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Committee on the Environment, Public Health and Food Safety

2012/0035(COD)

25.10.2012

AMENDMENT
134 - 278

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))

AM_Com_LegReport

Amendment 134
Philippe Juvin

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

Text proposed by the Commission	*Amendment*
Member States shall ensure that a decision on an application submitted in accordance with the requirements laid down in the Member State concerned, by a marketing authorisation holder to increase the price of a medicinal product is adopted and communicated to the applicant within ***60*** days of its receipt.	Member States shall ensure that a decision on an application submitted in accordance with the requirements laid down in the Member State concerned, by a marketing authorisation holder to increase the price of a medicinal product is adopted and communicated to the applicant within ***90*** days of its receipt.

Or. fr

Amendment 135
Bernadette Vergnaud

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

Text proposed by the Commission	*Amendment*
Member States shall ensure that a decision on an application submitted in accordance with the requirements laid down in the Member State concerned, by a marketing authorisation holder to increase the price of a medicinal product is adopted and communicated to the applicant within ***60*** days of its receipt.	Member States shall ensure that a decision on an application submitted in accordance with the requirements laid down in the Member State concerned, by a marketing authorisation holder to increase the price of a medicinal product is adopted and communicated to the applicant within ***90*** days of its receipt.

Or. fr

Justification

The new time limits are unrealistic and go well beyond what is required to achieve the Commission's aim, namely that of ensuring the prompt availability of new medicinal products for which a 'normal' marketing authorisation has been granted.

Amendment 136
Michèle Rivasi

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

Text proposed by the Commission	*Amendment*
Member States shall ensure that a decision on an application submitted in accordance with the requirements laid down in the Member State concerned, by a marketing authorisation holder to increase the price of a medicinal product is adopted and communicated to the applicant within ***60*** days of its receipt.	Member States shall ensure that a decision on an application submitted in accordance with the requirements laid down in the Member State concerned, by a marketing authorisation holder to increase the price of a medicinal product is adopted and communicated to the applicant within ***90*** days of its receipt.

Or. fr

Amendment 137
Zofija Mazej Kukovič

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

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

Or. sl

Amendment 138
Kārlis Šadurskis

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

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

Or. en

Amendment 139
Corinne Lepage

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

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

Or. en

Amendment 140
Philippe Juvin

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

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

expiry of the time limit set out in this paragraph.	expiry of the time limit set out in this paragraph.

Or. fr

Amendment 141
Bernadette Vergnaud

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

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

Or. fr

Justification

The new time limits are unrealistic and go well beyond what is required to achieve the Commission's aim, namely that of ensuring the prompt availability of new medicinal products for which a 'normal' marketing authorisation has been granted.

Amendment 142
Michèle Rivasi

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

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

Or. fr

Amendment 143
Corinne Lepage

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

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

Or. en

Amendment 144
Nessa Childers

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

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

Or. en

Amendment 145
Michèle Rivasi

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

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

Or. fr

Amendment 146
Corinne Lepage

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

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

Or. en

Amendment 147
Zofija Mazej Kukovič

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

Text proposed by the Commission	*Amendment*
The applicant shall furnish the competent authorities with adequate information, including details of those events intervening since the price of the medicinal product was last determined which in his opinion justify the price increase requested.	The applicant shall furnish the competent authorities with adequate information, including details of those events intervening since the price of the medicinal product was last determined which in his opinion justify the price increase requested.

If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within ***60 days*** of receipt of this additional information. Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.	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. Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.

Or. sl

Amendment 148
Kārlis Šadurskis

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

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

Or. en

Amendment 149
Philippe Juvin

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

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

Or. fr

Amendment 150
Michèle Rivasi

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

Text proposed by the Commission	*Amendment*
The applicant shall furnish the competent authorities with adequate information, including details of those events intervening since the price of the medicinal product was last determined which in his opinion justify the price increase requested. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within ***60*** days of receipt of this	The applicant shall furnish the competent authorities with adequate information, including details of those events intervening since the price of the medicinal product was last determined which in his opinion justify the price increase requested. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of what detailed additional information is required and take their final decision within ***90*** days of receipt of this

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

Or. fr

Amendment 151
Nessa Childers, Justas Vincas Paleckis

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

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

Or. en

Amendment 152
Bernadette Vergnaud

Proposal for a directive
Article 4 – paragraph 5

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

Or. fr

Justification

This provision goes well beyond the aim of the proposal, namely that of ensuring the prompt availability of new medicinal products, and is neither proportionate nor consistent with the subsidiarity principle. What is more, such a measure could undermine even further the already shaky budgetary situation of public health insurance systems.

Amendment 153
Bernadette Vergnaud

Proposal for a directive
Article 4 – paragraph 6

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

Or. fr

Justification

The requirement that the competent authorities should provide a detailed statement of reasons for every reassessment decision which runs counter to the commercial interests of manufacturers is disproportionate.

Amendment 154
Bernadette Vergnaud

Proposal for a directive
Article 5 – paragraph 1

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

Or. fr

Justification

The requirement that the competent authorities should provide a detailed statement of reasons for every re-assessment decision which runs counter to the commercial interests of manufacturers is disproportionate.

Amendment 155
Peter Liese

Proposal for a directive
Article 5 – paragraph 1

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

price reduction.

price reduction. ***Member States shall carry out an annual review.***

Or. en

Amendment 156
Milan Cabrnoch

Proposal for a directive
Article 5 – paragraph 2

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

Or. cs

Amendment 157
Bernadette Vergnaud

Proposal for a directive
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Marketing authorisation holders may apply for a derogation from a price freeze or price reduction if this is justified by particular reasons. The application shall contain an adequate statement of reasons. Member States shall ***ensure that applications for a derogation can be introduced by*** the marketing authorisation	2. Marketing authorisation holders may apply for a derogation from a price freeze or price reduction if this is justified by particular reasons. The application shall contain an adequate statement of reasons. Member States shall ***guarantee*** the marketing authorisation holder ***the right to submit an application for a derogation***.

holder ***at any point in time***. The competent authorities shall provide the applicant with an official acknowledgement of receipt.	The competent authorities shall provide the applicant with an official acknowledgement of receipt.

Or. fr

Justification

Drafting clarification and deletion of the phrase 'at any point in time', which would be a source of legal uncertainty.

Amendment 158
Michèle Rivasi

Proposal for a directive
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Marketing authorisation holders may apply for a derogation from a price freeze or price reduction if this is justified by particular reasons. The application shall contain an adequate statement of reasons. Member States shall ensure that applications for a derogation can be introduced by the marketing authorisation holder ***at any point in time***. The competent authorities shall provide the applicant with an official acknowledgement of receipt.	2. Marketing authorisation holders may apply for a derogation from a price freeze or price reduction if this is justified by particular reasons. The application shall contain an adequate statement of reasons. Member States shall ensure that applications for a derogation can be introduced by the marketing authorisation holder. 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 in the Member States, which would be submerged with applications following any decision to turn down an application for a derogation, even if circumstances have not changed.

Amendment 159
Nessa Childers, Justas Vincas Paleckis

Proposal for a directive
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Marketing authorisation holders may apply for a derogation from a price freeze or price reduction if this is justified by particular reasons. The application shall contain an adequate statement of reasons. Member States shall ensure that applications for a derogation can be introduced by the marketing authorisation holder ***at any point in time***. The competent authorities shall provide the applicant with an official acknowledgement of receipt.	2. Marketing authorisation holders may apply for a derogation from a price freeze or price reduction if this is justified by particular reasons. ***These reasons must be drawn from a pre-defined list determined and published in an appropriate publication by the Member State.*** The application shall contain an adequate statement of reasons. Member States shall ensure that applications for a derogation can be introduced by the marketing authorisation holder. The competent authorities shall provide the applicant with an official acknowledgement of receipt.

Or. en

Amendment 160
Zofija Mazej Kukovič

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

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

Or. sl

Amendment 161
Kārlis Šadurskis

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

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

Or. en

Amendment 162
Corinne Lepage

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

Text proposed by the Commission	*Amendment*
Member States shall ensure that a reasoned decision on an application referred to in paragraph 2 is adopted and communicated to the applicant within ***60*** days of the receipt of the application. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the	Member States shall ensure that a reasoned decision on an application referred to in paragraph 2 is adopted and communicated to the applicant within ***90*** days of the receipt of the application. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the

detailed additional information required and take their final decision within ***60*** days of receipt of this additional information. If the derogation is granted, the competent authorities shall forthwith publish an announcement of the price increase allowed.	detailed additional information required and take their final decision within ***90*** days of receipt of this additional information. If the derogation is granted, the competent authorities shall forthwith publish an announcement of the price increase allowed.

Or. en

Amendment 163
Philippe Juvin

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

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

Or. fr

Amendment 164
Bernadette Vergnaud

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

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

Or. fr

Justification

The requirement that the competent authorities should provide a detailed statement of reasons for every re-assessment decision which runs counter to the commercial interests of manufacturers is disproportionate.

Amendment 165
Michèle Rivasi

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

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

the derogation is granted, the competent authorities shall forthwith publish an announcement of the price increase allowed.	the derogation is granted, the competent authorities shall forthwith publish an announcement of the price increase allowed.

