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Committee on the Environment, Public Health and Food Safety

2012/0035(COD)

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AMENDMENTS
43 - 133

Draft report
Antonyia Parvanova
(PE491.292v01-00)

on the proposal for a directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems

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

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Amendment 43
Michèle Rivasi

Proposal for a directive

Proposal for rejection

The European Parliament rejects the Commission proposal.

Or. en

Justification

The Commission proposal should be rejected as it is solely driven by the interests of the pharmaceutical industry, at the expense of the rights of Member States, and ultimately at the expense of the interests of patients. Member States are straitjacketed (shorter assessment deadlines, disproportionate penalties, strict notification requirements), while pharmaceutical companies can achieve increases price via a tacit consent procedure. The Commission should present a new and balanced proposal.

Amendment 44
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 45
Alda Sousa

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 168(7) and*** 114 thereof,

Or. en

Amendment 46
Alda Sousa

Proposal for a directive
Recital 2

Text proposed by the Commission	*Amendment*
(2) In order to take into account the evolution of the pharmaceutical market and of national policies to control public expenditure on ***medicines***, substantive changes are necessary to all major provisions of Directive 89/105/EEC. Therefore, in the interest of clarity, Directive 89/105/EEC should be replaced.	(2) In order to take into account the evolution of the pharmaceutical market and of national policies to control public expenditure on ***medicinal products***, substantive changes are necessary to all major provisions of Directive 89/105/EEC. Therefore, in the interest of clarity, Directive 89/105/EEC should be replaced.

Or. en

Amendment 47
Justas Vincas Paleckis

Proposal for a directive
Recital 2

Text proposed by the Commission	*Amendment*
(2) In order to take into account the evolution of the pharmaceutical market and	(2) In order to take into account the evolution of the pharmaceutical market and

of national policies to control public expenditure on medicines, substantive changes are necessary to all major provisions of Directive 89/105/EEC. Therefore, in the interest of clarity, Directive 89/105/EEC should be ***replaced***;	of national policies to control public expenditure on medicines, substantive changes are necessary to all major provisions of Directive 89/105/EEC. Therefore, in the interest of clarity, Directive 89/105/EEC should be ***amended***.

Or. lt

Amendment 48
Zofija Mazej Kukovič

Proposal for a directive
Recital 4

Text proposed by the Commission	*Amendment*
(4) Member States have been confronted *to* a steady rise in pharmaceutical expenditure over the last decades, leading to the adoption of increasingly innovative and complex policies to manage the consumption of medicines in the framework of their public health insurance systems. In particular, Member States' authorities have implemented a broad range of measures to control the prescription of medicines, to regulate their prices or to establish the conditions of their public funding. Such measures mainly aim at promoting public health by ensuring the availability of adequate supplies of medicinal products at reasonable costs, while ensuring the financial stability of public health insurance systems.	(4) Member States have been confronted *with* a steady rise in pharmaceutical expenditure over the last decades, leading to the adoption of increasingly innovative and complex policies to manage the consumption of medicines in the framework of their public health insurance systems. In particular, Member States' authorities have implemented a broad range of measures to control the prescription of medicines, to regulate their prices or to establish the conditions of their public funding. Such measures mainly aim at promoting public health by ensuring the availability of adequate supplies of medicinal products ***on equal terms to all EU citizens*** at reasonable costs, while ensuring the financial stability of public health insurance systems. ***Medicines classed as essential on the WHO list should be available to patients in all Member States, whatever the size of the market.***

Or. sl

Amendment 49
Alda Sousa

Proposal for a directive
Recital 4

Text proposed by the Commission	*Amendment*
(4) Member States have been confronted to a steady rise in pharmaceutical expenditure over the last decades, leading to the adoption of increasingly innovative and complex policies to manage the consumption of ***medicines*** in the framework of their public health insurance systems. In particular, Member States' authorities have implemented a broad range of measures to control the prescription of ***medicines***, to regulate their prices or to establish the conditions of their public funding. Such measures mainly aim at promoting public health by ensuring the availability of adequate supplies of medicinal products at reasonable costs, while ensuring ***the financial stability of public health insurance systems***.	(4) Member States have been confronted to a steady rise in pharmaceutical expenditure over the last decades, leading to the adoption of increasingly innovative and complex policies to manage the consumption of ***medicinal products*** in the framework of their public health insurance systems. In particular, Member States' authorities have implemented a broad range of measures to control the prescription of ***medicinal products***, to regulate their prices or to establish the conditions of their public funding. Such measures mainly aim at promoting public health ***for all citizens*** by ensuring the availability of adequate supplies of ***effective*** medicinal products at reasonable costs, while ensuring ***an equal access to high quality healthcare for all***.

