P7_TA(2010)0429

Information on medicinal products (Community code relating to medicinal products) ***I

European Parliament legislative resolution of 24 November 2010 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 (COM(2008)0663 – C6-0516/2008 – 2008/0256(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2008)0663),

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0516/2008),

– having regard to the communication from the Commission to the European Parliament and the Council entitled: 'Consequences of the entry into force of the Treaty of Lisbon for ongoing interistitutional decision-making procedures' (COM(2009)0665),

– having regard to Article 294(3), Article 114 and Article 168(4)c) of the Treaty on the functioning of the European Union,

– having regard to the opinion of 10 June 2009 of the European Economic and Social Committee[1],

– having regard to the opinion of 7 October 2009 of the Committee of the Regions[2],

– having regard to Rule 55 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Industry, Research and Energy and the Committee on the Internal Market and Consumer Protection (A7-0290/2010),

1. Adopts the position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

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1 OJ C 306, 16.12.2009, p. 18.
2 OJ C 79, 27.3.2010, p. 50.

3. Instructs its President to forward its position to the Council, to the Commission and to the national parliaments.

P7_TC1-COD(2008)0256

Position of the European Parliament adopted at first reading on 24 November 2010 with a view to the adoption of Directive 2011/.../EU of the European Parliament and of the Council amending, as regards information to *patients and* 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 on the functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee[3],

Having regard to the opinion of the Committee of the Regions[4],

Acting in accordance with the ordinary legislative procedure[5],

Whereas:

(1) Directive 2001/83/EC of the European Parliament and of the Council[6] 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.

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3 OJ C 306, 16.12.2009, p. 18.
4 OJ C 79, 27.3.2010, p. 50.
5 Position of the European Parliament of 24 November 2010.
6 OJ L 311, 28.11.2001, p. 67.

(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 healthcare professionals) and the ***patient 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***.

(3) On the basis of Article 88a of Directive 2001/83/EC, on 20 December 2007 the Commission submitted a Communication entitled "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 patient 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.***

(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 interpreted consistently across the ***Union, and that this has 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 medicines. The notions of advertising and information should be defined and interpreted uniformly across all Member States so as to ensure patient safety.***

(5) Those disparities in the interpretation of the Union rules on ***making available information to patients and the general public***, and between national provisions on information, have a negative impact on the uniform application of Union rules on ***making available information to patients and the general public***, and on the effectiveness of provisions on product information contained in the summary of products characteristics and the ***patient package leaflet***. Although those rules are fully harmonised to ensure the same level of protection of public health across the Union, this objective is undermined if widely divergent national rules on the ***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 ***make available*** information on medicinal products is not the same across Member States, while information ***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 ***patient package leaflet***) is harmonised at Union level. This includes medicinal products authorised by the Member States under the mutual recognition framework of Chapter 4 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 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 as a summary of product characteristics and the patient package leaflet in electronic and printed form***. ***Certified and registered websites for independent, objective and non-promotional information are therefore necessary.***

(8) National competent authorities and healthcare 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 information provided by national authorities or healthcare professionals, the situation differs very much between Member States and between the different products available.*** Member States ***and the Commission*** should ***make much greater efforts to*** facilitate citizens' access to high-quality information through appropriate channels. ▌

(9) Without prejudice to the importance of the role played by national competent authorities and healthcare 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 patients and the general public. The ban on advertising to patients and the general public for prescription-only medicinal products should be maintained.

(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 Union rules allow the advertising to ***patients and*** 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. This Directive requires Member States to permit, via certain channels and subject to appropriate monitoring, the making available by a marketing authorisation holder or a third party acting on its behalf of certain information on authorised medicines subject to prescription to patients and the general public. Communications that do not fall within Title VIIIa of Directive 2001/83/EC are permitted, provided that they do not constitute advertising.***

(11) Provisions should be established to ensure that only high-quality non-promotional information about the benefits and the risks of ***authorised*** medicinal products subject to medical prescription ***is accessible***. 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 ***patients or*** the general public on prescription-only medicinal products should ***be approved in advance by the competent authorities and should made available only in an approved form***.

