COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,

Amended 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

(presented by the Commission pursuant to Article 293 of the Treaty on the functioning of the European Union)

~~{SEC(2008) 2667}~~
~~{SEC(2008) 2668}~~

EXPLANATORY MEMORANDUM

The Commission presents an amended proposal for a Directive of the European Parliament and of the Council on information to the general public on medicinal products subject to medical prescription. Incorporated within the amended proposal are amendments proposed by the European Parliament at its first reading which are acceptable to the Commission.

1 BACKGROUND

On 10 December 2008, the Commission adopted a proposal for a Directive of the European Parliament and of the Council on information to the general public on medicinal products subject to medical prescription. This proposal was forwarded to the European Parliament and the Council on 10 December 2008.

The Economic and Social Committee gave its opinion on 10 June 2009 and the Committee of the Regions, 7 October 2009.

The European Parliament adopted a legislative resolution at its first reading on 24 November 2010.

2 OBJECTIVE OF THE COMMISSION'S PROPOSAL

The general policy objectives of the proposals to amend Directive 2001/83/EC and Regulation (EC) No 726/2004 are in line with the overall objectives of the EU pharmaceutical legislation. These are intended to ensure the proper functioning of the internal market for medicinal products for human use and to better protect health of EU citizens. Following this line, the proposals aim specifically to:

- Provide for a clear framework for provision of information by marketing authorisation holders about their prescription-only medicines to the general public with a view to enhancing the rational use of these medicines, while ensuring that the legislative framework continues to prohibit direct-to-consumer advertising of prescription-only medicines.

This aim shall be achieved by:

- Ensuring the high quality of information provided by coherent application of clearly defined standards across the EU.
- Allowing information to be provided through channels addressing needs and capabilities of different types of patients.
- Allowing marketing authorization holders to provide in an understandable way objective and non-promotional information about the benefits and the risks of their medicines.
- Ensuring that monitoring and enforcement measures are in place to ensure that information providers comply with the quality criteria, while avoiding unnecessary bureaucracy.

This amended proposal is in line with those objectives and further reinforces the rights of patients. In particular, the marketing authorisation holders will have the obligation, and no

longer just the possibility, to make available certain information, such as the labelling and the package leaflet.

3 COMMISSION OPINION ON THE AMENDMENTS ADOPTED BY THE EUROPEAN PARLIAMENT:

On 24 November 2010, the European Parliament adopted 78 amendments on the proposal for a Directive on information to the general public on medicinal products subject to medical prescription. The Commission considers that a majority of the European Parliament's amendments are acceptable in full, in principle, or in part, as they maintain the aims and overall scheme of the proposal.

The Commission therefore accepts in full or in part, the following amendments of the European Parliament:

3.1 Amendments of a general nature

Some of the amendments of the European Parliament, in particular 1, 4 13 and 70, provide for the replacement of the words "disseminate" by "making available" the information. These changes have been incorporated within the whole revised text (recitals and articles) as foreseen by the amendments.

Amendment 2 modifies recital 2 in order to stress that inequalities in accessing information are not acceptable and should be adjust. The Commission introduces these changes within recital 3.

Amendment 3, that the amended proposal incorporates, modifies recital 4 calling for a distinction between advertisement and information in order that all citizens have access to information in all Member States.

Amendments 6 and 7 share the same aim which is to recognise that although some information is made available by national competent authorities and healthcare professionals, marketing authorisation holders may be an additional source of information. The Commission modifies accordingly recital 8.

3.2 Scope of title VIII "Advertising" (Article 86(2))

Article 86(2) of Directive 2001/83/EC, as currently in force, identifies types of information which are not covered by the Directive's title on advertising.

Amendment 20 adds to the list in Article 86(2) correspondence needed to answer a specific question about a medicinal product, and amendment 21 adds some factual, informative announcements. The Commission agrees in principle; however, it is not necessary to specifically mention these aspects as they are already covered by the general indent on "information by the marketing authorisation holder to the general public on medicinal products subject to medical prescription, which shall comply with the provisions of Title VIIIa".

Amendments 22 and 23 clarify the elements listed in the Commission proposal as not covered by the advertisement title. In particular, amendment 23 adds, to the fact that information to the general public should comply with Title VIIIa, the requirement for such information to be

approved by the authorities and to respect quality criteria. As these requirements are included in Title VIIa, it is not necessary to repeat them.

Amendment 24 adds to the list of elements which should not be covered by the advertisement title, factual, informative announcements for investors and employees on significant business developments provided they are not used to promote the product to the general public. This amendment is incorporated in the amended proposal; it is further specified that, however, if the information concerns individual medicinal products, the conditions of Title VIIIa should apply to ensure that the provisions of information to investors and employees is not used to circumvent the provisions of the Directive.

Amendment 25 clarifies that in cases not covered by the advertising title, the marketing authorisation holder and any third party acting on behalf of the marketing authorisation holder making available the information should be identified as such. This has been introduced in Article 100a for all activities covered by the Directive's title on information. .

3.3 Exception to advertising (Article 88(4))

Amendment 87 provides conditions that must be fulfilled by industry in order to be authorised to conduct advertising on vaccination campaigns.

