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Committee on the Environment, Public Health and Food Safety

2008/0256(COD)

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AMENDMENTS
28 - 300

Draft report
Christofer Fjellner
(PE439.410v02-00)

on the proposal for a directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use

Proposal for a directive – amending act
(COM(2008)0663 – C6-0156/2008 – 2008/0256(COD))

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Amendment 28
Gilles Pargneaux

Proposal for a directive - amending act

Proposal for rejection

The European Parliament rejects the Commission proposal.

Or. fr

Justification

These legislative proposals open the door to direct advertising by pharmaceutical companies. The Commission's only reason for proposing to amend the existing legislation seems to be the wish to serve the commercial interests of pharmaceutical companies by expanding their markets. This operation will be of no benefit to EU citizens or the Member States. On the contrary, it would mean higher costs, as well as greater risks for patients. These proposals must be completely rethought.

Amendment 29
Carl Schlyter

Proposal for a directive - amending act

Proposal for rejection

The European Parliament rejects the Commission proposal.

Or. en

Justification

The proposal is ill-founded. It does not set out a proper information strategy according to the needs of patients. Instead, its sole focus is to entitle industry with vested interests to disseminate "information". It blurs the distinction between advertisement and information, which is best seen by the attempt to allow publication of "information" in print media. A proper information strategy needs to be far wider and run by authorities, not by pharmaceutical companies. The new Commission should come forward with a new proposal,

instead of the EP having to rewrite it completely.

Amendment 30
Jiří Maštálka

Proposal for a directive - amending act
Recital 1

Text proposed by the Commission	*Amendment*
(1) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use establishes harmonised rules on the advertising of medicinal products for human use. In particular, it prohibits the advertising to the general public of medicinal products subject to medical prescription.	(1) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use establishes harmonised rules on the advertising of medicinal products for human use. In particular, it prohibits the advertising to the general public of medicinal products subject to medical prescription ***in order to protect public health***.

Or. en

Justification

It is important to remind that the prescription-only status and the advertising ban for the medicinal products subject to medical prescription are in place to protect public health.

Amendment 31
Carl Schlyter

Proposal for a directive - amending act
Recital 1

Text proposed by the Commission	*Amendment*
(1) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use establishes harmonised rules on the advertising of medicinal products for human use. In particular, it prohibits the advertising to the general public of	(1) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use establishes harmonised rules on the advertising of medicinal products for human use. In particular, it prohibits the advertising to the general public of

medicinal products subject to medical prescription.	medicinal products subject to medical prescription ***in order to protect human health***.

Or. en

Justification

It is important to remember that the advertising ban for the medicinal products subject to medical prescription is in place to protect public health.

Amendment 32
Nessa Childers

Proposal for a directive - amending act
Recital 2

Text proposed by the Commission	*Amendment*
(2) In the area of information, Directive 2001/83/EC lays down detailed rules on the documents to be annexed to the marketing authorisation and intended for information purposes: the summary of product characteristics (distributed to health-care professionals) and the package leaflet (inserted in the product's packaging when it is dispensed to the patient). On the other hand, as regards the dissemination of information from the marketing authorisation holder to the general public, the Directive only provides that certain information activities are not covered by the rules on advertising, without providing for a harmonised framework on the contents and the quality of non promotional information on medicinal products ***or on*** the channels through which this information may be disseminated.	(2) In the area of information, Directive 2001/83/EC lays down detailed rules on the documents to be annexed to the marketing authorisation and intended for information purposes: the summary of product characteristics (distributed to health-care professionals) and the package leaflet (inserted in the product's packaging when it is dispensed to the patient). On the other hand, as regards the dissemination of information from the marketing authorisation holder to the general public, the Directive only provides that certain information activities are not covered by the rules on advertising, without providing for a harmonised framework on the contents and the quality of non promotional information on medicinal products ***in*** the ***context of a wider information to patients' strategy. Furthermore, the Directive does not provide*** channels through which this information may be disseminated ***and does not provide for a package leaflet which is patient-friendly and responds to the real needs of patients***. ***The package leaflet should therefore be transformed into a***

patient leaflet.

Or. en

Justification

A crucial point that was extensively discussed and recognized by Member States and stakeholders, and endorsed by the Pharmaceutical Forum, was the need for a broader and comprehensive "information to patients strategy" including a commitment to health literacy. The present Package Information Leaflet is not patient friendly and does not correspond to the real needs of patients. EMA's work to improve the readability and patient-friendliness of the leaflet should be continued and should be followed as a model of good practice for national regulatory authorities.

Amendment 33
Thomas Ulmer

Proposal for a directive - amending act
Recital 2

Text proposed by the Commission	*Amendment*
(2) In the area of information, Directive 2001/83/EC lays down detailed rules on the documents to be annexed to the marketing authorisation and intended for information purposes: the summary of product characteristics (distributed to health-care professionals) and the package leaflet (inserted in the product's packaging when it is dispensed to the patient). ***On the other hand, as regards the dissemination of information from the marketing authorisation holder to the general public, the Directive only provides that certain information activities are not covered by the*** rules ***on advertising, without providing for a harmonised framework on the contents and the quality of non promotional information on medicinal products or on the channels through which this information may be disseminated***.	(2) In the area of information, Directive 2001/83/EC lays down detailed rules on the documents to be annexed to the marketing authorisation and intended for information purposes: the summary of product characteristics (distributed to health-care professionals) and the package leaflet (inserted in the product's packaging when it is dispensed to the patient). ***These*** rules ***should be improved and better enforced in order to allow for improvements of the readability of these documents***.

Or. en

Justification

The current wording raises the problem of the definition of advertising and "information" disseminated by the marketing authorisation holder. The priority should be to make the officially approved leaflet more useful and accessible for patients by ensuring that pharmaceutical companies consistently abide by their obligations relative to drug packaging and patient leaflets (i.e. consultations with target patient groups) (enforcement of article 59 of Directive 2001/83/EC modified by Directive 2004/27/CE).

Amendment 34
Peter Liese, Anja Weisgerber, Cristian Silviu Buşoi, Thomas Ulmer, Elena Oana Antonescu, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Recital 2

Text proposed by the Commission	*Amendment*
(2) In the area of information, Directive 2001/83/EC lays down detailed rules on the documents to be annexed to the marketing authorisation and intended for information purposes: the summary of product characteristics (distributed to health-care professionals) and the package leaflet (inserted in the product's packaging when it is dispensed to the patient). On the other hand, as regards the ***dissemination*** of information from the marketing authorisation holder to the general public, the Directive only provides that certain information activities are not covered by the rules on advertising, without providing for a harmonised framework on the contents and the quality of non promotional information on medicinal products or on the channels through which this information may be ***disseminated***.	(2) In the area of information, Directive 2001/83/EC lays down detailed rules on the documents to be annexed to the marketing authorisation and intended for information purposes: the summary of product characteristics (distributed to health-care professionals) and the package leaflet (inserted in the product's packaging when it is dispensed to the patient). On the other hand, as regards the ***making available*** of information from the marketing authorisation holder to ***patients and*** the general public, the Directive only provides that certain information activities are not covered by the rules on advertising, without providing for a harmonised framework on the contents and the quality of non promotional information on medicinal products or on the channels through which this information may be ***made available***. *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)*

Or. en

Justification

This Directive must be patient-centered. Therefore non-promotional information on medicinal products must be made available to patients and the general public by marketing authorisation holders according to the "pull principle" whereby patients/the public have access to information if they need it (contrary to the "push principle" whereby the marketing authorisation holders disseminate information among the patients and the general public).

Amendment 35
Gilles Pargneaux

Proposal for a directive – amending act
Recital 3

Text proposed by the Commission	*Amendment*
(3) On the basis of Article 88a of Directive 2001/83/EC, on 20 December 2007 the Commission submitted a Communication to the European Parliament and the Council on a "Report on current practices with regard to the provision of information to patients on medicinal products". The report concludes that Member States have adopted divergent rules and practices with regard to the provision of information, resulting in a situation where patients and the public at large have unequal access to information on medicinal products.	***deleted***

Or. en

Justification

Regulatory authorities should be encouraged to become more proactive and transparent providers of information, so as to guarantee full public access to data on the efficacy/effectiveness and safety of medicines (and their variations) both before and after a product is marketed.

Amendment 36
Marina Yannakoudakis

Proposal for a directive - amending act
Recital 3

Text proposed by the Commission	*Amendment*
(3) On the basis of Article 88a of Directive 2001/83/EC, on 20 December 2007 the Commission submitted a Communication to the European Parliament and the Council on a "Report on current practices with regard to the provision of information to patients on medicinal products". The report concludes that Member States have adopted divergent rules and practices with regard to the provision of information, resulting in a situation where patients and the public at large have unequal access to information ***on medicinal products***.	(3) On the basis of Article 88a of Directive 2001/83/EC, on 20 December 2007 the Commission submitted a Communication to the European Parliament and the Council on a "Report on current practices with regard to the provision of information to patients on medicinal products". The report concludes that Member States have adopted divergent rules and practices with regard to the provision of information, resulting in a situation where patients and the public at large have unequal access to information ***in the package leaflet and in the summary of product characteristics***. ***Such unjustifiable inequalities in accessing information that is publicly available in other Member States should be redressed.***

Or. en

Justification

All information needs to be available regardless of severity of diseases.

Amendment 37
Carl Schlyter

Proposal for a directive - amending act
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) For scientific information, transparency obligations for competent authorities have been established by Directive 2001/83/EC. However, evidence has shown that competent authorities restrict access to information for the general public due to a wide interpretation of commercial confidentiality. To avoid such divergent practices, the obligations of competent

authorities to provide access to information for the general public need to be clarified.

Or. en

Amendment 38
Gilles Pargneaux

Proposal for a directive – amending act
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) In the area of scientific information, Directive 2001/83/EC lays down transparency obligations for National competent authorities, but experience gained from the application of the current legal framework has also shown certain restrictions on the possibilities for the general public to access information from their National competent authorities due to a too extensive interpretation of commercial confidentiality.

Or. en

Justification

Regulatory authorities should be encouraged to become more proactive and transparent providers of information, so as to guarantee full public access to data on the efficacy/effectiveness and safety of medicines (and their variations) both before and after a product is marketed.

Amendment 39
Corinne Lepage

Proposal for a directive - amending act
Recital 4

Text proposed by the Commission	*Amendment*
(4) Experience gained from the application of the current legal framework has also	(4) Experience gained from the application of the current legal framework has also

shown that ***certain restrictions on the possibilities of pharmaceutical companies to provide information result from the fact that*** the distinction between the notions of advertising and information is not interpreted consistently across the ***Community***.	shown that the distinction between the notions of advertising and information is not interpreted consistently across the ***EU, and that this has given rise to situations where the general public is exposed to disguised advertising***.

Or. fr

Amendment 40
Nessa Childers

Proposal for a directive - amending act
Recital 4

Text proposed by the Commission	*Amendment*
(4) Experience gained from the application of the current legal framework has also shown that certain restrictions on the possibilities of pharmaceutical companies to provide information result from the fact that the distinction between the notions of advertising and information is not interpreted consistently across the Community.	(4) Experience gained from the application of the current legal framework has also shown that certain restrictions on the possibilities of pharmaceutical companies to provide information result from the fact that the distinction between the notions of advertising and information is not interpreted consistently across the Community. ***Each notion should be defined and should be interpreted uniformly across all EU Member States so to ensure patient safety.***

Or. en

Justification

In order to ensure equity of access to information and patient safety for all EU patients and in order to safeguard public health, it is crucial to make a clear distinction between what represents "information" and what represents "advertising". It is essential to have a harmonized understanding and interpretation of these concepts is all Member States.

Amendment 41
Gilles Pargneaux

Proposal for a directive – amending act
Recital 4

Text proposed by the Commission	*Amendment*
(4) Experience gained from the application of the current legal framework has also shown that ***certain restrictions on*** the ***possibilities of pharmaceutical companies to provide information result from the fact that the*** distinction between the notions of advertising and information is not ***interpreted consistently*** across the Community.	(4) Experience gained from the application of the current legal framework has also shown that the distinction between the notions of advertising and information is not ***clear*** across the Community***, resulting in exposure of the general public is disguised advertising***.

Or. en

Justification

The difference in interpretation of the notions of advertising and of information can lead to the public exposure to disguised advertising.

Amendment 42
Peter Liese, Anja Weisgerber, Cristian Silviu Buşoi, Thomas Ulmer, Elena Oana Antonescu, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Recital 4

Text proposed by the Commission	*Amendment*
(4) Experience gained from the application of the current legal framework has also shown that certain restrictions on the possibilities of pharmaceutical companies to ***provide*** information result from the fact that the distinction between the notions of advertising and information is not interpreted consistently across the Community.	(4) Experience gained from the application of the current legal framework has also shown that certain restrictions on the possibilities of pharmaceutical companies to ***make*** information ***available to patients and the general public*** result from the fact that the distinction between the notions of advertising and information is not interpreted consistently across the Community. *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)*

Or. en

Justification

This Directive must be patient-centered. Therefore non-promotional information on medicinal products must be made available to patients and to the general public by marketing authorisation holders according to the "pull principle" whereby patients/the public have access to information if they need it (contrary to the "push principle" whereby the marketing authorisation holders disseminate information among the patients and the general public).

Amendment 43
Gilles Pargneaux

Proposal for a directive – amending act
Recital 6

Text proposed by the Commission	*Amendment*
(6) The different national measures are also likely to have an impact on the proper functioning of the internal market for medicinal products, as the possibility for marketing authorisation holders to ***disseminate information*** on medicinal products is not the same across Member States, while ***information disseminated*** in one Member State ***is*** likely to have effects in other Member States. This impact will be greater in the case of medicinal products whose product information (summary of product characteristics and package leaflet) is harmonised at Community level. This includes medicinal products authorised by the Member States under the mutual recognition framework of Chapter IV of Title III of Directive 2001/83/EC.	(6) The different national measures are also likely to have an impact on the proper functioning of the internal market for medicinal products, as the possibility for marketing authorisation holders to ***communicate*** on medicinal products is not the same across Member States, while ***communications*** in one Member State ***are*** likely to have effects in other Member States. This impact will be greater in the case of medicinal products whose product information (summary of product characteristics and package leaflet) is harmonised at Community level. This includes medicinal products authorised by the Member States under the mutual recognition framework of Chapter IV of Title III of Directive 2001/83/EC.

Or. en

Justification

The current wording raises the problem of the definition of advertising and of "information" disseminated by the marketing authorisation holder. It is therefore preferable to refer to "communication" by the marketing authorisation holder.

Amendment 44
Gilles Pargneaux

Proposal for a directive – amending act
Recital 7

Text proposed by the Commission	*Amendment*
(7) In the light of the above and taking into account technological progress with regard to modern communication tools and the fact that patients throughout the European Union have become increasingly active as regards healthcare, it is necessary to amend the existing legislation in order to reduce differences in access to information and to ***allow for the availability of good-quality, objective, reliable and non promotional*** information ***on medicinal products***.	(7) In the light of the above and taking into account technological progress with regard to modern communication tools and the fact that patients throughout the European Union have become increasingly active as regards healthcare, it is necessary to amend the existing legislation in order to reduce differences in access to ***relevant, independent and comparative health*** information and to ***protect patients from misleading or biased*** information.

Or. en

Justification

Useful patient information on therapeutics should be comparative, so that patients can learn about the different treatments available and what to expect from them, in order to make an informed choice (or to participate in the choice). The advertising ban for prescription medicines needs to be strengthened not weakened under the guise of "information". The "good-quality", "objective" and "non promotional" criteria are vague and totally unrealistic if the source of "information" is the marketing authorisation holder.

Amendment 45
Thomas Ulmer

Proposal for a directive - amending act
Recital 7

Text proposed by the Commission	*Amendment*
(7) In the light of the above and taking into account technological progress with regard to modern communication tools and the fact that patients throughout the European Union have become increasingly active as regards healthcare, it is necessary to amend the existing legislation in order to reduce differences in access to information and to	(7) In the light of the above and taking into account technological progress with regard to modern communication tools and the fact that patients throughout the European Union have become increasingly active as regards healthcare, it is necessary to amend the existing legislation in order to reduce differences in access to ***relevant,***

allow for the availability of good-quality, objective, reliable and non promotional information ***on medicinal products***.	***independent, and comparative health*** information and to ***protect patients from misleading or biased*** information.

Or. en

Justification

Useful patient information on therapeutics should be comparative, so that patients can learn about the different treatments available and what to expect from them, in order to make an informed choice (or to participate in the choice). The advertising ban for prescription medicines needs to be strengthened not weakened under the guise of "information". The "good-quality", "objective" and "non promotional" criteria are vague and unrealistic if the source of "information" is the marketing authorisation holder.

Amendment 46
Peter Liese, Anja Weisgerber, Cristian Silviu Buşoi, Thomas Ulmer, Elena Oana Antonescu, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Recital 7

Text proposed by the Commission	*Amendment*
(7) In the light of the above and taking into account technological progress with regard to modern communication tools and the fact that patients throughout the European Union have become increasingly active as regards healthcare, it is necessary to amend the existing legislation in order to reduce differences in access to information and to allow for the availability of good-quality, objective, reliable and non promotional information on medicinal products.	(7) In the light of the above and taking into account technological progress with regard to modern communication tools and the fact that patients throughout the European Union have become increasingly active as regards healthcare, it is necessary to amend the existing legislation in order to reduce differences in access to information and to allow for the availability of good-quality, objective, reliable and non promotional information on medicinal products ***by placing emphasis on the interests of patients***. ***They should have the right to easily access certain information such as a summary of product characteristics, and the package leaflet in electronic and printed form.***

Or. en

Justification

The Directive should be patient-centred. Therefore, it should focus on the patients and their interests. It should be made clear that patients have a right to certain information rather than the pharmaceutical industry having a right to disseminate information.

Amendment 47
Cristian Silviu Buşoi

Proposal for a directive - amending act
Recital 7

Text proposed by the Commission	*Amendment*
(7) In the light of the above and taking into account technological progress with regard to modern communication tools and the fact that patients throughout the European Union have become increasingly active as regards healthcare, it is necessary to amend the existing legislation in order to reduce differences in access to information and to allow for the availability of good-quality, objective, reliable and non promotional information on medicinal products.	(7) In the light of the above and taking into account technological progress with regard to modern communication tools and the fact that patients throughout the European Union have become increasingly active as regards healthcare, it is necessary to amend the existing legislation in order to reduce differences in access to information and to allow for the availability of good-quality, objective, reliable and non promotional information on medicinal products. ***Certified and registered Internet websites for independent, objective and non promotional information are therefore necessary.***

Or. en

Justification

Certified and registered websites will be a key channel for providing quality health information.

Amendment 48
Marina Yannakoudakis

Proposal for a directive - amending act
Recital 8

Text proposed by the Commission	*Amendment*
(8) National competent authorities and health care professionals should remain ***important*** sources of information on medicinal products for the general public. Member States should facilitate the access of citizens to high-quality information through appropriate channels. Marketing authorisation holders may be a valuable source of non promotional information on their medicinal products. This Directive should therefore establish a legal framework for the ***dissemination*** of specific information on medicinal products by marketing authorisation holders to the general public. The ban on advertising to the general public for prescription-only medicinal products should be maintained.	(8) National competent authorities and health care professionals should remain ***the main*** sources of information on medicinal products for the general public. Member States should facilitate the access of citizens to high-quality information through appropriate channels. Marketing authorisation holders may be a valuable source of non promotional information on their medicinal products. This Directive should therefore establish a legal framework for the ***making available*** of specific information on medicinal products by marketing authorisation holders to the general public ***in the context of a wider "information to patients" strategy***. The ban on advertising to the general public for prescription-only medicinal products should be maintained. ***The provisions of this Directive concerning the making available of information by marketing authorisation holders are without prejudice to the relationship between patients and their doctors and should contribute to ensuring that patients are better informed. The quality and accuracy of information should be increased with a view to better informing patients and therefore to achieving better health outcomes for patients. This information must be based on scientific criteria.***

Or. en

Justification

The information must be based on scientific criteria so that the general public are assured that the information is valid.

Amendment 49
Peter Liese, Anja Weisgerber, Cristian Silviu Buşoi, Thomas Ulmer, Elena Oana Antonescu, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis, Jo Leinen

Proposal for a directive - amending act
Recital 8

Text proposed by the Commission	*Amendment*
(8) National competent authorities and health care professionals should remain ***important sources*** of information on medicinal products for the general public. Member States should facilitate the access of citizens to high-quality information through appropriate channels***. Marketing authorisation holders may be a valuable source of non promotional information on their medicinal products. This Directive should therefore establish a legal framework for the dissemination of specific information on medicinal products by marketing authorisation holders to the general public. The ban on advertising to the general public for prescription-only medicinal products should be maintained***.	(8) National competent authorities and health care professionals should remain ***the main source*** of information on medicinal products for the general public. ***While there is already a lot of independent information on pharmaceuticals, for example by national authorities or health care professionals, the situation differs very much between Member States and among the different products available.*** Member States ***and Commission*** should ***take much more efforts to*** facilitate the access of citizens to high-quality information through appropriate channels.

Or. en

Amendment 50
Philippe Juvin

Proposal for a directive - amending act
Recital 8

Text proposed by the Commission	*Amendment*
(8) National competent authorities and health care professionals ***should*** remain ***important*** sources of information on medicinal products for the general public. Member States should facilitate the access of citizens to high-quality information through appropriate channels. ***Marketing*** authorisation holders may be ***a valuable*** source of non promotional information on	(8) National competent authorities and health care professionals ***must*** remain ***the main*** sources of information on medicinal products for the general public. Member States should facilitate the access of citizens to high-quality information through appropriate channels. ***Without prejudice to the importance of the role played by national competent authorities***

their medicinal products. This Directive should therefore establish a legal framework for the ***dissemination*** of specific information on medicinal products by marketing authorisation holders to the general public. The ban on advertising to the general public for prescription-only medicinal products should be maintained.	***and health care professionals in better informing patients and the general public, marketing*** authorisation holders may be ***an additional*** source of non promotional information on their medicinal products. This Directive should therefore establish a legal framework for the ***making available*** of specific information on medicinal products by marketing authorisation holders to the general public. The ban on advertising to the general public for prescription-only medicinal products should be maintained.

Or. en

Justification

It is important to underline that national competent authorities and healthcare professionals are the most important and main sources of reliable and objective information on medicinal products for the patients and the general public. Marketing authorisation holders can provide complementary information but cannot substitute themselves to the national competent authorities and the health care professionals.

Amendment 51
Gilles Pargneaux

Proposal for a directive – amending act
Recital 8

Text proposed by the Commission	*Amendment*
(8) National competent authorities and health care professionals should remain ***important*** sources of information on medicinal products for the general public. Member States should facilitate the access of citizens to high-quality information through appropriate channels***. Marketing authorisation holders may be a valuable source of non promotional information on their medicinal products. This Directive should therefore establish a legal framework for the dissemination of specific information on medicinal products by marketing authorisation***	(8) National competent authorities and health care professionals should remain ***the main*** sources of information on medicinal products for the general public. Member States should facilitate the access of citizens to high-quality information through appropriate channels. The ban on advertising to the general public for prescription-only medicinal products should be maintained.

holders to the general public. The ban on advertising to the general public for prescription-only medicinal products should be maintained.

Or. en

Justification

It has to be emphasised that the new provisions do not mean to replace the patient-health professional relationship just to support it. In a highly competitive environment, drug companies must promote their products above the use of other preventive or curative options, thus any "information" they provide will be, by definition, of a promotional nature.