(12) 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 that ***are made available*** should be defined. ***Marketing authorisation holders should make available the approved and most recent contents of summaries of product characteristics, labelling and patient package leaflet and the publicly accessible version of the assessment report.*** It is appropriate to allow marketing authorisation holders to ***make available*** other well-defined medicinal product-related information.

(13) Approval should be required by the competent authorities, during the course of marketing authorisation, for the summary of product characteristics, labelling and patient package leaflet, and the publicly accessible version of the assessment report or any updated versions of these documents. This information should therefore not be subject to further approval prior to its being made available pursuant to this Directive.

(14) Information to ***patients and*** the general public on prescription-only medicinal products should be provided only through specific channels of communication, including internet ▌, to avoid the effectiveness of the prohibition on advertising being undermined by unsolicited provision of information to ***patients or*** the general public. Where information is ***made available*** via television***,*** radio, ***newspapers, magazines and similar publications,*** patients are not protected against such unsolicited information and ***the making available of*** such ***information*** should therefore not be allowed.

(15) 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. Specific rules on the monitoring of 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.

(16) Monitoring of information on ***authorised*** prescription-only medicinal products ***under this Directive*** should ensure that marketing authorisation holders ***make available*** only 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 harmonised at Union level so as to ensure consistency. In cases of non-compliance, procedures should be put in place for marketing authorisation holders to 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 ***being made available***. ***Only*** information ***that*** has ▌been ***approved in advance*** by the competent authorities ***should be made available and it should be made available*** in ***an approved form only***.

(17) As this Directive introduces for the first time harmonised rules on the ***making available*** of information on medicinal products subject to medical prescription to ***patients and*** 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 all relevant stakeholders, such as patient organisations and healthcare professionals,*** in the monitoring of information.

(18) The Commission should consult all relevant stakeholders, such as independent patient, health and consumer organisations and healthcare professionals, on issues relating to the implementation of this Directive and its application by the Member States.

(19) The Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union in respect of the quality criteria of information made available to patients and the general public and web accessibility guidelines. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.

(20) Since the objective of this Directive, namely to harmonise the rules on information on medicinal products subject to prescription across the Union, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. 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 that objective.

(21) Directive 2001/83/EC should be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments to Directive 2001/83/EC

Directive 2001/83/EC is amended as follows:

(1) In Article 1, point 26 is replaced by the following:

"26. Patient package leaflet: A leaflet containing information for the patient which accompanies the medicinal product and which corresponds to patients' real needs.".

(2) In Article 59, the following paragraph is added:

"4. The patient package leaflet shall correspond to patients' real needs. To this end, patient organisations should be involved in developing and reviewing the information on medicinal products by national regulatory authorities and the Agency. The patient package leaflet shall include a short paragraph which sets out the benefits and potential harm of a medicinal product as well as a short description of further information aiming at safe and effective use of a medicinal product.".

(3) In Article 86, paragraph 2 is replaced by the following:

"2. The following are not covered by this Title:

– the labelling***, which shall always at least specify the International Non-proprietary Name,*** and the accompanying ***patient package leaflets***, which are subject to the provisions of Title V;

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

– factual, informative announcements ***(including announcements or statements such as those made to media organisations either in response to a direct enquiry or by making them available at conferences or by written releases*** and ***announcements or reports to shareholders and/or regulators)*** and reference material ***on a medicinal product,*** relating, for example, to its ***availability,*** packaging changes, adverse-reaction warnings as part of general drug precautions, trade catalogues, price lists, ***reimbursement and information on the environmental risk of the medicinal product and information relating to the disposal of unused medicinal products or waste derived from medicinal products as well as reference to any collection system in place,*** provided ***that such announcements and reference material*** include no ***promotional*** product claims ***and that they do not encourage or promote the consumption of the medicinal product***;

– information relating to human health or diseases, provided that there is no reference, even indirectly, to ***individual*** medicinal products;

– information ▌ on medicinal products subject to medical prescription ***that meets the quality criteria***, ***that has been approved by the competent authorities in the Member States, that has been made available to patients or the general public in approved form by the marketing authorisation holder and that*** is subject to the provisions of Title VIIIa***;***

– ***factual, informative announcements for investors and employees on significant business developments, provided they are not used to promote the medicinal product to patients or the general public***.