Directive 2001/83/EC provides that the prohibition of advertising does not apply to vaccination campaigns carried out by industry and approved by the competent authorities of the Member States. The original proposals extended this exception to public health campaigns in general. Amendment 87 deletes this proposed extension and imposes further requirements on possible vaccination campaigns. The amended proposal incorporates these changes; however the information should refer only to the vaccines and not to the diseases concerned as the scope of Directive 2001/83/EC is limited to medicinal products.

3.4 Advertising to healthcare professionals (Article 94)

Amendment 27 modifies Article 94 which regulates the advertising to healthcare professionals. It specifies that the rules should apply to direct or indirect promotion by marketing authorisation holder or a third party acting on its behalf or following its instructions. The Commission supports this clarification, which should not be restricted to one specific article. It should concern all Articles on advertising. Therefore the change is introduced in Article 86 at the beginning of the Title VIII on advertising.

3.5 Scope of the new title VIIIa "Information to the general public on medicinal products subject to medical prescription" (Article 100a)

Article 100a defines the scope of the title of the Directive on information. Amendment 84, modifying Article 100b on the content of the information, makes the distinction between information that marketing authorisation holders should make available and information that he may make available. By creating this distinction, the European Parliament re-orientates the text from the right of marketing authorisation holders to make available some information to the right of the patients to have information. This re-orientation should also be reflected in Article 100a. Furthermore, requirements added by this amendment regarding identification of the marketing authorisation holder and control mechanisms do not have to be specified in this Article as they are provided for in specific articles.

Amendment 29 provides that healthcare professionals who deliver information on medicinal products during public events should declare their financial interests with marketing authorisation holders. The Commission supports this amendment, which can however only concern medicinal products and not medical devices in view of the scope of the Directive. This amendment is covered by the introduction within the amended proposal of the obligation for any person making available information to the public to declare any financial or other benefits from marketing authorisation holders.

Amendment 31 modifies the list of types of information which should not be covered by the Directive's title on information. The Commission supports this amendment to the extent that it is consistent with Article 100b on the content of information that may be made available.

Amendments 8 and 32 exclude from the scope of the Directive information made available by third parties acting independently from the marketing authorisation holder in order for them to express their views on prescription-only medicinal products. The Commission supports this exclusion. In addition, in order to ensure transparency about information provided by third parties, they should declare their interests when making available information on medicinal products.

3.6 Content of the information (Article 100b)

Amendments 10 and 84 (modifying Article 100b) make the distinction between information that marketing authorisation holders should make available and information that they may make available. Such a distinction was not included in the original proposal, where no mandatory obligations were created. The Commission accepts these amendments.

However, regarding the list of information that can be made available, Directive 2010/84/EU amending Directive 2001/83/EC as regards pharmacovigilance provides within Article 106a requirements applicable to public announcements by marketing authorisation holders relating to information on pharmacovigilance. Therefore, information regarding adverse-reaction warnings should be excluded from the scope of the Directive's Title on information, as it is specifically addressed by the Title on pharmacovigilance.

Lastly, requirements linked to channels of information, persons with disabilities and control (also contained in the amendment) do not have to be specified in this Article as they are provided for in specific Articles.

3.7 Channels of information (Article 100c)

Amendments 12 and 34 delete the possibility to make available information through health-related publications and provide that it cannot be made available through newspapers, magazines and similar publications. However, the amendments introduce the possibility to make available information through printed materials about a medicinal product prepared by marketing authorisation holders upon specific request by a member of the general public. The Commission accepts these changes; however it is the issuing of these printed materials that should be on request, not their drafting.

3.8 Quality criteria and statements (Article 100d)

Amendments 35, 36 and 37 modify some of the quality criteria applicable to the information.

Amendments 39, 40, 41, 42 and 43 modify the statements that must be available with the information and add two others: a statement containing contact information allowing members of the public to contact competent authorities, and a statement containing a reference to the most recent package leaflet or an indication as to where that text can be found. These amendments have been included in Article 100d. The elements of amendment 41 which relate to monitoring are not included in the amended Article 100d, but are added in the specific Article on monitoring. The elements of amendment 43 referring to internet websites are included in Article 100h.

Amendment 44 requires a statement encouraging the report of undesirable effects to doctors, pharmacists, healthcare professionals and competent authorities. Although the Commission supports this proposal, it considers that a specific statement to encourage this reporting of undesirable effects is not necessary. Indeed, Directive 2010/84/EU already introduces such a statement within Article 59 of Directive 2001/83/EC on information to be included within the package leaflet.

Paragraph 3 of Article 100d provides the elements that the information should not include, such as comparisons between medicinal products. Amendment 46 adds the inducement to or the promotion of the consumption of the medicinal product. Although the Commission supports this principle, the text does not need to be modified to reflect this aspect as this follows already from the provisions of the Directive (Article 86). Indeed, all information that can be made available under Title VIIIa should not induce or promote the consumption of medicinal product.