Amendment 52
Corinne Lepage

Proposal for a directive - amending act
Recital 8

Text proposed by the Commission	*Amendment*
(8) National competent authorities and health care professionals should remain ***important*** sources of information on medicinal products for the general public. Member States should facilitate the access of citizens to high-quality information through appropriate channels. Marketing authorisation holders may be a valuable source of non promotional information on their medicinal products. This Directive should therefore establish a legal framework for the dissemination of specific information on medicinal products by marketing authorisation holders to the general public. The ban on advertising to the general public for prescription-only medicinal products should be maintained.	(8) National competent authorities and health care professionals should remain ***the main*** sources of information on medicinal products for the general public. Member States should facilitate the access of citizens to high-quality information through appropriate channels. Marketing authorisation holders may be a valuable source of non promotional information on their medicinal products. This Directive should therefore establish a legal framework for the dissemination of specific information on medicinal products by marketing authorisation holders to the general public. The ban on advertising to the general public for prescription-only medicinal products should be maintained.

Or. fr

Amendment 53
Peter Liese, Anja Weisgerber, Thomas Ulmer, Elena Oana Antonescu, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis, Jo Leinen

Proposal for a directive - amending act
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) Without prejudice to the importance of the role played by national competent authorities and health care professionals in better informing patients and the general public, marketing authorisation holders may be an additional source of non-promotional information on their medicinal products. This Directive should therefore establish a legal framework for the making available of specific information on medicinal products by marketing authorisation holders to the general public. The ban on advertising to the general public for prescription-only medicinal products should be maintained.

Or. en

Amendment 54
Peter Liese, Anja Weisgerber, Thomas Ulmer, Elena Oana Antonescu, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis, Jo Leinen

Proposal for a directive - amending act
Recital 9

Text proposed by the Commission	*Amendment*
(9) In accordance with the principle of proportionality, it is appropriate to limit the scope of this Directive to prescription-only medicinal products, as current Community rules allow the advertising to the general public of medicinal products not subject to prescription, under certain conditions.	(9) In accordance with the principle of proportionality, it is appropriate to limit the scope of this Directive to ***the supply of information on*** prescription-only medicinal products ***that has been approved by the competent authorities by the marketing authorisation holder***, as current Community rules allow the advertising to the general public of medicinal products not subject to prescription, under certain conditions.

Or. en

Amendment 55
Miroslav Ouzký

Proposal for a directive - amending act
Recital 9

Text proposed by the Commission	*Amendment*
(9) In accordance with the principle of proportionality, it is appropriate to limit the scope of this Directive to prescription-only medicinal products, as current Community rules allow the advertising to the general public of medicinal products not subject to prescription, under certain conditions.	(9) In accordance with the principle of proportionality, it is appropriate to limit the scope of this Directive to prescription-only medicinal products, as current Community rules allow the advertising to the general public of medicinal products not subject to prescription, under certain conditions. ***This Directive requires Member States to permit, via certain channels and subject to appropriate monitoring, the provision by a marketing authorisation holder or a third party acting on its behalf of certain information on authorised medicines subject to prescription to the general public. Communications that do not fall within the proposed Title VIIIa are permitted, provided that they do not constitute advertising.***

Or. en

Justification

Clarification of the scope of the proposed Directive. It is important that new legislation does not inadvertently prohibit certain communications, e.g. responses to healthcare professionals' enquiries on unlicensed uses.

Amendment 56
Nessa Childers

Proposal for a directive - amending act
Recital 9

Text proposed by the Commission	*Amendment*
(9) In accordance with the principle of	(9) In accordance with the principle of

proportionality, it is appropriate to limit the scope of this Directive to ***prescription-only*** medicinal products, as current Community rules allow the advertising to the general public of medicinal products not subject to prescription, under certain conditions.

proportionality, it is appropriate to limit the scope of this Directive to ***the making available of information on prescription only*** medicinal products ***by the marketing authorisation holder***, as current Community rules allow the advertising to the general public of medicinal products not subject to prescription, under certain conditions. ***The provisions of this Directive are without prejudice to the right of any other person or organisation, in particular the press or patients and patient organisations, to express their views on prescription only medicinal products, provided that they are acting independently and not directly or indirectly on behalf of, on the instructions of, or in the interest of the marketing authorisation holder and provided that they disclose the source of information.***

Or. en

Amendment 57
Nessa Childers

Proposal for a directive - amending act
Recital 10

Text proposed by the Commission	*Amendment*
(10) Provisions should be established to ensure that only high-quality non-promotional information about the benefits and the risks of medicinal products subject to medical prescription may be disseminated. The information should take into account patients needs and expectations in order to empower patients, allow informed choices and enhance the rational use of medicinal products. Therefore, any information to the general public on prescription-only medicinal products should comply with a set of quality criteria.	(10) Provisions should be established to ensure that only high-quality non-promotional information about the benefits and the risks of medicinal products subject to medical prescription may be disseminated. The information should take into account patients needs and expectations in order to empower patients, allow informed choices and enhance the rational use of medicinal products. Therefore, any information to the general public on prescription-only medicinal products should comply with a set of quality criteria***: objective and unbiased, patient-oriented, evidence-based, up-to-date, reliable, understandable, accessible,***

transparent, relevant, consistent with statutory information.

Or. en

Justification

The three-year process of the Pharmaceutical Forum – which included representatives of the European Commission, Member States, European Parliament and stakeholders - ended with an agreement on set of quality criteria for information to patients. These should be taken forward in the current legislative work. Examples of how the Quality Principles are being applied in practice were given at the Conference "Delivering for patients" (25 March 2009) and in EPF's Reference Document on Information to patients.

Amendment 58
Peter Liese, Anja Weisgerber, Cristian Silviu Buşoi, Thomas Ulmer, Elena Oana Antonescu, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis, Jo Leinen

Proposal for a directive - amending act
Recital 10

Text proposed by the Commission	*Amendment*
(10) Provisions should be established to ensure that only high-quality non-promotional information about the benefits and the risks of medicinal products subject to medical prescription may be disseminated. The information should take into account patients needs and expectations in order to empower patients, allow informed choices and enhance the rational use of medicinal products. Therefore, any information to the general public on prescription-only medicinal products should ***comply with a set of quality criteria***.	(10) Provisions should be established to ensure that only high-quality non-promotional information about the benefits and the risks of medicinal products subject to medical prescription may be disseminated. The information should take into account patients needs and expectations in order to empower patients, allow informed choices and enhance the rational use of medicinal products. Therefore, any information to the general public on prescription-only medicinal products should ***be approved in advance by the competent authorities und should be supplied only in the approved form***.

Or. en

Amendment 59
Gilles Pargneaux

Proposal for a directive – amending act
Recital 10

Text proposed by the Commission	*Amendment*
(10) Provisions should be established to ensure that only ***high-quality non-promotional*** information about the benefits and the risks of medicinal products subject to medical prescription may be disseminated. The information should take into account patients needs and expectations in order to empower patients, allow informed choices and enhance the rational use of medicinal products***. Therefore, any information to the general public on prescription-only medicinal products should comply with a set of quality criteria***.	(10) Provisions should be established to ensure that only ***reliable and comparative*** information about the benefits and the risks of medicinal products subject to medical prescription may be disseminated***, notably using the Community database referred to in Articles 57(1)(l) and 57(2) of Regulation (EC) No 726/2004 (hereinafter "the Eudrapharm database")***. The information should take into account patients needs and expectations in order to empower patients, allow informed choices and enhance the rational use of medicinal products.

Or. en

Justification

In a highly competitive environment, drug companies must promote their products above the use of other preventive or curative options, thus any 'information' they provide will be, by definition, of a promotional nature. Useful patient information should be comparative to enable users to analyse their concerns, give them a realistic idea of the evolution of their health status, help them to understand when further investigations are necessary, to know what treatments exist and what they can expect from them.

Amendment 60
Corinne Lepage

Proposal for a directive - amending act
Recital 10

Text proposed by the Commission	*Amendment*
(10) Provisions should be established to ensure that only high-quality non-promotional information about the benefits and the risks of medicinal products subject to medical prescription ***may be***	(10) Provisions should be established to ensure that only high-quality non-promotional information about the benefits and the risks of medicinal products subject to medical prescription ***is accessible***. The

disseminated. The information should take into account patients needs and expectations in order to empower patients allow informed choices and enhance the rational use of medicinal products. Therefore, any information to the general public on prescription-only medicinal products should comply with a set of quality criteria.	information should take into account patients needs and expectations in order to empower patients allow informed choices and enhance the rational use of medicinal products. Therefore, any information to the general public on prescription-only medicinal products should comply with a set of quality criteria.

Or. fr

Amendment 61
Carl Schlyter

Proposal for a directive - amending act
Recital 10

Text proposed by the Commission	*Amendment*
(10) Provisions should be established to ensure that only ***high-quality non-promotional*** information about the benefits and the risks of medicinal products subject to medical prescription may be ***disseminated***. The information should take into account patients needs and expectations in order to empower patients, allow informed choices and enhance the rational use of medicinal products***. Therefore, any information to the general public on prescription-only medicinal products should comply with a set of quality criteria***.	(10) Provisions should be established to ensure that only ***official*** information about the benefits and the risks of ***authorised*** medicinal products subject to medical prescription may be ***made available, notably through the Community database referred to in Articles 57(1)(l) and 57(2) of Regulation (EC) No 726/2004 (hereinafter 'the Eudrapharm database')***. The information should take into account patients needs and expectations in order to empower patients, allow informed choices and enhance the rational use of medicinal products.

Or. en

Justification

The provision of information should be limited to official documents. This makes the reference to quality criteria redundant.

Amendment 62
Jiří Maštálka

Proposal for a directive - amending act
Recital 11

Text proposed by the Commission	*Amendment*
(11) In order to further ensure that marketing authorisation holders ***disseminate*** only high-quality information and to distinguish non-promotional information from advertising, the types of information which may be ***disseminated*** should be defined. It is appropriate to ***allow*** marketing authorisation holders ***to disseminate*** the contents of the approved summaries of product characteristics and package leaflet***, information that is compatible with those documents without going beyond their key elements,*** and ***other well-defined medicinal product-related information***.	(11) In order to further ensure that marketing authorisation holders ***make available*** only high-quality information and to distinguish non-promotional information from advertising, the types of information which may be ***made available*** should be defined. It is appropriate to ***clarify that*** marketing authorisation holders ***can make available*** the contents of the approved summaries of product characteristics and package leaflet and ***the public assessment reports***.

Or. en

Justification

The proposal should be about the patients' rights to access high quality and non promotional information and not about the industry right to communicate directly to the public about its products.

Amendment 63
Gilles Pargneaux

Proposal for a directive – amending act
Recital 11

Text proposed by the Commission	*Amendment*
(11) In order to further ensure that marketing authorisation holders disseminate only ***high-quality*** information and to distinguish non-promotional information from advertising, the types of information ***which may be disseminated should be defined. It*** is appropriate to	(11) In order to further ensure that marketing authorisation holders disseminate only ***validated*** information and to distinguish non-promotional information from advertising, the types of information***, it*** is appropriate to allow marketing authorisation holders to ***make available*** the

allow marketing authorisation holders to ***disseminate*** the ***contents*** of the approved summaries of product characteristics and package leaflet***, information that is compatible with those documents without going beyond their key elements, and other well-defined medicinal product-related information***.	***last updated version*** of the approved summaries of product characteristics and ***of the approved*** package leaflet.

Or. en

Justification

To allow the pharmaceutical industry to draw up documents using only some of the elements of the SPC, disconnected from the other elements needed to understand them properly, and to produce a "free-style" leaflet is inefficient. It will also be potentially confusing to have two types of leaflets circulating, one officially approved and a rewritten version produced by the manufacturer. The risk is that it will lead to the public dissemination of promotional information on prescription only medicines and to administrative burden for health authorities.

Amendment 64
Peter Liese, Anja Weisgerber, Cristian Silviu Buşoi, Thomas Ulmer, Elena Oana Antonescu, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis, Jo Leinen

Proposal for a directive - amending act
Recital 11

Text proposed by the Commission	*Amendment*
(11) In order to further ensure that marketing authorisation holders ***disseminate*** only high-quality information and to distinguish non-promotional information from advertising, the types of information which may be ***disseminated*** should be defined. It is appropriate to allow marketing authorisation holders to ***disseminate*** the contents of the approved summaries of product characteristics and package leaflet, information that is compatible with those documents without going beyond their key elements, and other well-defined medicinal product-related information.	(11) In order to further ensure that marketing authorisation holders ***make available*** only high-quality information and to distinguish non-promotional information from advertising, the types of information which may be ***made available*** should be defined. It is appropriate to allow marketing authorisation holders to ***make available*** the contents of the approved summaries of product characteristics and package leaflet, information that is compatible with those documents without going beyond their key elements, and other well-defined medicinal product-related information.

(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)

Or. en

Justification

This Directive must be patient-centered. Therefore non-promotional information on medicinal products must be made available by marketing authorisation holders to patients and to the general public according to the "pull principle" whereby patients/the general public have access to information if they need it (contrary to the "push principle" whereby the marketing authorisation holders disseminate information among the patients and the general public).

Amendment 65
Nessa Childers

Proposal for a directive - amending act
Recital 11

Text proposed by the Commission	*Amendment*
(11) In order to further ensure that marketing authorisation holders disseminate only high-quality information and to distinguish non-promotional information from advertising, the types of information which may be disseminated should be defined. It is appropriate to allow marketing authorisation holders to disseminate the contents of the approved summaries of product characteristics and ***package*** leaflet***, information that is compatible with those documents without going beyond their key elements, and other well-defined medicinal product-related information***.	(11) In order to further ensure that marketing authorisation holders disseminate only high-quality information and to distinguish non-promotional information from advertising, the types of information which may be disseminated should be defined. It is appropriate to allow marketing authorisation holders to disseminate the contents of the approved summaries of product characteristics and ***patient*** leaflet.

Or. en

Justification

This is unclear, it needs to be more concrete and tangible.

Amendment 66
Carl Schlyter

Proposal for a directive - amending act
Recital 11

Text proposed by the Commission	*Amendment*
(11) In order to further ensure that marketing authorisation holders disseminate only ***high-quality*** information ***and to distinguish non-promotional information from advertising***, ***the types of information which may be disseminated should be defined. It*** is appropriate to allow marketing authorisation holders to ***disseminate*** the ***contents of the*** approved summaries of product characteristics and package leaflet***, information that is compatible with those documents without going beyond their key elements, and other well-defined medicinal product-related information***.	(11) In order to further ensure that marketing authorisation holders disseminate only ***validated statutory*** information, ***it*** is appropriate to allow marketing authorisation holders to ***make available*** the approved summaries of product characteristics and ***the approved*** package leaflet.

Or. en

Justification

Information should only be made available by the industry, not disseminated. The proposal should be about the patients' rights to access official documents. It should not allow the industry to provide "free style" 'information'.

Amendment 67
Peter Liese, Anja Weisgerber, Thomas Ulmer, Elena Oana Antonescu, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis, Jo Leinen

Proposal for a directive - amending act
Recital 11

Text proposed by the Commission	*Amendment*
(11) In order to further ensure that marketing authorisation holders disseminate only high-quality information and to distinguish non-promotional information from advertising, the types of information which may be disseminated	(11) In order to further ensure that marketing authorisation holders disseminate only ***competent authority-approved*** high-quality information ***in approved form*** and ***in order*** to distinguish non-promotional information from

should be defined. It is appropriate to allow marketing authorisation holders to disseminate the contents of the approved summaries of product characteristics and package ***leaflet***, ***information that is compatible with those documents without going beyond their key elements, and other well-defined medicinal product-related information***.

advertising, the types of information which may be disseminated should be defined. It is appropriate to allow marketing authorisation holders to disseminate the contents of the approved summaries of product characteristics and package ***leaflets***, ***including the "drug-fact-box"***.

Or. en

Amendment 68
Linda Mcavan

Proposal for a directive - amending act
Recital 11

Text proposed by the Commission	*Amendment*
(11) In order to further ensure that marketing authorisation holders ***disseminate*** only high-quality information and to distinguish non-promotional information from advertising, the types of information which may be ***disseminated*** should be defined. It is appropriate to ***allow*** marketing authorisation holders ***to*** disseminate the contents of the approved summaries of product characteristics ***and*** package leaflet, ***information that is compatible with those documents without going beyond their key elements,*** and ***other well-defined medicinal product-related information***.	(11) In order to further ensure that marketing authorisation holders ***make available*** only high-quality information and to distinguish non-promotional information from advertising, the types of information which may be ***made available*** should be defined. It is appropriate to ***clarify that*** marketing authorisation holders ***can*** disseminate the contents of the approved summaries of product characteristics***,*** package leaflet, and ***public assessment report***.

Or. en

Justification

A re-phrased version of the PIL risks detracting from the original - we should instead concentrate on improving the readability of the official PIL.

Amendment 69
Corinne Lepage

Proposal for a directive - amending act
Recital 11

Text proposed by the Commission	*Amendment*
(11) In order to further ensure that marketing authorisation holders ***disseminate*** only high-quality information ***and to distinguish non-promotional information from advertising***, the types of information which may be disseminated should be defined. It is appropriate to allow marketing authorisation holders to ***disseminate the contents*** of the ***approved*** summaries of product characteristics and package leaflet, ***information that is compatible with those documents without going beyond their key elements, and other well-defined medicinal product-related information***.	(11) In order to further ensure that marketing authorisation holders ***make*** only high-quality ***non-promotional*** information ***accessible***, the types of information which may be disseminated should be defined. It is appropriate to allow marketing authorisation holders to ***make accessible the most recent*** summaries of product characteristics and package leaflet, ***approved by the competent authorities***.

Or. fr

Justification

Steps must be taken to ensure that marketing authorisation holders provide comprehensive and up-to-date information. They should not be authorised to provide incomplete information.

Amendment 70
Nessa Childers

Proposal for a directive - amending act
Recital 12

Text proposed by the Commission	*Amendment*
(12) Information to the general public on prescription-only medicinal products should ***only*** be ***provided*** through specific channels of communication***,*** including Internet and ***health-related publications,*** to avoid that the effectiveness of the prohibition on advertising is undermined by unsolicited provision of information to	(12) Information to the general public on prescription-only medicinal products should be ***made available*** through specific channels of communication including ***health professionals, officially validated*** Internet ***websites, information booklets*** and ***medical journals*** to avoid that the effectiveness of the prohibition on

the public. Where information is ***disseminated*** via television ***or*** radio, patients are not protected against such unsolicited information and such ***dissemination*** should therefore not be allowed.	advertising is undermined by unsolicited provision of information to the public. Where information is ***made available by the marketing authorisation holder*** via television, radio***,*** or ***newspapers***, ***magazines and similar publications,*** patients are not protected against such unsolicited information and such ***making available of information*** should therefore not be allowed.

Or. en

Justification

Internet has become an important and powerful instrument for information seekers; in 2006, almost 80% of internet users had searched for online health information. Patients also use internet for information about living with disease which is not provided by conventional health care providers. To respond to patient's need, officially validated health websites should be set up in Member States languages, with a quality label. Health information booklets should complement the information received from health professionals and the information which is available on Internet.

Amendment 71
Gilles Pargneaux

Proposal for a directive – amending act
Recital 12

Text proposed by the Commission	*Amendment*
(12) ***Information*** to the general public on prescription-only medicinal products should only be provided through specific channels of communication, including Internet ***and health-related publications***, to avoid that the effectiveness of the prohibition on advertising is undermined by unsolicited ***provision of information*** to the public. Where information is disseminated via television or radio, patients are not protected against such unsolicited ***information*** and such dissemination should therefore not be allowed.	(12) ***Communication*** to the general public on prescription-only medicinal products ***by marketing authorisation holders*** should only be provided ***in writing*** through specific channels of communication, including Internet, to avoid that the effectiveness of the prohibition on advertising is undermined by unsolicited ***communication*** to the public. Where information is disseminated via television***, web TV, video broadcast materials, newspapers, magazines and similar publications,*** or radio, patients are not protected against such unsolicited ***communication*** and such dissemination

should therefore not be allowed.

Or. en

Justification

The current wording raises the problem of the definition of advertising and of "information" disseminated by the MAH; it is preferable to refer to "communication" by the MAH. Information to the public on medicines by MAHs should only be provided in writing to allow for monitoring. Where information is disseminated via television, web TV, radio, or health related publications, patients are not protected against unsolicited information and such dissemination should not be allowed. Video broadcasting in websites is prone to enable disguised advertising and should not be allowed.

Amendment 72
Peter Liese, Anja Weisgerber, Thomas Ulmer, Elena Oana Antonescu, Miroslav Mikolášik, Jorgo Chatzimarkakis, Jo Leinen

Proposal for a directive - amending act
Recital 12

Text proposed by the Commission	*Amendment*
(12) Information to the general public on prescription-only medicinal products should only be provided through specific channels of communication, including Internet and health-related publications, to avoid that the effectiveness of the prohibition on advertising is undermined by unsolicited provision of information to the public. Where information is disseminated via television or ***radio***, patients are not protected against such unsolicited information and such ***dissemination*** should therefore not be allowed.	(12) Information to the general public on prescription-only medicinal products ***that has been approved by the competent authorities*** should only be provided through specific channels of communication, including Internet and health-related publications, ***by the marketing authority holder*** to avoid that the effectiveness of the prohibition on advertising is undermined by unsolicited provision of information to the public. Where information is disseminated ***by the marketing authority holder*** via television***, radio*** or ***newspapers***, ***magazines and similar publications,*** patients are not protected against such unsolicited information and such ***supply of information*** should therefore not be allowed.

Or. en

Amendment 73
Marina Yannakoudakis

Proposal for a directive - amending act
Recital 12

Text proposed by the Commission	*Amendment*
(12) Information to the general public on prescription-only medicinal products should only be ***provided*** through specific channels of communication, including Internet and health-related publications, to avoid that the effectiveness of the prohibition on advertising is undermined by unsolicited provision of information to the public. Where information is ***disseminated*** via television ***or*** radio, patients are not protected against such unsolicited information and such ***dissemination*** should therefore not be allowed.	(12) Information to the general public on prescription-only medicinal products should only be ***made available by the marketing authorisation holder*** through specific channels of communication, including Internet and health-related publications, to avoid that the effectiveness of the prohibition on advertising is undermined by unsolicited provision of information to the public. Where information is ***made available by the marketing authorisation holder*** via television***, internet sites***, radio, or ***newspapers***, ***magazines and similar publications,*** patients are not protected against such unsolicited information and such ***making available of information*** should therefore not be allowed.

Or. en

Justification

'Internet sites' should be added to the list as it is one of the most important and effective ways of communicating at mass to the public.

Amendment 74
Peter Liese, Anja Weisgerber, Cristian Silviu Buşoi, Thomas Ulmer, Elena Oana Antonescu, Miroslav Mikolášik, Jo Leinen

Proposal for a directive - amending act
Recital 12 a (new)

Text proposed by the Commission	*Amendment*
	(12 a) The internet is a major source of information for a growing number of patients. This trend is likely increase in the coming years. In order to adapt to this

development and to add to the growing importance of e-health, information on medicinal products should also be made available via independent national health internet websites. These websites should be monitored by competent authorities in the Member States. Member States in co-operation with stakeholders such as health care professionals or patient organisations should be responsible for managing these websites.