3. When exemptions to advertising referred to in paragraph 2 are granted, 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 identified as such.".

(4) In Article 88, ***the following subparagraph is added to*** paragraph 4 ▌:

"***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 in the frame of the campaign by the industry on the causes of the disease, the efficacy of the vaccine, the adverse reactions and contra-indications of the vaccination.***".

(5) The heading "TITLE VIIIa Information and advertising" is deleted;

(6) Article 88a is deleted;

(7) In Article 94, paragraph 1 is 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.".

(8) The following Title is inserted after Article 100:

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

Article 100a

1. ***Without prejudice to the importance of the role that national competent authorities and healthcare professionals play in better informing patients and the general public on authorised medicinal products subject to medical prescription,*** Member States shall ***oblige*** the marketing authorisation holder to ***make available***, either directly or indirectly through a third party ***acting on behalf of the marketing authorisation holder***, information ***that has been officially approved by national or Union competent authorities*** to ***patients or*** the general public or members thereof on authorised medicinal products subject to medical prescription provided that ***such information and the manner in which it is made available*** is in accordance with the provisions of

this Title. Such information shall not be considered as 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.***

2. Healthcare professionals who make available information on medicinal products or medical devices during a public event, in print or broadcast media shall declare publicly their interests, for example any financial ties with marketing authorisation holders or with third parties acting on their behalf. This also covers the making available of information on medicinal products or medicinal devices in the course of consulting services and technical advice.

3. Information campaigns aimed at raising awareness among patients and the general public and members thereof about the risks of falsified medicinal products should be organised. Such information campaigns may be conducted by national competent authorities in collaboration with industry, healthcare professionals and patient organisations.

4. This Title shall not cover the following:

(a) ***factual, informative announcements (including announcements or statements made to media organisations either in response to a direct enquiry or by making them available at conferences or by written releases and announcements or reports to shareholders and/or regulators) and reference material on a medicinal product relating, for example, to packaging 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***;

(b) material provided ▌ to healthcare professionals for ***their own use***.

5. The provisions of this Directive shall be 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.

Article 100b

1. The marketing authorisation holder shall, in respect of authorised medicinal products subject to medical prescription***, make available*** to ***patients and*** the general public or members thereof ***the following information***:

(a) ***the most recent*** summary of product characteristics, ***as approved by the competent authorities during the course of marketing authorisation and authorisation renewal***;

(b) ***the most recent*** labelling and ***patient package leaflet*** as approved by the competent authorities ***during the course of marketing authorisation or authorisation variation;*** and

(c) the ***most recent,*** publicly accessible version of the assessment report ***as*** drawn up by the competent authorities ***during the course of marketing authorisation and authorisation updates***.

The information referred to in points (a), (b) and (c) shall be presented in a format that faithfully represents the officially approved information drawn up by the competent authorities. The information shall be made available both in electronic and printed form, and in formats appropriate for the blind and partially-sighted.

2. The marketing authorisation holder may, in respect of authorised medicinal products subject to medical prescription, make available to patients and the general public or members thereof the following information:

(a) information on the environmental impact of the medicinal product ***further to the information provided on the disposal and collection system pursuant to Article 54(j) and made available pursuant to paragraph 1 of this Article.***

(b) information on prices***;***

(c) information on packaging changes***;***

(d) adverse-reaction warnings ***further to the information provided pursuant to Article 59(1)(e) and made available pursuant to paragraph 1 of this Article***;

(e) instructions for use of the medicinal product, further to the information provided pursuant to Article 59(1)(d) and made available pursuant to paragraph 1 of this Article. This information may be supplemented, where necessary, with still or moving images of a technical nature demonstrating the proper way of using the product;

(f) the pharmaceutical and pre-clinical tests and the clinical trials of the medicinal product concerned presented in factual, non-promotional listings of summary information;

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

h) other types of information agreed by the competent authority that are relevant to supporting the appropriate use of the medicinal product.