Amendment 48 aligns to the Treaty of Lisbon the granting to the Commission o the power to adopt measures necessary for the implementation of Article 100d. The acts adopted by the Commission should be implementing acts and not delegated acts, as they are limited to the implementation of the quality criteria which are laid down in the proposal.

3.9 Language aspects (Article 100e)

Amendments 49, 50 and 52 refer to Article 100e on languages; however the modifications concern other aspects and therefore have been introduced, if not already provided for, in the corresponding Articles on quality criteria (Article 100d), monitoring (Article 100g), control (Article 100j) and internet websites (Article 100h).

3.10 Persons with disabilities (Article 100f)

Amendment 53 aligns with the Treaty of Lisbon the delegation to the Commission to amend the Article to take account of technical progress.

3.11 Control of the information (Article 100g)

Amendments 9, 11, 56 and 96 provide for the pre-control of the information by competent authorities, including through the marketing authorisation process, and delete the possibility for Member States to opt for voluntary control by self-regulatory or co-regulatory bodies. A derogation from the system of pre-control is foreseen for Member States which have implemented other type of control mechanisms before 31 December 2008.

The Commission accepts this principle of pre-control and the possibility for derogations. For the latter, in addition to the derogation for pre-existing systems foreseen by the amendments, an additional derogation should be included for cases where Member States cannot introduce

a system of pre-control for constitutional reasons related to the principles of freedom of expression and of the press. However, the Commission should not be tasked to verify and approve alternative national systems.

As the possibility to opt for voluntary control by self-regulatory or co-regulatory bodies are deleted in the new proposal, the provisions for a code of conduct adopted by the Commission has been deleted, while maintaining provisions for Commission guidelines.

Apart from the control mechanism, as some of the provisions introduced by this Directive may interfere with national constitutional rules relating to freedom of the press and freedom of expression in the media, the Commission introduces recital 16 clarifying that this Directive does not prevent Member States from applying these constitutional rules.

3.12 Internet websites (Article 100h)

Article 100h lays down rules for marketing authorisation holders' internet websites making available information on medicinal products under prescription status.

Amendment 58 clarifies that the information available on these websites shall comply with the requirements of the Directive and that it shall be in accordance with the marketing authorisation of the medicinal product. Although the Commission agrees with this, it is not necessary to specify it, as this already follows from other provisions of the Directive.

Amendment 59 foresees the identification of the marketing authorisation holder in the websites. However this identification is already provided for within Article 100d, paragraph 2.

Amendment 60 provides that any update of the information is subject to the monitoring without leading to a re-registration of the website. It should also be stated that the new information is also subject to the requirement of control provided by Article 100g.

Amendment 61 deals with the possibility of including video content on internet websites. The modification of Article 100d(2) by amendment 84 (allowing still or moving images of technical nature demonstrating the proper way of using the product) is sufficient in this regard.

The Commission agrees to the linkage of marketing authorisation holder websites to EU databases and portals on medicinal products, introduced by amendment 62. However, it is more appropriate to link marketing authorisation holder websites to the EU medicines web-portal established by Regulation (EU) No 1235/2010 than to the Eudrapharm database, as that portal is intended to become the central point of access to information on medicines. Furthermore, the identification of marketing authorisation holders providing the information is already required in Article 100d(2); therefore the Commission considers that a reference to this Article is sufficient.

3.13 Penalties (Article 100i)

Article 100i on penalties is modified in order to provide for the possibility to publish the name of marketing authorisation holders who have published information on a medicinal product which is non-compliant with the Directive (amendment 67), to lay down the right of appeal of marketing authorisation holders and to introduce the suspension of the dissemination of the information while the proceedings are on-going (amendment 69).

3.14 Monitoring of the information (Article 100j)

Article 100j refers to marketing authorisation holders' obligations to allow the monitoring of the information provided. Amendment 52, modifying Article 100e, to keep replies available for inspections by national competent authorities, should therefore be introduced within Article 100j.

3.15 Consultation (Article 100ka)

Amendments 16, 90, 92, 93 and 94 refer to the consultation of all relevant stakeholders such as independent patient, health and consumer organisations on issues relating to the implementation of the Directive and its application by the Member States. The consultation of appropriate stakeholders is part of the inter-institutional agreement on better law making (2003/C321/01) and therefore it is not necessary to mention each time examples of these stakeholders, neither to provide for a stand-alone article on that matter.

3.16 Information provided by other sources than the marketing authorisation holder (Articles 21 and 106)

Amendment 79 provides for information about diseases and health conditions and the prevention of such diseases and conditions. The Commission recognises the need for such broader information, however, this cannot be addressed within the Directive which covers medicinal products only.

The part of the amendment intended to task Member States with ensuring that objective, unbiased information is available to general public or members thereof has been introduced in Article 106. This Article following amendment of Directive 2001/83/EC by Directive 2010/84/EU already provides a key tool to fulfil the objective of the amendment (the creation of medicines web portals in every Member States).

3.17 Comitology alignment (Article 100k)

Amendments 15, 75 to 77 are intended to include in Directive 2001/83/EC, in view of the entry into force of the Treaty of Lisbon, general provisions on the granting of delegated powers to the Commission. However, these Articles have been introduced into the Directive by Directive 2010/84/EU. It is only necessary to adapt Article 121a on the exercise of the delegation to include the reference to Article 100f, paragraph 2 which provides for delegated acts.