Or. en

Justification

The internet has become an important and powerful source of information. As misinformation obtained on the internet can cause harm, there is an urgent need to respond to the needs of patients and set up officially validated health websites. In order to ensure that the information on these websites is independent and objective, Member States shall be responsible for controlling the information. Since the information should be patient-friendly, health care professionals and patient organisations should be involved in creating and managing the websites.

Amendment 75
Peter Liese, Anja Weisgerber, Thomas Ulmer, Elena Oana Antonescu, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis, Jo Leinen

Proposal for a directive - amending act
Recital 14

Text proposed by the Commission	*Amendment*
(14) Monitoring of information on prescription-only medicinal products should ensure that marketing authorisation holders only disseminate information which is in compliance with Directive 2001/83/EC. Member States should adopt rules establishing effective monitoring mechanisms and allowing effective enforcement in cases of non-compliance. Monitoring should be based on the control of information prior to its ***dissemination, unless the substance of the*** information has ***already*** been ***agreed*** by the competent	(14) Monitoring of information on prescription-only medicinal products should ensure that marketing authorisation holders only disseminate information which is in compliance with Directive 2001/83/EC. Member States should adopt rules establishing effective monitoring mechanisms and allowing effective enforcement in cases of non-compliance. Monitoring should be based on the control of information prior to its ***supply. Only such*** information ***that*** has been ***approved in advance*** by the competent authorities

authorities ***or if there is a different mechanism*** in ***place to ensure an equivalent level of adequate and effective monitoring***.	***should be provided, and it should be provided*** in ***the approved form only***.

Or. en

Amendment 76
Cristian Silviu Buşoi

Proposal for a directive - amending act
Recital 14

Text proposed by the Commission	*Amendment*
(14) Monitoring of information on prescription-only medicinal products should ensure that marketing authorisation holders only disseminate information which is in compliance with Directive 2001/83/EC. Member States should adopt rules establishing effective monitoring mechanisms and allowing effective enforcement in cases of non-compliance. Monitoring should be based on the control of information prior to its dissemination, unless the substance of the information has already been agreed by the competent authorities or if there is a different mechanism in place to ensure ***an equivalent level of*** adequate and ***effective*** monitoring.	(14) Monitoring of information on ***authorised*** prescription-only medicinal products ***under this Directive*** should ensure that marketing authorisation holders only disseminate information which is in compliance with Directive 2001/83/EC. Member States should adopt rules establishing effective monitoring mechanisms and allowing effective enforcement in cases of non-compliance. ***In cases of non-compliance, procedures should be put into place by means of which marketing authorisation holders can be represented and heard in the course of the consideration of their case.*** Monitoring should be based on the control of information prior to its dissemination, unless the substance of the information has already been agreed by the competent authorities or if there is a different mechanism in place to ensure adequate***,*** ***effective*** and ***independent*** monitoring.

Or. en

Justification

The amendment clarifies the scope of the Directive by reinforcing that the provision of information on certain types or groups of medicines is not covered by this legislation. For certain types of information the distinction between advertising and promotional information is more difficult to establish. Those types of information should be subject to approval by the national competent authorities before its dissemination. Independent monitoring mechanisms

controlled by authorities should be in place even when another institute takes over the monitoring of the information.

Amendment 77
Nessa Childers

Proposal for a directive - amending act
Recital 14

Text proposed by the Commission	*Amendment*
(14) Monitoring of information on prescription-only medicinal products should ensure that marketing authorisation holders only disseminate information which is in compliance with Directive 2001/83/EC. Member States should adopt rules establishing effective monitoring mechanisms and allowing effective enforcement in cases of non-compliance. Monitoring should be based on the control of information prior to its dissemination, unless the substance of the information has already been agreed by the competent authorities or if there is a different mechanism in place to ensure an equivalent level of adequate and effective monitoring.	(14) Monitoring of information on prescription-only medicinal products should ensure that marketing authorisation holders only disseminate information which is in compliance with Directive 2001/83/EC. Member States should adopt rules establishing effective monitoring mechanisms and allowing effective enforcement in cases of non-compliance. ***These rules should be harmonized at European level so as to ensure consistency.*** Monitoring should be based on the control of information prior to its dissemination, unless the substance of the information has already been agreed by the competent authorities or if there is a different mechanism in place to ensure an equivalent level of adequate and effective monitoring.

Or. en

Amendment 78
Gilles Pargneaux

Proposal for a directive – amending act
Recital 14

Text proposed by the Commission	*Amendment*
(14) Monitoring of information on prescription-only medicinal products should ensure that marketing authorisation holders only ***disseminate information***	(14) Monitoring of information on prescription-only medicinal products should ensure that marketing authorisation holders only ***make available material***

which is in compliance with Directive 2001/83/EC. Member States should adopt rules establishing effective monitoring mechanisms and allowing effective enforcement in cases of non-compliance. Monitoring should be based on the control of information prior to its dissemination, unless the substance of the information has already been agreed by the competent authorities ***or if there is a different mechanism in place to ensure an equivalent level of adequate and effective monitoring***.	which is in compliance with ***Title VIIIa of*** Directive 2001/83/EC. Member States should adopt rules establishing effective ***independent*** monitoring mechanisms and allowing effective enforcement in cases of non-compliance. Monitoring should be based on the control of information prior to its dissemination, unless the substance of the information has already been agreed by the competent authorities.

Or. en

Justification

Documents made available by the marketing authorisation holder should be accessible to those who are seeking such information themselves; i.e. the "pull principle" should apply. Measures intended to control a posteriori direct-to-consumer advertising in the United States and direct-to-prescriber advertising in Europe has clearly failed. The relevant 'regulatory bodies' tend to detect infringements too late, often when the damage has already been done, and have difficulties imposing penalties.

Amendment 79
Carl Schlyter

Proposal for a directive - amending act
Recital 14

Text proposed by the Commission	*Amendment*
(14) Monitoring of information on prescription-only medicinal products should ensure that marketing authorisation holders only ***disseminate information*** which is in compliance with Directive 2001/83/EC. Member States should adopt rules establishing effective monitoring mechanisms and allowing effective enforcement in cases of non-compliance. Monitoring should be based on the control of information prior to its dissemination***, unless the substance of the information has already been agreed by the competent***	(14) Monitoring of information on prescription-only medicinal products should ensure that marketing authorisation holders only ***make available material*** which is in compliance with ***Title VIIIa of*** Directive 2001/83/EC. Member States should adopt rules establishing effective ***independent*** monitoring mechanisms and allowing effective enforcement in cases of non-compliance. Monitoring should be based on the control of information prior to its dissemination.

authorities or if there is a different mechanism in place to ensure an equivalent level of adequate and effective monitoring.

Or. en

Justification

Title VIIIa is the appropriate reference for the information to be made available by companies. When the documents that companies can make available are limited to official documents, monitoring is far simpler.

Amendment 80
Jiří Maštálka

Proposal for a directive - amending act
Recital 14

Text proposed by the Commission	*Amendment*
(14) Monitoring of information on prescription-only medicinal products should ensure that marketing authorisation holders ***only disseminate information*** which is in compliance with Directive 2001/83/EC. Member States should adopt rules establishing effective monitoring mechanisms and allowing effective enforcement in cases of non-compliance. Monitoring should be based on the control of information prior to its dissemination, unless the ***substance*** of the information has already been agreed by the competent authorities ***or if there is a different mechanism in place to ensure an equivalent level of adequate and effective monitoring***.	(14) Monitoring of information on prescription-only medicinal products should ensure that ***the information made available by*** marketing authorisation holders which is in compliance with Directive 2001/83/EC. Member States should adopt rules establishing effective ***and efficient*** monitoring mechanisms and allowing effective enforcement in cases of non-compliance ***and redress mechanisms for consumers***. Monitoring should be based on the control of information prior to its dissemination, unless the ***content*** of the information has already been agreed by the competent authorities.

Or. en

Justification

The proposal should be about patients' rights to access high quality, non promotional information and not about the industry right to communicate directly to the public about its products. The monitoring system should be robust, effective and also efficient. It is necessary

to put in place also efficient and consumer friendly complaint procedures and redress mechanisms. The content and not only the substance of the information should be the same. This is also for consistency and coherence with article with art.100 g of the proposal that refers to the "content" and not to the "substance".

Amendment 81
Marina Yannakoudakis

Proposal for a directive - amending act
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) The Commission should consult patient organisations and healthcare professionals on issues relating to the implementation of this Directive and its application by the Member States.

Or. en

Justification

Healthcare professionals` views related to the implementation and application of this Directive should also be taken into account.

Amendment 82
Nessa Childers

Proposal for a directive – amending act
Article 1 – point – 1 a (new)
Directive 2001/83/EC
Article 1 – paragraph 26

Text proposed by the Commission	*Amendment*
	(-1a) Article 1, paragraph 26 shall be replaced by the following:
	"26. *Patient* leaflet: A leaflet containing information for the *patient* which accompanies the medicinal product *and which corresponds to the real needs patients have. Patients organisations shall be involved in developing and reviewing*

the information by National regulatory authorities and European Medicine Agency."

Or. en

Justification

See amendment to Recital 2.

Amendment 83
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point – 1 a (new)
Directive 2001/83/EC
Article 86 – paragraph 1

Text proposed by the Commission	*Amendment*
	(-1a) Article 86(1) shall be replaced by the following:
	"1. For the purposes of this Title, 'advertising of medicinal products' shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular:
	- the advertising of medicinal products to the general public, *including posts on blogs and websites, social media (so called 'buzz marketing') by the marketing authorisation holders either directly or indirectly through a third party;*
	- advertising of medicinal products to persons qualified to prescribe or supply them,
	- visits by medical sales representatives to persons qualified to prescribe medicinal products,
	- the supply of samples,

- the provision of inducements to prescribe, […]supply *or, for citizens, patients and their carers, use* medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal,

- drawing the general public's attention to a specific medicinal product or to a therapeutic class of medicinal products using therapeutic indications or signs and symptoms,

- sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products,

- sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.*"*

Or. en

Justification

The directive should take into account evolving marketing practices such as "buzz marketing" and advertising in social internet media. It is important to extend the ban on disproportionate inducements to citizens, patients and their carers. Suggesting medicinal products on the basis of signs and symptoms of diseases may encourage self-diagnosis, self-medication and the unnecessary taking of medicinal products.

Amendment 84
Linda Mcavan

Proposal for a directive – amending act
Article 1 – point – 1 a (new)
Directive 2001/83/EC
Article 86 – paragraph 1 – indent 7 a (new)

Text proposed by the Commission	*Amendment*
	(-1a) In Article 86 (1), the following indent shall be added:

- drawing the general public's attention to a specific medicinal product or to a therapeutic class of medicinal products using therapeutic indications or symptoms;

Or. en

Justification

Suggesting medicinal products on the basis of symptoms of diseases may encourage self-diagnosis, self-medication and the unnecessary taking of medicinal products.

Amendment 85
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point – 1 a (new)
Directive 2001/83/EC
Article 86 – paragraph 1 – indent 7 a (new)

Text proposed by the Commission	*Amendment*
	(-1a) In Article 86 (1), the following indent shall be added:
	- drawing the general public's attention to a specific medicinal product or to a therapeutic class of medicinal products using therapeutic indications or signs and symptoms

Or. en

Justification

Suggesting medicinal products on the basis of signs and symptoms of diseases may encourage self-diagnosis, self-medication and the unnecessary taking of medicinal products. Action should be taken to prevent this.

Amendment 86
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 1

Directive 2001/83/EC
Article 86 – paragraph 2 – indent 1

Text proposed by the Commission	*Amendment*
- the labelling and the accompanying package leaflets, which are subject to the provisions of Title V;	- the labelling ***which shall always at least specify the International Non-proprietary Name*** and the accompanying package leaflets, which are subject to the provisions of Title V;

Or. en

Justification

The International Non-proprietary Name (INN) (the name of the active substance which common stem identifies the therapeutic class the substance belongs to) should be systematically used to empower patients (it helps to raise awareness among patients of what active substance they are taking used).

Amendment 87
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 – paragraph 2 – indent 2 a (new)

Text proposed by the Commission	*Amendment*
	"- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question *including those of media organisations* about a particular medicinal product;"

Or. en

Justification

It is important maintain the possibility for "correspondence needed to answer a specific question about a particular medicinal product" in order to allow for example expert patients' organisations to access the scientific information they request for.

Amendment 88
Peter Liese, Anja Weisgerber, Thomas Ulmer, Elena Oana Antonescu, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 – paragraph 2 – indent 1a (new)

Text proposed by the Commission	*Amendment*
	– correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;

Or. en

Amendment 89
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 – paragraph 2 – indent 1a (new)

Text proposed by the Commission	*Amendment*
	– correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;

Or. en

Justification

Reinstating the text from the current legal text. It is more appropriate to clarify in in Title VIII

that this is not advertising.

Amendment 90
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 – paragraph 2 – indent 2

Text proposed by the Commission	*Amendment*
- factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims;	- factual, informative announcements and reference material relating, for example, to ***availability,*** pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, ***information on the environmental risk of the medicinal product and information relating to the disposal of unused medicinal product or waste derived from medicinal products as well as reference to any collection system in place,*** provided they include no product claims ***and they do not induce to or promote the consumption of the medicinal product***;

Or. en

Amendment 91
Miroslav Ouzký

Proposal for a directive - amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 **–** paragraph 2 – indent 2

Text proposed by the Commission	*Amendment*
- factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they	- factual, informative announcements ***(including announcements or statements such as those made to media organisations either in response to a direct enquiry or by dissemination of such***

include no product claims;	***information via conferences or written releases*** and ***announcements or reports to shareholders and/or regulators)*** and reference material relating ***to a medicinal product***, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, ***and reimbursement,*** provided ***that such announcements and reference material*** they include no product ***promotional*** claims;

Or. en

Justification

Clarification of scope of the Directive. Companies should be allowed to continue to provide certain information. For instance, stock market rules require that companies keep investors fully informed of significant developments and employees must be kept informed of business developments. "Product claim" could be taken to mean any statement about the properties of a product, positive and negative, and might inadvertently prohibit statements about adverse reactions and warnings.

Amendment 92
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 – paragraph 2 – indent 2

Text proposed by the Commission	*Amendment*
- factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims;	- factual, informative announcements and reference material relating, for example, to ***information on the environmental risk of the medicinal product, availability,*** pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims ***and do not induce to or promote the consumption of the medicinal product***;

Or. en

Justification

Article 86(2) of the existing Directive 2001/83/EC lists specific sources that are excluded from the definition of "advertising". The current wording raises the problem of the definition of advertising and "information" disseminated by the MAH. The numerous exceptions suggested by the Commission highly endanger the objectiveness of "information": advertisings could de facto be covered by a too broad definition of "information". It is therefore preferable to refer to specific "documents" produced by the MAH as listed in Title VIIIa.

Amendment 93
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 – paragraph 2 – indent 3

Text proposed by the Commission	*Amendment*
- information relating to human health or diseases**,** provided that there is no reference, even indirect, to medicinal products;	- information relating to human health or diseases provided that ***it is based on scientific evidence and that*** there is no reference, even indirect, to medicinal products;

Or. en

Justification

The information needs to be based on scientific evidence.

Amendment 94
Miroslav Ouzký

Proposal for a directive - amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 **–** paragraph 2 – indent 3

Text proposed by the Commission	*Amendment*
- information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal	- information relating to human health or diseases, provided that there is no reference, even indirect, to ***individual***

products;	medicinal products;

Or. en

Justification

Clarification of scope of the Directive. Companies should be allowed to continue to provide certain information. For instance, stock market rules require that companies keep investors fully informed of significant developments and employees must be kept informed of business developments. "Product claim" could be taken to mean any statement about the properties of a product, positive and negative, and might inadvertently prohibit statements about adverse reactions and warnings.

Amendment 95
Peter Liese, Anja Weisgerber, Thomas Ulmer, Elena Oana Antonescu, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 – paragraph 2 – indent 4

Text proposed by the Commission	*Amendment*
- information by the ***marketing authorisation holder to*** the general public ***on medicinal products*** subject to medical prescription, which is subject to the provisions of Title VIIIa.	- information ***on medicinal products that has been approved*** by the ***competent authorities in*** the ***Member States and that has been made available to the*** general public ***in approved form by the marketing authorisation holder and that is*** subject to medical prescription, which is subject to the provisions of Title VIIIa.

Or. en

Justification

This Directive must be patient-centered. Therefore non-promotional information on medicinal products must be made available to patients and to the general public by marketing authorisation holders according to the "pull principle" whereby patients/the public have access to information if they need it (contrary to the "push principle" whereby the marketing authorisation holders disseminate information among the patients and the general public).

Amendment 96
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 – paragraph 2 – indent 4

Text proposed by the Commission	*Amendment*
- ***information*** by the marketing authorisation holder to the general public on medicinal products subject to medical prescription, which is subject to the provisions of Title VIIIa.	- ***officially approved documents*** by the marketing authorisation holder to the general public on medicinal products subject to medical prescription, which is subject to the provisions of Title VIIIa.

Or. en

Justification

Any information that goes beyond official documents or information listed in the previous indents of Article 86(2) needs to be officially approved, before it can be made available by pharmaceutical companies.

Amendment 97
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 – paragraph 2 – indent 4

Text proposed by the Commission	*Amendment*
- ***information by the marketing authorisation holder to the general public*** on medicinal products subject to medical prescription***, which is subject to the provisions of Title VIIIa***.	- ***officially approved documents*** on medicinal products subject to medical prescription**.**

Or. en

Justification

The current wording raises the problem of the definition of advertising and information disseminated by the MAH. The exceptions proposed by the Commission highly endanger the objectiveness of information as advertisings could be covered by a too broad definition of

information. Thus it is preferable to refer to specific documents produced by the MAH listed in Title VIIIa. Companies should also be allowed to continue to provide certain information to their investors and employees, without allowing for misuse of such information (buzz marketing).

Amendment 98
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 – paragraph 2 – indent 4 a (new)

Text proposed by the Commission	*Amendment*
	- factual, informative announcements for investors and employees on significant business developments, provided they are not use to promote the product to the general public;

Or. en

Justification

Article 86(2) of the existing Directive 2001/83/EC lists specific sources that are excluded from the definition of "advertising". The current wording raises the problem of the definition of advertising and "information" disseminated by the MAH. The numerous exceptions proposed by the Commission highly endanger the objectiveness of "information": advertisings could de facto be covered by a too broad definition of "information". It is therefore preferable to refer to specific "documents" produced by the MAH as listed in Title VIIIa.

Amendment 99
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 1 a (new)
Directive 2001/83/EC
Article 86 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	(1a) In Article 86, the following paragraph shall be inserted:
	"(2a) When exemptions to advertising referred to in paragraph 2 are made available, the marketing authorisation holder and any third party acting on behalf of the marketing authorisation holder shall be identified as such."

Or. en

Justification

It has to be clear for the public that information is made available by the pharmaceutical company: in case information is made available by a third party, it also has to be clear that the third party is acting on behalf of the pharmaceutical company.

Amendment 100
Thomas Ulmer

Proposal for a directive - amending act
Article 1 – point 1 a (new)
Directive 2001/83/EC
Article 86 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	(1a) In Article 86, the following paragraph shall be inserted:
	"(2a) When exemption to advertising referred to in paragraph are made available, the marketing authorisation holder and any third party acting on behalf of the marketing authorisation holder shall be identified as such."

Or. en

Justification

It has to be clear for the public that information is made available by the pharmaceutical company: in case information is made available by a third party, it also has to be clear that the third party is acting on behalf of the pharmaceutical company.

Amendment 101
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 1 b (new)
Directive 2001/83/EC
Article 86 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	(1b) In Article 86, the following paragraph shall be inserted:
	"2b. To this end, the statement "Conflict of interest: This information has been compiled and disseminated by [the name of the company] which is the producer of [the name of the medicinal product]" shall be included."

Or. en

Justification

A standard statement helps to easily identify that the information is made available by a pharmaceutical company or on behalf of a pharmaceutical company. It is important that the statement starts with the wording "Conflict of interest" to prevent the misuse of the statement: it could otherwise be understood as a guarantee of quality or be used to promote the image of the pharmaceutical company.

Amendment 102
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 1 a (new)
Directive 2001/83/EC
Article 88 – paragraph 2

Text proposed by the Commission	*Amendment*
	(1a) Article 88(2) is replaced by the following:
	***"*2. Medicinal products may be advertised to the general public, *except on television,* which, by virtue of their**

composition and purpose, are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary."

Or. en

Justification

Television advertisement for non-prescription drugs should be prohibited. It only seeks to increase consumption of that product. The short duration of TV advertisement spots does not allow to provide relevant information and appropriate safeguards.

Amendment 103
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 2
Directive 2001/83/EC
Article 88 – paragraph 4

Text proposed by the Commission	*Amendment*
(2) Article 88(4) is ***replaced by the following:***	(2) Article 88(4) is ***deleted.***
"4. The prohibition set out in paragraph 1 shall not apply to vaccination campaigns and other campaigns in the interest of public health carried out by the industry and approved by the competent authorities of the Member States.";	

Or. en

Justification

The existing legislation limits the possibility of public "information" campaigns to vaccinations. This already proved to be questionable (one-sided information). The new wording would allow industry to make campaigns on any topic "in the interest of public health". This is unacceptable. Only competent authorities should be allowed to run campaigns on public health. The law already allows industry to provide information on public health, provided there is no reference to medicinal products (Article 86(2) (third indent)).

Amendment 104
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 2
Directive 2001/83/EC
Article 88 – paragraph 4

Text proposed by the Commission	*Amendment*
(2) Article 88(4) is replaced by the following:	***deleted***
"4. The prohibition set out in paragraph 1 shall not apply to vaccination campaigns and other campaigns in the interest of public health carried out by the industry and approved by the competent authorities of the Member States."	

Or. en

Justification

The new wording of Article 88(4) grants the possibility for the industry to make disease awareness campaigns on any topic "in the interest of public health". The existing legislation limits this possibility to vaccination campaigns. The proposed change to the legislation can lead to disease mongering, posing major public health risks. In addition, the existing legislation already grants companies the possibility of making campaigns on health issues (e.g. cancer screening) provided there is no product claim.

Amendment 105
Linda Mcavan

Proposal for a directive - amending act
Article 1 – point 2
Directive 2001/83/EC
Article 88 – paragraph 4

Text proposed by the Commission	*Amendment*
(2) Article 88(4) is replaced by the following:	***deleted***
"4. The prohibition set out in paragraph 1 shall not apply to vaccination campaigns	

and other campaigns in the interest of public health carried out by the industry and approved by the competent authorities of the Member States."

Or. en

Justification

The Commission's proposal waives the advertising ban in the context of disease awareness campaigns approved by Member States. This is unnecessary and risks leading to disease mongering. The existing legislation already allows companies to run campaigns on health issues (e.g. cancer screening).

Amendment 106
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 2
2001//83/EC
Article 88 – paragraph 4

Text proposed by the Commission	*Amendment*
(2) Article 88(4) is replaced by the following:	***deleted***
"4. The prohibition set out in paragraph 1 shall not apply to vaccination campaigns and other campaigns in the interest of public health carried out by the industry and approved by the competent authorities of the Member States."	

Or. en

Justification

To exclude in general "other campaigns" from the DTCA ban carries the inherent danger that in future advertising campaigns referring to prescription-only-medicines are disguised as "campaigns in the interest of public health" to reach the patients. Recent evidence of abuse, for example the aggressive marketing campaign for the HPV vaccine Gardasil° warrants against the exception to the ban of direct-to-consumer advertising for vaccines. Alternatively, public health campaigns run by health authorities should replace the promotion of vaccines.