Or. en

Amendment 50
Françoise Grossetête, Philippe Juvin

Proposal for a directive
Recital 4

Text proposed by the Commission	*Amendment*
(4) Member States have been confronted to a steady rise in pharmaceutical expenditure over the last decades, leading to the adoption of increasingly innovative and complex policies to manage the consumption of medicines in the framework of their public health insurance systems. In particular, Member States' authorities have implemented a broad range of measures to control the prescription of medicines, to regulate their	(4) Member States have been confronted to a steady rise in pharmaceutical expenditure over the last decades, leading to the adoption of increasingly innovative and complex policies to manage the consumption of medicines in the framework of their public health insurance systems. In particular, Member States' authorities have implemented a broad range of measures to control the prescription of medicines, to regulate their

prices or to establish the conditions of their public funding. Such measures mainly aim at promoting public health by ensuring the availability of adequate supplies of medicinal products at reasonable costs, while ensuring the financial stability of public health insurance systems.	prices or to establish the conditions of their public funding. Such measures mainly aim at promoting public health by ensuring the availability of adequate supplies of medicinal products at reasonable costs, while ensuring the financial stability of public health insurance systems. ***These measures should also aim to promote research and development of new medicinal products and to recognise medical innovation.***

Or. fr

Justification

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

Amendment 51
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 52
Horst Schnellhardt, Anja Weisgerber, Thomas Ulmer

Proposal for a directive
Recital 8

Text proposed by the Commission	*Amendment*
(8) Due to diversity of national measures managing the consumption of medicines, regulating their prices or establishing the conditions of their public funding it is necessary to clarify Directive 89/105/EEC. In particular this Directive should cover all types of measures devised by Member States and susceptible to impact the internal market. Since the adoption of Directive 89/105/EEC, the pricing and reimbursement procedures have evolved and have become more complex. While some Member States have interpreted the scope of Directive 89/105/EEC restrictively, the Court of Justice ruled that those pricing and reimbursement procedures fall within the scope of Directive 89/105/EEC given the objectives of that Directive and the need to ensure its effectiveness. Therefore, this Directive should reflect the developments in national pricing and reimbursement policies. ***Given that*** specific rules and procedures ***exist*** in the area of public procurement and voluntary contractual agreements, national measures involving public procurement and voluntary contractual agreements should be excluded from the scope of this Directive.	(8) Due to diversity of national measures managing the consumption of medicines, regulating their prices or establishing the conditions of their public funding it is necessary to clarify Directive 89/105/EEC. In particular this Directive should cover all types of measures devised by Member States and susceptible to impact the internal market. Since the adoption of Directive 89/105/EEC, the pricing and reimbursement procedures have evolved and have become more complex. While some Member States have interpreted the scope of Directive 89/105/EEC restrictively, the Court of Justice ruled that those pricing and reimbursement procedures fall within the scope of Directive 89/105/EEC given the objectives of that Directive and the need to ensure its effectiveness. Therefore, this Directive should reflect the developments in national pricing and reimbursement policies. ***Despite the existence of*** specific rules and procedures in the area of public procurement and voluntary contractual agreements, national measures involving public procurement and voluntary contractual agreements should ***only*** be excluded from the scope of this Directive ***to the extent that the voluntary agreements also allow transparency about the drug sales price which is of primary concern to the insured person. It must be clear to doctors and pharmacists as distribution points for drugs which costs are incurred by the patient and the health care systems for a medicine in order to be able to choose the most economically rational drug regardless of the type of agreement***.

Or. de

Amendment 53
Michèle Rivasi

Proposal for a directive
Recital 9

Text proposed by the Commission	*Amendment*
(9) Any measure to regulate, either directly or indirectly, the prices of medicinal products, as well as any measure to determine their coverage by public health insurance systems should be based on objective and verifiable criteria that are independent from the origin of the product ***and should provide adequate legal remedies, including judicial remedies, to affected companies***. These requirements should equally apply to national, regional or local measures to control or promote the prescription of specific medicinal products as such measures also determine their effective coverage by health insurance systems.	(9) Any measure to regulate, either directly or indirectly, the prices of medicinal products, as well as any measure to determine their coverage by public health insurance systems should be based on objective and verifiable criteria that are independent from the origin of the product. These requirements should equally apply to national, regional or local measures to control or promote the prescription of specific medicinal products as such measures also determine their effective coverage by health insurance systems.

Or. fr

Justification

In its judgment in Case C-62/09 the Court of Justice authorised measures to monitor or encourage the prescription of certain medicinal products. What is more, those measures have no bearing on decisions to include medicinal products in the scope of national health insurance systems. A proposal such as this would also enable the manufacturers of all competing medicinal products to submit appeals, creating an administrative and legal nightmare.

Amendment 54
Karin Kadenbach

Proposal for a directive
Recital 9

Text proposed by the Commission	*Amendment*
(9) Any measure to regulate, either directly or indirectly, the prices of medicinal	(9) Any measure to regulate, either directly or indirectly, the prices of medicinal

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

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

Or. en

Amendment 55
Nessa Childers, Justas Vincas Paleckis

Proposal for a directive
Recital 9

Text proposed by the Commission	*Amendment*
(9) Any measure to regulate, either directly or indirectly, the prices of medicinal products, as well as any measure to determine their coverage by public health insurance systems should be based on objective and verifiable criteria that are independent from the origin of the product ***and should provide adequate legal remedies, including judicial remedies, to affected companies***. These requirements should equally apply to national, regional or local measures to control or promote the prescription of specific medicinal products as such measures also determine their effective coverage by health insurance systems.	(9) Any measure to regulate, either directly or indirectly, the prices of medicinal products, as well as any measure to determine their coverage by public health insurance systems should be based on objective and verifiable criteria that are independent from the origin of the product. These requirements should equally apply to national, regional or local measures to control or promote the prescription of specific medicinal products as such measures also determine their effective coverage by health insurance systems.

