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From:	Presidency
To:	Delegations
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Subject:	Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC *- Exchange of views*

Delegations will find in Annex the revised Articles on labelling/advertising and prescriptions to be discussed at the meetings of the Working Party on 12-13 March 2025.

Changes compared to the Commission proposals are indicated in ~~strikethrough~~ for deletions and **bold/underline** for new text. In addition, changes compared to those made in document 5861/25 are highlighted in grey.

ANNEX

Chapter VI
Product information and labelling

Article 62

Summary of product characteristics

1. The summary of product characteristics shall contain the particulars listed in Annex V.

2. For marketing authorisations under Articles 9 ~~and~~ **to** 1~~1~~**2** and subsequent variations to such marketing authorisations, if one or more of the therapeutic indications, posologies, pharmaceutical forms, methods or routes of administration or any other way in which the medicinal product may be used are still covered by patent law or a supplementary protection certificate for medicinal products at the time when the generic**,** ~~or~~ biosimilar**, hybrid or biohybrid** medicinal product was marketed, the applicant for an authorisation for a generic ~~or~~**,** biosimilar**, hybrid or biohybrid** medicinal product may request not to include this information in their marketing authorisation**, however all relevant safety information related to the safe use of the medicinal product ~~is to~~ shall be included**.

3. ~~For all medicinal products, a standard text shall be included in the summary of product characteristics expressly asking healthcare professionals to report any suspected adverse reaction in accordance with the national reporting system referred to in Article 106(1). Different ways of reporting, including electronic reporting, shall be available in compliance with Article 106(1), second subparagraph.~~

Article 63

General principles on package leaflet

1. A package leaflet shall be mandatory for medicinal products. **The package leaflet shall be made available in the packaging by the marketing authorisation holder in paper format and electronically.**

2. The package leaflet shall be written and designed in a clear and understandable way, enabling users to act appropriately, when necessary with the help of healthcare professionals.

3. **By derogation to paragraph 1,** Member States may decide that the package leaflet shall be made available **by the marketing authorisation holder** ~~in paper format or~~ **only** electronically~~, or both~~. ~~In the absence of such specific rules in a Member State, a package leaflet in paper format shall be included in the packaging of a medicinal product.~~ If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet ~~should~~ **shall** be guaranteed upon request and free of charge and it ~~should~~ **shall** be ensured that the information in digital format is easily accessible to all patients. **The marketing authorisation holder shall be responsible for preparing the electronic leaflet and shall be responsible for providing that the printed version of the package leaflet is available to the patient.**

4. By derogation from paragraphs 1 and 2, where the information required under Articles 64 and 73 is directly conveyed on the outer packaging or on the immediate packaging, a package leaflet shall not be required.

~~5. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend paragraph 3 by making mandatory the electronic version of the package leaflet.~~ **~~This is without prejudice to the right of a Member State to require package leaflet also in paper format in its territory in accordance with Article 63 paragragh 3.~~** ~~That delegated act shall also establish the patient's right to a printed copy of the package leaflet upon request and free of charge~~**~~, if in the territory of the Member State the package leaflet in the paper format will no longer be required~~**~~. The marketing authorisation holder shall be responsible for providing that the printed version of the package leaflet is available to the patient~~**~~. The delegation of powers shall apply as of [OP please insert the date = five years following 18 months after the date of entering into force of this Directive]. The delegated act shall not be adopted before at least half of the Member States have introduced an electronic version of the package leaflet, and when an assessment carried out by the Commission underpins the readiness of the Member States to take such a measure.~~**

6. The Commission shall **[by 12 months after entry into force of the Directive]** adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies **as well as the provision of such information through secure digital platforms ~~or websites~~**.

7. Where the package leaflet is made available electronically, the ~~individual right to privacy~~ **personal data protection** shall be ensured **in line with Regulation (EU) 2016/679 and Directive 2002/58/EC**. Any technology giving access to the information shall not allow the identification or tracking of individuals, nor shall it be used for commercial purposes.

Recital:

(128) Member States have varying levels of digital literacy and internet access. In addition, patient and healthcare professional needs may differ. It is therefore necessary that Member States have a discretion on the adoption of measures enabling the electronic provision of product information while ensuring that no patient is left behind, taking into account the needs of different age categories and the different levels of digital literacy in the population, and making sure that product information is easily accessible to all patients. Member States should progressively allow the possibility for electronic product information, while ensuring full compliance with the rules on protection of personal data, and adhere to harmonised standards developed at EU level **with regard to all or specific categories of medicinal products. Member States could, for example, begin this process by requiring only electronic provision of product information where a medicinal product[2] is used in a hospital setting and is not intended to be delivered directly to the patient, or in order to protect public health when there are severe problems in respect of the availability of that medicinal product.**

Article 218

Transitional provisions

[…] Medicinal products placed on the market or labelled prior to [18 months after the date of entering into force of this Directive] which do not comply with the requirements of this Directive may be marketed until the stocks of the medicinal products are exhausted.

For medicinal products authorised before [OP please insert the date the date of entering into force of this Directive] and medicinal products for which the application for marketing authorisation was validated before [entering into application], the requirement to make the package leaflet available in the package electronically, pursuant to Article 63, paragraph 1 shall apply on [OP please insert the date = 3 years after the date of entering into force of this Directive], unless a Member State chooses to apply the requirement earlier in its territory.

Stocks of medicinal products produced, packaged and labelled prior to [OP please insert the date the date of entering into force of this Directive] which do not comply with the requirement to make the package leaflet available in the package electronically, pursuant to Article 63, paragraph 1 may continue to be placed on the market, distributed, dispensed, sold and used until stocks are exhausted.

Article 219

Transposition

Member States shall bring into force the laws, regulations and administrative provisions to comply with this Directive by [18 months after the date of entering into force of this Directive]. They shall immediately communicate the text of those measures to the Commission. **Member States shall apply those provisions from [18 months after the date of entering into force of this Directive].**

Article 64

Content of package leaflet

1. The package leaflet shall be drawn up in accordance with the summary of product characteristics, referred to in Article 62(1) and shall include the particulars listed in Annex VI.

~~2. For all medicinal products, a standardised text shall be included, expressly asking patients to communicate any suspected adverse reaction to their doctor, pharmacist, healthcare professional or directly to the national reporting system referred to in Article 106(1), and specifying the different ways of reporting available (electronic reporting, postal address or others) in compliance with Article 106(1), second subparagraph.~~

3. The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use.

Article 65

Labelling of the outer packaging ~~*Content of labelling particulars*~~

1. The outer packaging of medicinal products or, where there is no outer packaging, the immediate packaging, with the exception of the packaging referred to in Article 66, paragraphs 2 and 3, shall include the labelling particulars listed in Annex IV.