Or. fr

Justification

The 90-day time limit should be retained in order not to jeopardise the quality of assessments of medicinal products in the Member States and, therefore, the quality of the service provided to patients.

Amendment 166
Bernadette Vergnaud

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

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

Or. fr

Justification

The new time limits are unrealistic and go well beyond what is required to achieve the Commission's aim, namely that of ensuring the prompt availability of new medicinal products for which a 'normal' marketing authorisation has been granted.

Amendment 167
Zofija Mazej Kukovič

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

Text proposed by the Commission	*Amendment*
If there is an exceptional number of applications, the relevant time limit set out in paragraph 3 may be extended once only for a further ***60 days***. The applicant shall be notified of such extension before the expiry of the time limit set out in paragraph 3	If there is an exceptional number of applications, the relevant time limit set out in paragraph 3 may be extended once only for a further ***90 days***. The applicant shall be notified of such *an* extension before the expiry of the time limit set out in paragraph 3

Or. sl

Amendment 168
Kārlis Šadurskis

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

Text proposed by the Commission	*Amendment*
If there is an exceptional number of applications, the relevant time limit set out in paragraph 3 may be extended once only for a further ***60*** days. The applicant shall be notified of such extension before the expiry of the time limit set out in paragraph 3	If there is an exceptional number of applications, the relevant time limit set out in paragraph 3 may be extended once only for a further ***90*** days. The applicant shall be notified of such extension before the expiry of the time limit set out in paragraph 3

Or. en

Amendment 169
Corinne Lepage

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

Text proposed by the Commission	*Amendment*
If there is an exceptional number of applications, the relevant time limit set out in paragraph 3 may be extended once only for a further ***60*** days. The applicant shall be notified of such extension before the expiry of the time limit set out in paragraph 3	If there is an exceptional number of applications, the relevant time limit set out in paragraph 3 may be extended once only for a further ***90*** days. The applicant shall be notified of such extension before the expiry of the time limit set out in paragraph 3

Or. en

Amendment 170
Philippe Juvin

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

Text proposed by the Commission	*Amendment*
If there is an exceptional number of applications, the relevant time limit set out in paragraph 3 may be extended once only for a further ***60*** days. The applicant shall be notified of such extension before the expiry of the time limit set out in paragraph 3.	In case of an exceptional number of applications, the time limit set out in this paragraph may be extended once only for a further ***90*** days. The applicant shall be notified of such extension before the expiry of the time limit set out in paragraph 3.

Or. fr

Amendment 171
Michèle Rivasi

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

Text proposed by the Commission	*Amendment*
If there is an exceptional number of applications, the relevant time limit set out in paragraph 3 may be extended once only for a further ***60*** days. The applicant shall be notified of such extension before the expiry of the time limit set out in paragraph 3.	In case of an exceptional number of applications, the time limit set out in this paragraph may be extended once only for a further ***90*** days. The applicant shall be notified of such extension before the expiry of the time limit set out in paragraph 3.

Or. fr

Justification

The 90-day time limit should be retained in order not to jeopardise the quality of assessments of medicinal products in the Member States and, therefore, the quality of the service provided to patients.

Amendment 172
Horst Schnellhardt, Thomas Ulmer, Anja Weisgerber

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

Text proposed by the Commission	*Amendment*
	3a. Member States shall ensure that dispensaries possess information about the sale price of the medicinal product applicable to the insured person in order to prevent possible distorting effects caused by a lack of transparency in prices displayed on the market.

Or. de

Justification

Voluntary agreements such as discount agreements between producers of medicines and health insurance funds have become more common and apply to a large proportion of the medicines dispensed. These agreements make it impossible for doctors and pharmacists to ascertain the actual price, and the economically most advantageous medicament is not always dispensed.

Amendment 173
Peter Liese, Zofija Mazej Kukovič

Proposal for a directive
Article 5 a (new)

Text proposed by the Commission	*Amendment*
	Article 5a
	Member States shall ensure that the patient or the insured person also genuinely has the benefit of the agreed reimbursement prices. Any possible lack of transparency at dispensaries which results in distortion because of failure to present prices transparently shall be avoided.

Or. de

Amendment 174
Milan Cabrnoch

Proposal for a directive
Article 6

Text proposed by the Commission	*Amendment*
Article 6	***deleted***
Controls on profits	
Where a Member State adopts a system of direct or indirect controls on the profitability of persons responsible for placing medicinal products on the market, the Member State concerned shall publish the following information in an appropriate publication and communicate it to the Commission:	
(a) the method or methods used in the Member State concerned to define profitability: return on sales and/or return on capital;	
(b) the range of target profit currently permitted to persons responsible for placing medicinal products on the market in the Member State concerned;	
(c) the criteria according to which target rates of profit are accorded to an individual responsible for placing medicinal products on the market, together with the criteria according to which they will be allowed to retain profits above their targets in the Member State concerned;	
(d) the maximum percentage profit which any person responsible for placing medicinal products on the market is allowed to retain above his target in the Member State concerned.	
The information referred to in the first subparagraph shall be updated once a year or when significant changes are made.	
Where, in addition to operating a system	

of direct or indirect controls on profits, a Member State operates a system of controls on the prices of certain types of medicinal products which are excluded from the scope of the profit control scheme, Articles 3, 4 and 5 shall, where relevant, apply to such price controls. However, those Articles shall not apply where the normal operation of a system of direct or indirect controls on profits results exceptionally in a price being fixed for an individual medicinal product.	

Or. cs

Amendment 175
Milan Cabrnoch

Proposal for a directive
Article 7 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that an application to include a medicinal product in the scope of the public health insurance system can be introduced by the marketing authorisation holder at any point in time. If the public health insurance system comprises several schemes or categories of coverage, the marketing authorisation holder shall be entitled to apply for the inclusion of its product in the scheme or category of its choice. ***The competent authorities shall provide the applicant with an official acknowledgement of receipt.***	2. Member States shall ensure that an application to include a medicinal product in the scope of the public health insurance system can be introduced by the marketing authorisation holder at any point in time. If the public health insurance system comprises several schemes or categories of coverage, the marketing authorisation holder shall be entitled to apply for the inclusion of its product in the scheme or category of its choice.

Or. cs

Amendment 176
Françoise Grossetête

Proposal for a directive
Article 7 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that an application to include a medicinal product in the scope of the public health insurance system can be introduced by the marketing authorisation holder at any point in time. If the public health insurance system comprises several schemes or categories of coverage, the marketing authorisation holder shall be entitled to apply for the inclusion of its product in the scheme or category of its choice. The competent authorities shall provide the applicant with an official acknowledgement of receipt.	2. Member States shall ensure that an application to include a medicinal product in the scope of the public health insurance system can be introduced by the marketing authorisation holder 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***. If the public health insurance system comprises several schemes or categories of coverage, the marketing authorisation holder ***or the applicant*** shall be entitled to apply for the inclusion of its product in the scheme or category of its choice. The competent authorities shall provide the applicant with an official acknowledgement of receipt.

Or. fr

Justification

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 177
Corinne Lepage

Proposal for a directive
Article 7 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that an application to include a medicinal product in the scope of the public health insurance	2. Member States shall ensure that an application to include a medicinal product in the scope of the public health insurance

system can be introduced by the marketing authorisation holder at any point in time. ***If the public health insurance system comprises several schemes or categories of coverage, the marketing authorisation holder shall be entitled to apply for the inclusion of its product in the scheme or category of its choice.*** The competent authorities shall provide the applicant with an official acknowledgement of receipt.	system 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.

Or. en

Amendment 178
Bernadette Vergnaud

Proposal for a directive
Article 7 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ***ensure that an application to include a medicinal product in the scope of the public health insurance system can be introduced by*** the marketing authorisation holder ***at any point in time***. ***If the public health insurance system comprises several schemes or categories of coverage, the marketing authorisation holder shall be entitled to apply for the inclusion of its product in the scheme or category of its choice.*** The competent authorities shall provide the applicant with an official acknowledgement of receipt.	2. Member States shall guarantee the marketing authorisation holder ***the right to submit an application to include a medicinal product in the scope of the public health insurance scheme***. The competent authorities shall provide the applicant with an official acknowledgement of receipt.

Or. fr

Justification

Drafting clarification and deletion of the phrase 'at any point in time', which would be a source of legal uncertainty. Moreover, the decision as to whether or not to allow the holder of the marketing authorisation to apply for the inclusion of a medicinal product in a specific category is a Member State matter.

Amendment 179
Nessa Childers

Proposal for a directive
Article 7 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that an application to include a medicinal product in the scope of the public health insurance system can be introduced by the marketing authorisation holder ***at any point in time. If the public health insurance system comprises several schemes or categories of coverage, the marketing authorisation holder shall be entitled to apply for the inclusion of its product in the scheme or category of its choice***. The competent authorities shall provide the applicant with an official acknowledgement of receipt.	2. Member States shall ensure that an application to include a medicinal product in the scope of the public health insurance system can be introduced by the marketing authorisation holder. The competent authorities shall provide the applicant with an official acknowledgement of receipt.