The information referred to in points (a) to (g) shall be made available both in electronic and printed form, and in formats appropriate for the blind and partially-sighted.

The information referred to in points (a) to (g) shall be approved by the competent authorities, or in case of Union marketing authorisation, by the Agency, prior to its being made available for the purposes of this Article.

Article 100c

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

▌

(a) internet websites ***registered and managed in accordance with Article 100h***, relating to medicinal products, to the exclusion of unsolicited material actively distributed to ***patients or*** the general public or members thereof;

(b) ▌ answers to ***specific*** requests for information ***about a medicinal product*** of a ***patient or a*** member of the general public***;***

(c) printed material about a medicinal product prepared by the marketing authorisation holder pursuant to Article 100b upon specific request by a patient or a member of the general public.

Article 100d

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

(a) it must be objective and unbiased, and, in this regard, if the information refers to the benefits of a medicinal product, its risks shall also be stated;

(b) it must ***be patient oriented to better meet patients'*** needs ▌;

(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 ***and perfectly legible*** for ***a patient and*** the general public ***and*** members thereof***, paying particular attention to elderly people***;

(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 ***patient package leaflet*** of the medicinal product, as approved by the competent authorities.

2. By ...*, the Commission shall present to the European Parliament and the Council an assessment report on current shortcomings in the summary of product characteristics and the patient package leaflet and how they could be improved in order to better meet the needs of patients and healthcare professionals. The Commission shall, if appropriate, and on the basis of the report, and after consultation with appropriate stakeholders, present proposals in order to improve the readability, layout and content of these documents.

3. 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 ***patient 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 healthcare professionals and that a healthcare professional should be contacted if the patient requires clarification ***or further information*** on the information provided;

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

(d) a ***postal*** address or e-mail address allowing ***patients and*** members of the general public to send comments to***, or requests for further information from,*** the marketing authorisation holder. ***Comments sent by private individuals and the replies from marketing authorisation holders shall be duly recorded and monitored;***

(e) a postal address or e-mail address allowing patients and members of the general public to send comments to the national competent authorities;

(f) the text of the current patient package leaflet or an indication as to where that text may be found. In the case of internet websites under the control of marketing authorisation holders that are directed specifically at citizens of one or more Member States, they shall contain the summary of product characteristics and the patient package leaflet of the medicinal products concerned in the official languages of the Member States where they are authorised if the information on medicinal products is available in those languages;

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* ***24 months after the entry into force of this Directive.***

(g) a statement indicating that patients and 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.

4. The information shall not include:

(a) comparisons between medicinal products ***regarding their quality, safety and efficiency, if the information is made available by marketing authorisation holders except where those comparisons are:***

- ***included in officially approved documents, such as the summary of product characteristics***;
- ***based on comparative scientific studies published by the relevant national authorities or the Agency;***
- ***contained in the summary of the European Public Assessment Reports referred to in Article 13 of Regulation (EC) No 726/2004, which will list the other available therapeutic options and whether the new medicinal product brings about a therapeutic value;***

(b) any inducement to, or promotion of, the consumption of the medicinal product;

(c) any of the material referred to in Article 90***;***

(d) information on other medicinal products for which the pharmaceutical company is not the marketing authorisation holder.

5. ***In order to ensure the quality of information made available to patients or the general public or members thereof,*** the Commission shall adopt***, by means of delegated acts in accordance with Article 100n, and subject to the conditions of Articles 100n and 100o,*** the measures necessary for the ***application*** of paragraphs 1, 2, 3 and 4.

▌

Article 100e

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 ***patient package leaflet*** of the medicinal products ***subject to medical prescription that they market*** in the official languages of the Member States in which they are authorised.

2. Member States shall ensure that each webpage from a marketing authorisation holder's website referring to a medicinal product subject to medical prescription includes a link to the corresponding webpage of the

Union database (hereinafter the "EudraPharm database") referred to in Articles 57(1)(l) and 57(2) of Regulation (EC) No 726/2004, and the national medicines web-portals referred to in Article 106 of this Directive or the European medicines web-portal referred to in Article 26 of Regulation (EC) No 726/2004.