2. The Commission is empowered to adopt delegated acts in accordance with Article 215 to:
   (a) amend the list of labelling particulars set out in Annex IV in order to take account of scientific progress or patient needs;
   (b) supplement Annex IV by setting out a reduced list of mandatory labelling particulars that shall appear on the outer packaging of multi-language**, multi-country** packages.

Recital:

(130) The use of multi-language**, multi-country** packages can be a tool for access to medicinal products, in particular for small markets and in public health emergencies. Where multi-language**, multi-country** packages are used, Member States may also allow the use on the labelling and package leaflet of an official language of the Union that is commonly understood in the Member States where the multi-language**, multi-country** package is marketed.

Article 66

Labelling of ~~blister packs or small~~ immediate packaging

1. The particulars laid down in Annex IV shall appear on immediate packagings other than those referred to in the paragraphs 2 and 3.

2. The following particulars at least shall appear on immediate packagings that take the form of blister packs and are placed in an outer packaging that complies with the requirements laid down in Articles 65 and 73.
   (a) the name of the medicinal product **followed by its strength, if available, and pharmaceutical form; where the medicinal product contains up to three active substances, the international non-proprietary name (INN) shall be included or, if one does not exist, the common name**;
   (b) the name of the marketing authorisation holder placing the product on the market;
   (c) the expiry date;
   (d) the batch number.

3. The following particulars at least shall appear on small immediate packaging units on which the particulars laid down in Articles 65 and 73 cannot be displayed, ~~shall include at least the following labelling particulars~~:
   (a) the name of the medicinal product **followed by its strength, if available, and pharmaceutical form** and, ~~if necessary, the route of administration;~~ **where the medicinal product contains up to three active substances, the international non-proprietary name (INN) shall be included or, if one does not exist, the common name;**

~~**(aa) the name of the marketing authorisation holder placing the medicinal product on the market;**~~

(b) **if not already evident from the name or pharmaceutical form of the ~~of the~~ medicinal product,** the ~~method~~ **route** of administration;

(c) the expiry date;

(d) the batch number;

(e) the contents by weight, by volume or by unit.

Article 67

Safety features

1. Medicinal products subject to prescription shall bear the safety features referred to in Annex IV, unless they have been listed in accordance with the procedure referred to in paragraph 2, second subparagraph, point (b).

Medicinal products not subject to prescription shall not bear the safety features referred to in Annex IV, unless, by way of exception, they have been listed in accordance with the procedure referred to in paragraph 2, second subparagraph, point (b).

2. The Commission shall adopt delegated acts in accordance with Article 215 to supplement Annex IV by laying down detailed rules for the safety features.

Those delegated acts shall set out:

(a) the characteristics and technical specifications of the unique identifier of the safety features referred to in Annex IV **point (o)** that enables the authenticity of medicinal products to be verified and individual packs to be identified;

(b) the lists containing the medicinal products or product categories that, in the case of medicinal products subject to prescription shall not bear the safety features, and in the case of medicinal products not subject to prescription shall bear the safety features referred to in Annex IV **point (o)**;

(c) the procedures for the notification to the Commission provided for in paragraph 4 and a rapid system for evaluating and deciding on such notification for the purpose of applying point (b);

(d) the modalities for the verification of the safety features referred to in Annex IV **point (o)** by the manufacturers, wholesale distributors, pharmacists and natural or legal persons authorised or entitled to supply medicinal products to the public and by the competent authorities;

(e) provisions on the establishment, management and accessibility of the repositories system in which information on the safety features, enabling the verification of the authenticity and identification of medicinal products, as provided for in Annex IV **point (o)**, shall be contained.

The lists referred to in the second subparagraph, point (b), shall be established considering the risk of falsification relating to the medicinal products or categories of medicinal products concerned. To this end, at least the following criteria shall be applied:

(a) the price and sales volume of the medicinal product;

(b) the number and frequency of previous cases of falsified medicinal products being reported within the Union and in third countries and the evolution of the number and frequency of such cases to date;

(c) the specific characteristics of the medicinal products concerned;

(d) the severity of the conditions intended to be treated;

(e) other potential risks to public health.

The modalities referred to in the second subparagraph, point (d), shall allow the verification of the authenticity of each supplied pack of the medicinal products bearing the safety features referred to in Annex IV **point (o)** and determine the extent of such verification. When establishing those modalities, the particular characteristics of the supply chains in Member States, and the need to ensure that the impact of verification measures on particular actors in the supply chains is proportionate, shall be taken into account.

For the purposes of the second subparagraph, point (e), the costs of the repositories system shall be borne by the **marketing** authorisation holders of medicinal products bearing the safety features.

3. When adopting delegated acts referred to in paragraph 2, the Commission shall take due account of at least the following:
   (a) the protection of personal data as provided for in Union law;
   (b) the legitimate interests to protect information of a commercially confidential nature;
   (c) the ownership and confidentiality of the data generated by the use of the safety features; and
   (d) the cost-effectiveness of the measures.

4. The competent authorities of the Member States shall notify the Commission of non-prescription medicinal products that they judge to be at risk of falsification and may inform the Commission of medicinal products that they deem not to be at risk of falsification in accordance with the criteria set out in paragraph 2, second subparagraph, point (b).

5. Member States may, for the purposes of reimbursement or pharmacovigilance, extend the scope of application of the unique identifier referred to in Annex IV **point (o)** to any medicinal product subject to prescription or subject to reimbursement.

6. **The competent authorities** ~~Member States~~ may, for the purposes of reimbursement, pharmacovigilance, pharmacoepidemiology or ~~for data protection prolongation for market launch~~ **to monitor any expected potential or actual shortage of a medicinal product** use the information contained in the repositories system referred to paragraph 2, second subparagraph, point (e).

7. Member States may, for the purposes of patient safety, extend the scope of application of the anti-tampering device referred to in Annex IV to any medicinal product.

Article 68

Labelling and instruction ~~**package**~~ **leaflet** *of radionuclides and radiopharmaceuticals*

1. In addition to the rules laid down in this Chapter, the outer carton and the container of medicinal products containing radionuclides shall be labelled in accordance with the regulations for the safe transport of radioactive materials laid down by the International Atomic Energy Agency. Moreover, the labelling shall comply with the provisions set out in paragraphs 2 and 3.

