the year following the date referred to in the first subparagraph of Article 18(1)*], and by ***1 July*** of every year thereafter, Member States shall communicate to the Commission and publish in an appropriate publication a detailed report providing the following information:
(a) the number of applications received in accordance with Articles 3, 4 and 7 during the preceding year;	(a) the number of applications received in accordance with Articles 3, 4 and 7 during the preceding year;
(b) the amount of time taken to issue a decision on each of the applications received in accordance with Articles 3, 4, and 7.	(b) the amount of time taken to issue a decision on each of the applications received in accordance with Articles 3, 4, and 7.
(c) an analysis of the main reasons for delays, if any***, together with recommendations to bring decision-making processes into line with the time limits laid down in this Directive***.	(c) an analysis of the main reasons for delays, if any.

Justification

A yearly report should be enough for the Commission to obtain the relevant data. The date should be set at 1 July to allow a sufficient number of application under the new national provisions transposing this Directive so that the first report contains sufficient data. The recommendations to bring decision-making processes in line with the time limits of the Directive should be made either by the Commission or an independent body, not by the national authorities.

Amendment 47

Proposal for a directive
Article 17 – paragraph 1 – subparagraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) a list of those medicinal products whose prices were registered during the period in question and the prices which can be obtained for these products;

Justification

Price transparency and comparability of the price of medicinal products between the Member States are important. The ongoing EURIPID project, which is jointly funded by the Commission and the Member States, aims to provide a comparison of the prices of medicinal products between the Member States. The project should be continued for the purpose of price transparency. In terms of communicating the prices to the Commission, there is therefore a need for the contents of the 'Transparency Directive' in force (89/105/EEC) to appear in the new Directive. This explains the suggested addition to the first paragraph.

Amendment 48

Proposal for a directive
Article 17 – paragraph 1 – subparagraph 1 – point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) a list of those medicinal products whose prices were authorised to rise during the period in question and the new prices which can be obtained for these products.

Justification

Price transparency and comparability of the price of medicinal products between the Member States are important. The ongoing EURIPID project, which is jointly funded by the Commission and the Member States, aims to provide a comparison of the prices of medicinal products between the Member States. The project should be continued for the purpose of price transparency. In terms of communicating the prices to the Commission, there is therefore a need for the contents of the 'Transparency Directive' in force (89/105/EEC) to appear in the new Directive. This explains the suggested addition to the first paragraph.

Amendment 49

Proposal for a directive
Article 17 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission shall publish every ***six months*** a report on the information submitted by Member States according to paragraph 1.	2. The Commission shall publish every ***year*** a report on the information submitted by Member States according to paragraph 1.

Justification

A yearly report from the Commission would be more useful, as it would be drawn up on the basis of a wider range on data submitted by the Member States through their own reports. Alignment with the previous amendment on yearly national reports on the implementation of time limits.

PROCEDURE

Title	Transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems
References	COM(2012)0084 – C7-0056/2012 – 2012/0035(COD)
Committee responsible Date announced in plenary	ENVI 13.3.2012
Opinion by Date announced in plenary	IMCO 13.3.2012
Rapporteur Date appointed	Cristian Silviu Buşoi 20.3.2012
Discussed in committee	18.9.2012 5.11.2012
Date adopted	6.11.2012
Result of final vote	+: 37 –: 0 0: 0
Members present for the final vote	Pablo Arias Echeverría, Adam Bielan, Cristian Silviu Buşoi, Jorgo Chatzimarkakis, Sergio Gaetano Cofferati, Birgit Collin-Langen, Lara Comi, Anna Maria Corazza Bildt, António Fernando Correia de Campos, Cornelis de Jong, Christian Engström, Vicente Miguel Garcés Ramón, Louis Grech, Małgorzata Handzlik, Malcolm Harbour, Iliana Ivanova, Philippe Juvin, Sandra Kalniete, Edvard Kožušník, Toine Manders, Hans-Peter Mayer, Sirpa Pietikäinen, Phil Prendergast, Mitro Repo, Zuzana Roithová, Heide Rühle, Christel Schaldemose, Andreas Schwab, Catherine Stihler, Róża Gräfin von Thun und Hohenstein, Bernadette Vergnaud, Barbara Weiler
Substitute(s) present for the final vote	Jürgen Creutzmann, Marielle Gallo, María Irigoyen Pérez, Konstantinos Poupakis, Kyriacos Triantaphyllides

PROCEDURE

Title	Transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems			
References	COM(2012)0084 – C7-0056/2012 – 2012/0035(COD)			
Date submitted to Parliament	1.3.2012			
Committee responsible Date announced in plenary	ENVI 13.3.2012			
Committee(s) asked for opinion(s) Date announced in plenary	EMPL 13.3.2012	ITRE 13.3.2012	IMCO 13.3.2012	JURI 13.3.2012
Not delivering opinions Date of decision	EMPL 15.3.2012	ITRE 19.3.2012	JURI 26.3.2012	
Rapporteur(s) Date appointed	Antonyia Parvanova 19.4.2012			
Legal basis disputed Date of JURI opinion	JURI 22.1.2013			
Discussed in committee	10.10.2012	28.11.2012		
Date adopted	18.12.2012			
Result of final vote	+: –: 0:	54 0 2		
Members present for the final vote	Sophie Auconie, Pilar Ayuso, Paolo Bartolozzi, Sandrine Bélier, Milan Cabrnoch, Martin Callanan, Nessa Childers, Tadeusz Cymański, Esther de Lange, Anne Delvaux, Bas Eickhout, Edite Estrela, Karl-Heinz Florenz, Gerben-Jan Gerbrandy, Matthias Groote, Satu Hassi, Jolanta Emilia Hibner, Dan Jørgensen, Christa Klaß, Eija-Riitta Korhola, Holger Krahmer, Jo Leinen, Peter Liese, Zofija Mazej Kukovič, Linda McAvan, Radvilė Morkūnaitė-Mikulėnienė, Miroslav Ouzký, Vladko Todorov Panayotov, Antonyia Parvanova, Andres Perello Rodriguez, Mario Pirillo, Pavel Poc, Frédérique Ries, Anna Rosbach, Dagmar Roth-Behrendt, Kārlis Šadurskis, Horst Schnellhardt, Richard Seeber, Claudiu Ciprian Tănăsescu, Salvatore Tatarella, Thomas Ulmer, Anja Weisgerber, Marina Yannakoudakis			
Substitute(s) present for the final vote	Margrete Auken, Jutta Haug, Jiří Maštálka, Judith A. Merkies, Marit Paulsen, Britta Reimers, Giancarlo Scottà, Alda Sousa, Anna Záborská, Andrea Zanoni			
Substitute(s) under Rule 187(2) present for the final vote	Reinhard Bütikofer, Jean Lambert, Csaba Sógor			
Date tabled	25.1.2013			