Or. en

Amendment 180
Michèle Rivasi

Proposal for a directive
Article 7 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that an application to include a medicinal product in the scope of the public health insurance system can be introduced by the marketing authorisation holder ***at any point in time***. ***If the public health insurance system comprises several schemes or categories of coverage, the marketing authorisation holder shall be entitled to apply for the inclusion of its product in the scheme or category of its choice.*** The competent authorities shall provide the applicant with an official acknowledgement of receipt.	2. Member States shall ensure that an application to include a medicinal product in the scope of the public health insurance system can be introduced by the marketing authorisation holder. The competent authorities shall provide the applicant with an official acknowledgement of receipt.

Or. fr

Justification

Contrary to the subsidiarity principle. The procedure concerning the choice of a category of cover should remain a Member State matter.

Amendment 181
Corinne Lepage

Proposal for a directive
Article 7 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall establish ***in detail the*** particulars and documents to be submitted by the applicant.	3. Member States shall establish ***the categories of*** particulars and documents to be submitted by the applicant.

Or. en

Amendment 182
Nessa Childers

Proposal for a directive
Article 7 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall establish in detail the particulars and documents to be submitted by the applicant.	3. Member States shall establish in detail the particulars and ***the main*** documents to be submitted by the applicant.

Or. en

Amendment 183
Michèle Rivasi

Proposal for a directive
Article 7 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall establish in detail the particulars and documents to be submitted by the applicant.	3. 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 184
Erik Bánki

Proposal for a directive
Article 7 – paragraph 4

Text proposed by the Commission	*Amendment*
(4) Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within 60 days of its receipt. However, with respect to medicines for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. With respect to generic medicinal products, that time limit shall be ***15 days***, provided that the reference medicinal product has already been included in the public health insurance system.	(4) Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within 60 days of its receipt. However, with respect to medicines for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. With respect to generic medicinal products, that time limit shall be ***25 days***, provided that the reference medicinal product has already been included in the public health insurance system.

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 185
Zofija Mazej Kukovič

Proposal for a directive
Article 7 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within ***60 days*** of its receipt. ***However,*** with respect to medicines for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. With respect to generic medicinal products, that time limit shall be ***15 days***, provided that the reference medicinal product has already been included in the public health insurance system.	4. Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within ***90 days*** of its receipt. With respect to medicines for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. With respect to generic medicinal products, that time limit shall be ***30 days***, provided that the reference medicinal product has already been included in the public health insurance system.

Or. sl

Amendment 186
Kārlis Šadurskis

Proposal for a directive
Article 7 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall ensure that a decision on an application to include a	4. Member States shall ensure that a decision on an application to include a

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

Or. en

Amendment 187
Corinne Lepage

Proposal for a directive
Article 7 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within ***60*** days of its receipt. ***However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days.*** With respect to generic medicinal products, that time limit shall be ***15*** days, provided that the reference medicinal product has already been included in the public health insurance	4. Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within ***90*** days of its receipt. With respect to generic medicinal products, that time limit shall be ***30*** days, provided that the reference medicinal product has already been included in the public health insurance system.

system.

Or. en

Amendment 188
Bernadette Vergnaud

Proposal for a directive
Article 7 – paragraph 4

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

Or. fr

Justification

The new time limits are unrealistic and go well beyond what is required to achieve the Commission's aim, namely that of ensuring the prompt availability of new medicinal products for which a 'normal' marketing authorisation has been granted.

Amendment 189
Erik Bánki

Proposal for a directive
Article 7 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within 60 days of its receipt. However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. With respect to generic medicinal products, that time limit shall be ***15*** days, provided that the reference medicinal product has already been included in the public health insurance system.	4. Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within 60 days of its receipt. However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. With respect to generic medicinal products, that time limit shall be ***25 days, provided that the reference medicinal product has already been included in the public health insurance system. With respect to biosimilar medicinal products, that time limit shall be 60*** days, provided that the reference medicinal product has already been included in the public health insurance system.

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 190
Christofer Fjellner

Proposal for a directive
Article 7 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within ***60*** days of its receipt. ***However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days.*** With respect to generic medicinal products, that time limit shall be ***15*** days, provided that the reference medicinal product has already been included in the public health insurance system.	4. Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within ***90*** days of its receipt. With respect to generic medicinal products, that time limit shall be ***45*** days, provided that the reference medicinal product has already been included in the public health insurance system.

Or. en

Amendment 191
Philippe Juvin

Proposal for a directive
Article 7 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within ***60*** days of its receipt. ***However, with respect to medicines for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90***	4. Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within ***90*** days of its receipt. With respect to generic medicinal products, that time limit shall be ***45*** days, provided that the reference medicinal product has already been included in the public health

days. With respect to generic medicinal products, that time limit shall be ***15*** days, provided that the reference medicinal product has already been included in the public health insurance system.

insurance system. ***Member States shall consider basing their decision on an application to include a medicinal product in the scope of the national health insurance system on a health technology assessment.***

Or. fr

Amendment 192
Nessa Childers, Justas Vincas Paleckis

Proposal for a directive
Article 7 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within 60 days of its receipt. However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. With respect to generic medicinal products, that time limit shall be ***15*** days, provided that the reference medicinal product has already been included in the public health insurance system.	4. Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within 60 days of its receipt. However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. With respect to generic medicinal products, that time limit shall be ***30*** days, provided ***that the generic product is essentially similar to the reference medicinal product, according to Directive 2001/83/EC and*** that the reference medicinal product has already been included in the public health insurance system.

Or. en

Amendment 193
Michèle Rivasi

Proposal for a directive
Article 7 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within ***60*** days of its receipt. ***However, with respect to medicines for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days.*** With respect to generic medicinal products, that time limit shall be ***15*** days, provided that the reference medicinal product has already been included in the public health insurance system.	4. Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within ***90*** days of its receipt. With respect to generic medicinal products, that time limit shall be ***30*** days, provided that the reference medicinal product ***is essentially similar, within the meaning of Directive 2001/83/EC, and*** has already been included in the public health insurance system. ***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 re-assessment.***

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.

Amendment 194
Erik Bánki

Proposal for a directive
Article 7 – paragraph 5

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

Or. 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 195
Milan Cabrnoch

Proposal for a directive
Article 7 – paragraph 5

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

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

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

Or. cs

Amendment 196
Zofija Mazej Kukovič

Proposal for a directive
Article 7 – paragraph 5

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

Or. sl

Amendment 197
Kārlis Šadurskis

Proposal for a directive
Article 7 – paragraph 5

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

Or. en

Amendment 198
Corinne Lepage

Proposal for a directive
Article 7 – paragraph 5

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

respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. With respect to generic medicinal products, that time limit shall be ***15*** days, provided that the reference medicinal product has already been included in the public health insurance system. ***Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.***	generic medicinal products, that time limit shall be ***30*** days, provided that the reference medicinal product has already been included in the public health insurance system.

Or. en

Amendment 199
Philippe Juvin

Proposal for a directive
Article 7 – paragraph 5

Text proposed by the Commission	*Amendment*
5. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within ***60*** days of receipt of this additional information. ***However, with respect to medicines for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days.*** With respect to generic medicinal products, that time limit shall be ***15*** days, provided that the reference medicinal product has already been included in the public health insurance system. Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.	5. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of 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 ***45*** days, provided that the reference medicinal product has already been included in the public health insurance system. Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.

Or. fr

Amendment 200
Erik Bánki

Proposal for a directive
Article 7 – paragraph 5

Text proposed by the Commission	*Amendment*
5. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within 60 days of receipt of this additional information. However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. With respect to generic medicinal products, that time limit shall be ***15*** days, provided that the reference medicinal product has already been included in the public health insurance system. Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.	5. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within 60 days of receipt of this additional information. However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. With respect to generic medicinal products, that time limit shall be ***25*** days, provided that the reference medicinal product has already been included in the public health insurance system. ***With respect to biosimilars medicinal products, that time limit shall be 60 days, provided that the reference medicinal product has already been included in the public health insurance system.*** Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.

Or. en

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 201
Christofer Fjellner

Proposal for a directive
Article 7 – paragraph 5

Text proposed by the Commission	*Amendment*
5. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within ***60*** days of receipt of this additional information. ***However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days.*** With respect to generic medicinal products, that time limit shall be ***15 days***, provided that the reference medicinal product has already been included in the public health insurance system. Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.	5. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within ***90*** days of receipt of this additional information. With respect to generic medicinal products, that time limit shall be ***45 days,*** , provided that the reference medicinal product has already been included in the public health insurance system. Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.

Or. en

Amendment 202
Nessa Childers, Justas Vincas Paleckis

Proposal for a directive
Article 7 – paragraph 5

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

respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. With respect to generic medicinal products, that time limit shall be ***15*** days, provided that the ***reference medicinal*** product ***has already been included in the public health insurance system. Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines***.	respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days. With respect to generic medicinal products, that time limit shall be ***30*** days, provided that the ***generic*** product ***is essentially similar to the reference medicinal product, according to Directive 2001/83/EC and that the reference medicinal product has already been included in the public health insurance system***.

