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Committee on the Internal Market and Consumer Protection

2012/0035(COD)

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AMENDMENTS
25 - 118

Draft opinion
Cristian Silviu Buşoi
(PE494.638v02-00)

Transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems

Proposal for a directive
(COM(2012)0084 – C7-0056/2012 – 2012/0035(COD))

AM_Com_LegOpinion

Amendment 25
Bernadette Vergnaud

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,

Or. fr

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 26
Cristian Silviu Buşoi

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.

Or. en

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 27
Bernadette Vergnaud

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 medicinal products.	(5) Disparities in national measures may hinder or distort intra-Union trade in medicinal products, thereby directly affecting the functioning of the internal market in medicinal products.

Or. fr

Amendment 28
Louis Grech

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	(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***

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.

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.

Or. en

Amendment 29
Ashley Fox

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	(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.

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.

Or. en

Amendment 30
Jorgo Chatzimarkakis

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	(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. ***In addition to measures of direct and indirect***

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.	***pricing policies in accordance with objective criteria subject to evaluation, price transparency should be ensured. A distortion of competition can only be avoided through price transparency. Distorting effects*** in the ***perception of prices created by different decision making procedures in the Member States for pricing and reimbursement between manufacturer and insurance carrier can be averted by more transparency of pricing methods. Improved transparency on prices leads to cost-effectiveness and cost-efficiency, as intended by*** this Directive. ***That again means cost savings for health systems.***

Or. en

Amendment 31
Ashley Fox

Proposal for a directive
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8 a) 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.

Or. en

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 32
Ashley Fox

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 medicinal products ***and the similarity of biosimilar 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, which should not be re-assessed in the framework of pricing and reimbursement procedures.***

Or. en

Amendment 33
Cristian Silviu Buşoi, Sirpa Pietikäinen

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 medicinal products ***an the similarity of biosimilar medicines*** 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.

Or. en

Amendment 34
Phil Prendergast

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 ***and the biosimilarity of*** 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***, bioequivalence or biosimilarity*** of the medicinal product.

Or. en

Amendment 35
Bernadette Vergnaud

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 medicinal products with the reference product ***and the similarity of biosimilar medicinal products***, are ascertained in the framework of marketing authorisation procedures ***and may be re-assessed in*** the framework of pricing and reimbursement procedures.

Or. fr

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 36
Sirpa Pietikäinen

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. Consequently, intellectual property issues should neither interfere with nor delay pricing and reimbursement procedures in the Member States.	(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 ***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.

Or. en

Amendment 37
Ashley Fox

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. Consequently, intellectual property issues should neither interfere with nor delay pricing and reimbursement procedures in the Member States.	(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 ***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.

Or. en

Amendment 38
Phil Prendergast

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. Consequently, intellectual property issues should neither interfere with nor delay pricing and reimbursement procedures in the Member States.	(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 ***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.

Or. en

Amendment 39
Ashley Fox

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

Text proposed by the Commission	*Amendment*
This Directive shall not apply to the following:	***This Directive shall apply to measures intended to determine which medicinal products may be included in contractual agreements or public procurement***

	procedures.
	This Directive shall not apply to the following:

Or. en

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 40
Jorgo Chatzimarkakis

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;	***deleted***

Or. en

Amendment 41
Ashley Fox

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***	(a) agreements concluded ***at the written request of*** the holder of a marketing

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***;	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***;

Or. en

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 42
Ashley Fox

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***

Or. en

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 43
Jorgo Chatzimarkakis

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 public procurement procedures.

Or. en

Amendment 44
Bernadette Vergnaud

Proposal for a directive
Article 2 – paragraph 1 – 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;

Or. fr

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 45
Bernadette Vergnaud

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 ***guarantee that the marketing authorisation holder has the possibility to introduce an application to approve the price of the product***. The competent authorities shall provide the applicant with an official acknowledgement of receipt.

Or. fr

Justification

Clarification of the wording and removal of the phrase 'at any point in time', which is a source of legal uncertainty.

Amendment 46
Nora Berra, Sirpa Pietikäinen

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 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 ***15*** days, provided that the price of the reference medicinal product has been	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 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 ***30*** days, provided that the price of the reference medicinal product has been

approved by the competent authorities.	approved by the competent authorities.

Or. fr

Amendment 47
Phil Prendergast

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 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 ***30*** days, provided that the price of the reference medicinal product has been approved by the competent authorities.