Or. en

Amendment 56
Andres Perello Rodriguez

Proposal for a directive
Recital 9 a (new)

Text proposed by the Commission	*Amendment*
	(9a) The criteria underlying any decision directly or indirectly regulating the prices of medicinal products, as well as any measure determining the extent to which they shall be covered by public health insurance systems should include the assessment of unmet medical needs, clinical and social benefits and innovation, as laid down in the European Economic and Social committee opinion on the proposal for a directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems, of 12 June 2012[1]. Such criteria should also include protection for the most vulnerable groups of the population.
	1 OJ C 299, 4.10.2012 p. 83

Or. es

Amendment 57
Karin Kadenbach

Proposal for a directive
Recital 10

Text proposed by the Commission	*Amendment*
(10) Applications to approve the price of a medicinal product or to determine its coverage by the health insurance system should not delay the placing on the market	(10) Applications to approve the price of a medicinal product or to determine its coverage by the health insurance system should not delay the placing on the market

of that product beyond what is necessary. It is therefore desirable that this Directive sets out mandatory time limits within which national decisions should be made. In order to be effective, the prescribed time periods should run from the receipt of an application until the entry into force of the corresponding decision. They should include all expert evaluations, including health technology assessments where applicable, and all administrative steps required for the decision to be adopted and take legal effect.	of that product beyond what is necessary. It is therefore desirable that this Directive sets out mandatory time limits within which national decisions should be made. In order to be effective, the prescribed time periods should run from the receipt of an application until the entry into force of the corresponding decision. They should include all ***recommendations and*** expert evaluations, including health technology assessments where applicable, and all administrative steps required for the decision to be adopted and take legal effect.

Or. en

Amendment 58
Nessa Childers

Proposal for a directive
Recital 11

Text proposed by the Commission	*Amendment*
(11) The time-limits for the inclusion of medicinal products in the health insurance systems set out in Directive 89/105/EEC are mandatory as clarified by the case-law of the Court of Justice. Experience has shown that those time limits are not always respected and that there is need to ensure legal certainty and improve the procedural rules related to the inclusion of medicinal products in the scope of health insurance system. Therefore, ***an*** effective ***and*** rapid remedies ***procedure*** should be ***put in place.***	(11) The time-limits for the inclusion of medicinal products in the health insurance systems set out in Directive 89/105/EEC are mandatory as clarified by the case-law of the Court of Justice. Experience has shown that those time limits are not always respected and that there is need to ensure legal certainty and improve the procedural rules related to the inclusion of medicinal products in the scope of health insurance system. Therefore, effective rapid remedies ***procedures*** should be ***encouraged.***

Or. en

Amendment 59
Michèle Rivasi

Proposal for a directive
Recital 11

Text proposed by the Commission	*Amendment*
(11) The time-limits for the inclusion of medicinal products in the health insurance systems set out in Directive 89/105/EEC are mandatory as clarified by the case-law of the Court of Justice. Experience has shown that those time limits are not always respected and that there is need to ensure legal certainty and improve the procedural rules related to the inclusion of medicinal products in the scope of health insurance system. Therefore, an ***effective and rapid remedies procedure*** should be ***put in place***.	(11) The time-limits for the inclusion of medicinal products in the health insurance systems set out in Directive 89/105/EEC are mandatory as clarified by the case-law of the Court of Justice. Experience has shown that those time limits are not always respected and that there is need to ensure legal certainty and improve the procedural rules related to the inclusion of medicinal products in the scope of health insurance system. Therefore, ***effective and rapid measures of redress*** should be ***encouraged***.

Or. fr

Justification

Remedies procedures, including judicial procedures, already exist in the Member States. What is more, these procedures are Member State matters which fall outside the scope of this directive, which deals with administrative procedures for approving the price of medicinal products and authorising the reimbursement of their cost under health insurance systems.

Amendment 60
Alda Sousa

Proposal for a directive
Recital 12

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

included in the health insurance system. It is therefore appropriate to lay down shorter time limits for generic medicinal products in those cases.	already been priced and included in the health insurance system. It is therefore appropriate to lay down shorter time limits for generic ***or biosimilar*** medicinal products in those cases.