Or. en

Amendment 203
Michèle Rivasi

Proposal for a directive
Article 7 – paragraph 5

Text proposed by the Commission	*Amendment*
5. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within ***60*** days of receipt of this additional information. ***However, with respect to medicines for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days.*** With respect to generic medicinal products, that time limit shall be ***15*** days, provided that the reference medicinal product has already been included in the public health insurance system. ***Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.***	5. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of 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 ***30*** days, provided that the reference medicinal product ***is essentially similar, within the meaning of Directive 2001/83/EC of 6 November 2001, and*** has already been included in the public health insurance system.

Or. fr

Justification

The 90-day time limit should be retained in order not to jeopardise the quality of assessments of medicinal products in the Member States and, therefore, the quality of the service provided to patients. The public consultation carried out by the Commission revealed that most stakeholders, including originator companies, regard the current time limits as satisfactory. They are essential if proper assessments are to be carried out, given the existence of products developed by means of ever more complex and innovative research.

Amendment 204
Erik Bánki

Proposal for a directive
Article 7 – paragraph 6

Text proposed by the Commission	*Amendment*
(6) Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed 120 days. However, with respect to the medicinal products for which Member States use health technology assessment as part of their decision-making process, the time limit shall not exceed 180 days. With respect to generic medicinal products, that time limit shall not exceed ***30 days***, provided that the reference medicinal product has already been included in the public health insurance system. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5). .	(6) Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed 120 days. However, with respect to the medicinal products for which Member States use health technology assessment as part of their decision-making process, the time limit shall not exceed 180 days. With respect to generic medicinal products, that time limit shall not exceed ***50 days***, provided that the reference medicinal product has already been included in the public health insurance system. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5).

Or. hu

Justification

The 30-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 205
Zofija Mazej Kukovič

Proposal for a directive
Article 7 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed ***120 days***. ***However,*** with respect to the medicinal products for which Member States use health technology assessment as part of their decision-making process, the time limit shall not exceed 180 days. With respect to generic medicinal products, that time limit shall not exceed ***30 days***, provided that the reference medicinal product has already been included in the public health insurance system. Those *time-limits* may be extended in accordance with paragraph 5 of this Article or Article 3(5).	6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed ***180 days***. With respect to the medicinal products for which Member States use health technology assessment as part of their decision-making process, the time limit shall ***likewise*** not exceed 180 days. With respect to generic medicinal products, that time limit shall not exceed ***60 days***, provided that the reference medicinal product has already been included in the public health insurance system. Those *time limits* may be extended in accordance with paragraph 5 of this Article or Article 3(5).

Or. sl

Amendment 206
Kārlis Šadurskis

Proposal for a directive
Article 7 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed ***120 days. However, with respect to the medicinal products for***	6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed 180 days. With respect to generic medicinal products, that time limit

which Member States use health technology assessment as part of their decision-making process, the time limit shall not exceed 180 days. With respect to generic medicinal products, that time limit shall not exceed ***30*** days, provided that the reference medicinal product has already been included in the public health insurance system. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5).

shall not exceed ***180*** days, provided that the reference medicinal product has already been included in the public health insurance system. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5) ***or suspended in accordance with the provisions of the preceding paragraph***.

Or. en

Amendment 207
Corinne Lepage

Proposal for a directive
Article 7 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed ***120 days. However, with respect to the medicinal products for which Member States use health technology assessment as part of their decision-making process, the time limit shall not exceed*** 180 days. With respect to generic medicinal products, that time limit shall not exceed ***30*** days, provided that the reference medicinal product has already been included in the public health insurance system. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5).	6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed 180 days. With respect to generic medicinal products, that time limit shall not exceed ***60*** days, provided that the reference medicinal product has already been included in the public health insurance system. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5).

Or. en

Amendment 208
Philippe Juvin

Proposal for a directive
Article 7 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed ***120*** days. ***However, with respect to the medicinal products for which Member States use health technology assessment as part of their decision-making process, the time limit shall not exceed 180 days.*** With respect to generic medicinal products, that time limit shall not exceed ***30*** days, provided that the reference medicinal product has already been included in the public health insurance system. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5).	6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed ***180*** days. With respect to generic medicinal products, that time limit shall not exceed ***90*** days, provided that the reference medicinal product has already been included in the public health insurance system. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5).

Or. fr

Amendment 209
Erik Bánki

Proposal for a directive
Article 7 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed 120 days. However, with respect to the medicinal products for which	6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed 120 days. However, with respect to the medicinal products for which

Member States use health technology assessment as part of their decision-making process, the time limit shall not exceed 180 days. With respect to generic medicinal products, that time limit shall not exceed ***30*** days, provided that the reference medicinal product has already been included in the public health insurance system. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5).	Member States use health technology assessment as part of their decision-making process, the time limit shall not exceed 180 days. With respect to generic medicinal products, that time limit shall not exceed ***50*** days, provided that the reference medicinal product has already been included in the public health insurance system. ***With respect to biosimilar medicinal products, that time limit shall not exceed 120 days, provided that the reference medicinal product has already been included in the public health insurance system.*** Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5).

Or. en

Justification

The proposed 30-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 120 days maximum.

Amendment 210
Christofer Fjellner

Proposal for a directive
Article 7 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed ***120 days. However, with respect to the medicinal products for which Member States use health technology assessment as part of their decision-making process, the time limit***	6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed 180 days. With respect to generic medicinal products, that time limit shall not exceed ***90*** days, provided that the reference medicinal product has already been included in the public health

shall not exceed 180 days. With respect to generic medicinal products, that time limit shall not exceed ***30*** days, provided that the reference medicinal product has already been included in the public health insurance system. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5).

insurance system. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5).

Or. en

Amendment 211
Nessa Childers, Justas Vincas Paleckis

Proposal for a directive
Article 7 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed 120 days. However, with respect to the medicinal products for which Member States use health technology assessment as part of their decision-making process, the time limit shall not exceed 180 days. With respect to generic medicinal products, that time limit shall not exceed ***30*** days, provided that the reference medicinal product has already been included in the public health insurance system. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5).	6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed 120 days. However, with respect to the medicinal products for which Member States use health technology assessment as part of their decision-making process, the time limit shall not exceed 180 days. With respect to generic medicinal products, that time limit shall not exceed ***60*** days, provided ***that the generic product is essentially similar to the reference medicinal product, according to Directive 2001/83/EC and*** that the reference medicinal product has already been included in the public health insurance system. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5).

Or. en

Amendment 212
Michèle Rivasi

Proposal for a directive
Article 7 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed ***120*** days. ***However, with respect to the medicinal products for which Member States use health technology assessment as part of their decision-making process, the time limit shall not exceed 180 days.*** With respect to generic medicinal products, that time limit shall not exceed 30 days, provided that the reference medicinal product has already been included in the public health insurance system. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5).	6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed ***180*** days. With respect to generic medicinal products, that time limit shall be 30 days, provided that the reference medicinal product ***is essentially similar, within the meaning of Directive 2001/83/EC, and*** has already been included in the public health insurance system. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5).

Or. fr

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 213
Nessa Childers

Proposal for a directive
Article 7 – paragraph 7 – subparagraph 2

Text proposed by the Commission	*Amendment*
The decisions referred to in this paragraph shall also include any evaluation, expert opinion or recommendation on which they are based. The applicant shall be informed of all remedies available, including judicial remedies, ***and the remedies procedure set out Article 8,*** of the time limits for applying for such remedies.	The decisions referred to in this paragraph shall also include any evaluation, expert opinion or recommendation on which they are based. The applicant shall be informed of all remedies available, including judicial remedies, of the time limits for applying for such remedies.

Or. en

Amendment 214
Michèle Rivasi

Proposal for a directive
Article 7 – paragraph 7 – subparagraph 2

Text proposed by the Commission	*Amendment*
The decisions referred to in this paragraph shall also include any evaluation, expert opinion or recommendation on which they are based. The applicant shall be informed of all remedies available, including judicial remedies, and ***the remedies procedure set out Article 8,*** of the time limits for applying for such remedies.	Les décisions visées au présent paragraphe contiennent également toute évaluation, tout avis d'expert ou toute recommandation d'expert sur lesquels elles s'appuient. 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

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 215
Andres Perello Rodriguez

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

Text proposed by the Commission	*Amendment*
	The criteria governing the decisions referred to in the previous paragraph shall include assessments of unmet medical needs and of the clinical benefits, the social benefits, innovation and protection of the most vulnerable groups in the population.

Or. es

Amendment 216
Bernadette Vergnaud

Proposal for a directive
Article 7 – paragraph 8

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

Or. fr

Justification

As the decision whether or not to include a medicinal product within the scope of the public health insurance system is a national matter, Member States should not be required to communicate their assessment criteria to the Commission.