Amendment 107
Marina Yannakoudakis

Proposal for a directive - amending act
Article 1 – point 2
2001//83/EC
Article 88 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The prohibition set out in paragraph 1 shall not apply to vaccination campaigns and other campaigns in the interest of public health carried out by the industry ***and approved by the competent*** authorities ***of the Member States***.	4. The prohibition set out in paragraph 1 shall not apply to vaccination campaigns and other ***information*** campaigns in the interest of public health carried out by the industry***, where national*** authorities ***deem there to be a severe risk***.

Or. en

Justification

National authorities need to certify that there is a severe risk before any campaigns begin.

Amendment 108
Peter Liese, Thomas Ulmer, Elena Oana Antonescu, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 2
Directive 2001/83/EC
Article 88 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The prohibition set out in paragraph 1 shall not apply to vaccination campaigns ***and other campaigns*** in the interest of public health carried out by the industry and approved by the competent authorities of the Member States.	4. The prohibition set out in paragraph 1 shall not apply to vaccination campaigns in the interest of public health carried out by the industry and approved by the competent authorities of the Member States.

Or. en

Amendment 109
Corinne Lepage

Proposal for a directive - amending act
Article 1 – point 2
2001//83/EC
Article 88 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The prohibition set out in paragraph 1 shall not apply to vaccination campaigns ***and other campaigns*** in the interest of public health ***carried out by the industry*** and approved by the competent authorities of the Member States.	4. The prohibition referred to in paragraph 1 shall not apply to vaccination campaigns in the interest of public health approved by the competent authorities of the Member States.

Or. fr

Justification

The wording proposed by the Commission is far too vague and would open the door to campaigns on all kinds of public health issues.

Amendment 110
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point – 4 a (new)
Directive 2001/83/EC
Article 94 – paragraph 1

Text proposed by the Commission	*Amendment*
	(4a) Article 94(1) shall be replaced by the following:
	"*1. Where medicinal products are being promoted *directly or indirectly by a marketing authorisation holder or a third party acting on its behalf or following its instructions* to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons […].*"

Or. en

Justification

There should be no gifts or other advantages whatsoever, as research evidence indicates that the instinct to reciprocate is a powerful influence on the behaviour even when small gifts are concerned.

Amendment 111
Peter Liese, Anja Weisgerber, Thomas Ulmer, Elena Oana Antonescu, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 - a (new), to be inserted before Article 100a

Text proposed by the Commission	*Amendment*
	Article 100 -a
	Member States and the European Commission shall support independent information on medical products to the general public. To this end the Member States shall present a national program on information to patients following consultation with stakeholders such as health care professionals and patient organisations. Information shall be presented in electronic as well as in printed form. The Commission shall provide assistance and organise the exchange of best practice.
	Member States and the Commission shall grant financial support to independent drug information centres, encourage the development of independent, continuing education programmes for health professionals and the development of their critical appraisal skills.

Or. en

Amendment 112
Peter Liese, Anja Weisgerber, Cristian Silviu Buşoi, Thomas Ulmer, Elena Oana Antonescu, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 - a a (new), to be inserted before Article 100a

Text proposed by the Commission	*Amendment*
	Article 100 –a a
	Member States shall ensure that the mandatory information referred to in Article 100b (1) shall be made available through national health internet websites in the official language(s) of the Member State where the website is registered.
	Such websites shall be monitored by a competent authority of the Member State or by a body assigned by the competent authority in accordance with Article 100g.The websites shall be administered and managed in co-operation with stakeholders such as health care professionals and patient organisations.
	The information shall communicate both benefits and risks in a clear descriptive manner that is patient friendly and link to the national medicinal products safety website.The internet websites shall provide patients with the mandatory information on all available medicinal products in that Member State both centrally approved by the European Medicines Agency and locally approved in that Member State.
	The internet websites should also include general information about medicinal and non-medicinal treatment of various diseases, including rare diseases, in order to promote a high level of public health.
	They may also contain other information as referred to in Article 100b (2) and as defined by the Commission's guidelines

concerning information allowed.

Or. en

Amendment 113
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall allow the marketing authorisation holder ***to disseminate***, either directly or indirectly through a third party, ***information to the general public or members thereof*** on authorised medicinal products subject to medical prescription ***provided that it is in accordance with the provisions*** of ***this Title***. ***Such information shall not be considered advertising for the purposes of the application of Title VIII***.	1. Member States shall allow the marketing authorisation holder, either directly or indirectly through a third party, ***to make available on their website official documents*** on authorised medicinal products subject to medical prescription ***in the official languages of the Member States where they are authorised***.
	Member States shall also allow the marketing authorisation holder to make available on their websites information on authorised medicinal products subject to medical prescription as listed in Article 86(2).
	When such information is made available, the marketing authorisation holder and any third party acting on behalf of ***the marketing authorisation holder shall be clearly identified***.

Or. en

Justification

Pharmaceutical companies should only be allowed to publish official documents, or documents that are covered by Article 86(2).

Amendment 114
Philippe Juvin

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall allow the marketing authorisation holder to disseminate, either directly or indirectly through a third party, information to the general public or members thereof on authorised medicinal products subject to medical prescription provided that it is in accordance with the provisions of this Title. Such information shall not be considered advertising for the purposes of the application of Title VIII.	1. ***Without prejudice to the importance of the role played by national competent authorities and health care professionals in informing the patients and the general public on authorised medicinal products subject to medical prescription,*** Member States shall allow the marketing authorisation holder to disseminate, either directly or indirectly through a third party, information to the general public or members thereof on authorised medicinal products subject to medical prescription provided that it is in accordance with the provisions of this Title. Such information shall not be considered advertising for the purposes of the application of Title VIII.

Or. en

Justification

It is important to underline that national competent authorities and healthcare professionals are the most important and main sources of reliable and objective information on medicinal products for the patients and the general public. Marketing authorisation holders can provide complementary information but cannot substitute themselves to the national competent authorities and the health care professionals.

Amendment 115
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall allow the marketing authorisation holder to ***disseminate***, either directly or indirectly through a third party, ***information*** to the general public or members thereof on authorised medicinal products subject to medical prescription provided that it is in accordance with the provisions ***of this Title. Such information shall not be considered advertising for the purposes of the application*** of Title ***VIII***.	1. Member States shall allow the marketing authorisation holder to ***make available***, either directly or indirectly through a third party ***identified as acting on behalf of the marketing authorisation holder***, ***officially approved documents or factual, informative announcement*** to the general public or members thereof on authorised medicinal products subject to medical prescription provided that it is in accordance with the provisions of ***this*** Title .

Or. en

Justification

The Directive should focus on the right of patients to access reliable information. The current wording raises the problem of the definition of advertising and "information" disseminated by the marketing authorisation holder. For the sake of clarity, it is therefore preferable to refer to "officially approved documents or factual, informative announcement" as listed in title VIIIa.

Amendment 116
Peter Liese, Anja Weisgerber, Cristian Silviu Buşoi, Thomas Ulmer, Elena Oana Antonescu, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a - paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall allow the marketing authorisation holder to ***disseminate***, either directly or indirectly through a third party, information to the general public or members thereof on authorised medicinal products subject to medical prescription provided that it is in accordance with the provisions of this Title. Such information shall not be considered advertising for the	1. Member States shall allow the marketing authorisation holder to ***make available***, either directly or indirectly through a third party ***that is acting in the name of the marketing authorization holder***, information ***that has been approved by the competent authorities*** to the general public or members thereof on authorised medicinal products subject to medical

purposes of the application of Title VIII.	prescription provided that ***this information and the way*** it is ***supplied is*** in accordance with the provisions of this Title. Such information shall not be considered advertising for the purposes of the application of Title VIII. ***When such information is made available, the marketing authorisation holder and any third party shall be identified, and any third party that acts on behalf of the marketing authorisation holder shall be clearly identified as such.***

Or. en

Justification

This Directive must be patient-centered. Therefore non-promotional information on medicinal products must be made available to patients and to the general public by marketing authorisation holders according to the "pull principle" whereby patients/the public have access to information if they need it (contrary to the "push principle" whereby the marketing authorisation holders disseminate information among the patients and the general public).

Amendment 117
Nessa Childers

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall allow the marketing authorisation holder to disseminate, either directly or indirectly through a third party, information to the general public or members thereof on authorised medicinal products subject to medical prescription provided that it is in accordance with the provisions of this Title. Such information shall not be considered advertising for the purposes of the application of Title VIII.	1. Member States shall allow the marketing authorisation holder to disseminate, either directly or indirectly through a third party, information ***that has been officially approved by national or European competent authorities*** to the general public or members thereof on authorised medicinal products subject to medical prescription provided that it is in accordance with the provisions of this Title. Such information shall not be considered advertising for the purposes of the application of Title VIII. ***When such***

information is made available, the marketing authorisation holder and any third party shall be identified, and any third party acting on behalf of the marketing authorisation holder shall be clearly indentified as such.

Or. en

Justification

The information provided by market authorization holders or by third parties on their behalf to patients and the general public should be validated by national regulatory authorities and should be subject to robust control mechanisms with monetary sanctions enforced by national and European regulators. The sources of information should be always disclosed.

Amendment 118
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall allow the marketing authorisation holder to ***disseminate, either directly or indirectly through a third party,*** information to the general public or members thereof on authorised medicinal products subject to medical prescription provided that it is in accordance with the provisions of this Title. Such information shall not be considered advertising for the purposes of the application of Title VIII.	1. Member States shall allow the marketing authorisation holder to ***make available*** information to the general public or members thereof on authorised medicinal products subject to medical prescription provided that it is in accordance with the provisions of this Title. Such information shall not be considered advertising for the purposes of the application of Title VIII.

Or. en

Justification

It is important that the marketing authorization holder who is willing to communicate to the public about its product does so directly in order to prevent problems in attributing responsibility in the event of an infringement of the legislation.

Amendment 119
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Health professionals who deliver information on pharmaceutical products or medical devices during a public event, in print and/or broadcast media shall declare publicly their interests, i.e. any financial ties with marketing authorisation holders or with third parties working on their behalf. This also includes the provision of consulting services and technical advice about the product(s) in question.

Or. en

Amendment 120
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a – paragraph 2

Text proposed by the Commission	*Amendment*
2. This Title shall not cover the following:	***deleted***
a) information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products;	
b) material provided by the marketing authorisation holder to healthcare professionals for distribution to patients.	

Or. en

Justification

For consistency and coherency with the stated aims of the proposal and to better ensure that information provided is not of promotional nature, of the directive points the provisions set our in point a) and b) should fall under the scope of Title VIII.

Amendment 121
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
a) information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products;	***deleted***

Or. en

Justification

This is redundant, as covered by Article 86(2).

Amendment 122
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
a) information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products;	***deleted***

Or. en

Justification

For the coherency of the text notably the sake of clarity between Title VIII and VIIIa, this provision (“information” relating to human health or diseases by a marketing authorisation holder) should remain considered as an exemption to advertising ban (article 86(2) of the existing Directive 2001/83/EC consolidated) and fall into the scope of Title VIII.

Amendment 123
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
b) material provided by the marketing authorisation holder to healthcare professionals for distribution to patients.	***deleted***

Or. en

Justification

Material provided by the marketing authorisation holder to healthcare professionals for distribution to patients shouldn’t be excluded from the title "Information to the general public on medicinal products subject to medical prescription": there is no reason why they shouldn’t be monitored. Health professionals shouldn’t be used as advertising distributors.

Amendment 124
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
b) material provided by the marketing authorisation holder to healthcare professionals for distribution to patients.	***deleted***

Or. en

Justification

Printed material provided to healthcare professionals for distribution to patients should respect the same criteria as the other means for disseminating information. It would be, therefore, reasonable that this kind of material is also covered by this Title. Healthcare professionals might also be influenced by material containing advertising. There is no objective reason why material provided by companies to healthcare professionals for distribution to patients isn't subject to the provisions of this Title.

Amendment 125
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
b) material provided by the marketing authorisation holder to healthcare professionals ***for distribution to patients***.	b) material provided by the marketing authorisation holder to healthcare professionals.

Or. en

Justification

It is unacceptable to exclude material that marketing authorisation holders provide to patients via healthcare professionals. This Title can therefore only exclude material that is solely provided to health care professionals.

Amendment 126
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	ba) factual, informative announcements (including announcements or statements made to media organisations either in response to a direct enquiry or by

dissemination of such information via conferences or written releases and announcements or reports to shareholders and/or regulators) and reference material on a medicinal product relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues, price lists and reimbursement, provided that they do not intend to promote an individual medicinal product;

Or. en

Justification

This amendment is coherent with the amendment on article 86(2) and aims at clarifying the scope of the directive. Market authorization holders should be allowed to provide certain information. Stock market rules require that companies keep investors fully informed of significant developments and employees must be kept informed of business developments. It is necessary to specify this to allow appropriate provision of such information.

Amendment 127
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a – paragraph 2 – point b b (new)

Text proposed by the Commission	*Amendment*
	bb) material provided to healthcare professionals for their own use.

Or. en

Justification

It should be ensured that information provided to healthcare professionals for their own use is not covered by the Directive.

Amendment 128
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a a (new)

Text proposed by the Commission	*Amendment*
	Article 100 aa
	National authorities in collaboration with the industry, health care professionals and patient organizations shall organize information campaigns aimed at improving health literacy of the general public or members thereof or at the promotion of healthy lifestyles. Such information campaigns could cover, among others, issues such as the risks of falsified medicines, the rational use of medicines, patients' rights when they take part in clinical trials or good governance (transparency, possible conflicts of interests).These campaigns shall not contain any product promotional claims.

Or. en

Justification

In order to better protect human health, information campaigns aimed at improving health literacy, initiated by national authorities could be very useful and beneficial to patients. In order to increase the quality of these information campaigns and to ensure that they reach patients in an effective way, national authorities should take into consideration the expertise on the matter coming from the industry, health care professionals and patient organizations.

Amendment 129
Peter Liese, Cristian Silviu Buşoi, Anja Weisgerber, Elena Oana Antonescu, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – introductory part and point a

Text proposed by the Commission	*Amendment*
The ***following types*** of ***information on*** authorised medicinal products subject to medical prescription ***may be disseminated by the marketing authorisation holder*** to the general public or members thereof***:***	The ***marketing authorisation holder shall, in respect*** of authorised medicinal products subject to medical prescription, ***make available*** to the general public or members thereof the summary of product characteristics, labelling and package leaflet of the medicinal product as approved by the competent authorities and the publicly accessible version of the assessment report drawn up by the competent authorities***. A drug-fact-box shall be added to the package leaflet. The information provided in the drug-fact-box shall be presented in a form that is clearly legible, prominent and clearly distinguishable from the rest of the text. This drug-fact-box shall contain a short description of the necessary facts of the medicinal product in order to enable the patient to understand the utility and the possible risks of the medicinal product and in order to apply the medicinal product safely and in the right way. It shall also contain a short summary of the results of the clinical trials. Before supplying it, the drug-fact-box shall be approved by the competent authorities; and prior to such approval, patient organizations shall be heard in an appropriate way in order to guarantee a form that is suitable to the patients. This information shall be made available both in electronic and printed form in all languages of the EU and in a format accessible to people with disabilities.***
a) the summary of product characteristics, labelling and package leaflet of the medicinal product, as approved by the competent authorities, and the publicly accessible version of the assessment report drawn up by the competent authorities;	

Or. en

Justification

This Directive must be patient-centered. Therefore non-promotional information on medicinal products must be made available to patients and to the general public by marketing authorisation holders according to the "pull principle" whereby patients/the public have access to information if they need it (contrary to the "push principle" whereby the marketing authorisation holders disseminate information among the patients and the general public).

Amendment 130
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – introductory part

Text proposed by the Commission	*Amendment*
The following ***types of information*** on authorised medicinal products subject to medical prescription may be ***disseminated*** by the marketing authorisation holder to the general public or members thereof:	The following ***documents*** on authorised medicinal products subject to medical prescription may be ***made available*** by the marketing authorisation holder to the general public or members thereof:

Or. en

Justification

The current wording raises the problem of the definition of advertising and information . It is therefore preferable to refer to "documents".

Amendment 131
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – introductory part

Text proposed by the Commission	*Amendment*
The following ***types of information*** on authorised medicinal products subject to medical prescription may be ***disseminated*** by the marketing authorisation holder to the general public or members thereof***:***	The following ***documents*** on authorised medicinal products subject to medical prescription may be ***made available*** by the marketing authorisation holder to the general public or members thereof**.**

Or. en

Justification

While it should be compulsory for competent authorities to make certain information available, it should only be optional for marketing authorisation holders.

Amendment 132
Linda Mcavan

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – introductory part

Text proposed by the Commission	*Amendment*
The following types of information on authorised medicinal products subject to medical prescription may be ***disseminated*** by the marketing authorisation holder to the general public or members thereof:	The following types of information on authorised medicinal products subject to medical prescription may be ***made available*** by the marketing authorisation holder to the general public or members thereof***, via their websites***:

Or. en

Amendment 133
Linda Mcavan

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point a

Text proposed by the Commission	*Amendment*
a) the summary of product characteristics, labelling and package leaflet of the medicinal product, as approved by the competent authorities, and the publicly accessible version of the assessment report drawn up by the competent authorities***;***	a) the summary of product characteristics, labelling and package leaflet of the medicinal product, as approved by the competent authorities, and the publicly accessible version of the assessment report drawn up by the competent authorities***. This information should be presented in the form of a list classified in alphabetical order or by therapeutic class and should not be accompanied by pictures or additional information. It should include a statement regarding the availability of the same information on website of the national competent authority and the website of the European Medicines Agency. The documents should be made***

available in a pdf format that faithfully represents the officially approved information drawn up by the competent authorities.

Or. en

Amendment 134
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point a

Text proposed by the Commission	*Amendment*
a) the summary of product characteristics, labelling and package leaflet of the medicinal product, as approved by the competent authorities, and the publicly accessible version of the assessment report drawn up by the competent authorities***;***	a) the summary of product characteristics, labelling and package leaflet of the medicinal product, as approved by the competent authorities, and the publicly accessible version of the assessment report drawn up by the competent authorities***.*** ***This information should be presented in the form of a list classified in alphabetical order or by therapeutic class and should not be accompanied by pictures or additional information to the exclusion of a statement regarding the availability of the same information in the website of the national competent authority or the European Medicines Agency.*** ***It should be available in a pdf format that faithfully represents the officially approved information drawn up by the competent authorities.***

Or. en

Justification

Officially approved information should be equally available in all Member States. For it not to be used in for promotional purposes it must be ensured that it is presented in neutral manner. The information should be identical to the one officially approved and people should be informed about the fact that the same information is accessible also in the competent authorities' web sites which provide information on all products and not only those of the

given pharmaceutical company.

Amendment 135
Nessa Childers

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point a

Text proposed by the Commission	*Amendment*
a) the summary of product characteristics, labelling and ***package*** leaflet of the medicinal product, as approved by the competent authorities, and the publicly accessible version of the assessment report drawn up by the competent authorities;	a) the summary of product characteristics, labelling and ***patient*** leaflet of the medicinal product, as approved by the competent authorities, and the publicly accessible version of the assessment report drawn up by the competent authorities; ***and the publicly accessible version of the assessment report drawn up by the competent authorities. This information should be made equally available in all Member States, both in electronic and printed format, and in a format accessible to people with disabilities. Representative patients' organisations shall be involved in developing this information and making it available to patients.***

Or. en

Justification

There should be a move towards a real "patient leaflet" and patients' organization should be part of this process. Pharmaceutical companies may place on their website information which has been officially validated, and the information published on the EudraCT database on clinical trials. When the information has not been officially validated but may be considered valid and useful, it has to be made available to experts and analysed to be processed and shared with relevant patient groups. Information shall be provided on both successful and failed trials. The collection of self-reported data and experience from patients and families should be recognised as a relevant and valid source of information.

Amendment 136
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point a

Text proposed by the Commission	*Amendment*
a) the summary of product characteristics, labelling and package leaflet of the medicinal product, as approved by the competent authorities, and the publicly accessible version of the assessment report drawn up by the competent authorities;	a) the ***most recent*** summary of product characteristics, labelling and package leaflet of the medicinal product, as approved by the competent authorities, and the publicly accessible version of the assessment report drawn up by the competent authorities;

Or. en

Justification

It should be stated explicitly that only the most recent information may be made available.

Amendment 137
Linda Mcavan

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point b

Text proposed by the Commission	*Amendment*
b) information which does not go beyond the elements of the summary of product characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities, but presents them in a different way;	***deleted***

Or. en

Justification

A re-phrased version of the PIL risks detracting from the original - we should instead concentrate on improving the readability of the official PIL.

Amendment 138
Corinne Lepage

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point b

Text proposed by the Commission	*Amendment*
b) information which does not go beyond the elements of the summary of product characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities, but presents them in a different way;	***deleted***

Or. fr

Justification

It is important to rule out partial presentation of summaries of product characteristics or package leaflets. Moreover, allowing such summaries to be presented in various ways is likely to create more confusion for patients.

Amendment 139
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point b

Text proposed by the Commission	*Amendment*
b) information which does not go beyond the elements of the summary of product characteristics, labelling and the package	***deleted***

leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities, but presents them in a different way;

Or. en

Justification

There is no need for free-style information.

Amendment 140
Nessa Childers

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point b

Text proposed by the Commission	*Amendment*
b) information which does not go beyond the elements of the summary of product characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities, but presents them in a different way;	***deleted***

Or. en

Amendment 141
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point b

Text proposed by the Commission	*Amendment*
b) information which does not go beyond the elements of the summary of product	***deleted***

characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities, but presents them in a different way;

Or. en

Justification

Scientific data belong to the public and should be made available to independent researchers who wish to analyse them to allow for the early detection of safety risks. Allowing the pharma industry to draw up documents using only some elements of the SPC and produce a "free-style" leaflet is inefficient. It will also be potentially confusing to have two types of leaflets, a officially approved and another one rewritten by the manufacturer, as it will lead to the dissemination of promotional information on prescription only medicines and to administrative burden for health authorities.

Amendment 142
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point b

Text proposed by the Commission	*Amendment*
b) information which does not go beyond the elements of the summary of product characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities, but presents them in a different way;	***deleted***

Or. en

Justification

Lot of efforts are put by the national and European authorities (EMA consultation on the package leaflet template) and by the Commission (Pharmacovigilance proposal) to improve package leaflets. Pharmaceutical companies are also investing into making more user friendly package leaflet with user testing. There is a need to improve the officially approved

information and to make it more easily accessible but there is no need to spend additional resources in producing and monitoring a "free style" leaflet. Having an officially approved and a free style leaflet would confuse consumers.

Amendment 143
Theodoros Skylakakis

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point b

Text proposed by the Commission	*Amendment*
b) information which does not go beyond the elements of the summary of product characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities, but presents them in a different way;	b) information which does not go beyond the elements of the summary of product characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities, but presents them in a different way ***that is comprehensible to the general public or members thereof without compromising the quality and reliability of the information. The reason for presenting the information in a different way much be clearly justified***;

Or. en

Justification

It has to be emphasised that information should be presented in layman language while its quality is preserved. Furthermore, taking into consideration that this information already exists and is presented in a given way, there should be a strong reason why to present it in a different, so as to avoid confusion of the public.