Or. en

Amendment 61
Michèle Rivasi

Proposal for a directive
Recital 12

Text proposed by the Commission	*Amendment*
(12) In its Communication "Executive Summary of the Pharmaceutical Sector Inquiry Report" the Commission demonstrated that pricing and reimbursement procedures often unnecessarily delay the launch of generic medicines in Union markets. Approving the price of generic medicinal products and their coverage by the health insurance system should not require any new or detailed assessment when the reference product has already been priced and included in the health insurance system. It is therefore appropriate to lay down shorter time limits for generic medicinal products in those cases.	(12) In its Communication "Executive Summary of the Pharmaceutical Sector Inquiry Report" the Commission demonstrated that pricing and reimbursement procedures often unnecessarily delay the launch of generic medicines in Union markets. Approving the price of generic medicinal products and their coverage by the health insurance system should not require any new or detailed assessment when the reference product ***is essentially similar, within the meaning of Directive 2001/83/EC, and*** has already been priced and included in the health insurance system. It is therefore appropriate to lay down shorter time limits for generic medicinal products in those cases. ***If generic medicinal products display differences by comparison with the reference medicinal product, for example as regards their packaging or their therapeutic indications, Member States may provide for their assessment.***

Or. fr

Justification

Although decision-making concerning generic medicines whose reference medicinal products have already been evaluated should be expedited, it should still be possible to assess generics

which are not essentially similar to their reference product. Certain generics may differ from their reference product in respect of their packaging or therapeutic indications.

Amendment 62
Corinne Lepage

Proposal for a directive
Recital 13

Text proposed by the Commission	*Amendment*
(13) The judicial remedies available in the Member States have played a limited role in ensuring compliance with the time limits due to the often lengthy procedures in national jurisdictions, which deter affected companies from initiating legal action. Therefore, effective mechanisms are necessary to control and enforce compliance with the time limits for pricing and reimbursement decisions.	***deleted***

Or. en

Amendment 63
Michèle Rivasi

Proposal for a directive
Recital 13

Text proposed by the Commission	*Amendment*
(13) The judicial remedies available in the Member States have played a limited role in ensuring compliance with the time limits due to the often lengthy procedures in national jurisdictions, which deter affected companies from initiating legal action. Therefore, effective mechanisms are necessary to control and enforce compliance with the time limits for pricing and reimbursement decisions.	***deleted***

Or. fr

Justification

Remedies procedures, including judicial procedures, are Member State matters which fall outside the scope of this directive, which deals with administrative procedures for approving the price of medicinal products and authorising the reimbursement of their cost under health insurance systems.

Amendment 64
Nessa Childers, Justas Vincas Paleckis

Proposal for a directive
Recital 13

Text proposed by the Commission	*Amendment*
(13) The judicial remedies available in the Member States have played a limited role in ensuring compliance with the time limits due to the often lengthy procedures in national jurisdictions, which deter affected companies from initiating legal action. Therefore, effective mechanisms are necessary to control and enforce compliance with the time limits for pricing and reimbursement decisions.	***deleted***

Or. en

Amendment 65
Alda Sousa

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***	(14) The quality, safety and efficacy of medicinal products, including ***orphan medicinal products and*** the bioequivalence of generic ***or biosimilar*** medicinal products with the reference product, are ascertained in the framework of marketing authorisation procedures.

which the marketing authorisation is based, including the quality, safety, efficacy or bioequivalence of the medicinal product.

Or. en

Amendment 66
Zofija Mazej Kukovič

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, are ascertained in the framework of marketing authorisation procedures. In the framework of pricing and reimbursement procedures, ***where legitimate reservations have arisen from knowledge newly obtained,*** Member States should therefore *reassess* the elements on which the marketing authorisation is based, including the quality, safety, efficacy or bioequivalence of the medicinal product.

Or. sl

Amendment 67
Corinne Lepage

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	(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.	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 ***(***quality, safety, efficacy or bioequivalence of the medicinal product***). Member States shall be guaranteed full access to the data used by the marketing authorisation authority in assessing these elements, with a view to evaluating the relative safety, efficacy and effectiveness of the medicine in the context of the health insurance scheme. Competent authorities should also have the right to request additional data for the purpose of their evaluation***.

Or. en

Amendment 68
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 Member States should have full access to the data used in the marketing authorisation procedure so that they can assess the relative*** safety ***and*** efficacy ***of a*** medicinal product ***in the context 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 69
Michèle Rivasi

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) ***Proof of the*** quality, safety and efficacy of medicinal products, including the bioequivalence of generic medicinal products with the reference product, ***is verified*** in the framework of marketing authorisation procedures. In the framework of pricing and reimbursement procedures, Member States should therefore not re-assess the ***essential*** elements ***(quality, safety, efficacy or biosimilarity)*** on which the marketing authorisation is based, including the quality, safety, efficacy or bioequivalence of the medicinal product**.** ***However, Member States must be guaranteed full access to the data used by the authorities responsible for granting the marketing authorisation so that they can assess the relative*** safety, ***efficiency and*** efficacy ***of a medicinal product in the context of its inclusion in the scope of the mandatory health insurance system. The competent authorities should also be able to include or generate additional relevant data for the purposes of assessing medicinal products.***

Or. fr

Justification

Misinterpreting this recital could result in Member States being prevented from using data or requesting additional data they need to assess the relative risk-benefit ratio and the relative efficacy of medicinal products by comparison with treatments already covered by their national health insurance systems.