Or. en

Amendment 48
Louis Grech

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	3. Member States shall ensure that a ***reasoned and objectively justified*** decision on the price which may be charged for the

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.

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. ***That decision should be made available to the public in a clear and transparent manner within a reasonable time following adoption.***

Or. en

Amendment 49
Bernadette Vergnaud

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 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 ***15*** days, provided that the price of the reference medicinal	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.

product has been approved by the competent authorities.

Or. fr

Justification

The new deadlines are unrealistic and go well beyond what is necessary to attain the objective pursued by the Commission, namely the rapid availability of new treatments that have a 'normal' marketing authorisation.

Amendment 50
Phil Prendergast

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 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.

Or. en

Amendment 51
Bernadette Vergnaud

Proposal for a directive
Article 3 – paragraph 6

Text proposed by the Commission	*Amendment*
6. In the absence of a decision within the relevant time limit set out in paragraphs 3 and 5, the applicant shall be entitled to market the product at the price proposed.	***deleted***

Or. fr

Justification

This provision goes well beyond the desired objective of the rapid availability of new treatments and is neither proportionate nor in accordance with the principle of subsidiarity. In addition, a measure of this type could upset the already delicate budget balance of public health insurance systems.

Amendment 52
Bernadette Vergnaud

Proposal for a directive
Article 3 – paragraph 7

Text proposed by the Commission	*Amendment*
7. If the competent authorities decide not to permit the marketing of the medicinal product concerned at the price proposed by the applicant, 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 applicant shall be informed of all remedies available, including judicial remedies, and of the time limits for applying for such remedies.	7. If the competent authorities decide not to permit the marketing of the medicinal product concerned at the price proposed by the applicant, the decision shall contain a statement of reasons based on objective and verifiable criteria. The applicant shall be informed of all remedies available, including judicial remedies, and of the time limits for applying for such remedies.

Or. fr

Justification

The requirement to provide expert reports in support of any decision by the authorities that is contrary to the commercial interests of manufacturers is disproportionate.

Amendment 53
Bernadette Vergnaud

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.	***deleted***

Or. fr

Justification

Given that the pricing of medicinal products is a national competence, Member States do not a priori have to communicate to the Commission their criteria for assessing the price of a medicinal product.

Amendment 54
Bernadette Vergnaud

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	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

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.	informed of all remedies available, including judicial remedies, and of the time limits for applying for such remedies.

Or. fr

Justification

The requirement to provide expert reports in support of any decision by the authorities that is contrary to the commercial interests of manufacturers is disproportionate.

Amendment 55
Bernadette Vergnaud

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 ***guarantee that the marketing authorisation holder has the possibility to introduce an application to increase the price of a medicinal product***. The competent authorities shall provide the applicant with an official acknowledgement of receipt.

Or. fr

Justification

Clarification of the wording and removal of the phrase 'at any point in time', which is a source of legal uncertainty.

Amendment 56
Bernadette Vergnaud

Proposal for a directive
Article 4 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
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 the price of a medicinal product is adopted and communicated to the applicant within ***60*** days of its receipt.	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 the price of a medicinal product is adopted and communicated to the applicant within ***90*** days of its receipt.

Or. fr

Justification

The new deadlines are unrealistic and go well beyond what is necessary to attain the objective pursued by the Commission, namely the rapid availability of new treatments that have a 'normal' marketing authorisation.

Amendment 57
Bernadette Vergnaud

Proposal for a directive
Article 4 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
In case of an exceptional number of applications, the time limit set out in this paragraph may be extended once only for a further ***60*** days. The applicant shall be notified of such an extension before the expiry of the time limit set out in this paragraph.	In case of an exceptional number of applications, the time limit set out in this paragraph may be extended once only for a further ***90*** days. The applicant shall be notified of such an extension before the expiry of the time limit set out in this paragraph.

Or. fr

Justification

The new deadlines are unrealistic and go well beyond what is necessary to attain the objective pursued by the Commission, namely the rapid availability of new treatments that have a 'normal' marketing authorisation.

Amendment 58
Bernadette Vergnaud

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***

Or. fr

Justification

This provision goes well beyond the desired objective of the rapid availability of new treatments and is neither proportionate nor in accordance with the principle of subsidiarity. In addition, a measure of this type could upset the already delicate budget balance of public health insurance systems.