2. The label on the shielding shall include the particulars laid down in Article 65. In addition, the label on the shielding shall explain in full, the codings used on the vial and shall indicate, where necessary, for a given time and date, the amount of radioactivity per dose or per vial and the number of capsules, or, for liquids, the number of millilitres in the container.

3. The vial shall be labelled with the following information:
   (a) the name or code of the medicinal product, including the name or chemical symbol of the radionuclide;
   (aa) strength and pharmaceutical form;
   (b) the batch identification and expiry date;
   (c) the international symbol for radioactivity;
   (d) the name and address of the manufacturer;
   (e) the amount of radioactivity as specified in paragraph 2.

4. The ~~competent authority~~ **marketing authorisation holder** shall ensure that a detailed instruction ~~**package**~~ leaflet is enclosed with the packaging of radiopharmaceuticals, radionuclide generators, radionuclide kits or radionuclide precursors. The text of this leaflet shall be established in accordance with Article 64(1). In addition, the leaflet shall include any precautions to be taken by the user and the patient during the preparation and administration of the medicinal product and special precautions for the disposal of the packaging and its unused contents.

Article 69

Special information requirements for antimicrobials

1. The marketing authorisation holder shall ensure availability of educational material to healthcare professionals, including through medical sales representatives as referred to in Article 175(1), point (c), regarding the appropriate use of diagnostic tools, testing or other diagnostic approaches related to antimicrobial-resistant pathogens, that may inform on the use of the antimicrobial.

2. The marketing authorisation holder shall include in the package**ing leaflet** of antimicrobials a ~~document~~ **section** that contains specific information about the medicinal product concerned ~~and that is made available to the patient in addition to the product leaflet ("awareness card")~~ with information on antimicrobial resistance and the appropriate use and disposal of antimicrobials.

~~Member States may decide that the awareness card shall be made available in paper format or electronically, or both. In the absence of such specific rules in a Member State, an awareness card in paper format shall be included in the packaging of an antimicrobial.~~

~~3. The text of the awareness card shall be aligned with Annex VI.~~

4. On the outer packaging the marketing authorisation holder shall include the antimicrobial resistance worldwide symbol and the warning referred to in ~~point 8 of~~ Annex VI point 8.

Article 70

Legibility

The package leaflet and labelling particulars referred to in this Chapter shall be easily legible, clearly comprehensible and indelible.

Article 71

Accessibility for persons with disabilities

The name of the medicinal product**, followed by its strength, if available, and pharmaceutical form, if applicable, ~~as well as the location of the reference to the electronic package leaflet,~~** shall also be expressed in Braille format on the packaging**~~, with the exception of medicinal products that are to be administered by healthcare professionals~~**. The marketing authorisation holder shall ensure that the package leaflet referred to in Article 63 is made available upon request from patients' organisations in formats appropriate for persons with disabilities, including blind and partially-sighted persons. ~~**This includes providing the package leaflet in audio format, whenever the package leaflet is made available electronically**~~.

Article 72

Member States labelling requirements

1. Notwithstanding Article 7~~7~~**8** Member States may require the use of certain forms of labelling of the medicinal product making it possible to ascertain:
   (a) the price of the medicinal product;
   (b) the reimbursement conditions ~~of social security organisations~~;
   (c) the legal status for supply to the patient, in accordance with Chapter IV;
   (d) authenticity and identification in accordance with Article 67(5)**;**
   ~~**(e) symbols and pictograms referred to in art. 73**~~.

2. For medicinal products for which a centralised marketing authorisation as referred to in Article 5 has been granted, Member States shall, when applying this Article, ~~observe~~ **consider** the detailed guidance referred to in Article 77.

Article 73

Symbols and pictogram

1. The ~~outer~~ packaging and the package leaflet may include symbols or pictograms designed to clarify certain information set out in Articles 64(1)**,** ~~and~~ 65 **and 66** and other information compatible with the summary of product characteristics that is useful for the patient, to the exclusion of any element of a promotional nature.

2. Symbols and pictograms and other information referred to in paragraph 1 shall be construed also as quick response codes, as well as other similar carriers of information, as allowed by technology.

Article 74

Requirements on languages

1. The particulars ~~for labelling~~ listed in Articles 64 ~~and~~ **to** 65**6**, shall appear in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State.

2. Paragraph 1 shall not prevent those particulars from ~~being~~ ~~indicated~~ **appearing** in several languages, provided that the same particulars appear in all the languages used.

3. The package leaflet must be clearly legible in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State.

4. ~~The competent authorities of the~~ Member State may ~~also~~ grant a full or partial exemption to the obligation that the labelling and the package leaflet must be in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State **in the following cases:**

(a) where the medicinal product is not intended to be delivered directly to the patient;

(b) where there is insufficient the availability of the medicinal product to meet the needs of patients in that Member State;

~~(c) in the context of a public health emergency at Union level~~.

~~The Member State that avails of this possibility shall ensure that the labelling and the package leaflet appear in an official language of the other Member State that is commonly understood in that Member State~~.

For the purpose of multi-language**, multi-country** packages, Member States may allow the use on the labelling and package leaflet of an official language of the Union that is commonly understood in the Member States where the multi-language**, multi-country** package is marketed.

Article 75

Member States exemptions from requirements for labelling and package leaflet

The competent authorities of the Member States may, subject to measures they consider necessary to safeguard public health, grant an exemption to the obligation that the particulars required in Articles 64**,** ~~and~~ 65 **and 66** should appear on the labelling and in the package leaflet in the following cases:

(a) where the medicinal product is not intended to be delivered directly to the patient;

(b) where there are problems in respect of the availability of the medicinal product;

(c) where there are space constraints due to the size of the packaging or of the package leaflet or in case of multilingual packages or package leaflets;

(d) in the context of a public health emergency;

(e) to facilitate access to medicines in Member States.

Article 76

Approval of the labelling and package leaflet information

1. One or more mock-ups of the outer packaging and the immediate packaging of a medicinal product, together with the package leaflet, shall be submitted to the competent authorities for authorising marketing when the marketing authorisation is requested. The results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority.

2. The competent authority shall refuse the marketing authorisation if the labelling or the package leaflet do not comply with the provisions of this Chapter or if they are not in accordance with the particulars listed in the summary of product characteristics.

3. All proposed changes to an aspect of the labelling or the package leaflet covered by this Chapter and not connected with the summary of product characteristics shall be submitted to the competent authorities. If the competent authorities have not opposed a proposed change within 90 days following the ~~introduction~~ **submission** of the request, the applicant may put the change into effect.

4. The fact that the competent authority does not refuse a marketing authorisation pursuant to paragraph 2 or a change to the labelling or the package leaflet pursuant to paragraph 3 does not alter the general legal liability of the manufacturer and the marketing authorisation holder.

