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LIMITE

SAN	**VETER**
PHARM	**ENV**
MI	**RECH**
COMPET	**CODEC**
	PI

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CONTRIBUTION

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Pharmaceutical package
Subject:	Pharma package - Comments from the delegations

Delegations will find enclosed comments from delegations on the 'Labelling/advertising and prescriptions' and the 'Pharmacovigilance' clusters.

COMMENTS FROM THE DELEGATIONS

On the 'Labelling/advertising and prescriptions' and the 'Pharmacovigilance' clusters

1. AUSTRIA (p 6)

2. CZECH REPUBLIC (p 92)

3. DENMARK (p 135)

4. FINLAND

Please find below FI comments on **Pharmacoviglance** (doc 7998) and **reading package 1 (Chapter II Application requirements for national and centralized marketing authorization**).

Pharmacoviglance
Article 105. Para 6. (doc. 7998) and Article 104 para 4.

Justification:
It seems unreasonable to demand that distributors have systems capable of reporting directly to the EV database. However, medicine wholesalers/distributors and marketing authorisation holders often have agreements for exchanging information about adverse reaction reports among themselves. Therefore, it is suggested that the distributor should report adverse reactions to the EU/EEA-area marketing authorisation holder, or if there is none, to the national authority (but not both, to avoid duplicates).

FI Proposal:
Undertakings supplying medicinal products used in accordance with Article 3, paragraphs 1 or 2, shall without delay forward to the MAH located in the EU/ETA or to the competent authority of the Member State any notification they receive regarding suspected adverse effects relating to those medicinal products.

5. FRANCE (p 225)

6. GERMANY

DE thanks the Presidency for providing the final compromise texts on labelling and pharmacovigilance. We have noted that some of DE´s written comments regarding environmental issues such as the explicit designation of environmental information in PI and SPC, including information for radionuclides and radiopharmaceuticals as well as the immediate provision of a PI in paper form if patients so wish, and the possibility of a ban on advertising for particularly environmentally critical medicinal products at national level have not been taken into account. Ultimately, these requirements do not go beyond the current practice, but would create significantly more clarity in the legal text and thus in daily practice and avoid room for interpretation. DE explicitly wants to point this out once again.

7. GREECE (p 227)

8. IRELAND (p 270)

9. NETHERLANDS (p 277)

Pharmacovigilance:

- **DIR article 99(7)** We support the addition. However, MAH should not be obliged to comply all pharmacovigilance tasks after withdrawal. Our interpretation of the current text doesn't allow this. We propose to change the text and work out guidance to clarify the specific pharmacovigilance tasks the MAH should still comply with after withdrawal.
- We have two small coherence remarks on DIR art 102 and REG 107(2)

Labelling:

- **DIR 51(1(f)** We support the categorisation in this PARA. However, the "and" is directly placed after category (iv), which now implies that this condition is only linked to category (iv) instead (i) to (iv). We therefore propose to clarify the text on this.

10. SPAIN

1. Article 63, article 69 and Annex (IV):

For ES it is important to include the ***"Global Antimicrobial Resistance Symbol"*** on the ***outer packaging*** **and the** ***leaflet.*** Please find below ES proposal (in yellow)

Article 63 (leaflet)

6.e: the details of implementing commonly recognised global antimicrobial resistance symbol in the section that contains specific information about the medicinal product concerned, information on antimicrobial resistance and the importance of appropriate use and disposal of antimicrobials.

Article 69

2. The marketing authorisation holder shall include in the beginning of the package leaflet of antimicrobials a section that contains the global antimicrobial resistance symbol, specific information about the medicinal product concerned and information on antimicrobial resistance and the importance of appropriate use and disposal of antimicrobials.

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

Annex IV (outer packaging)

Ja) the global antimicrobial resistance symbol referred to in Article 69 paragraph 4;

Annex VI (CONTENTS OF PACKAGE LEAFLET)

Here again the PRES is talking about warning and it is not in line with the proposal in 69.2. To ensure the articles are aligned ES proposes the following text:

8) for antimicrobials, a section that contains the global antimicrobial resistance symbol, specific information about the medicinal product concerned and information on antimicrobial resistance and the importance of appropriate use and disposal of antimicrobials referred to in Article 69 paragraph 2.