Amendment 59
Bernadette Vergnaud

Proposal for a directive
Article 4 – paragraph 6

Text proposed by the Commission	*Amendment*
6. If the competent authorities decide not to permit the whole or part of the price increase requested, ***the decision shall contain a statement of reasons based on objective and verifiable criteria and*** the applicant shall be informed of all remedies available, including judicial remedies, and of the time limits for applying for such remedies.	6. If the competent authorities decide not to permit the whole or part of the price increase requested, the applicant shall be informed of all remedies available, including judicial remedies, and of the time limits for applying for such remedies.

Or. fr

Justification

The requirement to provide a detailed justification in support of any decision by the authorities regarding price re-assessment that is contrary to the commercial interests of manufacturers is disproportionate.

Amendment 60
Nora Berra, Sirpa Pietikäinen

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.

Or. fr

Amendment 61
Bernadette Vergnaud

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	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, including, if applicable, a justification of the categories

applicable, a justification of the categories of products subject to the price freeze or price reduction.	of products subject to the price freeze or price reduction.

Or. fr

Justification

The requirement to provide a detailed justification in support of any decision by the authorities regarding price re-assessment that is contrary to the commercial interests of manufacturers is disproportionate.

Amendment 62
Bernadette Vergnaud

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 ***guarantee that the marketing authorisation holder has the possibility to introduce an application for a derogation***. The competent authorities shall provide the applicant with an official acknowledgement of receipt.

Or. fr

Justification

Clarification of the wording and removal of the phrase 'at any point in time', which is a source of legal uncertainty.

Amendment 63
Bernadette Vergnaud

Proposal for a directive
Article 5 – paragraph 3 – subparagraph 1

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

Or. fr

Justification

The requirement to provide a detailed justification in support of any decision by the authorities regarding price re-assessment that is contrary to the commercial interests of manufacturers is disproportionate.

Amendment 64
Bernadette Vergnaud

Proposal for a directive
Article 5 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
If there is an exceptional number of applications, the relevant time limit set out in paragraph 3 may be extended once only for a further 60 days. The applicant shall be notified of such extension before the expiry of the time limit set out in paragraph 3.	***deleted***

Or. fr

Justification

The new deadlines are unrealistic and go well beyond what is necessary to attain the objective pursued by the Commission, namely the rapid availability of new treatments that have a 'normal' marketing authorisation.

Amendment 65
Anja Weisgerber

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.

Or. de

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 66
Bernadette Vergnaud

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***	2. Member States shall ***guarantee that the marketing authorisation holder has the possibility to introduce an application to include a medicinal product in the scope***

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.	***of the public health insurance system***. 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.

Or. fr

Justification

Clarification of the wording and removal of the phrase 'at any point in time', which is a source of legal uncertainty.

Amendment 67
Nora Berra, Sirpa Pietikäinen

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 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 ***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 60 days of its receipt. 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 ***30*** days, provided that the reference medicinal product has already been included in the public health insurance system.

Or. fr

Amendment 68
Phil Prendergast

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 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 ***30*** days, provided that the reference medicinal product has already been included in the public health insurance system.

Or. en

Amendment 69
Bernadette Vergnaud

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	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 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 15 days, provided that the reference medicinal product has already been included in the public health insurance system.	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 15 days, provided that the reference medicinal product has already been included in the public health insurance system.

Or. fr

Justification

The new deadlines are unrealistic and go well beyond what is necessary to attain the objective pursued by the Commission, namely the rapid availability of new treatments that have a 'normal' marketing authorisation.

Amendment 70
Nora Berra, Sirpa Pietikäinen

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 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 ***15*** days, provided that the reference medicinal product has already	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 ***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.	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.

Or. fr

Amendment 71
Phil Prendergast

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 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.	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 ***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.

Or. en

Amendment 72
Nora Berra, Sirpa Pietikäinen

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).

Or. fr

Amendment 73
Phil Prendergast

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	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).	***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).

Or. en

Amendment 74
Bernadette Vergnaud

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.	***deleted***

Or. fr

Justification

Given that the decision on whether or not to include a medicinal product within the scope of the public health insurance system is a national competence, Member States do not a priori have to communicate their assessment criteria to the Commission.