Amendment 144
Philippe Juvin

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point b

Text proposed by the Commission	*Amendment*
b) information which does not go beyond the elements of the summary of product characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities, but presents them in a ***different*** way;	b) information which does not go beyond the elements of the summary of product characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities, but presents them in a ***patient-friendly*** way***, without prejudice to the comprehensive and impartial nature of the information made available***;

Or. en

Justification

Improving the package leaflet is essential to better inform the patients and the general public on medicinal products. However, giving the opportunity to MAHs to present key information in a different way might create confusion among patients and the general public, and enable MAHs to provide biased information (e.g. omission of information, emphasis put on the benefits of a medicine and downplaying the risks). Therefore it is essential to underline that information can be made available in a more patient-friendly way as long as it does not question the quality of the information.

Amendment 145
Anja Weisgerber, Thomas Ulmer

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point b

Text proposed by the Commission	*Amendment*
b) information which does not go beyond the elements of the summary of product characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities, but presents them in a ***different*** way;	b) information which does not go beyond the elements of the summary of product characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities, but presents them in a way ***that is comprehensible to the general public or member thereof without jeopardising the quality or reliability of***

the information;

Or. en

Justification

It should be clarified that putting information in a different way must enhance patients' ability to better understand the information and in order to present them in a more patient-friendly way.

Amendment 146
Peter Liese, Elena Oana Antonescu, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point b

Text proposed by the Commission	*Amendment*
b) information which does not go beyond the elements of the summary of product characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities, ***but presents them in a different way;***	b) information which does not go beyond the elements of the summary of product characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities,

Or. en

Justification

The pharmaceutical industry should not be given the freedom to produce "free-style" leaflets which would open the door for selective information and lead to the situation where two types of leaflets are circulating: the officially approved one and the free-style version. Instead, the official, approved leaflet should be improved and made more accessible to patients. In particular, Article 59 of the Directive, which specifies the content of the package leaflet, should be optimized to improve the quality and clarity of the package labelling and the leaflet.

Amendment 147
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point b a (new)

Text proposed by the Commission	*Amendment*
	ba) the package leaflet;

Or. en

Justification

To allow the pharmaceutical industry to draw up documents using only some of the elements of the SPC, disconnected from the other elements needed to understand them properly, and to produce a "free-style" leaflet is inefficient. It will also be potentially confusing to have two types of leaflets circulating, one officially approved and a rewritten version produced by the manufacturer. The risk is that it will lead to the public dissemination of promotional information on medicines and to administrative burden for health authorities.

Amendment 148
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point c

Text proposed by the Commission	*Amendment*
c) information on the environmental impact of the medicinal product, prices and factual, informative announcements and reference material relating, for example, to pack changes or adverse-reaction warnings;	***deleted***

Or. en

Justification

This paragraph is redundant as Article 86 of the existing Directive 2001/83/EC already allows for "factual, informative announcements (...) provided they include no product claims" (AM 11 proposes to add "information on the environmental risk of the medicinal

product"). It is important to keep the mention "provided they include no product claims" in order to maintain the ban on DTCA.

Amendment 149
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point c

Text proposed by the Commission	*Amendment*
c) information on the environmental impact of the medicinal product, prices and factual, informative announcements and reference material relating, for example, to pack changes or adverse-reaction warnings;	***deleted***

Or. en

Justification

This is partially redundant with existing provisions in Article 86(2). The author suggests to add information on environmental impact to Article 86(2), in which case this provision is entirely redundant.

Amendment 150
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point c

Text proposed by the Commission	*Amendment*
c) information ***on the environmental impact of the*** medicinal product***, prices and factual, informative announcements and reference material relating, for example, to pack changes or adverse-reaction warnings;***	c) information ***relating to the disposal of unused*** medicinal product ***or waste derived from medicinal products as well as reference to any collection system in place.***

Or. en

Justification

It is necessary to clarify the meaning of information regarding the environmental impact of the medicine. The second part of the paragraph should be deleted as it is inconsistent with Arrt.86 of the existing legislation that already allows "factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims" are not covered by Title VIII.

Amendment 151
Daciana Octavia Sârbu

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point c

Text proposed by the Commission	*Amendment*
c) information ***on the environmental impact of the*** medicinal product***, prices and factual, informative announcements and reference material relating, for example, to pack changes or adverse-reaction warnings***;	c) information ***relating to the disposal of unused*** medicinal product ***or waste derived from medicinal products as well as reference to any collection system in place, provided there is no product claim***;

Or. en

Justification

It is necessary to clarify the meaning of information regarding the environmental impact of the medicine and to ensure there is no product claim. The second part of the paragraph should be deleted. As it is referred to in the proposed Art.100 b point c, it could lead to statements such as "As of today, prescription medicine XH is 20% less expensive than before". Or "The new LK box now includes 30 tablets more than before". This should be avoided as it would clearly constitute advertising.

Amendment 152
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5

Directive 2001/83/EC
Article 100 b – point c

Text proposed by the Commission	*Amendment*
c) information on the environmental impact of the medicinal product, prices and factual, informative announcements and reference material relating, for example, to pack changes or adverse-reaction warnings;	c) information on the environmental impact of the medicinal product, ***availability and*** prices**,** and factual, informative announcements***, provided that no comparison is made to a previous situation or to another medicinal product of the same kind,*** and reference material ***on a medicinal product*** relating, for example, to pack changes***, reimbursement,*** or adverse-reaction warnings;

Or. en

Justification

Some clarifications are needed concerning the information about prices and reimbursement, so that market authorization holders don't make comparisons to previous situations and other similar products that would have an effect on patients' choice. This is to make sure that information remains objective, factual, without any purchase incentive. It would also be useful to include reimbursement status in the list as an example of factual information that should be permitted under this clause.

Amendment 153
Nessa Childers

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point c

Text proposed by the Commission	*Amendment*
c) information on the environmental impact of the medicinal product***, prices and factual***, ***informative announcements*** and reference material relating, for example, to pack changes or adverse-reaction warnings;	c) information on the environmental impact of the medicinal product, and reference material relating, for example, to pack changes or adverse-reaction warnings;

Or. en

Amendment 154
Thomas Ulmer

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point c

Text proposed by the Commission	*Amendment*
c) information on the environmental impact of the medicinal product, prices and factual, informative announcements and reference material relating, for example, to pack changes or adverse-reaction warnings;	c) information on the environmental impact of the medicinal product, prices and factual, informative announcements and reference material relating, for example, to pack changes or adverse-reaction warnings***, interactions and contraindications***;

Or. en

Justification

Interactions and contraindications are as important as adverse-reaction warnings.

Amendment 155
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point c a (new)

Text proposed by the Commission	*Amendment*
	ca) the periodic safety update reports;

Or. en

Justification

Scientific data belong to the public and should be made available to independent researchers who wish to analyse them to allow for the early detection of safety risks. Allowing the pharma industry to draw up documents using only some elements of the SPC and produce a "free-style" leaflet is inefficient. It will also be potentially confusing to have two types of leaflets, a officially approved and another one rewritten by the manufacturer, as it will lead to the dissemination of promotional information on prescription only medicines and to administrative burden for health authorities.

Amendment 156
Linda Mcavan

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point d

Text proposed by the Commission	*Amendment*
d) medicinal product-related information about non-interventional scientific studies, or accompanying measures to prevention and medical treatment, or information which presents the medicinal product in the context of the condition to be prevented or treated.	***deleted***

Or. en

Justification

MAH should not be able to make available information about the results of non interventional scientific studies - as these are often promotional, and are not regulated.

Amendment 157
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point d

Text proposed by the Commission	*Amendment*
d) medicinal product-related information about non-interventional scientific studies, or accompanying measures to prevention and medical treatment, or information which presents the medicinal product in the context of the condition to be prevented or treated.	***deleted***

Or. en

Justification

According to the Commission, non-interventional scientific studies are "often of poor quality and frequently promotional". Moreover, any relevant information relating to studies is included in the patient leaflet and the Summary of Product Characteristics, which is part of the registration file for approval. There is no need to allow the pharmaceutical industry to pick only some information disconnected from the other elements, which are all needed to understand them properly. The presentation of a specific medicinal product should be considered advertising.

Amendment 158
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point d

Text proposed by the Commission	*Amendment*
d) medicinal product-related information about non-interventional scientific studies, or accompanying measures to prevention and medical treatment, or information which presents the medicinal product in the context of the condition to be prevented or treated.	***deleted***

Or. en

Justification

According to the European Commission (see public consultation on pharmacovigilance, point 3.2.5) non-interventional scientific studies are "often of poor quality and frequently promotional». Therefore they should not be used as a basis to inform the public. The presentation of a specific medicinal product as a solution to prevent or treat a disease should be considered advertising.

Amendment 159
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point d

Text proposed by the Commission	*Amendment*
d) medicinal product-related information about non-interventional scientific studies, or accompanying measures to prevention and medical treatment, or information which presents the medicinal product in the context of the condition to be prevented or treated.	***deleted***

Or. en

Justification

The paragraph relates to information not approved by competent authorities, and it is a hidden "push" information that could lead to off-label use. The Commission noted that non interventional studies are often of poor quality and frequently promotional. Any relevant information relating to studies is included in the patient leaflet and the SPC, which is part of the registration file for approval; there is no need to allow the industry to pick up some elements of the SPC out of their context as the risk is that it will lead to the public dissemination of promotional information.

Amendment 160
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point d

Text proposed by the Commission	*Amendment*
d) medicinal product-related information about non-interventional scientific studies, or accompanying measures to prevention and medical treatment, or information which presents the medicinal product in the context of the condition to be prevented or treated.	***deleted***

Or. en

Justification

The proposed amendment relates to information not approved by competent authorities

during the registration of medicinal products and is in fact hidden "push" information. Any relevant information relating to studies is included in the patient leaflet and the Summary of Product Characteristics (SPC), which is part of the registration file for approval.

Amendment 161
Miroslav Ouzký

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point d

Text proposed by the Commission	*Amendment*
d) ***medicinal product-related information about non-interventional scientific studies, or accompanying measures to prevention and medical treatment, or information which presents the medicinal product in the context of the condition*** to ***be prevented or treated***.	d) ***other information on medicinal products provided under this title that meets the criteria set out in Article 100d and does not intend to promote an individual product***.

Or. en

Justification

The wording of the proposed text is difficult to understand and to apply in practice. It would lead to divergent practices in Member States. For example, it would also put at risk the provision of information on clinical trials presented in clinical trial transparency databases, which would be clearly detrimental to public health and cannot be in the interest of anyone.

Amendment 162
Peter Liese, Anja Weisgerber, Thomas Ulmer, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point d

Text proposed by the Commission	*Amendment*
d) ***medicinal product-related information about non-interventional scientific studies, or accompanying*** measures to	d) measures to prevention and medical treatment***. Such*** information ***shall be vetted by*** the ***Agency prior to its being made***

prevention and medical treatment***, or*** information ***which presents*** the ***medicinal product*** in ***the context*** of ***the condition to be prevented or treated***.	***available*** in ***accordance with Article 20 b (1)*** of ***Regulation EC (No) 726/2004***.

Or. en

Amendment 163
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point d a (new)

Text proposed by the Commission	*Amendment*
	da) other information on medicinal products subject to medical prescription provided under this Title, such as the results of the pharmaceutical and pre-clinical tests or clinical trials, that meets the criteria set out in Article 100d and does not promote any individual product.

Or. en

Justification

Patients should be given the opportunity to get information about the pharmaceutical and pre-clinical tests and the clinical trials. Considering, however, the commercial sensitivity of these tests and trials, pharmaceutical companies cannot be obliged to make such test and trial documentation available; they, however, should be allowed to make that documentation public if they wish so.

Amendment 164
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point d a (new)

Text proposed by the Commission	*Amendment*
	da) the pre-clinical and clinical data on their product.

Or. en

Justification

Scientific data belong to the public and should be made available to independent researchers who wish to analyse them to allow for the early detection of safety risks. Allowing the pharma industry to draw up documents using only some elements of the SPC and produce a "free-style" leaflet is inefficient. It will also be potentially confusing to have two types of leaflets, a officially approved and another one rewritten by the manufacturer, as it will lead to the dissemination of promotional information on prescription only medicines and to administrative burden for health authorities.

Amendment 165
Peter Liese, Anja Weisgerber, Thomas Ulmer, Elena Oana Antonescu, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – introductory part

Text proposed by the Commission	*Amendment*
Information on authorised medicinal products subject to medical prescription ***disseminated*** by the marketing authorisation holder to the general public or members thereof shall not be made available on television or ***radio***. ***It*** shall only be made available through the following channels:	Information on authorised medicinal products subject to medical prescription ***that has been approved*** by the ***competent authorities and is made available by the*** marketing authorisation holder to the general public or members thereof shall not be made available on television***, radio*** or ***newspapers, magazines and similar publications***. ***The marketing authorisation holder shall be allowed to supply the information approved in Article 100b on the internet. This information*** shall ***not be supplied to the general public or members thereof unasked or actively and shall*** only be made available through the following channels:

Or. en

Amendment 166
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c

Text proposed by the Commission	*Amendment*
Information on authorised medicinal products subject to medical prescription ***disseminated*** by the marketing authorisation holder to the general public or members thereof shall not be made available on television or radio. It shall only be made available through the ***following channels:***	***Communication*** on authorised medicinal products subject to medical prescription ***made available*** by the marketing authorisation holder to the general public or members thereof shall not be made available on television***, web TV, video broadcast materials, newspapers, magazines and similar publications*** or radio. It shall only be made available through the ***internet websites of the marketing authorisation holder, in order to prevent that*** unsolicited material ***is*** actively distributed to the general public or members thereof***;***
a) health-related publications as defined by the Member State of publication, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	
b) internet websites on medicinal products, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	
c) written answers to requests for information of a member of the general public.	

Or. en

Justification

The current wording raises the problem of the definition of advertising and information; it is preferable to use "communication". Information to the public by MAHs should be provided through specific channels, incl. the MAHs' website, so that the public seeking for information

knows easily where to search for and aware that the source is the MAH. Where information is disseminated via other channels, patients are not protected against unsolicited information and such dissemination should not be allowed. Video broadcasting is prone to enable disguised advertising and should not be allowed.

Information to the general public on prescription-only medicinal products by MAHs should only be provided through specific channels of communication, including the Internet websites of the marketing authorisation holders, so that the public seeking for information on a medicinal product knows easily where to search for and is aware that the source is the MAH. Where information is disseminated via e.g. web, patients are not protected against such unsolicited information and such dissemination should therefore not be allowed.

To ensure text coherence and for clarify between Title VIII and VIIIa, this provision should remain under the Title VIII with Article 86 of Directive 2001/83/EC.

Amendment 167
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c

Text proposed by the Commission	*Amendment*
Information on authorised medicinal products subject to medical prescription ***disseminated*** by the marketing authorisation holder to the general public ***or members thereof shall not be made available on television or radio***. ***It shall only be made available through the following channels:***	***Documents*** on authorised medicinal products subject to medical prescription ***shall only be made available*** by the marketing authorisation holder to the general public ***via their website***.
a) health-related publications as defined by the Member State of publication, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	
b) internet websites on medicinal products, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	
c) written answers to requests for information of a member of the general public.	

Or. en

Justification

There are many more inappropriate formats of providing information than just television and radio. As any negative list risks being non-comprehensive, it is better to clearly specify the only channel that is allowed (website by companies). Industry is already allowed pursuant to Article 86(2) to provide information in response to a specific question, so there is not need to specify this here.

This is far too general. As stated in the introductory sentence, the only acceptable channel is the website of the marketing authorisation holders themselves, not any unidentified internet websites on medicinal products.

This is redundant with Article 86(2), second indent.

Amendment 168
Marina Yannakoudakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – introductory part

Text proposed by the Commission	*Amendment*
Information on authorised medicinal products subject to medical prescription ***disseminated*** by the marketing authorisation holder to the general public or members thereof shall not be made available on television or ***radio***. It shall only be made available through the following channels:	Information on authorised medicinal products subject to medical prescription ***made available*** by the marketing authorisation holder to the general public or members thereof shall not be made available on television***, internet sites, radio*** or ***newspapers, magazines and similar publications***. It shall only be made available through the following channels:

Or. en

Justification

´Internet sites` should be added to the list as it is a popular way of communicating to the public.

Amendment 169
Thomas Ulmer

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – introductory part

Text proposed by the Commission	*Amendment*
Information on authorised medicinal products subject to medical prescription ***disseminated*** by the marketing authorisation holder to the general public or members thereof shall not be made available on television or radio. It shall only be made available through the following channels:	Information on authorised medicinal products subject to medical prescription ***made available*** by the marketing authorisation holder to the general public or members thereof shall not be made available on television***, web TV, video broadcast materials, newspapers, magazines and similar productions*** or radio. It shall only be made available through the following channels:

Or. en

Justification

Information to the public on medicines by MAHs should be provided through specific channels of communication, incl. the MAH's websites, so that the public seeking for information on a medicine knows easily where to search for and aware that the source is the MAH. Where information is disseminated via television, web TV, radio, or health related publications, patients are not protected against unsolicited information and such dissemination should therefore not be allowed. Video broadcasting in websites is prone to enable disguised advertising and should therefore not be allowed.

Amendment 170
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – introductory part

Text proposed by the Commission	*Amendment*
Information on authorised medicinal products subject to medical prescription ***disseminated*** by the marketing authorisation holder to the general public	Information on authorised medicinal products subject to medical prescription ***made available*** by the marketing authorisation holder to the general public

or members thereof shall not be made available on television ***or*** radio. It shall only be made available through the following channels:	or members thereof shall not be made available on television, radio or ***printed mass media***. It shall only be made available through the following channels:

Or. en

Justification

Printed material provided for distribution to patients is not an appropriate mean of disseminating information on prescription-only medicines. This would constitute "push" information, whereas the scope of the directive should be confined to information which patients are actively looking for. The option of disseminating information by means of printed media should therefore be deleted.

Amendment 171
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – point a

Text proposed by the Commission	*Amendment*
a) health-related publications as defined by the Member State of publication, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	***deleted***

Or. en

Justification

Information provided in health related publication constitutes an unsolicited form of communication. Therefore it is not an appropriate channel of dissemination.

Amendment 172
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – point a

Text proposed by the Commission	*Amendment*
a) health-related publications as defined by the Member State of publication, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	***deleted***

Or. en

Justification

Commissioner Verheugen previously stated that any publication with a health section could qualify as "health-related". Health sections can be found in just about any print medium, from the yellow press to quality press. This would open the door to advertising in print-media. This clause is one of the most obvious proofs of the ill-founded character of this proposal. While the print media would like to gain a significant new client, this cannot be in the interest of public health.

Amendment 173
Linda Mcavan

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – point a

Text proposed by the Commission	*Amendment*
a) health-related publications as defined by the Member State of publication, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	***deleted***

Or. en

Justification

Information provided in health related publications constitutes an unsolicited form of communication and is not therefore an appropriate channel of dissemination.

Amendment 174
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – point a

Text proposed by the Commission	*Amendment*
a) health-related publications as defined by the Member State of publication, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	***deleted***

Or. en

Justification

Information to the public on prescription-only medicinal products by MAHs should only be provided through specific channels of communication, so that the public seeking for specific information on a medicine knows easily where to search for it while being aware of the fact that the source is the MAH. Where information is disseminated via e.g. health related publications, patients are not protected against such unsolicited information and such dissemination should therefore not be allowed.

Amendment 175
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – point a

Text proposed by the Commission	*Amendment*
a) health-related publications as defined by the ***Member State of publication***, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	a) ***booklets, leaflets, and other categories of printed information, including*** health-related publications as defined by the ***Commission's guidelines concerning information allowed***, to the exclusion of unsolicited material actively distributed to the general public or members thereof;

Or. en

Justification

It is unclear what is meant by "health-related publications" and likely to lead to divergent practices. However, printed material is and remains an important way to respond to patients' and citizens' demand to better access information on prescription medicines (e.g. population groups without internet access) provided that it is solicited by the general public. It is important to clarify that such material could be provided, as well as other material defined by individual MSs, while excluding "pushed" information on medicines through classical mass media channels.

Amendment 176
Miroslav Ouzký

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – point a

Text proposed by the Commission	*Amendment*
a) health-related publications as defined by the Member State of publication, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	a) ***booklets, leaflets, audiovisual information and other categories of printed information, including*** health-related publications as defined by the Member State of publication, to the exclusion of unsolicited material actively distributed to the general public or members thereof;

Or. en

Justification

It is unclear what is meant by "health-related publications" and likely to lead to divergent practices. However, printed material and other communication tools (e.g. CD ROMS to support the safe and effective use of medicines) are and remain an important way to respond to patients' and citizens' demand to better access information on medicines (e.g. population groups without internet access). It is important to clarify that such material could be provided, as well as other material defined by individual MSs, while excluding "pushed" information through classical mass media channels.

Amendment 177
Anja Weisgerber

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – point a

Text proposed by the Commission	*Amendment*
a) health-related publications as defined by the ***Member State of publication***, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	a) health-related publications as defined by the ***Commission's guidelines concerning the information allowed, such as booklets, leaflet, and other categories of printed information including peer reviewed medical journals***, to the exclusion of unsolicited material actively distributed to the general public or members thereof;

Or. en

Justification

The directive aims at addressing inequalities across Europe in relation to patients' access to information; therefore there should be a common definition for health related publications. The amendments makes clear that health related publications do no include mass media.

Amendment 178
Nessa Childers

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – point a

Text proposed by the Commission	*Amendment*
a) health-related publications as defined by ***the Member State of publication***, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	a) health-related publications as defined by ***European Guidelines concerning information allowed***, to the exclusion of unsolicited material actively distributed to the general public or members thereof;

Or. en

Justification

By enabling different Member States to define "health related publications" , a fundamental objective of the Directive - which is to address the inequalities across the EU in relation to patients' and the public's access to information (Recital (3))– will not be met. The European guidelines concerning information that is allowed - proposed under Art 100g(2) - will ensure an equitable access to information to all patients, across all EU Member States.

Amendment 179
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – point b

Text proposed by the Commission	*Amendment*
b) internet websites on medicinal products, to the exclusion of unsolicited ***material actively distributed*** to ***the general public or members thereof***;	b) internet websites ***and other electronic repositories containing information*** on medicinal products, to the exclusion of unsolicited ***distribution*** to ***citizens through mass communications such as e-mails and telephone text messages to multiple recipients***;

Or. en

Justification

It is necessary to clarify that the provision of high-quality non-promotional information through electronic repositories which are not strictly Internet websites is allowed. There are already electronic communication media that are not websites but through which information seekers can access reference information (e.g. reference text pages made available through TV sets or via telephone systems. The Internet is also becoming much more dynamic and is going beyond static websites. It is important that the directive is fit for the future.

Amendment 180
Miroslav Ouzký

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – point b

Text proposed by the Commission	*Amendment*
b) internet websites ***on medicinal products***, to the exclusion of unsolicited ***material actively distributed*** to ***the general public or members thereof;***	b) internet websites ***and other electronic repositories containing information***, to the exclusion of unsolicited ***distribution*** to ***citizens through mass communications such as e-mails and telephone text messages to multiple recipients.***

Or. en

Justification

It is necessary to clarify that provision of high-quality, non-promotional information by electronic repositories (not strictly Internet websites) is allowed. It is important that the directive fits for the future as Internet becomes more dynamic and goes beyond static sites. Only the provision of information patients can seek ('pull') is acceptable, 'pushing' unsolicited information is not. The reference to mass communications highlights the distinction between "push" and "pull" information; and strengthens the prohibition of the unsolicited distribution of information.