Amendment 217
Andres Perello Rodriguez

Proposal for a directive
Article 7 – paragraph 8

Text proposed by the Commission	*Amendment*
8. Member States shall publish in an appropriate publication and communicate to the Commission the criteria which the competent authorities must take into account when deciding whether or not to include medicinal products within the scope of the public health insurance system.	8. Member States shall publish in an appropriate publication and communicate to the Commission the criteria which the competent authorities must take into account when deciding whether or not to include medicinal products within the scope of the public health insurance system.***These criteria shall include assessments of unmet medical needs and of the clinical benefits, the social benefits, innovation and the protection of the most vulnerable groups of the population.***

Or. es

Amendment 218
Milan Cabrnoch

Proposal for a directive
Article 8

Text proposed by the Commission	*Amendment*
Article 8	***deleted***
Remedies procedure in case of non-compliance with the time limits related to the inclusion of medicinal products in health insurance systems	
1. Member States shall ensure that effective and rapid remedies are available to the applicant in case of non-compliance with the time limits set in Article 7.	
2. For the purposes of the remedies procedure Member States shall designate	

a body and entrust it with the powers to:

(a) take, at the earliest opportunity and by way of interlocutory procedures, interim measures with the aim of correcting the alleged infringement or preventing further damage to the interests concerned;

(b) award damages to the applicant in case of non-compliance with time limits set in Article 7 where damages are claimed, unless the competent authority may prove that the delay is not imputable to it;

(c) impose a penalty payment, calculated by day of delay.

For the purposes of point (c), the penalty payment shall be calculated depending on the seriousness of the infringement, its duration, the need to ensure that the penalty itself is a deterrent to further infringements.

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

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

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

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

insurance systems.

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

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

Or. cs

Amendment 219
Michèle Rivasi

Proposal for a directive
Article 8

Text proposed by the Commission	*Amendment*
Article 8	***deleted***
Remedies procedure in case of non-compliance with the time limits related to the inclusion of medicinal products in	

health insurance systems

1. Member States shall ensure that effective and rapid remedies are available to the applicant in case of non-compliance with the time limits set in Article 7.

2. For the purposes of the remedies procedure Member States shall designate a body and entrust it with the powers to:
(a) take, at the earliest opportunity and by way of interlocutory procedures, interim measures with the aim of correcting the alleged infringement or preventing further damage to the interests concerned;
(b) award damages to the applicant in case of non-compliance with time limits set in Article 7 where damages are claimed, unless the competent authority may prove that the delay is not imputable to it;
(c) impose a penalty payment, calculated by day of delay.

For the purposes of point (c), the penalty payment shall be calculated depending on the seriousness of the infringement, its duration, the need to ensure that the penalty itself is a deterrent to further infringements.

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

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

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

enforced.

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

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

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

Or. fr

Justification

This proposal, in addition to being questionable in terms of compliance with the subsidiarity principle, adds complexity and redundancy by comparison with the existing arrangements. It would impose an unnecessary administrative and financial burden, since remedies procedures, including judicial procedures, already exist in the Member States. What is more,

these procedures 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 220
Nessa Childers, Justas Vincas Paleckis

Proposal for a directive
Article 8

Text proposed by the Commission	*Amendment*
Article 8	***deleted***
Remedies procedure in case of non-compliance with the time limits related to the inclusion of medicinal products in health insurance systems	
1. Member States shall ensure that effective and rapid remedies are available to the applicant in case of non-compliance with the time limits set in Article 7.	
2. For the purposes of the remedies procedure Member States shall designate a body and entrust it with the powers to:	
(a) take, at the earliest opportunity and by way of interlocutory procedures, interim measures with the aim of correcting the alleged infringement or preventing further damage to the interests concerned;	
(b) award damages to the applicant in case of non-compliance with time limits set in Article 7 where damages are claimed, unless the competent authority may prove that the delay is not imputable to it;	
(c) impose a penalty payment, calculated by day of delay.	
For the purposes of point (c), the penalty payment shall be calculated depending on the seriousness of the infringement, its duration, the need to ensure that the	

penalty itself is a deterrent to further infringements.

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

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

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

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

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

The members of the body referred to in paragraph 2 shall be appointed and leave office under the same conditions as members of the judiciary as regards the authority responsible for their

appointment, their period of office, and their removal. At least the president of that body shall have the same legal and professional qualifications as members of the judiciary. That body shall take its decisions following a procedure in which both sides are heard, and these decisions shall, by means determined by each Member State, be legally binding.

Or. en

Amendment 221
Zofija Mazej Kukovič

Proposal for a directive
Article 8

Text proposed by the Commission	*Amendment*
Article 8	***deleted***
Remedies procedure in case of non-compliance with the time limits related to the inclusion of medicinal products in health insurance systems	
1. Member States shall ensure that effective and rapid remedies are available to the applicant in case of non-compliance with the time limits set in Article 7.	
2. For the purposes of the remedies procedure Member States shall designate a body and entrust it with the powers to:	
(a) take, at the earliest opportunity and by way of interlocutory procedures, interim measures with the aim of correcting the alleged infringement or preventing further damage to the interests concerned;	
(b) award damages to the applicant in case of non-compliance with time limits set in Article 7 where damages are claimed, unless the competent authority may prove that the delay is not imputable	

to it;

(c) impose a penalty payment, calculated by day of delay.

For the purposes of point (c), the penalty payment shall be calculated depending on the seriousness of the infringement, its duration, *and* ***the need to ensure that the penalty itself is a deterrent to further infringements.***

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

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

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

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

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

the competent authority and the body referred to in paragraph 2.

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

Or. sl

Amendment 222
Kārlis Šadurskis

Proposal for a directive
Article 8

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that effective and rapid remedies are available to the applicant in case of non-compliance with the time limits set in Article 7.	Member States shall ensure that effective and rapid remedies are available to the applicant in case of non-compliance with the time limits set in Article 7.
2. For the purposes of the remedies procedure Member States shall designate a body and entrust it with the powers to:	***deleted***
(a) take, at the earliest opportunity and by way of interlocutory procedures, interim measures with the aim of correcting the alleged infringement or preventing further damage to the interests concerned;	
(b) award damages to the applicant in case of non-compliance with time limits set in Article 7 where damages are claimed, unless the competent authority	

may prove that the delay is not imputable to it;

(c) impose a penalty payment, calculated by day of delay.

For the purposes of point (c), the penalty payment shall be calculated depending on the seriousness of the infringement, its duration, the need to ensure that the penalty itself is a deterrent to further infringements.

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

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

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

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

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

European Union and independent of both the competent authority and the body referred to in paragraph 2.

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

Or. en

Amendment 223
Bernadette Vergnaud

Proposal for a directive
Article 8

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that effective and rapid remedies are available to the applicant in case of non-compliance with the time limits set in Article 7.	Member States shall ensure that effective and rapid remedies are available to the applicant in case of non-compliance with the time limits set in Article 7.
2. For the purposes of the remedies procedure Member States shall designate a body and entrust it with the powers to:	
(a) take, at the earliest opportunity and by way of interlocutory procedures, interim measures with the aim of correcting the alleged infringement or preventing further damage to the interests concerned;	
(b) award damages to the applicant in case of non-compliance with time limits set in Article 7 where damages are	

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

(c) impose a penalty payment, calculated by day of delay.

For the purposes of point (c), the penalty payment shall be calculated depending on the seriousness of the infringement, its duration, the need to ensure that the penalty itself is a deterrent to further infringements.

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

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

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

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

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

Treaty on the Functioning of the European Union and independent of both the competent authority and the body referred to in paragraph 2.

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

Or. fr

Justification

Although it is essential that the Member States should make provision for remedies procedures, the Commission has exceeded its powers by laying down overly prescriptive implementing arrangements. It is also difficult to accept that an authority should be required to pay damages to a pharmaceuticals firm as a result of its failure to comply with a time limit.

Amendment 224
Corinne Lepage

Proposal for a directive
Article 8

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that effective and rapid remedies are available to the applicant in case of non-compliance with the time limits set in Article 7.	Member States shall ensure that effective and rapid remedies are available to the applicant in case of non-compliance with the time limits set in Article 7.
2. For the purposes of the remedies procedure Member States shall designate a body and entrust it with the powers to:	***deleted***
(a) take, at the earliest opportunity and by way of interlocutory procedures, interim	

measures with the aim of correcting the alleged infringement or preventing further damage to the interests concerned;

(b) award damages to the applicant in case of non-compliance with time limits set in Article 7 where damages are claimed, unless the competent authority may prove that the delay is not imputable to it;

(c) impose a penalty payment, calculated by day of delay.

For the purposes of point (c), the penalty payment shall be calculated depending on the seriousness of the infringement, its duration, the need to ensure that the penalty itself is a deterrent to further infringements.

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

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

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

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

6. The body referred to in paragraph 2 shall state reasons for its decision. Furthermore, where that body is not

judicial in character, provision must be made to guarantee procedures whereby any allegedly illegal measure taken by the independent body or any alleged defect in the exercise of powers conferred on it can be subject to judicial review or review by another body which is a court or tribunal within the meaning of Article 267 of the Treaty on the Functioning of the European Union and independent of both the competent authority and the body referred to in paragraph 2.