3.18 Pharmacovigilance

In addition to the changes introduced on the basis of the European Parliament resolution regarding the Commission proposal on information to patients, the Commission considers that certain changes to Directive 2001/83/EC in the area of pharmacovigilance should be introduced.

Directive 2001/83/EC has been recently amended by Directive 2010/84/EU to revise the EU pharmacovigilance system. Directive 2010/84/EU substantially strengthens the legal framework for the surveillance of medicinal products authorised by the Member States, with provisions to reinforce the coordinating role of the Agency, the possibilities for signal detection, and the operation of coordinated procedures at European level to respond to safety

concerns. However, in view of recent pharmacovigilance events in the EU, the Commission has detected certain areas where the legislation could be further strengthened. Therefore:

- Articles 107i is modified in order to provide for an automatic procedure at European level in the cases of specific serious safety issues with nationally authorised products, with a view to ensuring that the matter is assessed and addressed in all Member States where the medicinal product is authorised. Articles 31 and 34 are also modified to clarify the respective scopes of this provision and the revised automatic procedure, as well as the links between these procedures and procedures involving medicinal products authorised in accordance with Regulation (EC) No 726/2004.

- Articles 23a and 123 are modified to avoid that the voluntary withdrawal of a marketing authorisation or product by the holder could lead to safety issues not being addressed in the EU, by clarifying information obligations for the marketing authorisation holder.

4. CONCLUSION

Having regard to Article 293 of the Treaty on the functioning of the European Union, the Commission modifies its proposal as follows:

2008/0256 (COD)

Amended~~P~~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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty ~~establishing the European Community~~ **on** the Functioning of **the European Union**, and in particular Article ~~95~~ **114** thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the European Economic and Social Committee[2],

Acting in accordance with the procedure laid down in Article ~~251~~ **294** of the Treaty[3],

Whereas:

(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[4] 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.

(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~~ **making available** of information from the marketing authorisation holder to the general public**, including patients**, 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~~ **made available**.

(3) On the basis of Article 88a of Directive 2001/83/EC, on 20 December 2007 the

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[1] OJ C , , p. .
[2] OJ C , , p. .
[3] OJ C , , p. .
[4] OJ L 311, 28.11.2001, p. 87.

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"[5] . 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. **Such unjustifiable inequalities in accessing information that is publicly available in other Member States should be redressed.**

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(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~~ **Union, and that this has also given rise to situations where the general public is exposed to disguised advertising. As a result citizens in certain Member States may be denied the right to have access, in their own language, to high-quality, non-promotional information on medicinal products. The distinction between advertising and information should be clarified in order to be interpreted uniformly across all Member States so to ensure patient safety.**

(5) Those disparities in the interpretation of the ~~Community~~ **European Union** rules on advertising, and between national provisions on information have a negative impact on the uniform application of **European Union** ~~Community~~ rules on advertising, and on the effectiveness of the provisions on product information contained in the summary of products characteristics and the package leaflet. Although those rules are fully harmonised to ensure the same level of protection of public health across the ~~Community~~ **EU**, this objective is undermined if widely divergent national rules on the ~~dissemination~~ **making available** of such key information are allowed.

(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~~ **make available** information on medicinal products is not the same across Member States, while information ~~disseminated~~ **made available** 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~~ **EU** 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.

(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 rights and interests of patients. They should have the right to easily access certain information such**

[5] COM(2007) 862 final.

as the summary of the product characteristics, the package leaflet and the assessment report.

(8) National competent authorities and health care professionals should remain ~~important~~ **the main** sources of information on medicinal products for the general public. **While there is already independent information on medicinal products, for example by national authorities or health care professionals, the situation differs very much between Member States and among medicinal products.** Member States should facilitate the access of citizens to high-quality information through appropriate channels. Marketing authorisation holders may be a**n additional** valuable source of non promotional information on their medicinal products. This Directive should therefore establish a legal framework for the ~~dissemination~~ **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.

(9) Third parties, such as patients and patients' organisations or the press, should be able to express their views on prescription-only medicinal products, and therefore should not be covered by these provisions providing that they are acting independently from the marketing authorisation holder. To ensure transparency as to whether third parties act independently from marketing authorisation holders, when making available information, they should declare any financial or other benefits received from marketing authorisation holders.

(~~9~~**10**) In accordance with the principle of proportionality, it is appropriate to limit the scope of this Directive to **the making available of information on** prescription-only medicinal products, as current ~~Community~~ **EU** rules allow the advertising to the general public of medicinal products not subject to prescription, under certain conditions.

(~~10~~**11**) 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~~ **made available**. 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.

(~~11~~**12**) In order to further ensure that **patients have access to** ~~marketing authorisation holders disseminate only~~ high-quality information and to distinguish non-promotional information from advertising, the types of information which may be ~~disseminated~~ **made available by marketing authorisation holders** should be defined. **Marketing authorisation holders should be obliged to make available the approved and most recent contents of summaries of the product characteristics, labelling and package leaflet and the publicly accessible version of the assessment report.** It is appropriate to allow marketing authorisation holders to ~~disseminate~~ **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.