Amendment 70
Françoise Grossetête, Philippe Juvin

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, 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. ***Similarly, in the case of orphan drugs, Member states shall not re-assess the criteria of the orphan designation.***

Or. fr

Justification

It would be unacceptable for the medical added value of these medicinal products to be called into question at national level, because that added value is the essential precondition for their authorisation at EU level. A clarification of this kind would in no way be at odds with the decision by the national authorities whether or not to reimburse the cost of an orphan medicinal product, but would in fact encourage national authorities to make greater use of the expertise acquired at European level.

Amendment 71
Françoise Grossetête

Proposal for a directive
Recital 15

Text proposed by the Commission	*Amendment*
(15) In accordance with Directive	(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.

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 ***procedures for*** reimbursement ***of generic medicines*** in the Member States.

Or. fr

Justification

Clarification that this procedure refers only to generic medicines.

Amendment 72
Zofija Mazej Kukovič

Proposal for a directive
Recital 15

Text proposed by the Commission

(15) In accordance with Directive 2001/83/EC, intellectual property rights do not provide a valid ground to refuse, suspend or revoke a marketing

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.	authorisation. By the same token, applications, decision-making procedures and decisions to regulate the prices of medicinal products or to determine their coverage by health insurance systems should be considered administrative procedures which, as such, are independent from the enforcement of intellectual property rights. The national authorities in charge of those procedures, when examining an application with respect to a ***bioequivalent*** generic medicinal product, should not request information concerning the patent status of the reference medicinal product***, but they*** should ***be allowed to*** examine the validity of an alleged violation of intellectual property rights should the ***bioequivalent*** generic medicinal product be manufactured or placed on the market subsequently to their decision. ***That responsibility may not be removed from Member States. Without prejudice to the responsibility of Member States to examine information,*** intellectual property issues should neither interfere with nor delay pricing and reimbursement procedures in the Member States.
	Or. sl

Amendment 73
Zofija Mazej Kukovič

Proposal for a directive
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) Member States should make the relevant documents and information publicly available in an appropriate publication, in accordance with national practice, which could include electronic and online format. When publishing such information, they should ensure that the quantity of data supplied is reasonable

and not such as to jeopardise the competitiveness of the EU.

Or. sl

Amendment 74
Alda Sousa

Proposal for a directive
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a)) Member States should ensure the public availability of documents and information in an appropriate publication, in accordance with national practice, which should include electronic and online formats.

Or. en

Amendment 75
Zofija Mazej Kukovič

Proposal for a directive
Recital 15 b (new)

Text proposed by the Commission	*Amendment*
	(15b) The transparency, integrity, and independence of decision-making within national authorities should be ensured through publication of the names of the competent authorities and the procedural steps leading to pricing and reimbursement decisions.

Or. sl

Amendment 76
Alda Sousa

Proposal for a directive
Recital 15 b (new)

Text proposed by the Commission	*Amendment*
	(15b) The principles of transparency, integrity and independence of the decision-making processes should be carried out by national competent public authorities, who are responsible for pricing and reimbursement decisions.

Or. en

Amendment 77
Milan Cabrnoch

Proposal for a directive
Recital 16

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

Or. cs

Amendment 78
Alda Sousa

Proposal for a directive
Recital 16

Text proposed by the Commission	*Amendment*
(16) Member States have frequently	(16) Member States have frequently

amended their health insurance schemes or adopted new measures falling within the scope of Directive 89/105/EEC. It is therefore necessary to establish information mechanisms intended, on the one hand, to ensure the consultation of interested stakeholders and, on the other hand, to facilitate preventive dialogue with the Commission as regards the application of this Directive.	amended their health insurance schemes or adopted new measures falling within the scope of Directive 89/105/EEC. It is therefore necessary to establish information mechanisms intended, on the one hand, to ensure the consultation of interested stakeholders ***including patient and consumer organisations*** and, on the other hand, to facilitate preventive dialogue with the Commission as regards the application of this Directive.

Or. en

Amendment 79
Milan Cabrnoch

Proposal for a directive
Recital 18

Text proposed by the Commission	*Amendment*
(18) In accordance with the Joint Political Declaration of Member States and the Commission on explanatory documents of 28 September 2011, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified.	***deleted***

Or. cs

Amendment 80
Françoise Grossetête

Proposal for a directive
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that any national, regional or local measure, whether laid down by law, regulation or administrative action, to control the prices of medicinal products for human use or to determine the range of medicinal products covered by public health insurance systems, including the extent and conditions of their coverage, complies with the requirements of this Directive.	1. Member States shall ensure that any national, regional or local measure, whether laid down by law, regulation or administrative action, to control the prices of medicinal products for human use or to determine the range of medicinal products covered by public health insurance systems, including the extent and conditions of their coverage, complies with the requirements of this Directive. ***Member States shall ensure that these measures are not duplicated at regional or local level in their respective states.***

Or. fr

Justification

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

Amendment 81
Thomas Ulmer

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

Text proposed by the Commission	*Amendment*
	This Directive shall also apply to medicinal products which are available on prescription, but are not refundable by the national health insurance system.