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

Or. en

Amendment 225
Bernadette Vergnaud

Proposal for a directive
Article 9 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Any decision to exclude a medicinal product from the scope of the public health insurance system, or to modify the extent or the conditions of coverage of the product concerned, shall contain a statement of reasons based on objective and verifiable criteria. ***Such decisions shall include any evaluation, expert***	1. Any decision to exclude a medicinal product from the scope of the public health insurance system, or to modify the extent or the conditions of coverage of the product concerned, shall contain a statement of reasons based on objective and verifiable criteria. The applicant shall be informed of all remedies available,

opinion or recommendation on which they are based. The applicant shall be informed of all remedies available, including judicial remedies, and of the time limits for applying for such remedies.	including judicial remedies, and of the time limits for applying for such remedies.

Or. fr

Justification

The requirement that the competent authorities should provide an expert opinion or recommendation in support of every decision which runs counter to the commercial interests of manufacturers is disproportionate.

Amendment 226
Andres Perello Rodriguez

Proposal for a directive
Article 9 – paragraph 1

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

Or. es

Amendment 227
Bernadette Vergnaud

Proposal for a directive
Article 9 – paragraph 2

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

Or. fr

Justification

The requirement that the authorities should provide a detailed justification for any decision to exclude a medicinal product from the scope of the public health insurance system and which thus runs counter to the commercial interests of manufacturers is disproportionate.

Amendment 228
Andres Perello Rodriguez

Proposal for a directive
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Any decision to exclude a category of medicinal products from the scope of the public health insurance system, or to modify the extent or the conditions of coverage of the category concerned, shall contain a statement of reasons based on objective and verifiable criteria and be published in an appropriate publication.	2. Any decision to exclude a category of medicinal products from the scope of the public health insurance system, or to modify the extent or the conditions of coverage of the category concerned, shall contain a statement of reasons based on objective and verifiable criteria and be published in an appropriate publication. ***These criteria shall include assessments of unmet medical needs, the clinical impact and social costs and the protection of the most vulnerable groups of the population***

Or. es

Amendment 229
Milan Cabrnoch

Proposal for a directive
Article 10

Text proposed by the Commission	*Amendment*
Article 10	***deleted***
Classification of medicinal products in view of their inclusion in health insurance systems	
1. Paragraphs 2, 3 and 4 shall apply where medicinal products are grouped or classified according to therapeutic or other criteria for the purpose of their inclusion within the scope of the public health insurance system.	
2. Member States shall publish in an appropriate publication and communicate to the Commission the objective and verifiable criteria according to which medicinal products are classified in view of their inclusion in the public health insurance system.	
3. For the medicinal products subject to such grouping or classification, Member States shall publish in an appropriate publication and communicate to the Commission the methodologies used to determine the extent or conditions of their inclusion in the public health insurance system.	
4. At the request of the holder of a marketing authorisation, the competent authorities shall specify the objective data on the basis of which they have determined the arrangements of coverage for their medicinal product, in application of the criteria and methodologies referred to in paragraphs 2 and 3. In such a case, the competent authorities shall also inform the marketing authorisation holder of all remedies available, including judicial, and of the time limits for	

applying for such remedies.

Or. cs

Amendment 230
Milan Cabrnoch

Proposal for a directive
Article 11

Text proposed by the Commission	*Amendment*
Article 11	***deleted***
Measures to control or promote the prescription of specific medicinal products	
1. Paragraphs 2, 3 and 4 shall apply where a Member State adopts measures intended to control or promote the prescription of specific named medicinal products.	
2. Measures referred to in paragraph 1 shall be based on objective and verifiable criteria.	
3. Measures referred to in paragraph 1, including any evaluation, expert opinion or recommendation on which they are based, shall be published in an appropriate publication.	
4. At the request of the holder of a marketing authorisation whose interests or legal position are affected by the measures referred to in paragraph 1, the competent authorities shall specify the objective data and criteria on the basis of which these measures have been taken with respect to its medicinal product. In such a case, the competent authorities shall also inform the marketing authorisation holder of all remedies available, including judicial, and of the time limits for applying for such remedies.	

Or. cs

Amendment 231
Michèle Rivasi

Proposal for a directive
Article 11 – paragraph 1

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

Or. fr

Amendment 232
Bernadette Vergnaud

Proposal for a directive
Article 11 – paragraph 3

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

Or. fr

Justification

The requirement that the competent authorities should provide an expert opinion or recommendation in support of every decision which runs counter to the commercial interests of manufacturers is disproportionate.

Amendment 233
Zofija Mazej Kukovič

Proposal for a directive
Article 11 – paragraph 3

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

Or. sl

Amendment 234
Michèle Rivasi

Proposal for a directive
Article 11 – paragraph 4

Text proposed by the Commission	*Amendment*
4. At the request of the holder of a marketing authorisation whose interests or legal position are affected by the measures referred to in paragraph 1, the competent authorities shall specify the objective data and criteria on the basis of which these measures have been taken with respect to its medicinal product. In such a case, the competent authorities shall also inform the marketing authorisation holder of all remedies available, including judicial, and of the time limits for applying for such remedies.	***deleted***

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 235
Bernadette Vergnaud

Proposal for a directive
Article 11 – paragraph 4

Text proposed by the Commission	*Amendment*
4. At the request of the holder of a marketing authorisation whose interests or legal position are affected by the measures referred to in paragraph 1, the competent authorities shall specify the objective data and criteria on the basis of which these measures have been taken with respect to its medicinal product. ***In such a case, the competent authorities shall also inform the marketing authorisation holder of all remedies available, including judicial, and of the time limits for applying for such remedies.***	4. At the request of the holder of a marketing authorisation whose interests or legal position are affected by the measures referred to in paragraph 1, the competent authorities shall specify the objective data and criteria on the basis of which these measures have been taken with respect to its medicinal product.

Or. fr

Justification

Although it is normal that marketing authorisation holders should be informed of the reasons for the introduction of measures to monitor or encourage the prescription of certain medicinal products, such measures are the result of national decisions which are generally taken with the aim of limiting health expenditure. It is paradoxical, therefore, that provision should be made for financial compensation for such measures.

Amendment 236
Milan Cabrnoch

Proposal for a directive
Article 12

Text proposed by the Commission	*Amendment*
The time limits laid down in Articles 3, 4, 5 and 7 shall be construed as the period between the receipt of an application or additional information, as the case may be,	The time limits laid down in Articles 3, 4, 5 and 7 shall be construed as the period between the receipt of an application or additional information, as the case may be,

and the ***effective entry into force*** of the ***corresponding*** decision. All expert evaluations and administrative steps necessary for taking the decision and bringing it into effect shall be carried out within the prescribed time limits.	and the ***issuing*** of the decision. All expert evaluations and administrative steps necessary for taking the decision and bringing it into effect shall be carried out within the prescribed time limits.

Or. cs

Amendment 237
Christofer Fjellner

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

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

Or. en

Amendment 238
Philippe Juvin

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

Text proposed by the Commission	*Amendment*
	1a. If a decision-making process involving negotiations between the requesting laboratory and the competent authority is required, the time limits laid down in Articles 3, 4, 5 and 7 shall be suspended until the competent authority has received the requesting laboratory's response to its

proposals.

Or. fr

Amendment 239
Alda Sousa

Proposal for a directive
Article 13

Text proposed by the Commission	*Amendment*
Article 13	***deleted***
Additional proof of quality, safety, efficacy or bioequivalence	
In the framework of pricing and reimbursement decisions, Member States shall not re-assess the elements on which the marketing authorisation is based, including the quality, safety, efficacy or bioequivalence of the medicinal product.	

Or. en

Amendment 240
Bernadette Vergnaud

Proposal for a directive
Article 13 – title

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

Or. fr

Justification

The incorporation of specific provisions concerning generic medicinal products constitutes the main added value of this recast. However, if all types of generic medicinal products, including biotherapies, are to be covered, reference should be made to the concept of biosimilarity, as well as to that of bioequivalence.

Amendment 241
Michèle Rivasi

Proposal for a directive
Article 13 – title

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

Or. fr

Amendment 242
Corinne Lepage

Proposal for a directive
Article 13

Text proposed by the Commission	*Amendment*
In the framework of pricing and reimbursement decisions, Member States shall not re-assess the elements on which the marketing authorisation is based***,*** ***including*** the quality, safety, efficacy or bioequivalence of the medicinal product.	In the framework of pricing and reimbursement decisions, Member States shall not re-assess the elements on which the marketing authorisation is based ***(***the 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 243
Bernadette Vergnaud

Proposal for a directive
Article 13

Text proposed by the Commission	*Amendment*
In the framework of pricing and reimbursement decisions, Member States shall not re-assess the elements on which the marketing authorisation is based***, including the quality, safety, efficacy or bioequivalence of the medicinal product***.	In the framework of pricing and reimbursement decisions, Member States shall not re-assess the ***essential*** elements ***(quality, safety, efficacy or biosimilarity)*** on which the marketing authorisation is based. ***Nevertheless, Member States shall have access to all the data used by the authority which granted the marketing authorisation so that they can assess the relative safety and efficacy of a medicinal product in the context of the health insurance system.***

Or. fr

Justification

It is essential that the authorities should be able to carry out re-assessments of the relative therapeutic value of a medicinal product, since that relative value may be significantly affected by the arrival of new, competing products on the market or the discovery of a new therapeutic property. What is more, the remit of the agencies which issue marketing authorisations does not cover such comparative assessments. Finally, there is no need to re-assess bioequivalence.