Article 77

Guidance on labelling particulars

In consultation with the Member States and the parties concerned, the Commission shall draw up and publish detailed guidance concerning in particular:

(a) the wording of certain special warnings for certain categories of medicinal products;

(b) the particular information needs relating to non-prescription medicinal products;

(c) the legibility of particulars on the labelling and package leaflet;

(d) the methods for the identification and authentication of medicinal products;

~~(e) the list of excipients that must featurethat may feature on the labelling of medicinal products and the way in which these excipients must be indicated~~ **the information for specific excipients that feature on the labelling of medicinal products**;

(f) harmonised provisions for the implementation of Article 72~~.~~**;**

(g) harmonised use of symbols, pictograms and abbreviations.

~~*Article 77a*~~

~~*List of excipients*~~

~~The Commission shall adopt an implementing act in accordance with the examination procedure referred to in Article 214(2) to establish a list of excipients that shall feature on the labelling of medicinal products and the way in which these excipients shall be indicated.~~

Article 78

Placing on the market of labelled medicinal products

Member States may not prohibit or impede the placing on the market of medicinal products within their territory on grounds connected with labelling or the package leaflet where these comply with the requirements of this Chapter.

Article 79

Non-compliance with the requirements for labelling and package leaflet

Where the provisions of this Chapter are not complied with, and a notice served on the marketing authorisation holder concerned has remained without effect, the competent authorities of the Member States may suspend the marketing authorisation, until the labelling and the package leaflet of the medicinal product in question have been made to comply with the requirements of this Chapter.

ANNEX IV

LABELLING PARTICULARS

The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:

(a) the name of the medicinal product, including in Braille, followed by its strength**, if available,** and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults; where the medicinal product contains up to three active substances, the international non-proprietary name (INN) shall be included, or, if one does not exist, the common name;

(b) a statement of the active substances expressed qualitatively and quantitatively per dos~~eage~~ **or** unit or according to the form of administration for a given volume or weight, using their common names;

(c) the pharmaceutical form and the contents by weight, by volume or by number of doses of the medicinal product**, or number of units of administration of the medicinal product**;

(d) a list of those excipients**, expressed qualitatively,** known to have a recognised action or effect ~~and included in the detailed guidance **implementing act** published pursuant to Article 68 77a~~; **in the case of injectable medicinal products, topical preparations or eye drops, all excipients shall be listed**;

(e) the method of administration and, if necessary, the route**(s)** of administration. Space shall be provided for the prescribed dose to be indicated;

(f) **if appropriate,** a special warning that the medicinal product must be stored out of the reach and sight of children;

(g) ~~a~~ special warning, if ~~this is~~ necessary for the medicinal product;

(h) the expiry date in clear terms (month/year);

(i) special storage precautions, if any;

(j) specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products, where appropriate, as well as reference to any appropriate collection system in place;

(ja) the antimicrobial resistance worldwide symbol referred to in Article 69 paragraph 4;

(k) the name and address of the marketing authorisation holder and, where applicable, the name of the representative appointed by the holder to represent them;

(l) the number of the marketing authorisation for placing the medicinal product on the market;

(m) the manufacturer's batch number;

(n) in the case of non-prescription medicinal products, instructions for use;

(o) for medicinal products other than radiopharmaceuticals referred to in Article 67(1), safety features enabling wholesale distributors and persons authorised or entitled to supply medicinal products to the public to:

(i) verify the authenticity of the medicinal product, and

(ii) identify individual packs,

- as well as a device allowing verification of whether the outer packaging has been tampered with.

Annex V

CONTENTS OF SUMMMARY PRODUCT CHARACTERISTICS

The summary of product characteristics shall contain, in the order indicated below, the following information:

(1) name of the medicinal product followed by the strength**, if available,** and the pharmaceutical form.

(2) qualitative and quantitative composition in terms of the active substances and of the excipient**s**, knowledge of which is essential for proper administration of the medicinal product. The usual common name or chemical description shall be used.

(3) pharmaceutical form.

(4) clinical particulars:

  (a) therapeutic indications,

  (b) posology and method of administration for adults and, where necessary for children,

  (c) contra-indications,

  (d) special warnings and precautions for use and, in the case of immunological medicinal products, any special precautions to be taken by persons handling such medicinal products and administering them to patients, together with any precautions to be taken by the patient,

  (e) interaction with other medicinal products and other forms of interactions,

  (f) use during pregnancy**,** ~~and~~ ~~lactation~~ **breastfeeding, and information on influence on fertility**,

  (g) effects on ability to drive and to use machines,

  (h) undesirable effects**,** ~~**followed by**~~ **including standarised text expressly asking healthcare professionals to report any suspected adverse reaction in accordance with the national reporting system referred to in Article 106(1) and specifying the different ways of reporting available (electronic reporting, postal address or others) in compliance with Article 106(1), second subparagraph**;

  (i) overdose (symptoms, emergency procedures, antidotes).

(5) pharmacological properties:

  (a) pharmacodynamic properties,

  (b) pharmacokinetic properties,

(c) non-clinical safety data.

(6) pharmaceutical particulars:

(a) list of excipients,

(b) major incompatibilities,

(c) shelf life **and**, when necessary**, shelf life** after reconstitution**/dilution** of the medicinal product or when the immediate packaging is opened for the first time,

(d) ~~special~~ precautions for storage,

(e) nature and contents of container,

(f) ~~special~~ precautions for disposal of a used medicinal product or waste materials derived from such medicinal product, if appropriate. In case of antimicrobial medicinal products in addition to the precautions a warning that inappropriate disposal of the medicinal product contributes to antimicrobial resistance.

(7) marketing authorisation holder.

(8) marketing authorisation numbers.

(9) date of the first marketing authorisation or renewal of the marketing authorisation.

(10) date of revision of the text.

(11) for radiopharmaceuticals, full details of internal radiation dosimetry.

(12) for radiopharmaceuticals, additional detailed instructions for extemporaneous preparation and quality control of such preparation and, where appropriate, maximum storage time during which any intermediate preparation such as an eluate or the ready-to-use pharmaceutical will conform with its specifications.