General comment: From ES we are aware that outer packaging warning may pose a problem for multilingual countries. Thereby, we can be flexible in this point. Regarding the awareness card, we would prefer include it as a separate element as mentioned in the meetings. Nonetheless, we know that during Council discussions this card proposed by the Commission has not progressed. We welcome the work done by the Presidency as the text now include a section with special information on AMR and how to use and dispose of antimicrobials correctly so, although the card is our preferred option.

That said, we want to emphasise that we have been flexible in these two points and after revising the delegations comments and the last minutes meeting, we insist that Global Antimicrobial Resistance Symbol appears on the outer packaging.

Note: the official name of the Symbol "Global Antimicrobial Resistance Symbol".

2. 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**, as well as in the English language in the electronic version of the package leaflet**.

Rationale: As this article is part of the DIR, we do not consider it useful for an authorised medicinal product and for its use in Spain that the electronic package leaflet is in English.

11. SWEDEN (p 279)

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		AT General Comment: Regarding the provision of paper leaflets, it is essential for AT that member states' autonomy is not restricted.
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 the**		

packaging in paper format and electronically in accordance with the specifications, standards and format specified by the implementing act pursuant to paragraph 6. The competent authorities shall make publicly available the electronic package leaflet on their websites.		
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~~ from paragraph 1,** Member States may decide that the package leaflet shall be made available **by the marketing authorisation holder for specific categories of medicinal products or for all medicinal products,** ~~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 both preparing the electronic leaflet and ~~shall be responsible for providing~~ ensuring that the printed version of the package leaflet is readily available to the patient. If a Member State decides that the package leaflet shall be only made available electronically, it shall not preclude the marketing authorisation holder from providing the package leaflet in paper format in addition to the electronic format on a voluntary basis.**		
3a. The obligation to make available the package leaflet in paper format in a Member State shall not constitute a reason for the marketing authorisation holder to refuse to supply the medicinal product on the market in that Member State.		
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.~~**		AT: Liability for the accuracy of the information is missing; must be established in advance to have clarity right from the start (potentially in paragraph 6)

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**:**		
(a) establish common standards and formats for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies;		
(b) establish criteria for the provision of such information through secure digital platforms of the competent authorities~~;~~		
(c) set the necessary processes to validate the electronic version of the package leaflet and make it available to patients;		
(d) specify mandatory information on the packaging on how to access the electronic version of the package leaflet;		
(e) the details of implementing commonly recognised European antimicrobial symbol.		
~~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 **to maintain the paper package leaflet in parallel to**~~on~~ the adoption of measures enabling the electronic provision of product information**. It is necessary to** ~~while~~ ensur**e**~~ing~~ that no patient is left behind, taking into account the needs of different age categories and		AT: The content of Recital 128 should be directly represented under Article 63, paragraph 3.

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 **providing product information only in** electronic **format** ~~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' 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 162		
Wholesale distribution of medicinal products		
4. In the case of medicinal products covered by a national marketing authorisation, the notification referred to in		

paragraph 3 to the competent authority of the Member State shall be without prejudice to additional procedures provided for in the legislation of that Member State and to fees payable to the competent authority of the Member State for examining the notification. **A Member State may require that the imported medicinal product is labelled in accordance with Article 74. The Member State may also require that the electronic product information is provided in accordance with Article 63(3).**		
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 **packages that are also multi-lingual**.		
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 appropriate~~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~~appropriate, 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**, if not already evident from the name or pharmaceutical form of the ~~of the~~ medicinal product**;		
(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		

~~**manufacturing**~~ **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, as well as to assess the general supply situation to avoid shortages,** 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 ~~radio~~activity per dose or per vial and the number of capsules, or, for liquids, the number of millilitres in the container.		
3. **In addition to the requirements of Article 66,** ~~T~~**t**he 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 ~~radio~~activity 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 beginning of** 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”)~~ **and** ~~with~~ information on antimicrobial resistance and the appropriate use and disposal of antimicrobials.		
In the case of electronic version of the package leaflet, the information referred to in the previous subparagraph shall		