Amendment 244
Nessa Childers

Proposal for a directive
Article 13

Text proposed by the Commission	*Amendment*
In the framework of pricing and reimbursement decisions, Member States shall not re-assess the elements on which the marketing authorisation is based, including the quality, safety, efficacy or bioequivalence of the medicinal product.	In the framework of pricing and reimbursement decisions, Member States shall not re-assess the elements on which the marketing authorisation is based, including the quality, safety, efficacy or bioequivalence of the medicinal product. ***However, Member States shall have full access to the data used by the marketing authorisation authority in assessing these***

elements for the purpose of evaluation. Competent authorities should also have the right to request additional data for the purpose of evaluation.

Or. en

Amendment 245
Françoise Grossetête, Philippe Juvin

Proposal for a directive
Article 13

Text proposed by the Commission	*Amendment*
In the framework of pricing and reimbursement decisions, Member States shall not re-assess ***the elements on which*** the marketing authorisation ***is based***, including the quality, safety, efficacy or bioequivalence of the medicinal product.	In the framework of pricing and reimbursement decisions, Member States shall not re-assess the marketing authorisation, including the quality, safety, efficacy or bioequivalence of the medicinal product ***or the criteria for 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 sine qua non 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 246
Michèle Rivasi

Proposal for a directive
Article 13

Text proposed by the Commission	*Amendment*
In the framework of pricing and reimbursement decisions, Member States	In the framework of pricing and reimbursement decisions, Member States

shall not ***re-assess*** the elements on which the marketing authorisation is based***, including the quality, safety, efficacy or bioequivalence of the medicinal product***.	***should*** not ***be seeking to*** re-assess the ***essential*** elements ***(quality, safety, efficacy or bioequivalence)*** on which the marketing authorisation is based. ***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, efficacy and efficiency 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 article 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 247
Oreste Rossi, Giancarlo Scottà

Proposal for a directive
Article 14 – paragraph 1

Text proposed by the Commission	*Amendment*
1. ***Applications,*** decision-making procedures and decisions to regulate the prices of medicinal products in accordance with Article 3 or ***to*** determine their inclusion within the scope of public health insurance systems in accordance with Articles 7 and 9 shall be considered by Member States as administrative procedures which, as such, are independent from the enforcement of intellectual property rights.	1. Decision-making procedures and decisions to regulate the prices of medicinal products in accordance with Article 3 or ***which*** determine their inclusion within the scope of public health insurance systems in accordance with Articles 7 and 9 shall be considered by Member States as administrative procedures which, as such, are independent from the enforcement of intellectual property rights.

Or. it

Amendment 248
Paolo Bartolozzi, Sergio Berlato, Elisabetta Gardini

Proposal for a directive
Article 14 – paragraph 1

Text proposed by the Commission	*Amendment*
1. ***Applications,*** decision-making procedures and decisions to regulate the prices of medicinal products in accordance with Article 3 or ***to*** determine their inclusion within the scope of public health insurance systems in accordance with Articles 7 and 9 shall be considered by Member States as administrative procedures which, as such, are independent from the enforcement of intellectual property rights.	1. Decision-making procedures and decisions to regulate the prices of medicinal products in accordance with Article 3 or ***which*** determine their inclusion within the scope of public health insurance systems in accordance with Articles 7 and 9 shall be considered by Member States as administrative procedures which, as such, are independent from the enforcement of intellectual property rights.

Or. it

Amendment 249
Zofija Mazej Kukovič

Proposal for a directive
Article 14 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The protection of intellectual property rights shall not be a valid ground to refuse, suspend or revoke decisions relating to the price of a medicinal product or its inclusion within the public health insurance system.	2. The protection of intellectual property rights shall not be a valid ground to refuse, suspend or revoke decisions relating to the price of a medicinal product or its inclusion within the public health insurance system. ***Member States may not, however, under any circumstances, be deprived of the power to verify intellectual property.***

Or. sl

Amendment 250
Paolo Bartolozzi, Sergio Berlato, Elisabetta Gardini

Proposal for a directive
Article 14 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Paragraphs 1 and 2 shall apply without prejudice to the Union and national legislation relating to the protection of intellectual property.	3. Paragraphs 1 and 2 shall apply without prejudice to the Union and national legislation relating to the protection of intellectual property. ***With a view to ensuring that the provisions of this article are properly applied, those provisions shall not prevent applications submitted to the competent authorities or decisions by competent authorities regarding the setting of the price of a given product or the inclusion of that product in public health insurance systems from being considered objective and reasonable factors that may be taken into account by the competent judicial authorities when determining whether an intellectual property right is being or will be infringed.***

Or. it

Amendment 251
Oreste Rossi, Giancarlo Scottà

Proposal for a directive
Article 14 – paragraph 3 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	With a view to ensuring that the provisions of this article are properly applied, those provisions shall not prevent applications submitted to the competent authorities or decisions by competent authorities regarding the setting of the price of a given product or the inclusion of that product in public health insurance systems from being considered objective

and reasonable factors that may be taken into account by the competent judicial authorities when determining whether an intellectual property right is being or will be infringed.

Or. it

Amendment 252
Oreste Rossi, Giancarlo Scottà

Proposal for a directive
Article 14 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Paragraphs 1 and 2 may be waived in Member States in which the issue of a marketing authorisation or a reimbursement authorisation for a generic product results in a change in the price of and/or reimbursement terms for the relevant reference product.

Or. it

Amendment 253
Paolo Bartolozzi, Sergio Berlato, Elisabetta Gardini

Proposal for a directive
Article 14 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Paragraphs 1 and 2 may be waived in Member States in which the issue of a marketing authorisation or a reimbursement authorisation for a generic product results in a change in the price of and/or reimbursement terms for the relevant reference product.

Or. it

Amendment 254
Oreste Rossi, Giancarlo Scottà

Proposal for a directive
Article 14 – paragraph 3 b (new)

Text proposed by the Commission	*Amendment*
	3b. Member States may adopt specific measures and legal procedures to protect intellectual property rights in cases where the issue of a marketing authorisation or a reimbursement authorisation for a generic product results in a change in the price of and/or reimbursement terms for the relevant reference product.

Or. it

Amendment 255
Paolo Bartolozzi, Sergio Berlato, Elisabetta Gardini
Proposal for a directive
Article 14 – paragraph 3 b (new)

Text proposed by the Commission	*Amendment*
	3b. Member States may adopt specific measures and legal procedures to protect intellectual property rights in cases where the issue of a marketing authorisation or a reimbursement authorisation for a generic product results in a change in the price of and/or reimbursement terms for the relevant reference product.

Or. it

Amendment 256
Milan Cabrnoch

Proposal for a directive
Article 15

Text proposed by the Commission	*Amendment*
Article 15	***deleted***
Consultation of interested parties	
Where a Member State intends to adopt or amend any measure falling within the scope of this Directive, it shall give interested parties the opportunity to comment on the draft measure within a reasonable period. The competent authorities shall publish the rules applicable to consultations. The results of consultations shall be made publicly available, with the exception of confidential information in accordance with Union and national legislation regarding business confidentiality.	

Or. cs

Amendment 257
Alda Sousa

Proposal for a directive
Article 15

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

Or. en

Amendment 258
Philippe Juvin

Proposal for a directive
Article 15

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

Or. fr

Amendment 259
Nessa Childers, Justas Vincas Paleckis

Proposal for a directive
Article 15 a (new)

Text proposed by the Commission	*Amendment*
	Article 15a
	Price transparency
	1. At least once a year, the competent authorities shall publish in an appropriate publication and communicate to the Commission, a complete list of the medicinal products covered by their health insurance systems, the prices of which have been fixed during the relevant period, together with the prices which may be charged for such products.

2. The Commission and the Member States shall examine how to continue to co-operate on the functioning of the EURIPID price information database, which provides EU-wide added value in terms of price transparency.

Or. en

Amendment 260
Milan Cabrnoch

Proposal for a directive
Article 16

Text proposed by the Commission	*Amendment*
Article 16	***deleted***
Notification of draft national measures	
1. Where Member States intend to adopt or amend any measure falling within the scope of this Directive, they shall immediately communicate to the Commission the draft measure envisaged, together with the reasoning on which the measure is based.	
2. Where appropriate, Member States shall simultaneously communicate the texts of the basic legislative or regulatory provisions principally and directly concerned, if knowledge of such texts is necessary to assess the implications of the measure proposed.	
3. Member States shall communicate the draft measure referred to in paragraph 1 again if they make changes to the draft that have the effect of significantly altering its scope or substance, or shortening the timetable originally envisaged for implementation.	
4. The Commission may send its observations to the Member State which has communicated the draft measure	

within three months.

The observations of the Commission shall be taken into account as far as possible by the Member State concerned, in particular if the observations indicate that the draft measure may be incompatible with Union law.

5. When the Member State concerned definitively adopts the draft measure, it shall communicate the final text to the Commission without delay. If observations have been made by the Commission in accordance with paragraph 4, this communication shall be accompanied by a report on the actions taken in response to the observations of the Commission.