(~~12~~**13**) **This** ~~I~~**i**nformation**, obligatory or not,** 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 **or printed media**, patients are not protected against such unsolicited information and such ~~dissemination~~ **channels of information** should therefore not be allowed.

(~~13~~**14**) The Internet is of major importance with regard to the provision of information to patients and its importance is increasing. The Internet allows almost unlimited access to information disregarding national boundaries. **Registered websites for objective and non-promotional information are therefore necessary and** ~~S~~**s**pecific rules on the monitoring of **these** websites should be established to take account of the cross-border nature of information provided over the Internet and to allow cooperation between the Member States.

(~~14~~**15**) Monitoring of information on prescription-only medicinal products should ensure that marketing authorisation holders only ~~disseminate~~ **make available** 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~~ **being made available**, unless the substance of the information has already been agreed by the competent authorities **in the course of the marketing authorisation procedures, as it is the case for the summary of the product characteristics, labelling and package leaflet, and the publicly accessible version of the assessment report or any updated versions of these documents.** ~~or if there is a different mechanism in place to ensure an equivalent level of adequate and effective monitoring.~~

(~~15~~**16**) **This Directive enhances compliance with fundamental rights and is fully in line with the principles recognised by the Charter of Fundamental Rights of the European Union, in particular Article 11 thereof. In this regard, this Directive does not in any way prevent Member States from applying their constitutional rules relating to freedom of the press and freedom of expression in the media.**

(17) As this Directive introduces for the first time harmonised rules on the provision of information on medicinal products subject to medical prescription to the general public, the Commission should assess its operation and the necessity for a review five years after its entry into force. Provision should also be made for the drawing up of guidelines by the Commission based on Member States' experience**, in cooperation with stakeholders,** in the monitoring of information.

(18) Recent pharmacovigilance events in the EU have shown the need for an automatic procedure at European level in the cases of specific safety issues to ensure that the matter is assessed and addressed in all Member States where the medicinal product is authorised. The scope of different EU procedures concerning nationally authorised products should be clarified.

(19) In addition, voluntary action by the marketing authorisation holder should not lead to a situation where concerns related to the benefit-risk of a medicinal product authorised in the EU are not properly addressed in all Member States.

Therefore, provisions should be made for the marketing authorisation holder to inform competent authorities of the reasons for the withdrawal of medicinal product, interrupting placing on the market of medicinal product, for request for revoking a marketing authorisation, or for not renewing a marketing authorisation.

(20) The Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty in respect of information allowed and 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, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council. In addition, the Commission should be empowered to adopt implementing measures on the quality criteria to be fulfilled by information by the marketing authorisation holder to the general public on medicinal products subject to prescription.

(~~16~~**21**) Since the objective of this Directive to harmonise the rules on information on medicinal products subject to prescription across the ~~Community~~ **EU** cannot be sufficiently achieved by the Member States and can therefore be better achieved at ~~Community~~ **European Union** level, the ~~Community~~ **European Union** may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve this objective.

(~~17~~**22**) Directive 2001/83/EC should be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 2001/83/EC is amended as follows:

(1) In Article 23a, the second subparagraph is replaced by the following:

"The holder shall also notify the competent authority if the product ceases to be placed on the market of the Member State, either temporarily or permanently. Such notification shall, otherwise than in exceptional circumstances, be made no less than 2 months before the interruption in the placing on the market of the product. **The holder shall inform of the reasons for such action in accordance with Article 123.**"

(2) Article 31 is replaced by the following:

"1. The Member States, the Commission, the applicant or the marketing authorisation holder shall, in specific cases where the interests of the Union are involved, refer the matter to the Committee for application of the procedure laid down in Articles 32, 33 and 34 before any decision is reached on an application for a marketing authorisation or on the suspension or revocation of a marketing authorisation, or on any other variation of the marketing authorisation which appears necessary.

Where the referral results from the evaluation of data relating to pharmacovigilance of an authorised medicinal product, the matter shall be referred to the Pharmacovigilance Risk Assessment Committee and Article 107j(2) may be applied. The Pharmacovigilance Risk Assessment Committee shall issue a recommendation according to the procedure laid down in Article 32. The final recommendation shall be forwarded to the Committee for Medicinal Products for Human Use or to the coordination group, as appropriate, and the procedure laid down in Article 107k shall apply.

However, where **one of the criteria listed in Article 107i(1) is met** ~~urgent action is considered necessary~~, the procedure laid down in Articles 107i to 107k shall apply.

2. Where the referral to the Committee concerns a range of medicinal products or a therapeutic class, the Agency may limit the procedure to certain specific parts of the authorisation.

In that event, Article 35 shall apply to those medicinal products only if they were covered by the authorisation procedures referred to in this Chapter.

Where the scope of the procedure initiated under this Article concerns a range of medicinal products or therapeutic class, medicinal products authorised in accordance with Regulation (EC) No 726/2004 which belong to that range or class shall also be included in the procedure."