be made available to patients electronically in a distinct and immediately visible way.		
~~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~~appropriate, and pharmaceutical form, if ~~applicable~~appropriate, ~~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 **free of charge** 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) the identity of the medicinal product in accordance with national requirements, including for statistical reasons.		
~~**(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.		AT: It should be clearly defined which symbols are to be included („positive list“).
~~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** 6~~5~~**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**, as well as in the English language in the electronic version of the package leaflet**.		
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 **~~,~~or 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 ~~,~~ **or multi-country** package is marketed.		
Recital:		
(130) The use of multi-language~~,~~ **or 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~~,~~ **or** ~~-~~ **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~~,~~ **or 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~~**multi-language or multi-country** 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~~appropriate (including in Braille),** and pharmaceutical form **(including in Braille, if appropriate)**, 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**e**~~age~~ **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 standardised 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 **or~~/~~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 appropriate**~~**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**e**~~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 commonly recognised European 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** ~~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;**~~		AT: We would like to keep the sense of this restriction in the legislation
(d) the supply of samples of medicinal products **free of charge**~~**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;		AT: Clearer statement on the intrinsic value would be desirable (e.g. max. 50 EUR)
(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**, provided it does not promote the prescription ~~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 **and that it does not promote the prescription or consumption of the medicinal product**.		
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 **comparison of quality, safety and efficacy is supported objectively by the complete** ~~demonstrated and supported by the~~ summary of product characteristics **and/or assessment reports published by competent authorities**.		
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.**~~		**AT** We think it is justified if MS can ban the advertising of medicinal products that are a risk to the environment. We would prefert to keep paragraph 7
~~**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 of communication**~~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 **or professional activity**, 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.**~~		AT: We think it is important that healthcare professionals receive this information and would prefert to keep paragraph (c).

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.		AT:Inexpensive needs clarification! We propose to set a clear amount – e.g. max € 50 (or to establish a fluid reference to a limit established in other community law as in customs f.e. with a de minimis limit of 50 EUR currently)
2. **Where medicinal products are being promoted at promotional events, h**~~H~~ospitality ~~at sales promotion events~~ shall always be strictly limited to ~~their~~ **the** main purpose **of the event and shall respect the principles laid down in paragraph 1.** ~~and~~ **The hospitality** 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 **be respected when** ~~not prevent~~ hospitality **is** being offered, directly or indirectly, at events for purely professional and scientific purposes. Such hospitality **is justified only when indispensable for the fulfilment of** ~~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**.		*AT: in Art. 184 the wording should be rather aligned with Art. 183 (2).*
Article 185		

Provision of samples of medicinal products ***free of charge*** ~~***free of charge***~~		
1. ~~Free s~~**S**amples of medicinal products shall be provided ***free of charge*** ~~**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. **Member States may decide that o**~~O~~n 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** ~~**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 **intended for systemic administration,** ~~:~~ or **is an antibiotic in any pharmaceutical formulation**		
(f) contains an active substance which are		
(i) persistent, bioaccumulative and toxic, or		
(ii) very persistent and very bioaccumulative, or		
(iii) persistent, mobile and toxic, or		
(iv) 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 **(a), (b), (c), (d) and (f)**, 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.		

CZECH REPUBLIC

Unfortunately, on behalf of the Czech Republic we cannot support the compromise text on the Labelling/advertising and prescriptions. You can find the brief reasoning in the document attached (art. 69 and 74).

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 the packaging in paper format and electronically in accordance with the specifications, standards and format specified by the implementing act pursuant to paragraph 6. The competent authorities shall make publicly available the electronic package leaflet on their websites.**

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~~ from paragraph 1,** Member States may decide that the package leaflet shall be made available **by the marketing authorisation holder for specific categories of medicinal products or for all medicinal products,** ~~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 both preparing the electronic leaflet and ~~shall be responsible for providing~~ ensuring that the printed version of the package leaflet is readily available to the patient. If a Member State decides that the package leaflet shall be only made available electronically, it shall not preclude the marketing authorisation holder from providing the package leaflet in paper format in addition to the electronic format on a voluntary basis.**

3a. The obligation to make available the package leaflet in paper format in a Member State shall not constitute a reason for the marketing authorisation holder to refuse to supply the medicinal product on the market in that Member State.