Or. cs

Amendment 261
Erik Bánki

Proposal for a directive
Article 16

Text proposed by the Commission	*Amendment*
Article 16	***deleted***
Notification of draft national measures	
(1) Where Member States intend to adopt or amend any measure falling within the scope of this Directive, they shall immediately communicate to the Commission the draft measure envisaged, together with the reasoning on which the measure is based.	
(2) Where appropriate, Member States shall simultaneously communicate the texts of the basic legislative or regulatory provisions principally and directly concerned, if knowledge of such texts is necessary to assess the implications of the	

measure proposed.

(3) Member States shall communicate the draft measure referred to in paragraph 1 again if they make changes to the draft that have the effect of significantly altering its scope or substance, or shortening the timetable originally envisaged for implementation.

(4) The Commission may send its observations to the Member State which has communicated the draft measure within three months.

The observations of the Commission shall be taken into account as far as possible by the Member State concerned, in particular if the observations indicate that the draft measure may be incompatible with Union law.

(5) When the Member State concerned definitively adopts the draft measure, it shall communicate the final text to the Commission without delay. If observations have been made by the Commission in accordance with paragraph 4, this communication shall be accompanied by a report on the actions taken in response to the observations of the Commission.

Or. hu

Justification

We see cause for concern in the fact that the proposal provides for a preliminary notification requirement followed by a three-month waiting period before the deadline which the Commission must comply with. This provision would make it impossible for Member States to respond flexibly to macroeconomic circumstances which justify amending the subsidy rules.

Amendment 262
Alda Sousa

Proposal for a directive
Article 16

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

the Commission.

Or. en

Amendment 263
Nessa Childers

Proposal for a directive
Article 16

Text proposed by the Commission	*Amendment*
Article 16	***deleted***
Notification of draft national measures	
1. Where Member States intend to adopt or amend any measure falling within the scope of this Directive, they shall immediately communicate to the Commission the draft measure envisaged, together with the reasoning on which the measure is based.	
2. Where appropriate, Member States shall simultaneously communicate the texts of the basic legislative or regulatory provisions principally and directly concerned, if knowledge of such texts is necessary to assess the implications of the measure proposed.	
3. Member States shall communicate the draft measure referred to in paragraph 1 again if they make changes to the draft that have the effect of significantly altering its scope or substance, or shortening the timetable originally envisaged for implementation.	
4. The Commission may send its observations to the Member State which has communicated the draft measure within three months.	
The observations of the Commission shall be taken into account as far as possible by the Member State concerned, in particular if the observations indicate that	

the draft measure may be incompatible with Union law.

5. When the Member State concerned definitively adopts the draft measure, it shall communicate the final text to the Commission without delay. If observations have been made by the Commission in accordance with paragraph 4, this communication shall be accompanied by a report on the actions taken in response to the observations of the Commission.

Or. en

Amendment 264
Bernadette Vergnaud

Proposal for a directive
Article 16

Text proposed by the Commission	*Amendment*
Article 16	***deleted***
Notification of draft national measures	
1. Where Member States intend to adopt or amend any measure falling within the scope of this Directive, they shall immediately communicate to the Commission the draft measure envisaged, together with the reasoning on which the measure is based.	
2. Where appropriate, Member States shall simultaneously communicate the texts of the basic legislative or regulatory provisions principally and directly concerned, if knowledge of such texts is necessary to assess the implications of the measure proposed.	
3. Member States shall communicate the draft measure referred to in paragraph 1 again if they make changes to the draft that have the effect of significantly altering its scope or substance, or	

shortening the timetable originally envisaged for implementation.

4. The Commission may send its observations to the Member State which has communicated the draft measure within three months.

The observations of the Commission shall be taken into account as far as possible by the Member State concerned, in particular if the observations indicate that the draft measure may be incompatible with Union law.

5. When the Member State concerned definitively adopts the draft measure, it shall communicate the final text to the Commission without delay. If observations have been made by the Commission in accordance with paragraph 4, this communication shall be accompanied by a report on the actions taken in response to the observations of the Commission.

Or. fr

Justification

The provisions of this article go beyond what is required to achieve the aims of the proposal and are not consistent with the subsidiarity principle.

Amendment 265
Michèle Rivasi

Proposal for a directive
Article 16

Text proposed by the Commission	*Amendment*
Article 16	***deleted***
Notification of draft national measures	
1. Where Member States intend to adopt or amend any measure falling within the scope of this Directive, they shall immediately communicate to the	

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

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

3. Member States shall communicate the draft measure referred to in paragraph 1 again if they make changes to the draft that have the effect of significantly altering its scope or substance, or shortening the timetable originally envisaged for implementation.

4. The Commission may send its observations to the Member State which has communicated the draft measure within three months.

The observations of the Commission shall be taken into account as far as possible by the Member State concerned, in particular if the observations indicate that the draft measure may be incompatible with Union law.

5. When the Member State concerned definitively adopts the draft measure, it shall communicate the final text to the Commission without delay. If observations have been made by the Commission in accordance with paragraph 4, this communication shall be accompanied by a report on the actions taken in response to the observations of the Commission.

Or. fr

Justification

This bureaucratic procedure would make it impossible for the Member States to respond quickly to new developments threatening the sustainability of their health systems. What is more, this proposal is at odds with the right of Member States to organise their health systems and with the subsidiarity principle.

Amendment 266
Michèle Rivasi

Proposal for a directive
Article 16 – paragraph 1

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

Or. fr

Amendment 267
Michèle Rivasi

Proposal for a directive
Article 16 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall communicate the draft measure referred to in paragraph 1 again if they make changes to the draft that have the effect of significantly altering its scope or substance, or shortening the timetable originally envisaged for implementation.	***deleted***

Or. fr

Amendment 268
Michèle Rivasi

Proposal for a directive
Article 16 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission may send its observations to the Member State which has communicated the draft measure within three months.	***deleted***
The observations of the Commission shall be taken into account as far as possible by the Member State concerned, in particular if the observations indicate that the draft measure may be incompatible with Union law.	

Or. fr

Amendment 269
Zofija Mazej Kukovič

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

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

Or. sl

Amendment 270
Michèle Rivasi

Proposal for a directive
Article 16 – paragraph 5

Text proposed by the Commission	*Amendment*
5. When the Member State concerned definitively adopts the draft measure, it shall communicate the final text to the Commission without delay. If observations have been made by the Commission in accordance with paragraph 4, this communication shall be	***deleted***

accompanied by a report on the actions taken in response to the observations of the Commission.

Or. fr

Amendment 271
Milan Cabrnoch

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

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

Or. cs

Amendment 272
Bernadette Vergnaud

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

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

Or. fr

Amendment 273
Michèle Rivasi

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

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

Or. fr

Justification

The requirement should be for these reports to be published annually, in order to ensure that no excessive administrative burden is imposed on Member States and that the reports are based on a broader range of data, and thus offer a more comprehensive overview.

Amendment 274
Milan Cabrnoch

Proposal for a directive
Article 17 – paragraph 2

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

Or. cs

Amendment 275
Milan Cabrnoch

Proposal for a directive
Article 18 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Member States shall adopt and publish, by [last day of the ***12***th month following publication of this Directive in the Official journal of the European Union] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.	Member States shall adopt and publish, by [last day of the ***24***th month following publication of this Directive in the Official journal of the European Union] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

Or. cs

Amendment 276
Milan Cabrnoch

Proposal for a directive
Article 19

Text proposed by the Commission	*Amendment*
Article 19	***deleted***
Report on the implementation of this Directive	
1. Member States shall send a report to the Commission on the implementation of this Directive by [insert date - within two years after the date referred to in the second subparagraph of Article 18(1)] and every three years thereafter.	
2. By [insert date - within three years after the date referred to in the second subparagraph of Article 18(1)], the Commission shall submit a report to the European Parliament and the Council on the implementation of this Directive. The report may be accompanied by any	

appropriate proposals.

Or. cs

Amendment 277
Oreste Rossi, Giancarlo Scottà

Proposal for a directive
Article 19 – paragraph 2

Text proposed by the Commission	*Amendment*
2. By [insert date - within three years after the date referred to in the second subparagraph of Article 18(1)], the Commission shall submit a report to the European Parliament and the Council on the implementation of this Directive. The report may be accompanied by ***any appropriate*** proposals.	2. By [insert date - within three years after the date referred to in the second subparagraph of Article 18(1)], the Commission shall submit a report to the European Parliament and the Council on the implementation of this Directive. The report may be accompanied***, where appropriate,*** by proposals ***for the amendment of this Directive***.

Or. it

Amendment 278
Peter Liese, Zofija Mazej Kukovič, Anja Weisgerber

Proposal for a directive
Article 19 a (new)

Text proposed by the Commission	*Amendment*
	Article 19a
	Monitoring and Reporting
	1. Three years after entry into force of this Directive the Commission shall submit a report to the European Parliament and to the Council assessing the enforcement of this Directive.
	2. The Commission shall be equipped with sufficient resources to monitor the enforcement of the Directive.

Or. en