Amendment 75
Phil Prendergast

Proposal for a directive
Article 7 – paragraph 8

Text proposed by the Commission	*Amendment*
8. Member States shall publish in an	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.	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. ***The identity and statements of interest of the experts involved in the decision-making process shall also be published.***

Or. en

Amendment 76
Ildikó Gáll-Pelcz

Proposal for a directive
Article 8

Text proposed by the Commission	*Amendment*
[...]	***deleted***

Or. hu

Justification

The part of the proposal which would impose a fine and the payment of compensation on a determining authority for not reaching a decision within the deadline is unacceptable. This also applies to possible interim measures. A medicinal product cannot be included in the support scheme by means of an interim measure. Nor is it clear what the basis for calculating the amount of the fine and compensation would be. Therefore the idea of a 'super-authority' which would be created or appointed to implement the compensation should not be supported.

Amendment 77
Nora Berra

Proposal for a directive
Article 8 – paragraph 2

Text proposed by the Commission	*Amendment*
2. For the purposes of the remedies	***deleted***

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;

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.

Or. fr

Amendment 78
Phil Prendergast

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

Text proposed by the Commission	*Amendment*
(b) award damages to the applicant in case of non-compliance with time limits set in Article 7 where damages are	***deleted***

claimed, unless the competent authority may prove that the delay is not imputable to it;

Or. en

Amendment 79
Phil Prendergast

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

Text proposed by the Commission	*Amendment*
	(b a) 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.

Or. en

Amendment 80
Phil Prendergast

Proposal for a directive
Article 8 – paragraph 2 – subparagraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) impose a penalty payment, calculated by day of delay.	***deleted***

Or. en

Amendment 81
Phil Prendergast

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

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. en

Amendment 82
Phil Prendergast

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***

Or. en

Amendment 83
Phil Prendergast

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	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.	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.

Or. en

Amendment 84
Bernadette Vergnaud

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. The applicant shall be informed of all remedies available, including judicial remedies, and of the time limits for applying for such remedies.

Or. fr

Justification

The requirement to provide expert reports in support of any decision by the authorities that is contrary to the commercial interests of manufacturers is disproportionate.

Amendment 85
Bernadette Vergnaud

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.

Or. fr

Justification

The requirement to provide a detailed justification in support of any decision by the authorities regarding the exclusion of a medicinal product from the scope of the public health insurance system that is contrary to the commercial interests of manufacturers is disproportionate.

Amendment 86
Phil Prendergast

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***.

Or. en

Amendment 87
Phil Prendergast

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 medicinal products are classified in view of their inclusion in the public health insurance system.	2. Member States shall ***make publicly available*** and communicate to the Commission the objective and verifiable criteria according to which medicinal products are classified in view of their inclusion in the public health insurance system.

Or. en

Amendment 88
Phil Prendergast

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.

Or. en

Amendment 89
Bernadette Vergnaud

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.	***deleted***

Or. fr

Justification

The requirement to provide expert reports in support of any decision by the authorities that is contrary to the commercial interests of manufacturers is disproportionate.

Amendment 90
Phil Prendergast

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***.

Or. en

Amendment 91
Bernadette Vergnaud

Proposal for a directive
Article 11 – paragraph 4

Text proposed by the Commission	*Amendment*
4. At the request of the holder of a marketing authorisation whose interests or legal position are affected by the measures referred to in paragraph 1, the competent	4. At the request of the holder of a marketing authorisation whose interests or legal position are affected by the measures referred to in paragraph 1, the competent

authorities shall ***specify the objective data and criteria on the basis of which these measures have been taken with respect to its medicinal product. In such a case, the competent authorities shall also*** inform the marketing authorisation holder of all remedies available, including judicial, and of the time limits for applying for such remedies.	authorities shall inform the marketing authorisation holder of all remedies available, including judicial, and of the time limits for applying for such remedies.

Or. fr

Justification

The requirement to provide a detailed justification in support of any decision by the authorities regarding their prescription policy that would be contrary to the commercial interests of manufacturers is disproportionate.

Amendment 92
Sirpa Pietikäinen

Proposal for a directive
Article 13 – title

Text proposed by the Commission	*Amendment*
Additional proof of quality, safety, efficacy ***or bioequivalence***	Additional proof of quality, safety, efficacy***, bioequivalence or biosimilarity***

Or. en

Amendment 93
Ashley Fox

Proposal for a directive
Article 13 – title

Text proposed by the Commission	*Amendment*
Additional proof of quality, safety, efficacy ***or bioequivalence***	Additional proof of quality, safety, efficacy***, bioequivalence or biosimilarity***

Or. en

Justification

The non reassessment of the elements on which the marketing authorisation is based should also apply to biosimilar medicinal products approved according to Article 10.4 of Directive 2001/83/EC.