~~For marketing authorisations under Articles 9 to 12 and subsequent variations, those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms that are still covered by patent law at the time when a generic or biosimilar medicinal product is placed on the market need not be included.~~

Annex VI

CONTENTS OF PACKAGE LEAFLET

The package leaflet shall contain, in the order indicated below, the following information:

(1) for the identification of the medicinal product:

(a) the name of the medicinal product followed by its strength**, if available,** and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults. ~~The common name shall be included where the medicinal product contains only one active substance and if its name is an invented name~~ **Where the medicinal product contains up to three active substances, the international non-proprietary name (INN) shall be included, or, if one does not exist, the common name**;

(b) the pharmaco-therapeutic group or type of activity in terms easily comprehensible for the patient;

(2) the therapeutic indications;

(3) a list of information that is necessary before the medicinal product is taken:

(a) contra-indications;

(b) appropriate precautions for use;

(c) forms of interaction with other medicinal products and other forms of interaction (e.g. alcohol, tobacco, food **and herbal preparations**) that may affect the action of the medicinal product;

(d) special warnings;

(4) the necessary and usual instructions for proper use, and in particular:

(a) the dos~~age~~**/posology**,

(b) the method and, if necessary, route of administration;

(c) the frequency of administration, specifying if necessary the appropriate time at which the medicinal product may or must be administered;

~~• and, as appropriate, depending on the nature of the medicinal product:~~

(d) the duration of treatment, where it should be limited;

(e) the action to be taken in case of an overdose (such as symptoms, emergency procedures)**, if applicable**;

(f) what to do when one or more doses have not been taken;

(g) indication, if necessary, of the risk of withdrawal effects;

(h) a specific recommendation to consult the doctor or the pharmacist, as appropriate, for any clarification on the use of the medicinal product;

(5) a description of the adverse reactions that may occur under normal use of the medicinal product and, if necessary, the action to be taken in such a case – ~~**followed by**~~ **including standardised text expressly asking patients to communicate any suspected adverse reaction to their doctor, pharmacist, healthcare professional or directly to the national reporting system referred to in Article 106(1), and specifying the different ways of reporting available (electronic reporting, postal address or others) in compliance with Article 106(1), second subparagraph**;

(6) references to the following:

(a) the expiry date indicated on the label, with a warning against using the medicinal product after that date;

(b) where appropriate, ~~special~~ storage precautions;

(c) if necessary, a warning concerning certain visible signs of deterioration;

(d) the full qualitative composition (in active substances and excipients) and the quantitative composition in active substances, using common names, for each presentation of the medicinal product;

(e) for each presentation of the medicinal product, the pharmaceutical form and content in weight, volume or units of dosage;

(f) information on where the leaflet is available in formats accessible for persons with disabilities;

(g) the name**,** ~~and~~ address **and e-mail address** of the marketing authorisation holder and, where applicable, the name of their appointed representatives in the Member States;

(h) the name and address of the manufacturer.

(7) the date on which the package leaflet was last revised;

(8) for antimicrobials, a warning that improper use and disposal of the medicinal product contributes to antimicrobial resistance **and the antimicrobial worldwide symbol referred to in Article 69 paragraph 4**.

The list set out in point (3) shall:

(a) take into account the particular condition of certain categories of users (children, pregnant or breastfeeding women, ~~older adults~~ **elderly**, persons with specific pathological conditions and persons with disabilities);

(b) mention, if appropriate, possible effects on the ability to drive vehicles or to operate machinery;

(c) list those excipients the knowledge of which is important for the safe and effective use of the medicinal product ~~and that are included in the detailed guidance~~ **implementing act** ~~referred to in Article 77~~**a**.

Chapter XIII
Advertising

Article 175

Definition of advertising of medicinal products

1. For the purposes of this Chapter, 'advertising of medicinal products' shall include ~~**the representation in**~~ any form ~~of door-to-door~~ information~~, canvassing~~ activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products.

It shall include in particular:

(a) the advertising of medicinal products to the general public;

(b) advertising of medicinal products to persons qualified to prescribe, administer **while providing healthcare** or supply them**, referred to in this Chapter as healthcare professionals**;

(c) visits by medical sales representatives to **healthcare professionals** ~~persons qualified to prescribe **or qualified to supply** medicinal products~~;

(ca) other agreements or partnerships between undertakings and healthcare professionals or entities contracting their services~~, that can directly or indirectly influence prescribing behavior~~;

(d) the supply of samples of medicinal products ~~**free of charge**~~;

(e) 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;

(f) sponsorship of promotional meetings attended by **healthcare professionals** ~~persons qualified to prescribe or supply medicinal products~~;

(g) sponsorship ~~of~~ **or any other form of financial contribution for** scientific ~~congresses~~ **events**, attendend by ~~persons qualified to prescribe or supply medicinal products~~ **healthcare professionals** and in particular payment **to the organising entity,** of ~~their~~ **participants'** travelling ~~and~~, accomodation **and catering** expenses in connection therewith.

(h) advertising related to medicinal products, that does not refer to specific medicinal products.

2. The following are not covered by this Chapter:

(a) the labelling and package leaflets, which are subject to the provisions of Chapter VI;

(b) correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product**, without the intention of promoting the marketing or consumption of the medicinal product**;

(c) 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;

(d) information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products.

Article 176

General provisions on advertising of medicinal products

1. Member States shall prohibit any advertising of a medicinal product in respect of which a marketing authorisation has not been granted.

2. All parts of the advertising of a medicinal product must comply with the particulars listed in the summary of product characteristics.

3. The advertising of a medicinal product:
   (a) shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties;
   (b) shall be accurate, verifiable and not be misleading.

4. Any form of advertising that aims to highlight negatively another medicinal product shall be prohibited. Advertising that suggests that a medicinal product is safer or more effective than another medicinal product shall also be prohibited, unless demonstrated and supported by the summary of product characteristics.

Article 177

Restrictions on advertising of medicinal products

1. Member States shall prohibit the advertising to the general public of medicinal products that:
   (a) are available on medical prescription only, in accordance with Chapter IV;
   (b) contain substances classified as psychotropic or narcotic within the meaning of international conventions.

2. Medicinal products may be advertised to the general public where, by virtue of their composition and purpose, they are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.

3. Member States shall be entitled to ban, on their territory**:** ~~:~~
   - advertising to the general public of medicinal products the cost of which may be reimbursed**;**
   - **advertising related to medicinal products that does not refer to a specific medicinal product**.

4. The prohibition contained in paragraph 1 shall not apply to **promotion of** ~~vaccination~~ campaigns **promoting vaccinations** carried out **or** ~~by the industry and~~ approved by the ~~competent authorities of the~~ Member States.

5. The prohibition referred to in paragraph 1 shall apply without prejudice to Article 21 of Directive 2010/13/EU.

6. Member States shall prohibit the direct distribution of medicinal products to the public by the industry for promotional purposes.