(3) In Article 34(3), the following last subparagraph is inserted:

"Where the scope of the procedure includes medicinal products authorised in accordance with Regulation (EC) No 726/2004 in accordance with the third subparagraph of Article 31(2), the Commission shall where necessary adopt decisions to vary, suspend, revoke or refuse renewal of the marketing authorisations concerned".

(4) Article 86(1) is replaced by the following:

"1. For the purpose 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 **by the marketing authorisation holder directly or indirectly through a third party acting on his behalf or following his instructions**; it shall include in particular:

— the advertising of medicinal products to the general public,

— 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 or supply 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,

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— 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.

Any reference to marketing authorisation holders in this Title shall include marketing authorisation holders and third parties acting on their behalf or following their instructions".

(~~1~~**5**) Article 86(2) is replaced by the following:

"2. The following are not covered by this Title

(a) the labelling and the accompanying package leaflets, which are subject to the provisions of Title V;

~~– 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;~~

(b) information relating to human health or diseases, provided that there is no reference, even indirect, to **individual** medicinal products;

(c) information by the marketing authorisation holder to the general public on medicinal products subject to medical prescription, which **shall comply with** ~~is subject to~~ the provisions of Title VIIIa.

(d) information by the marketing authorisation holder to investors and employees on business developments, provided they are not used to promote medicinal products. If announcements concern individual medicinal products, the provisions of Title VIIIa shall apply. "

(~~2~~**6**) Article 88(4) is replaced by the following:

"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.

Such campaigns shall be approved by the competent authorities of the Member States only if it is ensured that objective, non-biased information is provided by the industry in the framework of the campaign on the efficacy, the adverse reactions and contra-indications of the vaccine";

(~~3~~**7**) The heading "TITLE VIIIa "Information and advertising" is deleted;

(~~4~~**8**) Article 88a is deleted;

(~~5~~**9**) The following Title VIIIa is inserted after Article 100:

"Title VIIIa – Information to the general public on medicinal products subject to medical prescription

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Article 100a

1. ~~Member States shall allow the marketing authorisation holder to disseminate, either directly or indirectly through a third party,~~ **This Title shall apply to** information to the general public or members thereof on authorised medicinal products subject to medical prescription **, which is made available by the marketing authorisation holders,** ~~provided that it is in accordance with the provisions of this Title.~~

Any reference to marketing authorisation holders in this Title shall include marketing authorisation holders and third parties acting on their behalf or following their instructions.

~~Such i~~**I**nformation **which complies with the provisions of this Title** shall not be considered advertising for the purposes of the application of Title VIII.

2. This Title shall not cover the following:

(a) public announcements by marketing authorisation holders relating to information on pharmacovigilance concerns, which are subject to Article 106a;

(~~a~~**b)** information relating to human health or diseases, provided that there is no reference, even indirect, to **individual** medicinal products;

(~~b~~**c**) material provided by the marketing authorisation holder to healthcare professionals for ~~distribution to patients~~ **their own use;** ~~.~~

(d) information by marketing authorisation holders to investors and employees on business developments, provided they do not concern individual medicinal products or they are not used to promote medicinal products.

3. Without prejudice to paragraph 1, when information is made available to the public by persons other than the marketing authorisation holder, any financial or other benefits from marketing authorisation holders shall be declared by the person making available the information.

Article 100b

1. The following information on authorised medicinal products subject to medical prescription shall be made available by the marketing authorisation holder to the general public or members thereof:

(a) The most recent summary of the product characteristics as approved by the competent authorities;

(b) The most recent labelling and package leaflet as approved by the competent authorities;

(c) The most recent publicly accessible version of the assessment report as drawn up by the competent authorities.

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

~~(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;~~

~~(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;~~

(~~e~~**a**) information on the environmental impact of the medicinal product **further to the information on the disposal and collection system contained in the documents referred to in paragraph 1 of this Article**,

(b) information on prices,

(~~d~~ **c**) information on ~~and factual, informative announcements and reference material relating, for example, to~~ pack changes ~~or adverse reaction warnings~~;

(d) information on the instructions for use of the medicinal product, further to the information contained in the documents referred to in paragraph 1 of this Article. This information may be completed, where necessary, with still or moving images of a technical nature demonstrating the proper way of using the product;

(e) information on the pharmaceutical and pre-clinical tests and the clinical trials of the medicinal product concerned,

(f) a summary of frequently submitted requests for information pursuant to Article 100c(c), and the subsequent answers;

(g) other types of information approved by competent authorities that are relevant to support the proper use of the medicinal product.

~~(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.~~

Article 100c

Information on authorised medicinal products subject to medical prescription ~~disseminated~~ **made available** by the marketing authorisation holder to the general public or members thereof shall not be made available on television**,** ~~or~~ radio **and printed media**. It shall only be made available through the following channels:

(a) **printed materials about a medicinal product prepared by the marketing authorisation holder made available to the general public or member thereof on request or through healthcare professionals**;~~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 **specific** requests for information **about a medicinal product** of a member of the general public.