Amendment 94
Bernadette Vergnaud

Proposal for a directive
Article 13 – title

Text proposed by the Commission	*Amendment*
Additional proof of quality, safety, efficacy ***or*** bioequivalence	Additional proof of quality, safety, efficacy***,*** bioequivalence ***or biosimilarity***

Or. fr

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 95
Cristian Silviu Buşoi

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***

Or. en

Justification

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

Amendment 96
Phil Prendergast

Proposal for a directive
Article 13 – title

Text proposed by the Commission	*Amendment*
Additional proof of quality, safety, efficacy ***or bioequivalence***	Additional proof of quality, safety, efficacy***, bioequivalence or biosimilarity***

Or. en

Amendment 97
Ashley Fox

Proposal for a directive
Article 13 – paragraph 1

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 bioequivalence ***or biosimilarity*** of the medicinal product.

Or. en

Justification

The non reassessment of the elements on which the marketing authorisation is based should also apply to biosimilar medicinal products approved according to Article 10.4 of Directive 2001/83/EC.

Amendment 98
Bernadette Vergnaud

Proposal for a directive
Article 13 – paragraph 1

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 ***may*** re-assess the elements on which the marketing authorisation is based, including the quality, safety ***or*** efficacy of the medicinal product.

Or. fr

Justification

The authorities need to be able to re-assess the therapeutic value of a medicinal product. The relative value of a medicinal product may in fact vary considerably depending on the appearance of new competing molecules on the market or the discovery of a new therapeutic property. In addition, these comparative assessments are not covered by the mandates of agencies issuing marketing authorisations. Finally, it is not necessary to re-assess bioequivalence.

Amendment 99
Cristian Silviu Buşoi

Proposal for a directive
Article 13 – paragraph 1

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.***

Or. en

Justification

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

Amendment 100
Phil Prendergast

Proposal for a directive
Article 13 – paragraph 1

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***, bioequivalence or biosimilarity*** of the medicinal product.

Or. en

Amendment 101
Sirpa Pietikäinen

Proposal for a directive
Article 13 – paragraph 1

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 ***criteria*** on which the marketing authorisation is based.

Or. en

Amendment 102
Phil Prendergast

Proposal for a directive
Article 15 – paragraph 1

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 measure falling within the scope of this Directive, it shall give interested parties***, civil society organisations and stakeholders*** 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.

Or. en

Amendment 103
Sirpa Pietikäinen

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.

Or. en

Amendment 104
Bernadette Vergnaud

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.

Or. fr

Justification

The provisions of this Article go beyond what is necessary to attain the objective pursued and infringe the principle of subsidiarity.

Amendment 105
Ildikó Gáll-Pelcz

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 shall communicate to the Commission the draft measure envisaged, together with the reasoning on which the measure is based.

Or. hu

Amendment 106
Adam Bielan

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.

Or. en

Amendment 107
Ildikó Gáll-Pelcz

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.	***deleted***

Or. hu

Amendment 108
Adam Bielan

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.

Or. en

Amendment 109
Ildikó Gáll-Pelcz

Proposal for a directive
Article 16 – paragraph 3

Text proposed by the Commission	*Amendment*
(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.	***deleted***

Or. hu

Amendment 110
Adam Bielan

Proposal for a directive
Article 16 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	3. Member States ***should*** 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.

Or. en

Amendment 111
Nora Berra

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

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

Or. fr

Amendment 112
Ildikó Gáll-Pelcz

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

Text proposed by the Commission	*Amendment*
The Commission may send its observations to the Member State which has communicated the draft measure within three months.	The Commission may send its observations to the Member State which has communicated the draft measure within three months***, and the Member State will then publish these in the form of an on-line database***.

Or. hu

Amendment 113
Adam Bielan

Proposal for a directive
Article 16 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
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***.	The observations of the Commission ***should*** be taken into account by the Member State concerned.

Or. en

Amendment 114
Ildikó Gáll-Pelcz

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. 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***, which will publish it in the form of a public on-line database***.

Or. hu

Amendment 115
Adam Bielan

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 ***should*** communicate the final text to the Commission without delay.

Or. en

Amendment 116
Phil Prendergast

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 online database containing comparative information on procurement prices for all medicines purchased by Member States.

Or. en

Amendment 117
Ildikó Gáll-Pelcz

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

Text proposed by the Commission	*Amendment*
	c a) 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;

Or. hu

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 118
Ildikó Gáll-Pelcz

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

Text proposed by the Commission	*Amendment*
	c b) 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;

Or. hu

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.