Or. de

Amendment 82
Zofija Mazej Kukovič

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

Text proposed by the Commission	*Amendment*
(a) voluntary contractual agreements concluded between public authorities and the holder of a marketing authorisation for a medicinal product that have as their object to enable the effective provision of this medicine to patients under specific conditions;	(a) voluntary contractual agreements***, subject to verification of elements concerning the efficacy and/or relative efficacy or the proper use of the given medicine,*** 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 ***for the agreed period***;

Or. sl

Amendment 83
Horst Schnellhardt, Anja Weisgerber, Thomas Ulmer

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

Text proposed by the Commission	*Amendment*
(a) voluntary contractual agreements concluded between public authorities and the holder of a marketing authorisation for a medicinal product that have as their object to enable the effective provision of this medicine to patients under specific conditions;	(a) 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***, provided that such arrangements also meet the transparency requirements of Article 5, paragraph 3 a (new)***;

Or. de

Justification

Even prices set under voluntary agreements should be notified to the distribution points to allow the sale of the cheapest medicines.

Amendment 84
Milan Cabrnoch

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. cs

Amendment 85
Françoise Grossetête, Philippe Juvin

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

Text proposed by the Commission	*Amendment*
	3a. This Directive may not call into question granted as per the procedure referred to in Article 6 of Directive 2001/83/EC.

Or. fr

Justification

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

Amendment 86
Erik Bánki

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

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

Or. en

Amendment 87
Bernadette Vergnaud

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

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

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 88
Michèle Rivasi

Proposal for a directive
Article 2 – point 4

Text proposed by the Commission	*Amendment*
4) "health technology" means a health technology as defined in point (l) of Article 3 of Directive 2011/24/EU of the European Parliament and of the Council;	***deleted***

Or. fr

Justification

Setting a definition of health technologies is arbitrary and unjustified because there is currently no common interpretation of what is meant by this concept. Coupled with the introduction of two different systems governing deadlines for approving the price and authorising the reimbursement of non-generic medicinal products, setting such a definition would further complicate matters.

Amendment 89
Michèle Rivasi

Proposal for a directive
Article 2 – point 5

Text proposed by the Commission	*Amendment*
5) "health technology assessment" means an assessment of the relative efficacy or of the short- and long-term effectiveness of the medicinal product compared to other health technologies in use for treating the associated condition.	***deleted***

Or. fr

Justification

Setting a definition of health technology assessment is arbitrary and unjustified because there is currently no common interpretation of what is meant by this concept. Coupled with the introduction of two different systems governing deadlines for approving the price and authorising the reimbursement of non-generic medicinal products, setting such a definition would further complicate matters.

Amendment 90
Peter Liese, Zofija Mazej Kukovič, Anja Weisgerber

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

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

as referred to in Article 1(2), point (a) means an agreement concluded between public authorities and the marketing authorisation holder for a medicinal product which is neither mandatory or required by law nor is the agreement the only alternative to be included in the national pricing and reimbursement scheme.

Or. en

Justification

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

Amendment 91
Andres Perello Rodriguez

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

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

Or. es

Amendment 92
Milan Cabrnoch

Proposal for a directive
Article 3 – paragraph 2

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

Or. cs

Amendment 93
Françoise Grossetête

Proposal for a directive
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that an application to approve the price of the product can be introduced by the marketing authorisation holder at any point in time. The competent authorities shall provide the applicant with an official acknowledgement of receipt.	2. Member States shall ensure that an application to approve the price of the product can be introduced by the marketing authorisation holder at any point in time ***or by the applicant once the Committee for Medicinal Products for Human Use (set up by Regulation (EC) No 726/2004) or a competent national authority has delivered a favourable opinion***. The competent authorities shall provide the applicant with an official acknowledgement of receipt.

Or. fr

Justification

A number of Member States already authorise applicants to submit a Price and Reimbursement Application once the Committee for Medicinal Products for Human Use or a competent national authority of a Member State has delivered a favourable opinion. In this way a dialogue is opened at an early stage, making it more likely that the time limits laid down in the directive will be complied with and thus facilitating patient access to new medicinal products.

Amendment 94
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 95
Nessa Childers

Proposal for a directive
Article 3 – paragraph 2

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

Or. en

Amendment 96
Michèle Rivasi

Proposal for a directive
Article 3 – paragraph 2

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

Or. fr

Justification

This proposal would considerably increase the administrative burden on the competent authorities, who would be submerged with applications following any decision to turn down an application, even if circumstances have not changed.

Amendment 97
Corinne Lepage

Proposal for a directive
Article 3 – paragraph 2 – subparagraph 1a (new)

Text proposed by the Commission	*Amendment*
	This Article shall not prevent Member States to refuse repeated applications following a negative decision if the circumstances have not significantly changed.

Or. en

Amendment 98
Erik Bánki

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

Or. hu

Justification

The 15-day time limit proposed by the Commission would be difficult for the authorities to comply with. An excessively short time limit would damage the quality of decision-making.

Amendment 99
Zofija Mazej Kukovič

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	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. ***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.

a marketing authorisation. With respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the *time limit* shall ***likewise*** 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. sl

Amendment 100
Corinne Lepage

Proposal for a directive
Article 3 – paragraph 3

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

Or. en

Amendment 101
Kārlis Šadurskis

Proposal for a directive
Article 3 – paragraph 3

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

Or. en

Amendment 102
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,***	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

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.