Article 100d

1. The content and presentation of information on authorised medicinal products subject to medical prescription ~~disseminated~~ **made available** by the marketing authorisation holder to the general public or members thereof shall fulfil the following conditions:

(a) it ~~must~~ **shall** 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~~ **shall be patient-oriented to adequately meet their needs** ~~take into account the general needs~~ and expectations ~~of patients~~;

(c) it ~~must~~ **shall** be based on evidence, be verifiable and include a statement on the level of evidence;

(d) it ~~must~~ **shall** be up-to-date and include the date of publication or last revision of the information;

(e) it ~~must~~ **shall** be reliable, factually correct and not misleading;

(f) it ~~must~~ **shall** be understandable **and legible** for the general public or members thereof;

(g) it ~~must~~ **shall** 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~~ **shall** not contradict the summary of product characteristics, labelling and package leaflet of the medicinal product, as approved by the competent authorities.

2. Any information shall include:

(a) a statement that the medicinal product concerned is available on prescription only and that instructions for use appear on the package leaflet or on the outer packaging, as the case may be;

(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 **or further information**;

(c) a statement indicating that the information is ~~disseminated by~~ **made available by or on behalf of or following instructions of** a **named** marketing authorisation holder;

(d) a **postal** ~~mail~~ address or e-mail address allowing members of the general public to send comments to**, or requests for further information from,** the marketing authorisation holder~~.~~**;**

(e) a postal address or e-mail address allowing members of the general public to contact the competent authorities which have authorised the medicinal product;

(f) the text of the most recent package leaflet or an indication as to where that text may be found.

3. The information shall not include:

(a) comparisons between medicinal products;

(b) any of the material referred to in Article 90.

4. **In order to ensure the quality of information made available to the general public and members thereof,** ~~T~~**t**he Commission shall adopt**, by means of implementing acts,** the measures necessary for the implementation of paragraphs 1, 2 and 3.

~~Those measures, designed to amend non essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 121(2a).~~

Article 100e

1. Member States shall ensure that marketing authorisation holders' Internet websites ~~for the dissemination of~~ **making available** information on medicinal products subject to medical prescription reproduce **the documents referred to in Article 100b (1).** ~~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.~~

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~~ **Union** 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.

Article 100f

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.

2. To ensure accessibility of information on a medicinal product provided by marketing authorisation holders through the Internet, the websites concerned shall conform to the World Wide Web Consortium's (W3C) Web Content Accessibility Guidelines version ~~1~~**2**.0, Level A. The Commission shall make those guidelines publicly available.

The Commission may amend this paragraph to take account of technical progress **by means of delegated acts in accordance with Article 121a and subject to the conditions of Articles 121b and 121c.** ~~This measure, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 121(2a).~~

Article 100g

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~~ **made available** by the marketing authorisation holder to the general public or members thereof **after it has been approved by the competent authorities.**

Notwithstanding the previous sub-paragraph, the documents referred to in Article 100b(1) shall not require further approval before they are made available to the general public or members thereof in addition to their approval in the context of a marketing authorisation procedure.

2. By way of derogation, Member States may rely on other mechanisms for the control of information after it has been made available, on the following grounds:

- such mechanisms already existed on 31 December 2008, or

- a system of control of information before it is made available is not compatible with constitutional rules of the Member State concerned.

Such me**chanisms**~~thods~~ shall **ensure** ~~be based on the control of information prior to its dissemination, unless~~

~~- the content of the information has already been approved by the competent authorities; or~~

~~- an equivalent~~ level of adequate and effective **control** ~~monitoring~~ **equivalent to paragraph 1** ~~is ensured through a different mechanism~~.

~~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.~~

~~2~~**3**. After consulting the Member States **and stakeholders**, 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.

Article 100h

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.

After registration of the Internet website, the information on a medicinal product contained therein may be provided by the marketing authorisation holder**s** on other **of their** Internet websites **containing information on medicinal products** throughout the ~~Community~~ **Union** if the contents are identical.

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.

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~~ **content** actively distributed to the general public or members thereof~~. Those websites shall not contain web-TV.~~

3. The Member State where the Internet website has been registered shall be responsible for **the control of the information made available at the time of registration and of subsequent information in accordance with Article 100g and with its** ~~the~~ monitoring~~,~~ **in accordance with Article 100j** ~~of the contents disseminated on that website~~.

4. A Member State shall not adopt any measure with regard to the content of an Internet website which reproduces an Internet website registered with the national competent authorities of another Member State, except on the following grounds:

(a) **If the Member State of registration controls the information after it has been made available in accordance with Article 100g(2), a Member State may require that the information is approved by the competent authorities before it is reproduced in a website in that Member State;**

(b) 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~~ **made available** on the Internet website registered with the national competent authority of another Member State.

(**c**~~b~~) If a Member State has reasons for doubts as to whether the information ~~disseminated~~ **made available** 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.

5. Member States shall ~~allow~~ **require** marketing authorisation holders which have registered Internet websites in accordance with paragraphs 1 to 4 to include**:**

(a) in addition to the statements listed in Article 100d paragraph 2, 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**, in cases where the information is not subject to approval prior to its being made available pursuant to Article 100g(2),** that the fact that the website is **registered and** monitored does not necessarily mean that all the information on the website has been subject to prior approval.