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**:**

(a) establish common standards and formats for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies;

(b) establish criteria for the provision of such information through secure digital platforms of the competent authorities~~;~~

(c) set the necessary processes to validate the electronic version of the package leaflet and make it available to patients;

(d) specify mandatory information on the packaging on how to access the electronic version of the package leaflet;

(e) the details of implementing commonly recognised European antimicrobial symbol.

~~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 **to maintain the paper package leaflet in parallel to**~~on~~ the adoption of measures enabling the electronic provision of product information**. It is necessary to** ~~while~~ ensur**e**~~ing~~ 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 **providing product information only in** electronic **format** ~~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' 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 162

Wholesale distribution of medicinal products

4. In the case of medicinal products covered by a national marketing authorisation, the notification referred to in paragraph 3 to the competent authority of the Member State shall be without prejudice to additional procedures provided for in the legislation of that Member State and to fees payable to the competent authority of the Member State for examining the notification. **A Member State may require that the imported medicinal product is labelled in accordance with Article 74. The Member State may also require that the electronic product information is provided in accordance with Article 63(3).**

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 **packages that are also multi-lingual**.

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 appropriate**~~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**~~**appropriate, 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**, if not already evident from the name or pharmaceutical form of the ~~of the~~ medicinal product**;

(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 ~~**manufacturing**~~ **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, as well as to assess the general supply situation to avoid shortages,** 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 ~~radio~~activity per dose or per vial and the number of capsules, or, for liquids, the number of millilitres in the container.

3. **In addition to the requirements of Article 66, ~~T~~t**he 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 ~~radio~~activity 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 beginning of** 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”)~~ **and** ~~with~~ information on antimicrobial resistance and the appropriate use and disposal of antimicrobials.

In the case of electronic version of the package leaflet, the information referred to in the previous subparagraph shall be made available to patients electronically in a distinct and immediately visible way.

~~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.

Commented [KP1]: CZ believes that „the beginning of“ is too detailed for the Directive and this issue should be solved in QRD template (Quality Review of documents).

Commented [KP2]: CZ proposes to delete this subpara as details of ePIL layout, including potentially highligted AMR warning, should be specified at the level of QRD template. Please see CZ comment above.

Article 71

Accessibility for persons with disabilities

The name of the medicinal product**, followed by its strength, if ~~available~~appropriate, and pharmaceutical form, if ~~applicable~~appropriate, ~~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 **free of charge** 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) the identity of the medicinal product in accordance with national requirements, including for statistical reasons.
   ~~(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~~5~~**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**, as well as in the English language in the electronic version of the package leaflet**.

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;**~~

Commented [KP3]: CZ proposes replacing the „package leaflet“ with „product information“ as we consider the extension to include an English version of SmPC to be a key part for ensuring availability of medicines in the MS.

~~(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 ~~,~~**or 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 ~~,~~**or multi-country** package is marketed.

Recital:

(130) The use of multi-language~~,~~ **or 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~~,~~ **or**~~,~~ **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~~,~~ **or 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~~**multi-language or multi-country** 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~~**appropriate (including in Braille),** and pharmaceutical form **(including in Braille, if appropriate)**, 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~~cage~~ **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 standardised 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 **or** ~~/~~**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 appropriate**~~**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**e**~~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 commonly recognised European 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** ~~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**~~**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**, provided it does not promote the prescription** ~~**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 **and that it does not promote the prescription or consumption of the medicinal product**.

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 **comparison of quality, safety and efficacy is supported objectively by the complete** ~~demonstrated and supported by the~~ summary of product characteristics **and/or assessment reports published by competent authorities**.

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 of communication** ~~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 **or professional activity**, 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 at promotional events, h**~~H~~ospitality ~~at sales promotion events~~ shall always be strictly limited to ~~their~~ **the** main purpose **of the event and shall respect the principles laid down in paragraph 1.** ~~and~~ **The hospitality** 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 **be respected when** ~~not prevent~~ hospitality **is** being offered, directly or indirectly, at events for purely professional and scientific purposes. Such hospitality **is justified only when indispensable for the fulfilment of** ~~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*** ~~***free of charge***~~

1. ~~Free s~~**S**amples of medicinal products shall be provided **free of charge** ~~**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. **Member States may decide that o**~~O~~n 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** ~~**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 **intended for systemic administration,** ~~;~~ or **is an antibiotic in any pharmaceutical formulation**
   (f) contains an active substance which are
   (i) persistent, bioaccumulative and toxic, or
   (ii) very persistent and very bioaccumulative, or
   (iii) persistent, mobile and toxic, or
   (iv) 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 **(a), (b), (c), (d) and (f)**, 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.