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 103
Erik Bánki

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 ***25 days, provided that the price of the reference medicinal product has been approved by the competent authorities. With respect to biosimilar medicinal products, that time limit shall be 60*** days, provided that the price of the reference medicinal product has been approved by the competent authorities.

Or. en

Justification

The proposed 15-day time limit may be too short for authorities which could have adverse effects on the quality of the decision. Since biological medicinal products have lost or are about to lose their exclusivity rights, biosimilar medicines are a relatively new category of medicinal products, the timelines from submission to approval should therefore be 60 days maximum.

Amendment 104
Christofer Fjellner

Proposal for a directive
Article 3 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall ensure that a decision on the price which may be charged for the medicinal product concerned is adopted and communicated to the applicant within ***60*** days of the receipt of an application submitted, in accordance with the requirements laid down in the Member State concerned, by the holder of a marketing authorisation. ***However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days.*** With respect to generic medicinal products, that time limit shall be ***15*** days, provided that the price of the reference medicinal product has been approved by the competent authorities.	3. Member States shall ensure that a decision on the price which may be charged for the medicinal product concerned is adopted and communicated to the applicant within ***90*** days of the receipt of an application submitted, in accordance with the requirements laid down in the Member State concerned, by the holder of a marketing authorisation. With respect to generic medicinal products, that time limit shall be ***45*** days, provided that the price of the reference medicinal product has been approved by the competent authorities.

Or. en

Amendment 105
Philippe Juvin

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 approved by the competent authorities.	3. Member States shall ensure that a decision on the price which may be charged for the medicinal product concerned is adopted and communicated to the applicant within ***90*** days of the receipt of an application submitted, in accordance with the requirements laid down in the Member State concerned, by the holder of a marketing authorisation. With respect to generic medicinal products, that time limit shall be ***45*** days, provided that the price of the reference medicinal product has been approved by the competent authorities. ***Member States shall consider basing their decision on the price which may be charged for a medicinal produce on a health technology assessment.***

Or. fr

Amendment 106
Michèle Rivasi

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	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 ***and that the generic product is essentially***

time limit shall be ***15*** days, provided that the price of the reference medicinal product has been approved by the competent authorities.	***similar to the reference product, within the meaning of Directive 2001/83/EC of 6 November 2001.***

Or. fr

Justification

Un seul régime de délai devrait être fixé. Il devrait être maintenu à quatre-vingt-dix jours afin de ne pas mettre en danger la qualité de l'évaluation des médicaments dans les Etats membres et ainsi la qualité du service rendu au patient. En effet, la consultation publique réalisée par la Commission européenne a montré que la majorité des parties prenantes, y compris l'industrie des princeps, considère les délais actuels satisfaisants. Ces délais sont nécessaires à une évaluation de qualité, compte tenu de l'existence de produits basés sur une recherche de plus en plus complexe et innovante.Même s'il est souhaitable d'accélérer la prise de décision pour les médicaments génériques dont le médicament de référence a déjà été évalué, l'évaluation des médicaments génériques devrait rester possible si le médicament concerné n'est pas essentiellement similaire au médicament de référence. En effet, certains médicaments génériques peuvent différer du médicament de référence quant au conditionnement ou encore aux indications thérapeutiques. Par conséquent, des délais suffisants devraient permettre aux autorités compétentes de réaliser une évaluation de ces médicaments de qualité.

Amendment 107
Nessa Childers, Justas Vincas Paleckis

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,	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.	that time limit shall be ***30*** days, provided ***that the generic product is essentially similar to the reference medicinal product, according to Directive 2001/83/EC and*** that the price of the reference medicinal product has been approved by the competent authorities.

Or. en

Amendment 108
Corinne Lepage

Proposal for a directive
Article 3 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall establish ***in detail*** the particulars and documents to be submitted by the applicant.	4. Member States shall establish the ***categories of*** particulars and documents to be submitted by the applicant.

Or. en

Amendment 109
Nessa Childers

Proposal for a directive
Article 3 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall establish in detail the particulars and documents to be submitted by the applicant.	4. Member States shall establish in detail the particulars and ***the main*** documents to be submitted by the applicant.

Or. en

Amendment 110
Michèle Rivasi

Proposal for a directive
Article 3 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall establish in detail the particulars and documents to be submitted by the applicant.	4. Member States shall establish in detail the ***categories of*** particulars and ***main*** documents to be submitted by the applicant.

Or. fr

Justification

The competent authorities must be granted at least some leeway so that they can respond to unexpected developments.

Amendment 111
Erik Bánki

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 ***25 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. hu

Justification

The 15-day time limit proposed by the Commission would be difficult for the authorities to comply with. An excessively short time limit would damage the quality of decision-making.

Amendment 112
Milan Cabrnoch

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 notify the applicant ***without undue delay*** 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.