~~**7. Member States may ban, in their territory, advertising to the general public of medicinal products that are a risk to the environment.**~~

~~**8. Member States may ban or restrict, in their territory, advertising related to medicinal products that does not refer to a specific medicinal product;**~~

9. Member States may suspend the advertising of a medicinal product in case of shortages or risk of shortage of -this- medicinal product. The suspension shall be withdrawn as soon as the shortage or risk of shortage ceases.

10. Member States may ~~maintain and~~ apply stricter measures with regard to advertisment of medicinal products to healthcare professionals qualified to administer medicinal products.

Article 178

Advertising to the general public

1. Without prejudice to Article 177, all advertising to the general public of a medicinal product shall:
   (a) be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product; **and**
   (b) include the following minimum information:
      (i) the name of the medicinal product, as well as the common name if the medicinal product contains only one active substance;
      (ii) the information necessary for correct use of the medicinal product;
      (iii) an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be.

2. Member States may decide that the advertising of a medicinal product to the general public may, notwithstanding paragraph 1, include only the name of the medicinal product or its active substance, or the trademark if it is intended solely as a reminder.

Article 179

Restrictions on advertising to the general public

1. The advertising of a medicinal product to the general public shall not contain any material that:
   (a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment **by any means** ~~by mail~~;
   (b) suggests that the effects of taking the medicinal product are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product;
   (c) suggests that the health of the subject can be enhanced by taking the medicinal product;
   (d) suggests that the health of the subject could be affected by not taking the medicinal product;
   (e) is directed exclusively or principally at children;
   (f) refers **directly or indirectly** to a recommendation by scientists, healthcare professionals**, healthcare facilities** or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products;
   (g) suggests that the medicinal product is a food, cosmetic or other consumer product;
   (h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is **of natural origin** ~~natural~~;
   (i) could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
   (j) refers, in improper, alarming or misleading terms, to claims of recovery;
   (k) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.

2. The prohibition set out in the paragraph 1, point (d), shall not apply to the **promotion of** vaccination campaigns referred to in Article 177(4).

Article 180

Advertising to ~~persons qualified to prescribe, administer or supply medicinal products~~ ***healthcare professionals***

1. Any advertising of a medicinal product to ~~persons qualified to prescribe, administer or supply such products~~ **healthcare professionals** shall include **both of the following**:

   (a) essential information compatible with the summary of product characteristics;

   (b) the ~~supply~~ prescription status of the medicinal product~~.~~**;**

   ~~**(c) information regarding any risks to the environment caused by the medicinal product.**~~

   Member States may also require such advertising to include the selling price or indicative price of the various presentations and the conditions for reimbursement ~~by social security bodies~~.

2. Member States may decide that the advertising of a medicinal product to ~~persons qualified to prescribe, administer or supply such products~~ **healthcare professionals** may, notwithstanding paragraph 1, include only the name of the medicinal product, or its international non-proprietary name, where this exists, or the trademark, if it is intended solely as a reminder.

Article 181

Supporting documentation for advertising to ~~persons qualified to prescribe, administer or supply medicinal products~~ ***healthcare professionals***

1. Any documentation relating to a medicinal product that is transmitted as part of the promotion of that medicinal product to persons qualified to prescribe, administer or supply it shall include, as a minimum, the particulars listed in Article 180(1) and shall state the date on which it was drawn up or last revised.

2. All the information contained in the documentation referred to in paragraph 1 shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicinal product concerned.

3. Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works for use in the documentation referred to in paragraph 1 shall be faithfully reproduced and the precise sources indicated.

Article 182

Obligations related to medical sales representatives

1. Medical sales representatives shall be given adequate training by the**ir employer** ~~undertaking that employs them~~ and shall have sufficient scientific knowledge to be able to provide information that is precise and as complete as possible about the medicinal products that they promote. The information provided by medical sales representatives shall be in accordance with Article 176.

2. During each visit, medical sales representatives shall give the persons visited, or have available for them, summaries of the product characteristics of each medicinal product they present together, if the legislation of the Member State so permits, with details of the price and conditions for reimbursement referred to in Article 180(1), second subparagraph.

3. Medical sales representatives shall transmit to the scientific service referred to in Article 187(1) any information about the use of the medicinal products they advertise, with particular reference to any adverse reactions reported to them by the persons they visit.

Article 183

Promotion of medicinal products

1. Where medicinal products are being promoted to ~~persons qualified to prescribe or supply them~~ **healthcare professionals**, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.

2. **Where medicinal products are being promoted, h**~~H~~ospitality at sales promotion events shall always be strictly limited to their main purpose and must not be extended to persons other than ~~persons qualified to prescribe or supply medicinal products~~ **healthcare professionals**. ~~**Member States may decide to extend this provision to representatives of patient organisations.**~~

3. ~~Persons qualified to prescribe or supply medicinal products~~ **Healthcare professionals** shall not solicit or accept any inducement prohibited under paragraph 1 or contrary to paragraph 2.

4. Existing measures or trade practices in Member States relating to prices, margins and discounts shall not be affected by the rules set out in paragraphs 1, 2 and 3.

Article 184

Hospitality at scientific events

The provisions of Article 183(1) shall not prevent hospitality being offered, directly or indirectly, at events for purely professional and scientific purposes. Such hospitality shall always be strictly limited to the main scientific objective of the event. It must not be extended to persons other than ~~persons qualified to prescribe or supply medicinal products~~ **healthcare professionals**.

Article 185

Provision of samples of medicinal products ~~***free of charge***~~

1. ~~Free s~~**S**amples of medicinal products shall be provided ~~**free of charge**~~ on an exceptional basis only to persons qualified to prescribe them and on the following conditions:
   (a) the number of samples for each medicinal product each year on prescription shall be limited;
   (b) any supply of samples shall be in response to a written request, signed and dated, from the persons qualified to prescribe or supply medicinal products;
   (c) the persons ~~qualified to~~ **who** supply samples shall maintain an adequate system of control and accountability;
   (d) each sample shall be no larger than the smallest presentation on the market;

(e) each sample shall be marked ‘free medical sample — not for sale’ or shall show some other wording having the same meaning;

(f) each sample shall be accompanied by a copy of the summary of product characteristics;

(g) no samples of medicinal products containing substances classified as psychotropic or narcotic within the meaning of international conventions may be supplied.

2. On an exceptional basis, free samples of medicinal products not subject to medical prescription may also be provided to persons qualified to supply them, subject to the conditions of paragraph 1.

3. Member States may also place further restrictions on the distribution of samples of certain medicinal products ~~**free of charge**~~.