Amendment 181
Corinne Lepage

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – point b

Text proposed by the Commission	*Amendment*
b) internet websites on medicinal products, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	b) ***marketing authorisation holders'*** internet websites on medicinal products, to the exclusion of unsolicited material actively distributed to the general public or members thereof;

Or. fr

Justification

Information on medicinal products should not be disseminated on just any website. Marketing authorisation holders are responsible for the content placed online.

Amendment 182
Peter Liese, Anja Weisgerber, Thomas Ulmer, Elena Oana Antonescu, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – point b

Text proposed by the Commission	*Amendment*
b) internet websites on medicinal products, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	b) ***marketing authorisation holders'*** internet websites on medicinal products, to the exclusion of unsolicited material actively distributed to the general public or members thereof;

Or. en

Justification

It must be clarified that non-promotional information on medicinal products made available by marketing authorisation holders to the general public should be published on the marketing authorisation holders' website.

Amendment 183
Thomas Ulmer

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – point b

Text proposed by the Commission	*Amendment*
b) internet websites on medicinal products, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	b) ***Marketing authorisation holders' own*** internet websites on medicinal products, to the exclusion of unsolicited material actively distributed to the general public or members thereof;

Or. en

Justification

It is of utmost importance that the patient is able to see at first glance, who the operator of the website is. This can (in addition to a clearly formulated impressum, etc.) only be guaranteed

by assuring that the address (URL) of the website includes the name of the marketing authorization holder. Transparency is essential: the patient needs to know who the author of the given information is (e.g. pharmaceutical companies, medical professionals, health insurers) and in addition it is important to be able to distinguish easily between legitimate and illegitimate websites.

Amendment 184
Linda Mcavan

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – point b

Text proposed by the Commission	*Amendment*
b) internet websites on medicinal products, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	b) ***Marketing authorisation holders'*** internet websites on medicinal products, to the exclusion of unsolicited material actively distributed to the general public or members thereof;

Or. en

Amendment 185
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – point c

Text proposed by the Commission	*Amendment*
c) ***written*** answers to requests for information of a member of the general public.	c) answers to requests for information of a member of the general public.

Or. en

Justification

Patients often require immediate and direct clarification on information given in the package leaflet or wish to obtain additional information. Requiring that a response be only allowed in writing would add delays for the patients that could, in some circumstances negatively impact

their health. Therefore, both verbal and written responses to individual requests for medical information should be possible.

Amendment 186
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – paragraph 1a and 1 b(new)

Text proposed by the Commission	*Amendment*
	"Where deemed appropriate by national competent authorities, they may also make available information on medicinal products and other relevant health information to the general public by way of agreements with Internet Service Providers who may disseminate public interest information in accordance with Article 21(4) of Directive 2009/136/EC on universal service and users' rights relating to electronic communications networks and services.
	In this case information is to be made available by the same means used for regular communications between the undertakings and their subscribers. Since information on medicinal products falls out of the scope of article 21(4) of Directive 2009/136/EC, Internet Service Providers may charge national authorities for making available such information."

Or. en

Justification

The public messages concerned in Directive 2009/136/EC relate to electronic communications services. However, information on medicines and broader health information might also be of public interest. Since this type of information falls out of the scope of the provisions in the USD, it is proposed that this framework should be used on the basis of voluntary agreements between ISPs and national authorities. This channel should be used only when national authorities consider it necessary and that it has an added value in terms of effectiveness compared to the other regular channels.

Amendment 187
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 1

Text proposed by the Commission	*Amendment*
1. The content and presentation of information on authorised medicinal products subject to medical prescription disseminated by the marketing authorisation holder to the general public or members thereof shall fulfil the following conditions:	***deleted***
a) it must be objective and unbiased; in this regard, if the information refers to the benefits of a medicinal product, its risks shall also be stated;	
b) it must take into account the general needs and expectations of patients;	
c) it must be based on evidence, be verifiable and include a statement on the level of evidence;	
d) it must be up-to-date and include the date of publication or last revision of the information;	
e) it must be reliable, factually correct and not misleading;	
f) it must be understandable for the general public or members thereof;	
g) it must clearly state the source of the information indicating its author and giving references to any documentation that the information is based on;	
h) it must not contradict the summary of product characteristics, labelling and package leaflet of the medicinal product, as approved by the competent authorities.	

Or. en

Justification

The "conditions" listed are unrealistic and do not allow for useful patient information (the pharmaceutical forum's diabetes data sheet sent out for consultation in May 2007 was based on these "quality criteria" but has been unanimously found of mediocre quality and useless) .

Amendment 188
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 1

Text proposed by the Commission	*Amendment*
1. The content and presentation of information on authorised medicinal products subject to medical prescription disseminated by the marketing authorisation holder to the general public or members thereof shall fulfil the following conditions:	***deleted***
a) it must be objective and unbiased; in this regard, if the information refers to the benefits of a medicinal product, its risks shall also be stated;	
b) it must take into account the general needs and expectations of patients;	
c) it must be based on evidence, be verifiable and include a statement on the level of evidence;	
d) it must be up-to-date and include the date of publication or last revision of the information;	
e) it must be reliable, factually correct and not misleading;	
f) it must be understandable for the general public or members thereof;	
g) it must clearly state the source of the information indicating its author and giving references to any documentation	

that the information is based on;

h) it must not contradict the summary of product characteristics, labelling and package leaflet of the medicinal product, as approved by the competent authorities.

Or. en

Justification

As long as the information is limited to official documents, there is no need to have any quality criteria.

Amendment 189
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
b) it must ***take into account the general*** needs ***and expectations of patients***;	b) it must ***be patient-oriented to better meet their*** needs;

Or. en

Justification

Re-wording to better reflect one of the main objectives of the proposal, namely to provide information that patients want and that better meets their individual needs.

Amendment 190
Peter Liese, Anja Weisgerber, Cristian Silviu Buşoi, Elena Oana Antonescu, Thomas Ulmer, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Within one year of the entry into force of this Directive, the Commission shall, following a public consultation with patient and consumer organisations, doctor and pharmacist organisations, Member States and other interested parties, present to the European Parliament and the Council an assessment report regarding the readability and the accuracy of the summaries of product characteristics and the packaging leaflets and their value to the general public and healthcare professionals. Following an analysis of the above data, the Commission shall, if appropriate, put forward guideline proposals to improve the layout and the content of the summaries of product characteristics and of the packaging leaflet to ensure they are a valuable source of information for the general public and healthcare professionals.

Or. en

Justification

The priority is to improve readability, clarity and understandability of the SPC and PIL across the Members States.

Amendment 191
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5 – introductory part
Directive 2001/83/EC
Article 100 d – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. Any ***information*** shall include:	2. Any ***factual, informative announcements on authorised medicinal products subject to medical prescription***

referred to in Article 86(2) disseminated by the marketing authorisation holder to the general public shall include:

Or. en

Justification

It is important to prevent for factual, informative announcements to be solely used as "reminder advertisings" or as tools to promote the marketing authorisation holder image and name.

Amendment 192
Thomas Ulmer

Proposal for a directive – amending act
Article 1 – point 5 – introductory part
Directive 2001/83/EC
Article 100 d – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. Any ***information*** shall include:	2. Any ***factual, informative announcements on authorised medicinal products subject to medical prescription referred to in Article 86(2) disseminated by the marketing authorisation holder to the general public*** shall include:

Or. en

Justification

It is necessary to specify that this article refers to the information provided by the marketing authorisation holder.

Amendment 193
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
b) a statement indicating that the ***information*** is intended to support, not to replace, the relationship between patient and health professionals and that a health professional should be contacted if the patient requires clarification on the information provided;	b) a statement indicating that the ***announcement*** is intended to support, not to replace, the relationship between patient and health professionals and that a health professional should be contacted if the patient requires clarification on the information provided;

Or. en

Justification

It is important to prevent for factual, informative announcements to be solely used as "reminder advertisings" or as tools to promote the marketing authorisation holder image and name.

Amendment 194
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
c) a statement ***indicating*** that the ***information*** is disseminated by a marketing authorisation holder;	c) a statement ***starting with the indication*** that the ***announcement*** is disseminated by ***or on behalf of*** a marketing authorisation holder;

Or. en

Justification

It is important to prevent for factual, informative announcements to be solely used as "reminder advertisings" or as tools to promote the marketing authorisation holder image and name.

Amendment 195
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
c) a statement indicating that the information is disseminated by a marketing authorisation holder;	c) a statement indicating that the information is disseminated by ***[name of the*** marketing authorisation holder***]***;

Or. en

Justification

The wording « marketing authorisation holder » is not commonly used and understood by the general public. Consumers have the right to know the name of the company that pays to provide the information and is also responsible and liable for the information provided.

Amendment 196
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
c) a statement indicating that the information is ***disseminated*** by a marketing authorisation holder;	c) a statement indicating that the information is ***made available*** by ***or on behalf of*** a ***named*** marketing authorisation holder;

Or. en

Justification

A third party may undertake dissemination on behalf of the Marketing Authorisation Holder. Readers of the statement may not be familiar with the term "marketing authorisation holder". A statement bearing the name of the marketing authorisation holder is more meaningful and understandable.

Amendment 197
Marina Yannakoudakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
d) a ***mail*** address or e-mail address allowing members of the general public to send comments to the marketing authorisation holder.	d) a ***postal*** address or e-mail address allowing members of the general public to send comments to***, or request for further information from,*** the marketing authorisation holder.

Or. en

Justification

The word 'postal' is better than ´mailing`.

Amendment 198
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 2 – point d a (new)

Text proposed by the Commission	*Amendment*
	da) a mail address or e-mail address allowing members of the general public to send comments to the national competent authorities;

Or. en

Justification

The general public should know who to contact of the authorities if the information is misleading or inappropriate.

Amendment 199
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 2 – point d a (new)

Text proposed by the Commission	*Amendment*
	da) mail address or e-mail address allowing members of the general public to send comments to the national competent authorities;

Or. en

Justification

If the reader perceives that the information is misleading or inappropriate he/she should be informed about where to address to make a complain. The statement regarding the report of side effects is in line with the provision of the Directive on pharmacovigilance.

Amendment 200
Linda Mcavan

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 2 – point d a (new)

Text proposed by the Commission	*Amendment*
	da) a mail or e-mail address allowing members of the general public to send comments to the national competent authorities;

Or. en

Amendment 201
Linda Mcavan

Proposal for a directive - amending act
Article 1 – point 5

Directive 2001/83/EC
Article 100 d – paragraph 2 – point d b (new)

Text proposed by the Commission	*Amendment*
	db) a statement indicating that members of the general public are encouraged to report all suspected adverse reactions of medicinal products to their doctor, pharmacist, healthcare professional, or to the national competent authority, and indicating the name and web-address, postal address and / or telephone number of that national competent authority.

Or. en

Amendment 202
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d – paragraph 2 – point d b (new)

Text proposed by the Commission	*Amendment*
	"db) A statement indicating that members of the general public should report all suspected adverse reactions to their doctor, pharmacist, healthcare professional or to the national competent authority."

Or. en

Justification

Statement in line with the compromise drafted in the context of the legislative proceedings on pharmacovigilance.

Amendment 203
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 2 – point d b (new)

Text proposed by the Commission	*Amendment*
	(db) a statement indicating that members of the general public are encouraged to report negative side effects of prescription drugs to their doctor, pharmacist or to the national competent authorities.

Or. en

Justification

The statement regarding the report of side effects is in line with the provision of the Directive on pharmacovigilance.

Amendment 204
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
3. ***The information*** shall not include:	3. ***These factual, informative announcements*** shall not include:

Or. en

Justification

Only reliable comparative information can enable patients to make informed choices. It is important to prevent for factual, informative announcements to be used as a pretext to disseminate advertisings

Amendment 205
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
a) comparisons between medicinal products;	***deleted***

Or. en

Justification

Unfortunately, comparisons between medicinal products are not yet made. There is therefore also no need to refer to this here.

Amendment 206
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
a) comparisons between medicinal products;	***deleted***

Or. en

Justification

It is important to prevent for factual, informative announcements to be used as a pretext to disseminate advertisings. The distinction between information and advertisement should be further emphasised.

Amendment 207
Thomas Ulmer

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d– paragraph 3 – point a

Text proposed by the Commission	*Amendment*
a) comparisons between medicinal products;	***deleted***

Or. en

Justification

Only reliable comparative information can enable patients to make informed choices. It is important to prevent for factual, informative announcements to be used as a pretext to disseminate advertisings.

Amendment 208
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
a) comparisons between medicinal products;	a) comparisons between medicinal products ***regarding their quality, safety and efficiency, if disseminated by marketing authorisation holders except:***
	- where those comparisons are included in officially approved documents, such as the Summary of Product Characteristics;
	- where those comparisons are based on comparative scientific studies published by the relevant national authorities or the European Medicines Agency;
	- where those comparisons are contained in the summary of the European Public Assessment Reports referred to in Article

13 of Regulation (EC) No 726/2004, which shall list the other available therapeutic options and whether the new medicinal product brings about a therapeutic value.

Or. en

Justification

Comparisons exist in the Summary of Product Characteristics (SmPC) and package leaflets of some medicines. To exclude those existing comparisons would in effect require that information provided by marketing authorisation holders is incomplete. This could also prejudice the approval process. Comparative scientific studies on the quality, safety and efficiency of different medicinal products by independent National Authorities and the EMEA should not be discouraged as they can provide a valuable source for consumer information.

Amendment 209
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 3 – point a a (new)

Text proposed by the Commission	*Amendment*
	aa) any inducement to, or promotion of, the consumption of the medicinal product;

Or. en

Justification

It is important to prevent for factual, informative announcements to be used as a pretext to disseminate advertisings. The distinction between information and advertisement should be further emphasised.

Amendment 210
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5

Directive 2001/83/EC
Article 100 d – paragraph 3 – point b a (new)

Text proposed by the Commission	*Amendment*
	ba) information on other medicinal products for which the pharmaceutical company is not the marketing authorisation holder.

Or. en

Justification

Misinformation campaigns by third party companies on medicinal products which have obtained a marketing authorisation from competent authorities must be prohibited by any means. The prohibition should be extended to advertising and information to healthcare professionals. Misinformation campaigns from originator companies on generic medicines, for instance, towards the general public has been identified as one of the delaying strategies in the Preliminary Report of the Pharmaceutical Sector Inquiry.

Amendment 211
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Within three years of the entry into force of this Directive, the Commission shall, following a public consultation involving patient and consumer organisations, doctor and pharmacist organisations, Member States and other interested parties, present to the European Parliament and the Council an assessment report regarding the readability and the accuracy of the summaries of product characteristics and the packaging leaflets and their value to the general public and healthcare professionals. Following an analysis of the above data, the Commission shall, if

appropriate, put forward guideline proposals to improve the layout and the content of the summaries of product characteristics and of the packaging leaflet to ensure they are a valuable source of information for the general public and healthcare professionals.

Or. en

Justification

The priority is to improve readability, clarity and understandability of the SPC and PIL across the Members States.

Amendment 212
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 e – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that marketing authorisation holders' Internet websites ***for*** the ***dissemination*** of ***information on medicinal products subject to medical prescription reproduce*** the summary of product characteristics and the package leaflet of the medicinal products ***concerned*** in the official languages of the Member States where they are authorised.	1. Member States shall ensure that marketing authorisation holders' Internet websites ***reproduce*** the ***last updated version as approved by the competent authorities*** of the summary of product characteristics and ***of*** the package leaflet of the medicinal products ***subject to medical prescription they commercialise*** in the official languages of the Member States where they are authorised.

Or. en

Justification

The documents on prescription-only medicinal products provided by marketing authorisation holders via their Internet websites should be up-to-date.

Amendment 213
Corinne Lepage

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 e – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that marketing authorisation holders' Internet websites for the dissemination of information on medicinal products subject to medical prescription reproduce the summary of product characteristics and the package leaflet of the medicinal products concerned in the official languages of the Member States where they are authorised.	1. Member States shall ensure that marketing authorisation holders' Internet websites for the dissemination of information on medicinal products subject to medical prescription ***faithfully*** reproduce the summary of product characteristics and the package leaflet of the medicinal products concerned in the official languages of the Member States where they are authorised.

Or. fr

Amendment 214
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 e – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that marketing authorisation holders' Internet websites for the ***dissemination*** of ***information*** on medicinal products subject to medical prescription reproduce the summary of product characteristics and the package leaflet of the medicinal products ***concerned*** in the official languages of the Member States where they are authorised.	1. Member States shall ensure that marketing authorisation holders' Internet websites for the ***making available*** of ***documents*** on medicinal products subject to medical prescription ***faithfully*** reproduce the summary of product characteristics and the package leaflet of the medicinal products in the official languages of the Member States where they are authorised.

Or. en

Justification

The information made available should be reproduced without changes or omissions.

Amendment 215
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 e – Paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that marketing authorisation holders' Internet websites for the dissemination of information on medicinal products subject to medical prescription reproduce the summary of product characteristics and the package leaflet of the medicinal products concerned in the official languages of the Member States where they are authorised.	1. Member States shall ensure that marketing authorisation holders' Internet websites for the dissemination of information on medicinal products subject to medical prescription ***faithfully*** reproduce the summary of product characteristics and the package leaflet of the medicinal products concerned in the official languages of the Member States where they are authorised.

Or. en

Justification

The approved information should be reproduced with no changes or omissions.

Amendment 216
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 e – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Member States shall ensure that each webpage from marketing authorisation holders referring to a medicinal product subject to medical prescription contains a

prominent link to the corresponding webpage of the Community database referred to in Articles 57(1)(l) and 57(2) of Regulation (EC) No 726/2004 (hereinafter 'the Eudrapharm database').

Or. en

Justification

A link to the Eudrapharm database, developed as "a source of information on all medicinal products for human or veterinary use that have been authorised in the European Union and the European Economic Area", would raise public awareness about the existence of this Community database which offers a wide range of functionalities and search facilities.

Amendment 217
Linda Mcavan

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 e – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Member States shall ensure that each webpage from a marketing authorisation holders' website referring to a medicinal product subject to medical prescription includes a link to the corresponding webpage of the Community database referred to in Articles 57(1)(l) and 57(2) of Regulation EC 726/2004, and the national or Community safety web portal referred to in Article 106 of the Directive, and Article 26 of Regulation (EC) No 726/2004.

Or. en

Justification

A link to the Eudrapharm database would raise awareness of this useful source of information to patients, which offers a wide range of functionalities and search facilities. A link to the national and Community safety web portals would allow patients to access additional information about the safety of a medicinal product.

Amendment 218
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 e – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Member States shall ensure that each webpage of the Internet website of the marketing authorisation holders that refers to a medicinal product subject to medical prescription links to the corresponding webpage of the Community database referred to in Articles 57(1)(l) and 57(2) of Regulation (EC) No 726/2004 (hereinafter 'the Eudrapharm database').

Or. en

Justification

Such a link to the Eudrapharm database, developed as « a source of information on all medicinal products for human or veterinary use that have been authorised in the European Union and the European Economic Area », would help to raise awareness of the public of the existence of this Community database which offers a wide range of functionalities and search facilities.

Amendment 219
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 e – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. The Agency shall reproduce on the Eudrapharm database, and the competent authorities of Member States on their

websites, the last updated version of:

- the approved summary of product characteristics;

- the approved package leaflet;

- the mock-ups of the secondary and primary packaging as well as of any devices also included;

- the Public Assessment Reports (PARs), and when available their summary written in a manner that is understandable to the public.

The competent authorities of Member States shall, on each webpage that refers to a medicinal product subject to medical prescription, insert a link to the corresponding webpage of the Eudrapharm database.

Or. en

Justification

It is important to tackle inequalities by ensuring public access to statutory information (labelling, SPC, package leaflets, mock-ups of packaging) and scientific information (Public Assessment Reports) both at national level, in each Member State, and at Community level. Inserting a link from the website of the national competent authority to the Eudrapharm database would help to raise awareness of the public of the existence of this Community database which offers a wide range of functionalities and search facilities.

Amendment 220
Thomas Ulmer

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 e – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. The Agency shall reproduce on the Eudrapharm database, and the competent authorities of Member States on their websites, the last updated version of:

- the approved summary of product characteristics;

- the approved package leaflet;

- the mock-ups of the secondary and primary packaging as well as of any devices also included;

- the Public Assessment Reports (PARs), and when available their summary written in a manner that is understandable to the public.

The competent authorities of Member States shall, on each webpage that refers to a medicinal product subject to medical prescription, insert a link to the corresponding webpage of the Eudrapharm database.

Or. en

Justification

It is important to tackle inequalities by ensuring public access to statutory information (labelling, SPC, package leaflets, mock-ups of packaging) and scientific information (Public Assessment Reports) both at national level, in each Member State, and at Community level. Such a link from the National Drug Regulatory Agency's website to the Eudrapharm database would help to raise awareness of the public of the existence of this Community database which offers a wide range of functionalities and search facilities.

Amendment 221
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5 (new)
Directive 2001/83/EC
Article 100 e – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1 b. Member States shall make available on the website of the national competent authorities the approved and updated version of the summary of product characteristics, labelling and package leaflet of the medicinal product, the publicly accessible version of the

assessment report and its summary where applicable.

The relevant websites of the national competent authorities shall include a link to the Eudrapharm web site.

Or. en

Justification

The obligations of competent authorities need to be clearly laid out.

Amendment 222
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5 (new)
Directive 2001/83/EC
Article 100e – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. Member States shall make available on the website of the national competent authorities the approved and updated version of the summary of product characteristics, labelling and package leaflet of the medicinal product, the publicly accessible version of the assessment report and its summary where applicable. The website of the national competent authorities shall include a link to the Eudrapharm website.

Or. en

Justification

The existing legislation already requires Member States to make this information available but it is important to clarify this obligation and to ensure that consumers can access this information via the internet.

Amendment 223
Thomas Ulmer

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 e – Paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. The summary of the European Public Assessment Reports referred to in Article 13 of Regulation (EC) No 726/2004 shall list the other available therapeutic options and whether the new medicinal product brings about a tangible therapeutic advantage.

Or. en

Justification

Only reliable comparative information can enable patients to make informed choices. Some SPCs and package leaflets already provide such comparative information. This should be generalised and be systematically presented in the same section of the EPAR's summaries. For example the section "Why has this product been approved?" should list the other available therapeutic options and whether the new medicinal product brings about a tangible therapeutic advantage ("added therapeutic value" in terms of effectiveness, safety, or convenience).

Amendment 224
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 e – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. The summary of the European Public Assessment Reports referred to in Article 13 of Regulation (EC) No 726/2004 shall list the other available therapeutic options and whether the new medicinal product brings about a tangible therapeutic

advantage.

Or. en

Justification

Only reliable comparative information can enable patients to make informed choices. Some SPCs and package leaflets already provide such comparative information. This should be generalised and be systematically presented in the same section of the EPAR's summaries. For example the section "Why has this product been approved?" should list the other available therapeutic options and whether the new medicinal product brings about a tangible therapeutic advantage ("added therapeutic value" in terms of effectiveness, safety, or convenience).

Amendment 225
Thomas Ulmer

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 e – paragraph 1 c (new)

Text proposed by the Commission	*Amendment*
	1c. The summary of the European Public Assessment Reports referred to in Article 13 of Regulation (EC) No 726/2004 shall be hyperlinked with the corresponding studies in the clinical trials database provided for in Article 11 of Directive 2001/20/EC (hereinafter 'the EudraCT database').

Or. en

Justification

Such a link to the EudraCT database would facilitate access to the scientific results of studies. The scientific results of studies are essential to the development and to the understanding of reliable information.