(b) a link to the European medicines web portal referred to in Article 26 of Regulation (EC) No 726/2004.

6. Member States shall ensure that information on medicinal products authorised in accordance with Regulation (EC) No 726/2004 is not made available in Internet websites that they have registered until the information has been approved by the Agency in accordance with Articles 20b and 20c of that Regulation.

Article 100i

1. Member States shall take appropriate measures to ensure that the provisions of this Title are applied and that adequate and effective measures are adopted to sanction non-compliance with those provisions. Such measures shall include the following:

(a) the determination of the penalties which shall be imposed should the provisions adopted for the implementation of this Title be infringed;

(b) the obligation to sanction cases of non-compliance;

(c) the conferment of powers on the courts or administrative authorities enabling them to order the cessation of dissemination of information that does not comply with this Title or, if such information has not been ~~disseminated~~ **made available** but ~~dissemination~~ **this** is imminent, to order prohibition of such ~~dissemination~~ **availability;**

(d) the possibility to publish the name of marketing authorisation holders responsible for making available information not compliant with this Title.

2. Member States shall make provision for the measures referred to in paragraph 1 to be taken under an accelerated procedure either with interim effect or with definitive effect.

3. 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.

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Article 100j

Member States shall ensure that marketing authorisation holders, through the scientific service referred to in Article 98(1):

(a) keep available for the **competent** authorities ~~or bodies~~ responsible for monitoring information on medicinal products, a sample of all information ~~disseminated~~ **made available** in accordance with this Title and information on its volume ~~of dissemination~~, together with a statement indicating the persons to whom it is addressed, the method of ~~dissemination~~ **communication** and the date of first **making available**~~dissemination~~,

(b) keep available for the competent authorities responsible for monitoring information on medicinal products, the replies made in accordance with this Title together with a statement indicating the persons to whom they are addressed,

(~~b~~**c**) ensure that information on medicinal products by their undertaking complies with the requirements of this Title;

(~~c~~**d**) supply the authorities ~~or bodies~~ responsible for monitoring information on medicinal products with the information and assistance they require to carry out their responsibilities;

(~~d~~**e**) ensure that the decisions taken by the authorities ~~or bodies~~ responsible for monitoring information on medicinal products are immediately and fully complied with.

Article 100k

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.

Article 100l

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 consultation of stakeholders,** and shall also assess the need for a review thereof. The Commission shall submit this report to the European Parliament and to the Council."

(10) In Paragraph 1 of Article 121a, the words "Article 22b, 47, 52b and 54a" are replaced by "Articles 22b, 47, 52b, 54a and 100f (2)".

(11) In Paragraph 1 of Article 121b, the words "Articles 22b, 47, 52b and 54a" are replaced by " Articles 22b, 47, 52b, 54a and 100f(2)".

(12) In Article 106, the following 1st sub-paragraph is introduced:

"Each Member States shall ensure that objective, unbiased information is available to general public or members thereof on medicinal products placed on the market on its territory".

(13) In Article 107i, paragraph 1 is replaced by the following:

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"1. A Member State or the Commission, as appropriate, shall initiate the procedure provided for in this section, by informing the other Member States, the Agency and the Commission ~~when urgent action is considered necessary, as a result of the evaluation of data resulting from pharmacovigilance activities~~, in any of the following cases:

(a) it considers suspending or revoking a marketing authorisation;

(b) it considers prohibiting the supply of a medicinal product;

(c) it considers refusing the renewal of a marketing authorisation;

(d) it is informed by the marketing authorisation holder that, on the basis of safety concerns, he has interrupted the placing on the market of a medicinal product or has taken action to have a marketing authorisation withdrawn, or that he intends to do so**, or has not applied for the renewal of a marketing authorisation**;

(e) it considers that a new contraindication, a reduction in the recommended dose, or a restriction to the indications is necessary.

The Agency shall verify whether the safety concern relates to medicinal products other than the one covered by the information, or whether it is common to all products belonging to the same range or therapeutic class.

Where the medicinal product involved is authorised in more than one Member State, the Agency shall without undue delay inform the initiator of the procedure of the outcome of this verification, and the procedures laid down in Articles 107j and 107k shall apply. Otherwise, the safety concern shall be addressed by the Member State concerned. The Agency or the Member State, as applicable, shall make information that the procedure has been initiated available to marketing authorisation holders."

(14) In Article 123, paragraph 2 is replaced by the following:

"2. The marketing authorization holder shall be obliged to notify the Member States concerned forthwith of any action taken by him to suspend the marketing of a medicinal product**,** ~~or~~ to withdraw a medicinal product from the market, **to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation,** together with the reasons for such action. **The marketing authorisation holder shall in particular declare if such action is linked to any of the grounds described in Articles 116 and 117**. ~~if the latter concerns the efficacy of the medicinal product or the protection of public health.~~ **In such case,** Member States shall ensure that this information is brought to the attention of the Agency."

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [*12 months after publication in the Official Journal; exact date inserted at time of publication*] at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*