3. 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 European database on information about clinical trials (the "EudraCT database") provided for in Article 11 of Directive 2001/20/EC.

4. Member States shall ensure that requests for information to a marketing authorisation holder on a medicinal product subject to medical prescription by ***a patient or*** a member of the general public may be drafted in any of the official languages of the Union which are official languages in the Member States in which the medicinal product is authorised. The reply shall be drafted in the language of the request. ***The replies shall be kept available for inspection by national competent authorities.***

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 1.0, Level A. The Commission shall make those guidelines publicly available.

In order to take account of technical progress, the Commission may ***adopt, by means of delegated acts in accordance with Article 100m, and subject to the conditions of Articles 100n and 100o, measures necessary for the application of this paragraph***.

Article 100g

1. Member States shall ensure that ▌misuse ▌is ***avoided by ensuring that only*** the marketing authorisation holder ***supplies information, and that he supplies only such information as has been approved by the competent authorities about approved medicinal products subject to medical prescription, and that it is supplied in the form that has been approved for the making available*** to ***patients and*** the general public or members thereof. ***By way of derogation, Member States may continue those types of control mechanism which they implemented before 31 December 2008 not excluding enhancements to such control mechanisms. The Commission shall verify and approve such mechanisms and their enhancements, taking advice from the competent authorities.***

Such ***mechanisms*** shall be based on the control of information prior to its ***being made available***, unless:

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

– an equivalent level of adequate and effective monitoring is ensured through a different mechanism.

▌

2. After consulting the Member States ***and all relevant stakeholders, such as patient organisations and healthcare professionals***, 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 ***patients and*** the general public or members thereof on authorised medicinal products subject to medical prescription. ***The guidelines shall contain provisions to ensure that patients and 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 by ... [*] 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 ***under their control that are directed specifically at citizens of one or more Member States and that contain authority-approved*** information on ***prescription-only medicinal products covered*** by ***this Title***, prior to making it available to ***patients or*** 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. ***This information shall comply with the requirements laid down in this Directive and shall be in accordance with the registration dossier for the medicinal product.***

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 Union if the contents are identical. ***Such websites shall clearly identify the marketing authorisation holder.***

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 4. Such changes shall not require re-registration of the website.

2. Each Member State shall draw up and update a list of registered

[*] The entry into force of this Directive.

internet websites. Those lists shall be made available to consumers.

3. 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 ***patients or*** members of the general public which have access to those websites ***without their explicit prior consent,*** or the appearance therein of unsolicited ***content*** distributed to ***patients or*** the general public or members thereof. ***Internet*** websites ***may provide video content if it is useful for supporting the safe and effective use of the medicine***.

Registered websites shall display a notification at the top of each webpage informing patients and the general public that the information contained therein is developed by a named marketing authorisation holder. A link to the EudraPharm database on medicinal products shall also be included in that notification.

4. The Member State in which 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.

5. 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 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 a certified translation of the ***authority-approved*** information ***made available*** on the internet website registered with the national competent authority of another Member State.

(b) If a Member State has reasons for doubts as to whether the ***authority-approved*** information ***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 referred to in Article 84. 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.

6. Member States shall ***require*** marketing authorisation holders which have registered internet websites in accordance with paragraphs 1 to 5 to include a

message at the ***top of each webpage informing patients and the general 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-only medicinal products***. The ***message*** 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 ***and shall include a link to the EudraPharm database specifying that validated information is available there***.

7. The Commission shall establish, by means of delegated acts in accordance with Article 100m and subject to the conditions of Articles 100n and 100o, the detailed rules and conditions for registration and monitoring of internet websites referred to in this Title and of information provided therein, with a view to guaranteeing the reliability of the data presented and their compliance with the authorisation and registration of the medicinal products concerned so as to provide a guarantee for consumers that the website or information concerned is accurate and based on facts. Those rules and conditions shall include certification or qualification criteria to be applied with respect to registered websites.