Or. cs

Amendment 113
Zofija Mazej Kukovič

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	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 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.	authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within ***90 days*** of receipt of this additional information. With respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the *time limit* shall ***likewise*** 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. sl

Amendment 114
Corinne Lepage

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***	5. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within ***90*** days of receipt of this additional information. With respect to generic medicinal products, that time limit shall be in all events ***30*** days, provided that the price of the reference medicinal product has been approved by the competent authorities.

information which is not explicitly required under national legislation or administrative guidelines.

Or. en

Amendment 115
Kārlis Šadurskis

Proposal for a directive
Article 3 – paragraph 5

Text proposed by the Commission	*Amendment*
5. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within ***60*** days of receipt of this additional information. ***However, with respect to medicines for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days.*** With respect to generic medicinal products, that time limit shall be in all events ***15*** days, provided that the price of the reference medicinal product has been approved by the competent authorities. Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.	5. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within ***90*** days of receipt of this additional information. With respect to generic medicinal products, that time limit shall be in all events ***90*** 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 116
Philippe Juvin

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 what detailed additional information is required and take their final decision within ***90*** days of receipt of this additional information. With respect to generic medicinal products, that time limit shall be in all events ***45*** 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. fr

Amendment 117
Michèle Rivasi

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	5. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of what detailed additional information is required and take their final decision within ***90*** 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.	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 ***and that the generic product is essentially similar to the reference product, within the meaning of Directive 2001/83/EC of 6 November 2001***.

Or. fr

Justification

Même s'il est souhaitable d'accélérer la prise de décision pour les médicaments génériques dont le médicament de référence a déjà été évalué, l'évaluation des médicaments génériques devrait rester possible si le médicament concerné n'est pas essentiellement similaire au médicament de référence. En effet, certains médicaments génériques peuvent différer du médicament de référence quant au conditionnement ou encore aux indications thérapeutiques. Par conséquent, des délais suffisants devraient permettre aux autorités compétentes de réaliser une évaluation de ces médicaments de qualité.

Amendment 118
Erik Bánki

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	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 ***25*** 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.	product has been approved by the competent authorities. ***With respect to biosimilar medicinal products, that time limit shall be in all events 60 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

Justification

The proposed 15-day time limit may be too short for authorities which could have adverse effects on the quality of the decision. Since biological medicinal products have lost or are about to lose their exclusivity rights, biosimilar medicines are a relatively new category of medicinal products, the timelines from submission to approval should therefore be 60 days maximum.

Amendment 119
Christofer Fjellner

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	5. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within ***90*** days of receipt of this additional information. With respect to generic medicinal products, that time limit shall be in all events ***45*** 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.

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

Or. en

Amendment 120
Nessa Childers, Justas Vincas Paleckis

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.

Or. en

Amendment 121
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 122
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 123
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 124
Zofija Mazej Kukovič

Proposal for a directive
Article 3 – paragraph 9

Text proposed by the Commission	*Amendment*
9. If the competent authorities decide to reduce the price of a specific named medicinal product on their own initiative, the decision shall contain a statement of reasons based on objective and verifiable criteria***, including any evaluation, expert opinion or recommendation on which it is based***. The decision shall be communicated to the holder of the marketing authorisation, who shall be informed of all remedies available, including judicial remedies, and of the time limits for applying for such remedies.	9. If the competent authorities decide to reduce the price of a specific named medicinal product on their own initiative, the decision shall contain a statement of reasons based on objective and verifiable criteria. The decision shall be communicated to the holder of the marketing authorisation, who shall be informed of all remedies available, including judicial remedies, and of the time limits for applying for such remedies. ***The decision and a summary justification shall be made available to public view.***

Or. sl

Amendment 125
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 to the holder of the marketing authorisation, who shall be informed of all remedies available, including judicial remedies, and of the time limits for applying for such remedies.	9. If the competent authorities decide to reduce the price of a specific named medicinal product on their own initiative, the decision shall contain a statement of reasons based on objective and verifiable criteria. The decision shall be communicated to the holder of the marketing authorisation, who shall be informed of all remedies available, including judicial remedies, and of the time limits for applying for such remedies.

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 126
Milan Cabrnoch

Proposal for a directive
Article 4 – paragraph 2

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

Or. cs

Amendment 127
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 128
Nessa Childers

Proposal for a directive
Article 4 – paragraph 2

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

Or. en

Amendment 129
Michèle Rivasi

Proposal for a directive
Article 4 – paragraph 2

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

Or. fr

Justification

This proposal would considerably increase the administrative burden on the competent authorities, who would be submerged with applications following any decision to turn down an application, even if circumstances have not changed.

Amendment 130
Corinne Lepage

Proposal for a directive
Article 4 – paragraph 2 – subparagraph 1a (new)

Text proposed by the Commission	*Amendment*
	This Article shall not prevent Member States to refuse repeated applications following a negative decision if the circumstances have not significantly changed.

Or. en

Amendment 131
Zofija Mazej Kukovič

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 ***to approve or reject*** 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 ***discussed,*** adopted***,*** and communicated to the applicant within ***90 days*** of receipt *of the application*.

Or. sl

Amendment 132
Kārlis Šadurskis

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. en

Amendment 133
Corinne Lepage

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

Or. en