Article 186

Implementation of advertising provisions by the Member States

1. Member States shall ensure that there are adequate and effective methods to monitor the advertising of medicinal products. Such methods, which may be based on a system of prior vetting, shall in any event include legal provisions under which persons or organisations regarded under national law as having a legitimate interest in prohibiting any advertisement inconsistent with this Chapter, may take legal action against such advertisement, or bring such advertisement before the competent authority of the Member State either to decide on complaints or to initiate appropriate legal proceedings.

2. Under the legal provisions referred to in paragraph 1, Member States shall confer upon the courts or competent authorities of the Member States powers enabling them, in cases where they deem such measures to be necessary, taking into account all the interests involved, and in particular the public interest:

(a) to order the cessation of, or to institute appropriate legal proceedings for an order for the cessation of, misleading advertising; or

(b) if misleading advertising has not yet been published but publication is imminent, to order the prohibition of, or to institute appropriate legal proceedings for an order for the prohibition of, such publication.

Member States shall confer upon the courts or competent authorities of the Member States the powers referred to in the first subparagraph, points (a) and (b), even without proof of actual loss or damage or of intention or negligence on the part of the advertiser.

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

It shall be for each Member State to decide which of the two options set out in the first subparagraph to select.

4. Member States may confer upon the courts or competent authorities of the Member States powers enabling them, with a view to eliminating the continuing effects of misleading advertising the cessation of which has been ordered by a final decision:
   (a) to require publication of that decision in full or in part and in such form as they deem adequate;
   (b) to require in addition the publication of a corrective statement.

5. The paragraphs 1 to 4 shall not exclude the voluntary control of advertising of medicinal products by self-regulatory bodies and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or administrative proceedings referred to in paragraph 1.

Article 187

Implementation of advertising provisions by the marketing authorisation holder

1. The marketing authorisation holders shall establish, within their undertaking or not-for-profit entities, a scientific service in charge of information about the medicinal products that they place on the market.

2. The marketing authorisation holder shall:
   (a) keep available for, or communicate to, the competent authorities of the Member States or bodies responsible for monitoring advertising of medicinal products, a sample of all advertisements emanating from its undertaking or not-for-profit entities together with a statement indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination;
   (b) ensure that advertising of medicinal products by their undertaking or not-for-profit entities conforms to the requirements of this Chapter;
   (c) verify that medical sales representatives employed by their undertaking or not-for-profit entities have been adequately trained and fulfil the obligations imposed upon them by Article 182, paragraphs 2 and 3;
   (d) supply the competent authorities of the Member States or bodies responsible for monitoring advertising of medicinal products with the information and assistance they require to carry out their responsibilities;
   (e) ensure that the decisions taken by the competent authorities of the Member States or bodies responsible for monitoring advertising of medicinal products are immediately and fully complied with.

3. The Member States shall not prohibit the co-promotion of a medicinal product by the marketing authorisation holders and one or more companies nominated by them.

Chapter IV
Prescription status

Article 50

Prescription status of medicinal products

1. When a marketing authorisation is granted, the competent authorities shall, by applying the criteria laid down in Article 51, specify the prescription status of the medicinal product as:
   (a) a medicinal product subject to medical prescription; or
   (b) a medicinal product not subject to medical prescription.

2. The competent authorities may fix sub-categories for medicinal products that are subject to medical prescription. In that case, they shall specify the following prescription status:
   (a) medicinal products subject to medical prescription for renewable or non-renewable delivery;
   (b) medicinal products subject to special medical prescription;
   (c) medicinal products on ‘restricted’ medical prescription, reserved for use in certain specialised areas.

Article 51

Medicinal products subject to medical prescription

1. A medicinal product shall be subject to medical prescription where it:
   (a) is likely to present a danger either directly or indirectly, even when used correctly, if used without medical supervision;
   (b) is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health;
   (c) contains substances or preparations thereof, the activity or adverse reactions of which require further investigation;
   (d) is normally prescribed by a doctor to be administered parenterally;

(e) is an antimicrobial; or

(f) contains an active substance which are persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, or persistent, mobile and toxic, or very persistent and very mobile**, and** for which medical prescription ~~is required~~ as risk minimisation measure with regard to the environment **is required**, unless **other circumstances of use justify** ~~the use of the medicinal product and the patient safety require~~ otherwise.

2. Member States may set additional conditions on the prescription of antimicrobials **or active substances which are persistent, bioaccumulative and toxic**, restrict the validity of medical prescription and limit the quantities prescribed to the amount required for the treatment or therapy concerned or submitting certain antimicrobial medicinal products to special medical prescription or restricted prescription.

3. Where Member States provide for the sub-category of medicinal products subject to special medical prescription, they shall take account of the following factors:

(a) the medicinal product contains, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic substance within the meaning of the international conventions;

(b) the medicinal product is likely, if incorrectly used, to present a substantial risk of medicinal abuse, to lead to addiction or be misused for illegal purposes; or

(c) the medicinal product contains a substance that, by reason of its novelty or properties, could be considered as belonging to the group set out in point (**b**~~a~~) as a precautionary measure.

4. Where Member States provide for the sub-category of medicinal products subject to restricted prescription, they shall take account of the following factors:

(a) the medicinal product, because of its pharmaceutical characteristics or novelty or in the interests of public health, is reserved for treatments that can only be followed in a hospital environment;

(b) the medicinal product is used in the treatment of conditions that must be diagnosed in a hospital environment or in institutions with adequate diagnostic facilities, although administration and follow-up may be carried out elsewhere;

(c) the medicinal product is intended for outpatients but its use may produce very serious adverse reactions requiring a prescription drawn up as required by a specialist and special supervision throughout the treatment.

5. A competent authority may waive application of **criteria set out in** ~~the~~ paragraphs 1, 3 and 4 **regarding the medical prescription,** having regard to:
   (a) the maximum single dose, the maximum daily dose, the strength, the pharmaceutical form, certain types of packaging; or
   (b) other circumstances of use that it has specified.

6. If a competent authority does not designate medicinal products into sub-categories referred to in Article 50(2), it shall nevertheless take into account the criteria laid down in paragraphs 3 and 4 in determining whether any medicinal product shall be classified as a medicinal product subject to medical prescription.

Article 52

Medicinal products not subject to medical prescription

A ~~M~~**m**edicinal product~~s~~ **shall** not **be** subject to medical prescription **if the medicinal product does** ~~shall be those that do~~ not meet the criteria laid down in Article 51**, paragraphs 1, 3 and 4 or if Article 51, paragraph 5, is applicable**.