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 are to be imposed should the provisions adopted for the implementation of this Title be infringed; ***those penalties shall be effective, proportionate and dissuasive;***

(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 ***the making available*** of information that does not comply with this Title or, if such information has not been ***made available*** but will be imminently, to prohibit the ***making available*** of such information.

Member States shall provide for the possibility to publish the name of a marketing authorisation holder responsible for making available non-compliant information on a medicinal product.

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 to a judicial or other body against any decision. During the appeal procedure the making available of information shall be suspended until a contrary decision is taken by the responsible body.

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 ***that have approved the information in advance***, a sample of all information ***made available*** in accordance 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 ***making it available*** and the date ***on which it was*** first ***made available***;

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

(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;

(d) 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. ***The same shall apply to information on herbal medicinal products or any other compounds or therapies that have been classified as prescription-only medicinal products.***

Article 100l

1. Notwithstanding the provisions of this Title on information by the marketing authorisation holder, each Member State shall ensure that objective, unbiased information is available to patients and the general public or members thereof on:

(a) medicinal products placed on the market on its territory. Such information shall include, but shall not be limited to, the most recent summary of product characteristics and labelling and patient package leaflet of the medicinal product as approved by the competent authorities during the course of marketing authorisation and its renewal, and the most recent, publicly accessible version of the assessment report as drawn up by the competent authorities, and

updates thereof;

(b) the diseases and health conditions which are to be treated with medicinal products placed on the market on its territory; and

(c) the prevention of such diseases and conditions.

2. The information referred to in paragraph 1 shall be made available both in electronic and printed form and in a format accessible for people with disabilities. The information shall be made available through the following channels:

(a) dedicated websites set up by the Member State or by a body assigned by the Member State, and monitored by the competent national authority or by a body assigned by the competent national authority;

(b) printed materials made available to patients and the general public;

(c) written answers to requests for information of patients and members of the general public.

3. The Commission shall facilitate the sharing of best practices between Member States and shall adopt guidelines.

*4. By ...*the Commission shall present a report to the European Parliament and the Council on the progress made by the Member States in applying this Article.*

Article 100m

*1. The power to adopt delegated acts referred to in Articles 100d(5), 100f(2) and 100h(7) shall be conferred on the Commission for a period of five years from ... **. The Commission shall draw up a report in respect of the delegated power at the latest six months before the end of the five- year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament and the Council revoke it in accordance with Article 100n.*

2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

3. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in Articles 100n and 100o.

Article 100n

1. The delegation of power referred to in Articles 100d(5), 100f(2) and 100h(7) may be revoked at any time by the European Parliament or by the Council.

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* *Three years from the entry into force of this Directive.*

** *The entry into force of this Directive.*

2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated powers which could be subject to revocation and possible reasons for a revocation.

3. The decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the Official Journal of the European Union.

Article 100o

1. The European Parliament or the Council may object to a delegated act within a period of three months from the date of notification.

At the initiative of the European Parliament or the Council that period shall be extended by one month.

2. If, on expiry of the period referred to in paragraph 1, neither the European Parliament nor the Council has objected to the delegated act it shall be published in the Official Journal of the European Union and shall enter into force at the date stated therein.

The delegated act may be published in the Official Journal of the European Union and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If either the European Parliament or the Council objects to the delegated act within the period referred to in paragraph 1, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Article 100p

By ... [*], the Commission shall publish a report on the experience acquired in the implementation of this Title ***after consulting all relevant stakeholders, such as independent patient, health and consumer organisations and the members of healthcare 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.".

(9) The words "package leaflet" and "package leaflets" shall be replaced by "patient package leaflet" and "patient package leaflets" throughout the text.

Article 2

Consultation of stakeholders

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[*] Five years from the entry into force of this Directive.

The Commission shall consult all relevant stakeholders, such as independent patient, health and consumer organisations on issues relating to the implementation of this Directive and its application by the Member States.

Article 3

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by ... [*]. 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.

[*] One year after the entry into force of this Directive.

Article 4

Entry into force

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

Article 5

Addressees

This Directive is addressed to the Member States.

Done at

For the European Parliament	For the Council
The President	The President