Amendment 226
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 e – Paragraph 1 c (new)

Text proposed by the Commission	*Amendment*
	In Article 100 e, the following paragraph shall be inserted:
	1c. The summary of the European Public Assessment Reports referred to in Article 13 of Regulation (EC) No 726/2004 shall be hyperlinked with the corresponding studies in in the clinical trials database provided for in Article 11 of Directive 2001/20/EC (hereinafter 'the EudraCT database').

Or. en

Justification

Such a link to the EudraCT database would facilitate access to the scientific results of studies. The scientific results of studies are essential to the development and to the understanding of reliable information.

Amendment 227
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/ec
Article 100 e – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that requests for information to a marketing authorisation holder on a medicinal product subject to medical prescription by a member of the general public may be drafted in any of the official languages of the Community which are official	2. Member States shall ensure that requests for information to a marketing authorisation holder on a medicinal product subject to medical prescription by a member of the general public may be drafted in any of the official languages of the Community which are official

languages in the Member States where the medicinal product is authorised. The reply shall be drafted in the language of the request.	languages in the Member States where the medicinal product is authorised. The reply shall be drafted in the language of the request. ***The request and the reply shall be kept by the marketing authorisation holder for 10 years following the request and be made available to the competent authorities upon their request.***

Or. en

Justification

Marketing authorisation holders need to keep available the questions raised by the public as well as the replies to provide for possibility of control by competent authorities upon their request.

Amendment 228
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 e – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that requests for information to a marketing authorisation holder on a medicinal product subject to medical prescription by a member of the general public may be drafted in any of the official languages of the Community which are official languages in the Member States where the medicinal product is authorised. The reply shall be drafted in the language of the request.	2. Member States shall ensure that requests for information to a marketing authorisation holder on a medicinal product subject to medical prescription by a member of the general public may be drafted in any of the official languages of the Community which are official languages in the Member States where the medicinal product is authorised. The reply shall be drafted in the language of the request. ***The replies shall be kept available for inspections by national competent authorities.***

Or. en

Justification

Marketing authorisation holder need to keep available the replies to allow easy control by the

National Competent Authorities.

Amendment 229
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 f – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall***, without creating a disproportionate burden for the marketing authorisation holder, ensure that marketing authorisation holders*** make information provided in accordance with this Title accessible to persons with disabilities.	1. Member States shall make information provided in accordance with this Title accessible to persons with disabilities.

Or. en

Amendment 230
Thomas Ulmer

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 f – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall***, without creating a disproportionate burden for the marketing authorisation holder, ensure that marketing authorisation holders*** make information provided in accordance with this Title accessible to persons with disabilities.	1. Member States shall make information provided in accordance with this Title accessible to persons with disabilities.

Or. en

Justification

Make important health information accessible to persons with disabilities is Member States'

responsibility.

Amendment 231
Peter Liese, Anja Weisgerber, Elena Oana Antonescu, Thomas Ulmer, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 g – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that ***there are adequate and effective methods of monitoring to avoid*** misuse ***when information on authorised medicinal products subject to medical prescription*** is ***disseminated by*** the marketing authorisation holder to the general public or members thereof.	1. Member States shall ensure that misuse is ***avoided*** by ***securing that only*** the marketing authorisation holder ***supplies information, and only such information which has been approved by the competent authorities about approved medicines subject*** to ***medical prescription, and in the form which has been approved for*** the ***dissemination*** to the general public or members thereof. ***By way of derogation Member States may continue those types of control mechanism which they have been implemented before 31.12.2008. The Commission verifies and approves these systems.***

Or. en

Amendment 232
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 g – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that there are adequate and effective methods of monitoring to avoid misuse when ***information*** on authorised medicinal	1. Member States shall ensure that there are adequate and effective methods of monitoring to avoid misuse when ***announcements*** on authorised medicinal

products subject to medical prescription ***is disseminated*** by the marketing authorisation holder to the general public or members thereof.	products subject to medical prescription ***are made available*** by the marketing authorisation holder to the general public or members thereof.

Or. en

Justification

Measures intended to control a posteriori direct-to-consumer advertising in the United States and direct-to-prescriber advertising in Europe has clearly failed. The relevant 'regulatory bodies' tend to detect infringements too late, often when the damage has already been done, and have difficulties imposing penalties . Measures such as "self-regulation" or "co-regulation" even based on a "code of good conduct" can not properly safeguard the independency of the monitoring.

Amendment 233
Nessa Childers

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 g – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that there are adequate and effective methods of monitoring to avoid misuse when information on authorised medicinal products subject to medical prescription is disseminated by the marketing authorisation holder to the general public or members thereof.	1. Member States ***and European Commission*** shall ensure that there are adequate and effective methods of monitoring to avoid misuse when information on authorised medicinal products subject to medical prescription is disseminated by the marketing authorisation holder to the general public or members thereof.

Or. en

Justification

Given the challenges that certain Member States encounter in establishing and implementing an appropriate monitoring system, it is important that the European Commission plays a stronger supporting role in monitoring.

Amendment 234
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 g – paragraph 1 – subparagraph 2 – introductory part

Text proposed by the Commission	*Amendment*
Such methods shall be based on the control of ***information*** prior to ***its*** dissemination, unless	Such methods shall be based on the control of ***announcements*** prior to ***their*** dissemination, unless

Or. en

Justification

Measures intended to control a posteriori direct-to-consumer advertising in the United States and direct-to-prescriber advertising in Europe has clearly failed. The relevant 'regulatory bodies' tend to detect infringements too late, often when the damage has already been done, and have difficulties imposing penalties . Measures such as "self-regulation" or "co-regulation" even based on a "code of good conduct" cannot properly safeguard the independency of the monitoring.

Amendment 235
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100g – paragraph 1 – subparagraph 2 – indent 1

Text proposed by the Commission	*Amendment*
- the ***content of*** the ***information has*** already been approved by the competent authorities***; or***	- the ***documents have*** already been approved by the competent authorities**.**

Or. en

Justification

No control of the information made available is necessary when it concerns documents already approved by the competent authorities.

Amendment 236
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 g – paragraph 1 – subparagraph 2 – indent 2

Text proposed by the Commission	*Amendment*
- an equivalent level of adequate and effective monitoring is ensured through a different mechanism.	***deleted***

Or. en

Justification

Prior authorisation is the only acceptable way of control.

Amendment 237
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 g – paragraph 1 – subparagraph 2 – indent 2

Text proposed by the Commission	*Amendment*
- an equivalent level of adequate and effective monitoring is ensured through a different mechanism.	***deleted***

Or. en

Justification

Measures intended to control a posteriori direct-to-consumer advertising in the United States and direct-to-prescriber advertising in Europe have clearly failed. The relevant 'regulatory bodies' tend to detect infringements too late, often when the damage has already been done, and have difficulties imposing penalties . Measures such as "self-regulation" or "co-regulation" even based on a "code of good conduct" cannot properly safeguard the independency of the monitoring.

Amendment 238
Thomas Ulmer

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 g – paragraph 1 – subparagraph 2 – indent 2

Text proposed by the Commission	*Amendment*
- an equivalent level of adequate and effective monitoring is ensured through a different mechanism.	- an equivalent level of adequate***, industry-independent*** and effective monitoring is ensured through a different mechanism.

Or. en

Justification

Because this is about prescription-only medicines and therefore highly sensitive information, it has to be guaranteed that the regulatory bodies are independent from any influence by the marketing authorisation holder.

Amendment 239
Thomas Ulmer

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 g – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
The methods may include the voluntary control of information on medicinal products by self-regulatory or co-regulatory bodies and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or administrative proceedings available in the Member States.	***deleted***

Or. en

Justification

From many Member States' points of view a voluntary system of control of information by self-regulatory or co-regulatory bodies is too weak. Nevertheless, a few Member States

practice self-regulatory systems. The effectiveness and the assertiveness of self-regulatory systems strongly depend on the cultural and judicial conception of a society and therefore should not be regulated for all Member States.

Amendment 240
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 g – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
The methods may include the voluntary control of information on medicinal products by self-regulatory or co-regulatory bodies and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or administrative proceedings available in the Member States.	***deleted***

Or. en

Justification

Prior authorisation is the only acceptable way of control.

Amendment 241
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
2001/838/EC
Article 100 g – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
The methods may include the voluntary control of information on medicinal products by self-regulatory or co-regulatory bodies and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or	***deleted***

administrative proceedings available in the Member States.

Or. en

Justification

Measures intended to control a posteriori direct-to-consumer advertising in the United States and direct-to-prescriber advertising in Europe have clearly failed. The relevant 'regulatory bodies' tend to detect infringements too late, often when the damage has already been done, and have difficulties imposing penalties . Measures such as "self-regulation" or "co-regulation" even based on a "code of good conduct" cannot properly safeguard the independency of the monitoring.

Amendment 242
Philippe Juvin

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 g – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
The methods may include the voluntary control of information on medicinal products by ***self-regulatory or*** co-regulatory bodies and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or administrative proceedings available in the Member States.	The methods may include the voluntary control of information on medicinal products by co-regulatory bodies and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or administrative proceedings available in the Member States.

Or. en

Justification

It is necessary to have an appropriate monitoring system in order to avoid information misuse. Self-regulation does not appear as a sufficiently coercive tool to reach this objective.

Amendment 243
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5

Directive 2001/83/EC
Article 100 g – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
The methods may include the voluntary control of information on medicinal products by ***self-regulatory or*** co-regulatory bodies and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or administrative proceedings available in the Member States.	The methods may include the voluntary control of information on medicinal products by co-regulatory bodies and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or administrative proceedings available in the Member States.

Or. en

Justification

Self regulation is not an appropriate tool to ensure the highest level of consumer protection.

Amendment 244
Thomas Ulmer

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 g – paragraph 2

Text proposed by the Commission	*Amendment*
After consulting the Member States, the Commission shall draw up guidelines concerning information allowed under this Title and containing a code of conduct for marketing authorisation holders providing information to the general public or members thereof on authorised medicinal products subject to medical prescription. The Commission shall draw up these guidelines on the entry into force of this directive and update them regularly on the basis of the experience gained.	***deleted***

Or. en

Justification

This paragraph could be interpreted or abused as a legal loophole. At least it carries the risk that the provisions of Article 100 b will be thwarted.

Amendment 245
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 g – paragraph 2

Text proposed by the Commission	*Amendment*
After consulting the Member States, the Commission shall draw up guidelines concerning ***information*** allowed under this Title and containing a code of conduct for marketing authorisation holders ***providing information to*** the ***general*** public ***or members thereof on authorised medicinal products subject to medical prescription***. The Commission shall draw up these guidelines on the entry into force of this directive and update them regularly on the basis of the experience gained.	After consulting the Member States, ***patients and consumers organisations***, ***social health insurance organisations and healthcare professionals,*** the Commission shall draw up guidelines concerning ***announcements*** allowed under this Title***, the elaboration of the package leaflets, publication of clinical trial results promotional practices toward prescribers,*** and containing a ***mandatory*** code of conduct ***and dissuasive sanctions*** for marketing authorisation holders ***that do not respect the code of conduct. The guidelines shall also contain provisions*** to ***ensure that members of*** the public ***may lodge complaints with competent authorities regarding misleading practices in the making available of information***. The Commission shall draw up these guidelines on the entry into force of this directive and update them regularly on the basis of the experience gained.

Or. en

Justification

As the information is targeted at general public, patients' and consumers' organisations have to be involved into the process of establishing the guidelines. The perspective of health professionals is also crucial as they are and should remain the main source of information to patients on prescribed pharmaceuticals.

Amendment 246
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 g – paragraph 2

Text proposed by the Commission	*Amendment*
After consulting the Member States, the Commission shall draw up guidelines concerning information allowed under this Title and containing a code of conduct for marketing authorisation holders providing information to the general public or members thereof on authorised medicinal products subject to medical prescription. The Commission shall draw up these guidelines on the entry into force of this directive and update them regularly on the basis of the experience gained.	After consulting the Member States ***and other stakeholders***, the Commission shall draw up guidelines concerning information allowed under this Title and containing a ***mandatory*** code of conduct for marketing authorisation holders providing information to the general public or members thereof on authorised medicinal products subject to medical prescription. The Commission shall draw up these guidelines on the entry into force of this directive and update them regularly on the basis of the experience gained.

Or. en

Justification

Other stakeholders such as patients, healthcare professionals and the industry should be consulted in drawing up the code and guidelines. In order to make sure that marketing authorization holders abide by the rules established by the Commission in the code of conduct, it should be specified that the latter should be mandatory, not voluntary.

Amendment 247
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that marketing authorisation holders register	1. Member States shall ensure that marketing authorisation holders register

Internet websites ***containing*** information on ***medicinal products with the national competent authorities of the Member State of the country code Top Level Domain used*** by ***the website concerned***, prior to making it available to the general public. Where the website does not use a country code Top Level Domain, the marketing authorisation holder shall select the Member State of registration.	Internet websites ***under their control that are directed specifically at citizens of one or more Member States and that contain*** information on ***prescription only medicines covered*** by ***this Title***, prior to making it available to the general public. Where the website does not use a country code Top Level Domain, the marketing authorisation holder shall select the Member State of registration.

Or. en

Justification

Necessary clarification as this Directive only covers websites that are under the control of the Marketing Authorisation Holder and aimed at EU citizens. It does not cover websites that are aimed outside the EU nor those aimed at a global audience, irrespective of whether the information was generated or the server was based in the EU. Also it does not cover business sites that contain corporate information including product sales figures and other product related business information.

Amendment 248
Peter Liese, Anja Weisgerber, Elena Oana Antonescu, Thomas Ulmer, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that marketing authorisation holders register Internet websites containing information on medicinal products with the national competent authorities of the Member State of the country code Top Level Domain used by the website concerned, prior to making it available to the general public. Where the website does not use a country code Top Level Domain, the marketing authorisation holder shall select the Member State of registration.	1. Member States shall ensure that marketing authorisation holders register Internet websites containing ***authority-approved*** information on medicinal products with the national competent authorities of the Member State of the country code Top Level Domain used by the website concerned, prior to making it available to the general public. Where the website does not use a country code Top Level Domain, the marketing authorisation holder shall select the Member State of registration.

Or. en

Amendment 249
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
After registration of the Internet website, the information on a medicinal product contained therein may be provided by the marketing authorisation holder on other Internet websites throughout the Community if the contents are identical.	***deleted***

Or. en

Justification

To allow the monitoring, and due to liability issues, it is important that the information is provided only in the registered web site. It is unrealistic to expect an effective monitoring if the information is provided in web sites other than the one which has been registered and even more if the information is translated in another language. The competent authorities will never be in the position to perform the monitoring under this provision.

Amendment 250
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
After registration of the Internet website, the information on a medicinal product contained therein may be provided by the marketing authorisation holder on other Internet websites throughout the Community if the contents are identical.	***deleted***

Or. en

Justification

For reasons of liability, and to allow proper monitoring, the information should be provided only on registered websites. It is unrealistic to expect an effective monitoring if the information is provided in websites other than the one which has been registered and even more if the information is translated in another language. The competent authorities will never be in the position to perform the monitoring under this provision.

Amendment 251
Marina Yannakoudakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
After registration of the Internet website, the information on a medicinal product contained therein may be provided by the marketing authorisation holder on other Internet websites throughout the Community if the contents are identical.	After registration of the Internet website, the information on a medicinal product contained therein may be provided by the marketing authorisation holder on other Internet websites ***registered by the marketing authorisation holder in accordance with the provisions of the first subparagraph*** throughout the Community if the contents are identical. ***These websites shall be linked to the website which will be created by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use .***

Or. en

Justification

The two websites, that created by the marketing authorisation holder and the website created by the Falsified Medicine Directive should be linked so that the general public understand that the information is genuine and that the website nor its contents are misleading.

Amendment 252
Linda Mcavan

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
After registration of the Internet website, the ***information on a*** medicinal ***product contained therein may*** be ***provided by the marketing authorisation holder on other Internet websites throughout the Community if the contents are identical***.	After registration of the Internet website, ***any amendments to*** the ***content relating to*** medicinal ***products subject to medical prescription shall*** be ***subject to monitoring in accordance with paragraph 3***.

Or. en

Amendment 253
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	After registration of the Internet website, any amendments to the content relating to medicinal products subject to medical prescription shall be subject to monitoring in accordance with paragraph 3.

Or. en

Justification

If changes to the content of a website are made, these should be monitored by the Member State where the Internet website has been registered.

Amendment 254
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	After registration of the Internet website, any amendments to the content relating to medicinal products subject to medical prescription shall be subject to monitoring in accordance with paragraph 3.

Or. en

Justification

If changes to the content of a website are made, these should be monitored by the Member State where the Internet website has been registered.

Amendment 255
Thomas Ulmer

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	After registration of the Internet website, any amendments to the content relating to medicinal products subject to medical prescription shall be subject to monitoring in accordance with paragraph 3.

Or. en

Justification

If changes to the content of a website are made, these should be monitored by the Member

State where the Internet website has been registered.

Amendment 256
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
2. Internet websites registered in accordance with paragraph 1 shall not ***contain links to other marketing authorisation holder websites unless they have also been registered in accordance with that paragraph. Those websites*** shall ***identify the competent authority which granted the marketing authorisation and its website address***.	2. Internet websites registered in accordance with paragraph 1 shall not ***allow the automatic identification of members of the general public which have access to those websites or the appearance therein of unsolicited material actively distributed to the general public or members thereof. Those websites shall not contain video broadcast materials.*** ***Without prejudice to this prohibition, Internet websites registered in accordance with paragraph 1 can provide video content when it aims at supporting safe and effective use of medicines in general and provided that it does not contain any product promotional claims. Compliance with these two conditions shall be subject to monitoring in accordance with Article 100g***.

Or. en

Justification

Video content, to the exclusion of promotional video materials, can bring an added value when showing the correct use of different medicines or medical devices such as inhalers. These video materials should be subject to monitoring in accordance with article 100g so that we ensure that they are completely neutral and do not contain any product promotional claims.

Amendment 257
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
2. Internet websites registered in accordance with paragraph 1 shall not contain links to other ***marketing authorisation holder*** websites unless they have also been registered in accordance with that paragraph. Those websites shall identify the competent authority which granted the marketing authorisation and its website address.	2. Internet websites registered in accordance with paragraph 1 shall not contain links to other websites***, with the exclusion of the competent authorities' websites,*** unless they have also been registered in accordance with that paragraph. Those websites shall identify the competent authority which granted the marketing authorisation and its website address.

Or. en

Justification

It is important to avoid not only links to other marketing authorisation holder web site (e.g. US web sites) but also to third parties web sites.

Amendment 258
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
2. Internet websites registered in accordance with paragraph 1 shall not contain links to other ***marketing authorisation holder*** websites unless they have also been registered in accordance with that paragraph. Those websites shall identify the competent authority which granted the marketing authorisation and its	2. Internet websites registered in accordance with paragraph 1 shall not contain links to other websites unless they have also been registered in accordance with that paragraph. Those websites shall identify the competent authority which granted the marketing authorisation and its website address.

website address.

Or. en

Justification

It is important to avoid not only links to other marketing authorisation holder web site (e.g. US web sites) but also to third parties web sites. The statement regarding the fact that the web site is registered and subject to monitoring might induce the readers to believe that also the other linked web sites are subject to the same conditions.

Amendment 259
Peter Liese, Anja Weisgerber, Elena Oana Antonescu, Thomas Ulmer, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited material actively distributed to the general public or members thereof. ***Those*** websites shall ***not contain web-TV***.	Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites ***without their explicit prior consent*** or the appearance therein of unsolicited material actively distributed to the general public or members thereof. ***Internet*** websites ***may provide video content if it is useful for the safe and effective use of the medicine. Video contents*** shall ***only reflect the package leaflet, the summary of the characteristics and the drug-fact-box and hints how to use this medicine safe and effectively***. ***Before publication video contents must be approved by the competent authorities.***

Or. en

Amendment 260
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited material actively distributed to the general public or members thereof. Those websites shall not contain web-TV.	Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited material actively distributed to the general public or members thereof. Those websites shall not contain web-TV***, pod casts, video streaming or any other digital information format not strictly authorised in accordance with this Directive***.

Or. en

Justification

With regards to digital information the proposal should take into account all possible new communication technologies and ensure they are covered.

Amendment 261
Nessa Childers

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited material actively distributed to the general public or members thereof. Those websites	Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited material actively distributed to the general public or members thereof. Those websites shall not contain ***video delivery of***

shall not contain ***web-TV***.	***information relating to the characteristics or usage of the medicinal product***.

Or. en

Justification

Individuals accessing the websites shall not be identified because then they risk becoming the target of unsolicited material from the pharmaceutical industry. The correct use of a medicinal product subject to medicinal prescription shall be demonstrated either by the doctor prescribing it or by the pharmacist, or any health professional entering into a personal relationship with the patient, not through a film on the Internet. The expression "web-TV" is too vague and therefore it is safer to define it more clearly.

Amendment 262
Marina Yannakoudakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited ***material actively*** distributed to the general public or members thereof. ***Those*** websites ***shall not contain web-TV***.	Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited ***content*** distributed to the general public or members thereof. ***Internet*** websites ***may provide video content if it is useful for the safe and effective use of the medicine***.

Or. en

Justification

Deleted `without their explicit prior consent` as all user information should remain completely confidential.

Amendment 263
Carl Schlyter

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited material actively distributed to the general public or members thereof. Those websites shall not contain web-TV.	Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited material actively distributed to the general public or members thereof. Those websites shall not contain web-TV***, web-radio, pod casts, video streaming or any other digital information format not strictly authorised in accordance with this Directive***.

Or. en

Justification

The legislation should ensure that only authorised digital formats may be used.

Amendment 264
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited material actively distributed to the general public or members thereof. Those websites shall not contain web-TV.	Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited material actively distributed to the general public or members thereof. Those websites shall not contain web-TV ***or video***

broadcast materials.

Or. en

Justification

Where information is disseminated via television, web TV, radio, or health related publications, patients are not protected against such unsolicited information and such dissemination should therefore not be allowed. Video broadcasting in websites is prone to enable disguised advertising and should therefore not be allowed.

Amendment 265
Thomas Ulmer

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited material actively distributed to the general public or members thereof. Those websites shall not contain web-TV.	Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited material actively distributed to the general public or members thereof. Those websites shall not contain web-TV ***or video broadcast materials***.

Or. en

Justification

Where information is disseminated via television, web TV, radio or health related publications, patients are not protected against unsolicited information and dissemination should therefore not be allowed. Video broadcasting in websites is prone to enable disguised advertising and should therefore not be allowed.

Amendment 266
Corinne Lepage

Proposal for a directive - amending act
Article 1 – point 5

Directive 2001/83/EC
Article 100 h – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited material actively distributed to the general public or members thereof. Those websites shall not contain web-TV.	Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited material actively distributed to the general public or members thereof. Those websites shall not contain web-TV***, podcasts or any other information in video format***.

Or. fr

Amendment 267
Peter Liese, Anja Weisgerber, Cristian Silviu Buşoi, Thomas Ulmer, Elena Oana Antonescu, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The registered internet websites shall display a notification at the top of each website page informing the public that the information contained therein is developed by a named marketing authorization holder. A link to the EudraPharm database on medicinal products shall also be included in that notification.

Or. en

Justification

The users of internet sites containing information on prescription medicines must be clearly informed that such information has been developed by a marketing authorization holder. The link to the Eudrapharm database will ensure that users have direct and easy access to comparable information on prescription medicines provided by a non-commercial source, ensuring greater transparency.