~~*Article 53*~~

~~*List of medicinal products subject to medical prescription*~~

~~The competent authorities shall draw up a list of the medicinal products subject, on their territory, to medical prescription, specifying, if necessary, the category of prescription status. They shall update this list annually.~~

Article 54

Amendment of prescription status

When new facts are brought to their attention, the competent authorities shall examine and, as appropriate, amend the prescription status of a medicinal product by applying the criteria listed in Article 51. **In such cases, the marketing authorisation holder shall on their own initiative or on request of a competent authority, ~~the marketing authorisation holder shall~~ submit a variation to amend the prescription status**.

In case of a potential or actual shortage of a medicinal product that puts patients' needs or public health at risk, a competent authority may temporarily amend the prescription status of a medicinal product. The amendment shall be withdrawn as soon as the shortage or risk of shortage ceases.

Article 55

Data protection of evidence for the change of prescription status

Where a change of prescription status of a medicinal product has been authorised on the basis of significant non-clinical tests or clinical studies, the competent authority shall not refer to the results of those tests or studies when examining an application by another applicant for or marketing authorisation holder for a change of prescription status of the same substance for one year after the initial change was authorised.

Chapter V

Obligations and liability of the marketing authorisation holder

Article 56

General obligations

1. The marketing authorisation holder shall be responsible for the making available on the market of the medicinal product covered by the marketing authorisation it has been granted. The designation of a marketing authorisation holder representative shall not relieve the marketing authorisation holder of its legal responsibility.

2. The marketing authorisation holder of a medicinal product placed on the market in a Member State shall notify the competent authority of the Member State concerned of the date of actual placing on the market of the medicinal product in that Member State, taking into account the various presentations authorised.

3. The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate and continued supplies of that medicinal product to wholesale distributors, pharmacies or persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.

   The arrangements for implementing the first subparagraph should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition.

4. The marketing authorisation holder shall, at all stages of manufacturing and distribution ensure that the starting materials and ingredients of the medicinal products and the medicinal products themselves comply with the requirements of this Directive and, where relevant, the [revised Regulation (EC) No 726/2004] and other Union law and shall verify that such requirements are met.

5. For integral combination of a medicinal product with a medical device and for combinations of a medicinal product with a product other than a medical device, the marketing authorisation holder shall be responsible for the whole product in terms of compliance of the medicinal product with the requirements of this Directive and the [revised Regulation (EC) No 726/2004].

6. The marketing authorisation holder shall be established in the Union.

7. Where the marketing authorisation holder considers or has reason to believe that the medicinal product it has made available on the market is not in conformity with the marketing authorisation or this Directive and the [revised Regulation (EC) No 726/2004] it shall immediately take the necessary corrective actions to bring that medicinal product into conformity, to withdraw it or recall it, as appropriate. The marketing authorisation holder shall immediately inform the competent authorities and the distributors concerned to that effect.

8. Upon request, the marketing authorisation holder shall provide the competent authorities with free samples in sufficient quantities to enable controls to be made on the medicinal products that it has placed on the market.

9. Upon request the marketing authorisation holder shall provide the competent authority with all data relating to the volume of sales of the medicinal product, and any data in its possession relating to the volume of prescriptions.

Article 57

Responsibility to report on public financial support

1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority or publicly funded body, in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.

2. Within 30 days after the marketing authorisation is granted the marketing authorisation holder shall:

(a) draw up an electronic report listing:

(i) the amount of financial support received and the date thereof;

(ii) the public authority or publicly funded body that provided the financial support referred to in point (i);

(iii) the legal entity that received the support referred to in point (i).

(b) ensure that the electronic report is accurate and that it has been audited by an independent external auditor;

(c) make the electronic report accessible to the public via a dedicated webpage;

(d) communicate the electronic link to such webpage to the competent authority of the Member State or, where appropriate, to the Agency.

3. For the medicinal products authorised under this Directive, the competent authority of the Member State shall communicate in a timely manner the electronic link to the Agency.

4. The marketing authorisation holder shall keep the electronic link up to date and, as necessary, update the report annually.

5. The Member States shall take appropriate measures to ensure that paragraphs 1, 2 and 4 are complied with by the marketing authorisation holder established in their country.

6. The Commission may adopt implementing acts to lay down the principles and format for the information to be reported pursuant to paragraph 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).

Article 58

Traceability of substances used in the manufacture of medicinal products

1. The marketing authorisation holder shall, when necessary, ensure the traceability of an active substance, starting material, excipient or any other substance intended or expected to be present in a medicinal product at all stages of manufacturing and distribution.

2. The marketing authorisation holder shall be able to identify any natural or legal person from whom they have been supplied with an active substance, starting material, excipient or any other substance intended or expected to be present in a medicinal product.

3. The marketing authorisation holder and its suppliers of an active substance, starting material, excipient or any other substance used in the manufacturing of a medicinal product shall have in place systems and procedures that allow for the information referred to in paragraph 2 to be made available, upon request, to the competent authorities.

4. The marketing authorisation holder and its suppliers shall have in place systems and procedures to identify the other natural or legal persons to whom products referred to in paragraph 2 have been supplied. This information shall, upon request, be made available to the competent authorities.

Article 59

Placing on the market of products with paediatric indications

Where medicinal products are authorised for a paediatric indication following completion of an agreed paediatric investigation plan and those medicinal products have already been marketed with other therapeutic indications, the marketing authorisation holder shall, within two years of the date on which the paediatric indication is authorised, place the medicinal product on the market taking into account the paediatric indication in all Member States where the medicinal product is already placed on the market.

A register, coordinated by the Agency, and made publicly available, shall mention these deadlines.

Article 60

Discontinuation of the placing on the market of paediatric products

If a medicinal product is authorised for a paediatric indication and the marketing authorisation holder has benefited from rewards or incentives under Article 86 of this Directive or Article 93 of [revised Regulation (EC) No 726/2004], and these periods of protection have expired, and if the marketing authorisation holder intends to discontinue placing the medicinal product on the market, the marketing authorisation holder shall transfer the marketing authorisation to a third party or allow a third party, which has declared its intention to continue to place the medicinal product in question on the market, to use the pharmaceutical, non-clinical and clinical documentation contained in the file of the medicinal product on the basis of Article 14.

The marketing authorisation holder shall inform the competent authorities of its intention to discontinue the placing on the market of the medicinal product no less than twelve months before the discontinuation. The competent authorities shall make this fact publicly available.

Article 61

Liability of the marketing authorisation holder

The marketing authorisation shall not affect the civil and criminal liability of the marketing authorisation holder.