Amendment 268
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. After registration of the Internet website, any amendments to the content relating to medicinal products subject to medical prescription shall be subject to monitoring in accordance with paragraph 3. Such changes shall not require re-registration of the Internet website.

Or. en

Justification

If changes to the content of a website are made, these should be monitored by the Member State where the Internet website has been registered. A re-registration should not be required to avoid unnecessary bureaucracy.

Amendment 269
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Member State where the Internet website has been registered ***shall be responsible*** for the ***monitoring of the*** contents ***disseminated*** on ***that*** website.	3. The ***marketing authorisation holder shall send the new contents and changes referred to in paragraph 1 to the competent authorities of the*** Member State where the Internet website has been registered for ***prior approval, before making available*** the ***new*** contents ***or***

changes on ***its*** website.

The marketing authorisation holder shall remain fully responsible and liable for all the information it disseminates to the general public.

Or. en

Justification

Marketing authorisation holders should be required to submit new content and changes to the competent authorities. It should be clearly stated that companies remain responsible for any information they provide to the general public

Amendment 270
Thomas Ulmer

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Member State where the Internet website has been registered ***shall be responsible*** for ***the monitoring of*** the contents ***disseminated*** on ***that*** website.	3. The ***marketing authorisation holder shall send the new contents and changes to the competent authorities of the*** Member State where the Internet website has been registered for ***prior approval before making available*** the ***new*** contents ***or changes*** on ***its*** website.

Or. en

Justification

Marketing authorisation holders should be required to submit new content and changes to the competent authorities.

Amendment 271
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5

Directive 2001/83/EC
Article 100 h – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Member State where the Internet website has been registered shall be responsible for the monitoring of the contents ***disseminated*** on that website.	3. The Member State where the Internet website has been registered shall be responsible for the monitoring of the contents ***relating to medicinal products subject to medical prescription made available*** on that website.

Or. en

Justification

The precision is important as much of the website's content could be unrelated to prescription medicinal products.

Amendment 272
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Member State where the Internet website has been registered shall be responsible for the monitoring of the contents disseminated on that website.	3. The Member State where the Internet website has been registered shall be responsible for the monitoring of the contents disseminated on that website. ***The marketing authorisation holder shall remain fully responsible and liable for all the information it disseminates to the general public.***

Or. en

Justification

It is unrealistic to expect the competent authorities to constantly monitor all the registered web sites and all the changes to the information. It is therefore essential to introduce specific references to companies' liability and ensure they remain accountable for any information they provide to the general public. This principle applies to all companies in all sector and

pharmaceutical companies should not be exempted.

Amendment 273
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Member State where the Internet website has been registered ***shall be responsible*** for the monitoring of the contents ***disseminated*** on ***that*** website.	3. The ***marketing authorisation holder shall send the new contents and changes to the competent authorities of the*** Member State where the Internet website has been registered for ***prior approval before making available*** the monitoring of the contents ***or changes*** on ***its*** website.

Or. en

Justification

Marketing authorisation holders should be required to submit new content and changes to the Competent authorities .

Amendment 274
Peter Liese, Anja Weisgerber, Elena Oana Antonescu, Thomas Ulmer, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 4 – point a

Text proposed by the Commission	*Amendment*
(a) If a Member State has reasons for doubts as to whether the translation of the reproduced information is correct, it may require a marketing authorisation holder to provide for a certified translation of the information disseminated on the Internet website registered with the national	(a) If a Member State has reasons for doubts as to whether the translation of the reproduced information is correct, it may require a marketing authorisation holder to provide for a certified translation of the ***authority-approved*** information disseminated on the Internet website

competent authority of another Member State.	registered with the national competent authority of another Member State.

Or. en

Amendment 275
Peter Liese, Anja Weisgerber, Elena Oana Antonescu, Thomas Ulmer, Horst Schnellhardt, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 4 – point b

Text proposed by the Commission	*Amendment*
(b) If a Member State has reasons for doubts as to whether the information disseminated on an Internet website registered with the national competent authorities of another Member State complies with the requirements of this Title, it shall inform that Member State of the reasons for its doubts. The Member States concerned shall use their best endeavours to reach agreement on the action to be taken. If they fail to reach an agreement within two months, the case shall be referred to the Pharmaceutical Committee set up by Decision 75/320/EEC. Any necessary measures may only be adopted after an opinion has been delivered by that Committee. Member States shall take account of opinions delivered by the Pharmaceutical Committee and shall inform the Committee of how its opinion has been taken into account.	(b) If a Member State has reasons for doubts as to whether the ***authority-approved*** information disseminated on an Internet website registered with the national competent authorities of another Member State complies with the requirements of this Title, it shall inform that Member State of the reasons for its doubts. The Member States concerned shall use their best endeavours to reach agreement on the action to be taken. If they fail to reach an agreement within two months, the case shall be referred to the Pharmaceutical Committee set up by Decision 75/320/EEC. Any necessary measures may only be adopted after an opinion has been delivered by that Committee. Member States shall take account of opinions delivered by the Pharmaceutical Committee and shall inform the Committee of how its opinion has been taken into account.

Or. en

Amendment 276
Thomas Ulmer

Proposal for a directive - amending act
Article 1 – point 5

Directive 2001/83/EC
Article 100 h – paragraph 4 a

Text proposed by the Commission	*Amendment*
	4a. Each Member State shall set up and maintain a national medicines web-portal, including a dedicated medicine safety web page, which shall be linked to the European medicines safety web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004. By means of the national medicines web-portals, the Member States shall make public at least the following:
	a). the leaflets for the medicines available on the national market at least in the national language;
	b) the summary of the product characteristics;
	c) the assessment reports together with the periodic safety update reports submitted by marketing authorisation holders to the health authorities;
	d) detailed descriptions of risk management systems, and detailed protocols for post-authorisation studies for medicinal products authorised in accordance with this Directive;
	e) the list of medicinal products under intensive monitoring referred to in Article 23 of Regulation (EC) No 726/2004;
	f) web-based structured forms for the reporting of suspected adverse reactions by healthcare professionals and patients based on the forms referred to in Article 25 of Regulation (EC) No 726/2004;
	g) agendas for meetings of the Pharmacovigilance Committee and of the coordination group and records of their meetings, accompanied by the decisions taken and by details and explanations of the votes, including minority opinions;
	h) requests from the national competent

authority to the marketing authorisation holder to operate a risk management system or to conduct a post-authorisation study, together with the explanations provided by the marketing authorisation holder to the national competent authority where necessary, and the final decision of the competent authority.

Or. en

Justification

Availability on the Internet guarantees that patients and the general public can access the package leaflets and SPCs 24/7, in their mother tongue, and even from abroad. All MSs should have a national medicine agency portal providing high quality information on medicines to the general public. The amendment aims at establishing the legal basis for such portals in response to the Commission's report on current practice with regard to the provision of information. The web portal should include a dedicated area for all information related to safety issues and pharmacovigilance.

Amendment 277
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 5

Text proposed by the Commission	*Amendment*
5. Member States shall ***allow*** marketing authorisation holders which have registered Internet websites in accordance with paragraphs 1 to 4 to include a ***statement therein to*** the ***effect*** that the ***site has been registered*** and is subject to monitoring in ***accordance with this Directive***. The statement shall identify the national competent authority monitoring the website concerned. It shall also specify that the fact that the website is monitored does not necessarily mean that all the information on the website has been subject to prior approval.	5. Member States shall ***require*** marketing authorisation holders which have registered Internet websites in accordance with paragraphs 1 to 4 to include a ***message at*** the ***top of each website page informing the public*** that ***information contained therein is developed by*** the ***marketing authorisation holder*** and is ***therefore*** subject to monitoring in ***order to avoid advertising of prescription medicines***. The statement shall identify the national competent authority monitoring the website concerned. It shall also specify that the fact that the website is monitored does not necessarily mean that all the

information on the website has been subject to prior approval ***and include a link to the EudraPharm database specifying that validated information is available there***.

Or. en

Justification

The fact that the website is registered and monitored in accordance with a Directive offers no added value for users, but can be misused. It is important that the users are clearly informed that the website is "monitored in order to avoid advertising of prescription medicines" because the general public is not well aware of the notion of vested interests. The link to the Eudrapharm database will ensure that users have direct and easy access to comparable information on prescription medicines provided by a non-commercial source.

Amendment 278
Thomas Ulmer

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 5

Text proposed by the Commission	*Amendment*
5. Member States shall ***allow*** marketing authorisation holders which have registered Internet websites in accordance with paragraphs 1 to 4 to include a ***statement therein to*** the ***effect*** that the ***site has been registered*** and is subject to monitoring in ***accordance with this Directive***. The statement shall identify the national competent authority monitoring the website concerned. It shall also specify that the fact that the website is monitored does not necessarily mean that all the information on the website has been subject to prior approval.	5. Member States shall ***require*** marketing authorisation holders which have registered Internet websites in accordance with paragraphs 1 to 4 to include a ***message at*** the ***top of each website page informing the public*** that ***information contained therein is developed by*** the ***marketing authorisation holder*** and is ***therefore*** subject to monitoring in ***order to avoid advertising of prescription medicines***. The statement shall identify the national competent authority monitoring the website concerned. It shall also specify that the fact that the website is monitored does not necessarily mean that all the information on the website has been subject to prior approval ***and shall include a link to the EudraPharm database specifying that validated information is***

available there.

Or. en

Justification

The fact that the website is registered and monitored in accordance with a Directive offers no added value for users, but can be misused. It is important that the users are clearly informed that the website is "monitored in order to avoid advertising of prescription medicines" because the general public is not well aware of the notion of vested interests. The link to the Eudrapharm database will ensure that users have direct and easy access to comparable information on prescription medicines provided by a non-commercial source.

Amendment 279
Peter Liese, Anja Weisgerber, Elena Oana Antonescu, Thomas Ulmer, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 5

Text proposed by the Commission	*Amendment*
5. Member States shall allow marketing authorisation holders which have registered Internet websites in accordance with paragraphs 1 to 4 to include a statement therein to the effect that the site has been registered and is subject to monitoring in accordance with this Directive. The statement shall identify the national competent authority monitoring the website concerned***. It shall also specify that the fact that the website is monitored does not necessarily mean that all the information on the website has been subject to prior approval***.	5. Member States shall allow marketing authorisation holders which have registered Internet websites in accordance with paragraphs 1 to 4 to include a statement therein to the effect that the site has been registered and is subject to monitoring in accordance with this Directive. The statement shall identify the national competent authority monitoring the website concerned.

Or. en

Amendment 280
Corinne Lepage

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 5

Text proposed by the Commission	*Amendment*
5. Member States shall allow marketing authorisation holders which have registered Internet websites in accordance with paragraphs 1 to 4 to include a statement therein to the effect that the site has been registered and is subject to monitoring in accordance with this Directive. The statement shall identify the national competent authority monitoring the website concerned. It shall also specify that the fact that the website is monitored does not necessarily mean that all the information on the website has been subject to prior approval.	5. Member States shall allow marketing authorisation holders which have registered Internet websites in accordance with paragraphs 1 to 4 to include a statement therein to the effect that the site has been registered and is subject to monitoring in accordance with this Directive. The statement shall ***clearly*** identify the national competent authority monitoring the website concerned ***and the marketing authorisation holder responsible for the website***. It shall also specify that the fact that the website is monitored does not necessarily mean that all the information on the website has been subject to prior approval.

Or. fr

Amendment 281
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 5

Text proposed by the Commission	*Amendment*
5. Member States shall ***allow*** marketing authorisation holders which have registered Internet websites in accordance with paragraphs 1 to 4 to include a statement therein to the effect that the ***site*** has been registered and is subject to monitoring in accordance with this Directive. The statement shall identify the national	5. Member States shall ***require*** marketing authorisation holders which have registered Internet websites in accordance with paragraphs 1 to 4 to include a statement therein to the effect that the ***website*** has been registered and is subject to monitoring in accordance with this Directive. The statement shall identify the

competent authority monitoring the website concerned. It shall also specify that the fact that the website is monitored does not necessarily mean that all the information on the website has been subject to prior approval.

national competent authority monitoring the website concerned. It shall also specify that the fact that the website is monitored does not necessarily mean that all the information on the website has been subject to prior approval.

Or. en

Justification

The general public has to be informed about the quality of the website they visit. It is, therefore, better that the availability of the statement about the registration and monitoring procedures is required not simply allowed. This is necessary to show the general public that they can trust the website.

Amendment 282
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 5 a

Text proposed by the Commission	*Amendment*
	5a. Member States shall require marketing authorization holder to add the following statements to the registered web site:
	- [the name of the marketing authorisation holder] is responsible for the information provided in this web site.
	- "If you believe that the information provided violate the law by being false, misleading or lacking in fair balance contact the national competent authority".
	- "You are encouraged to report negative side effects of prescription drugs to your doctor, pharmacists or to the national competent authorities".
	- "You can find information on prescription medicines authorised in the community on the following web site:

[link to Eudrapharm]."

Or. en

Justification

The readers have the right to know who provides the information. The readers also have the right to know to whom they can address if they have doubts with regard to the quality of the information provided. The third statement is consistent with the provisions of the Proposal on pharmacovigilance. The link to the Eudrapharm database will ensure that users have direct and easy access to comparable information on prescription medicines provided by a non-commercial source.

Amendment 283
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. Member States shall require marketing authorization holder to add the following statements to the registered web site:
	- [the name of the marketing authorisation holder] is responsible for the information provided in this web site.
	- "If you believe that the information provided is not in compliance with the law, please contact the national competent authority".
	- "You are encouraged to report negative side effects of prescription drugs to your doctor, pharmacist, health care professional or to the national competent authorities".
	- "You can find information on prescription medicines authorised in the community on the following web site: [link to Eudrapharm]."

Or. en

Amendment 284
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. The registered Internet websites shall display a notification message at the top of each website page, informing the public that information contained therein is developed by a named marketing authorization holder. A link to the EudraPharm database on medicinal products shall also be included in that notification message.

Or. en

Justification

The users of internet sites containing information on prescription medicines must be clearly informed that such information has been developed by a marketing authorization holder. The link to the Eudrapharm database will ensure that users have direct and easy access to comparable information on prescription medicines provided by a non-commercial source, ensuring greater transparency.

Amendment 285
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 i – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	ca) the obligation to put in place complaint-handling systems and efficient redress mechanisms to deal with consumer complaints and to ensure fair

compensation of victims.

Or. en

Justification

It is necessary to introduce a reference to a complaint and redress system to protect consumers and provide them the tools to enforce their rights and seek compensation in case of misleading information. Misleading information on prescription medicine can have serious consequences for public health.

Amendment 286
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 i – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Member States shall provide for the possibility to publish the name of a marketing authorisation holder responsible for disseminating non-compliant information on a medicinal product.

Or. en

Justification

This is an effective and dissuasive measure that would contribute to ensure the compliance with the legislation.

Amendment 287
Cristian Silviu Buşoi

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 i – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Member States shall ensure that marketing authorisation holders are represented and heard in any consideration of a case in which they are accused of non-compliance with the provisions set out in this Title. The marketing authorisation holders shall have the right to appeal any decision to a judicial or other body. During the appeal procedure the dissemination of information shall be suspended until a contrary decision is taken by the responsible body.

Or. en

Justification

This amendment aims to ensure greater efficiency and transparency in the process. Market authorization holders should be given the right to defend themselves in case they consider that the charges of non-compliance are unfounded. In order to protect the general public from information that would possibly not respect the provisions of this Title, it is necessary that the dissemination is suspended right after the decision of the competent authority. It should be resumed only in case the body responsible for analysing the marketing authorization holder's appeal decides so.

Amendment 288
Peter Liese, Anja Weisgerber, Elena Oana Antonescu, Thomas Ulmer, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 j – point a

Text proposed by the Commission	*Amendment*
a) keep available for the authorities or bodies responsible for monitoring information on medicinal products, a sample of all information ***disseminated*** in accordance with this Title and information on its volume of ***dissemination***, together	a) keep available for the ***competent*** authorities or bodies responsible for monitoring information on medicinal products ***that have approved the information in advance***, a sample of all information ***made available*** in accordance

with a statement indicating the persons to whom it is addressed, the method of ***dissemination*** and the date of first ***dissemination***,	with this Title and information on its volume of ***provision***, together with a statement indicating the persons to whom it is addressed, the method of ***provision*** and the date of first ***provision***,

Or. en

Amendment 289
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 j – point c

Text proposed by the Commission	*Amendment*
c) ***supply*** the authorities or bodies responsible for monitoring information on medicinal products with the information and assistance they require to carry out their responsibilities;	c) ***provide*** the authorities or bodies responsible for monitoring information on medicinal products with the information**,** ***the financial resources*** and assistance they require to carry out their responsibilities;

Or. en

Justification

The competent authorities should be given the appropriate financial resources in order to fulfil their tasks.

Amendment 290
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 j – point c

Text proposed by the Commission	*Amendment*
c) supply the authorities or bodies responsible for monitoring information on medicinal products with the information and assistance they require to carry out	c) supply the authorities or bodies responsible for monitoring information on medicinal products with the information**,** ***the financial resources*** and assistance they

their responsibilities;	require to carry out their responsibilities;

Or. en

Justification

The competent authorities should be given the appropriate financial resources in order to fulfil their tasks.

Amendment 291
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5 (new)
Directive 2001/83/EC
Article 100 j – point c a (new)

Text proposed by the Commission	*Amendment*
	ca) put in place complaint-handling systems and efficient redress mechanisms to deal with consumer complaints and to ensure fair compensation of victims.

Or. en

Justification

Misleading information on prescription medicine can have serious consequences for public health. A complaint and redress system to protect consumers and provide them the tools to enforce their rights and seek compensation in case of misleading information needs to be added.

Amendment 292
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5 (new)
Directive 2001/83/EC
Article 100 j – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Member States shall provide for the possibility to publish the name of a

marketing authorisation holder responsible for disseminating non-compliant information on a medicinal product.

Or. en

Justification

This could be an effective and dissuasive measure that would help to ensure compliance with the legislation.

Amendment 293
Jiří Maštálka

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 k

Text proposed by the Commission	*Amendment*
Information on homeopathic medicinal products referred to in Article 14(1) that have been classified as prescription-only shall be subject to the provisions of this Title.	Information on homeopathic ***and herbal*** medicinal products referred to in Article 14(1) that have been classified as prescription-only shall be subject to the provisions of this Title.

Or. en

Justification

Herbal medicinal products subject to medical prescription should be included in the scope of the legislation.

Amendment 294
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 k

Text proposed by the Commission	*Amendment*
Information on homeopathic medicinal products referred to in Article 14(1) that have been classified as prescription-only shall be subject to the provisions of this Title.	Information on homeopathic ***and herbal*** medicinal products referred to in Article 14(1) that have been classified as prescription-only shall be subject to the provisions of this Title.

Or. en

Justification

Herbal medicinal products subject to medical prescription should be included in the scope of the legislation.

Amendment 295
Peter Liese, Anja Weisgerber, Thomas Ulmer, Elena Oana Antonescu, Miroslav Mikolášik, Jorgo Chatzimarkakis

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 l

Text proposed by the Commission	*Amendment*
By [insert specific date five years from the entry into force of amending directive] at the latest, the Commission shall publish a report on the experience acquired in the implementation of this Title and shall also assess the need for a review thereof. The Commission shall submit this report to the European Parliament and to the Council.	By [insert specific date five years from the entry into force of amending directive] at the latest, the Commission shall publish a report on the experience acquired in the implementation of this Title ***after consulting the patient organisations*** and ***the members of health care professions and*** shall also assess the need for a review thereof. The Commission shall submit this report to the European Parliament and to the Council.

Or. en

Amendment 296
Carl Schlyter

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 l – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Within 12 months following the entry into force of this Directive, the Commission shall, following a public consultation, involving patient and consumer organisations, doctors' and pharmacists' organisations, present to the European Parliament and the Council an assessment report regarding the readability and the accuracy of the summaries of product characteristics and the packaging leaflets and their value to the general public and healthcare professionals. Following a data analysis and a systematic review of evidence, the Commission shall, if appropriate, put forward proposals to improve the layout and content of the summaries of product characteristics and of the package leaflet to ensure they are a valuable source of information for the general public and for healthcare professionals.

Or. en

Justification

If the Commission is really concerned about improving information to patients, it should improve the layout and content of the summaries of product characteristics and of the package leaflet.

Amendment 297
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5 (new)

Directive 2001/83/EC
Article 100 l a (new)

Text proposed by the Commission	*Amendment*
	Article 100 la)
	Under the coordination of the Agency, national competent authorities shall organise independent health and treatment literacy campaigns on the following topics:
	- Rational use of medicines: what is the INN; what does a risk and harm-benefit balance mean; what is an adverse drug reaction; what to do when experiencing an ADR; how to report an ADR; what is compliance;
	- Good governance: what is a conflict of interest; what is transparency;
	- Patient and Consumer Rights in Clinical trials: what is a clinical trial; what is informed consent; what are your rights as a participant; what are surrogate endpoints.

Or. en

Justification

The development of health literacy among members of the public is key so that patient and consumer are really empowered, which will in turn lead to a better management of conditions and better health outcomes. Direct spontaneous patient reporting generates multicultural knowledge and is a learning experience – in reflection and in self-expression contributing to health literacy.

Amendment 298
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 l b (new)

Text proposed by the Commission	*Amendment*
	Article 100 lb
	Under the coordination of the Agency, national competent authorities shall organise independent preventive health information, notably on health determinants, notably by supporting public campaigns on how to deal with an addiction, risk of alcohol addiction and dependence from addictive substances (tobacco, narcotics, etc.), why to opt for a healthier diet, or to do physical exercise on a regular basis, etc.

Or. en

Justification

Many diseases and conditions can be avoided by promoting healthier life styles (increased physical activity, less stress, rational use of medicines in order to avoid iatrogenic and dependence, avoid drug consumption) and nutrition measures (less alcohol, less tobacco, less salt and sugar, less fat, greater intake of vegetables and fruits, etc.).

Amendment 299
Thomas Ulmer

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 l c (new)

Text proposed by the Commission	*Amendment*
	Article 100 lc
	Member States shall make sure that undergraduate education of healthcare professionals ensures the development of their communications skills and their understanding of the basics of evidence based medicine.

Member States shall grant financial support to independent drug information centres, encourage the development of independent continuing education programmes for health professionals and the development of their critical appraisal skills.

Within three years of the entry into force of this Directive, the Commission shall, following a public consultation with Member States and continuing education programs for health professionals, establish a comprehensive report on best practices among Member States.

Or. en

Justification

Informing patients and fulfilling their needs implies a relationship of trust, interpersonal dialogue and expertise which are the core responsibilities of the healthcare professions. The communication skills of healthcare professionals must be developed during their undergraduate education.

Amendment 300
Gilles Pargneaux

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 l c (new)

Text proposed by the Commission	*Amendment*
	Article 100 lc
	Member States shall make sure that undergraduate education of healthcare professionals ensures the development of their communications skills and their understanding of the basics of evidence based medicine.
	Member States shall grant financial support to independent drug information centres, encourage the development of

independent continuing education programmes for health professionals and the development of their critical appraisal skills.

Within three years of the entry into force of this Directive, the Commission shall, following a public consultation with Member States and continuing education programs for health professionals, establish a comprehensive report on best practices among Member States.

Or. en

Justification

Informing patients and fulfilling their needs implies a relationship of trust, interpersonal dialogue and expertise which are the core responsibilities of the healthcare professions. The communication skills of healthcare professionals must be developed during their undergraduate education.