DENMARK

Denmark does not have red lines on the clusters. However please find attached important comments to article D176 (4), D183 og D184 on labelling /advertising and prescription. DK also have a comment to article D175, stk. 2 (litra d) on labelling and advertising – which I hope the presidency will take into consideration

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.~~

Commented [MDN1]: Should "the applicant for an authorisation" be amended to read "the applicant for an authorisation **or the marketing authorisation holder**" as the paragraph also covers "subsequent variations"?

Commented [MDN2]: Should "their marketing authorisation" be amended to read "the summary of product characteristics"?

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 the packaging in paper format and electronically in accordance with the specifications, standards and format specified by the implementing act pursuant to paragraph 6. The competent authorities shall make publicly available the electronic package leaflet on their websites.**

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~~ from paragraph 1,** Member States may decide that the package leaflet shall be made available **by the marketing authorisation holder for specific categories of medicinal products or for all medicinal products,** ~~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 both preparing the electronic leaflet and ~~shall be responsible for providing~~ ensuring that the printed version of the package leaflet is readily available to the patient. If a Member State decides that the package leaflet shall be only made available electronically, it shall not preclude the marketing authorisation holder from providing the package leaflet in paper format in addition to the electronic format on a voluntary basis.**

3a. The obligation to make available the package leaflet in paper format in a Member State shall not constitute a reason for the marketing authorisation holder to refuse to supply the medicinal product on the market in that Member State.

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**:**

(a) establish common standards and formats for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies;

(b) establish criteria for the provision of such information through secure digital platforms of the competent authorities~~;~~

(c) set the necessary processes to validate the electronic version of the package leaflet and make it available to patients;

(d) specify mandatory information on the packaging on how to access the electronic version of the package leaflet;

(e) the details of implementing commonly recognised European antimicrobial symbol.

~~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 and the protection of privacy** 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 **to maintain the paper package leaflet in parallel to**~~on~~ the adoption of measures enabling the electronic provision of product information**. It is necessary to** ~~while~~ ensur**e**~~ing~~ 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 **providing product information only in** electronic **format** ~~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' 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 162

Wholesale distribution of medicinal products

4. In the case of medicinal products covered by a national marketing authorisation, the notification referred to in paragraph 3 to the competent authority of the Member State shall be without prejudice to additional procedures provided for in the legislation of that Member State and to fees payable to the competent authority of the Member State for examining the notification. **A Member State may require that the imported medicinal product is labelled in accordance with Article 74. The Member State may also require that the electronic product information is provided in accordance with Article 63(3).**

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 ~~packages~~ **that are also multi-lingual**.

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 appropriate~~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~~appropriate, 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**, if not already evident from the name or pharmaceutical form of the ~~of the~~ medicinal product**;

(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 ~~**manufacturing**~~ **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, as well as to assess the general supply situation to avoid shortages,** 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 ~~radio~~activity per dose or per vial and the number of capsules, or, for liquids, the number of millilitres in the container.

3. **In addition to the requirements of Article 66, ~~T~~t**he 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 ~~radio~~activity 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 beginning of** 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”)~~ **and** ~~with~~ information on antimicrobial resistance and the appropriate use and disposal of antimicrobials.

In the case of electronic version of the package leaflet, the information referred to in the previous subparagraph shall be made available to patients electronically in a distinct and immediately visible way.

~~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~~appropriate, and pharmaceutical form, if ~~applicable~~appropriate, ~~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 **free of charge** 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) the identity of the medicinal product in accordance with national requirements, including for statistical reasons.
   ~~(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** 6~~5~~**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**, as well as in the English language in the electronic version of the package leaflet**.

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 ~~,~~**or 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 ~~,~~**or multi-country** package is marketed.

Recital:

(130) The use of multi-language~~,~~ **or 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~~,~~ **or**~~,~~ **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~~,~~ **or 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~~**multi-language or multi-country** 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~~**appropriate (including in Braille),** and pharmaceutical form **(including in Braille, if appropriate)**, 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~~cage~~ **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** appropriate ~~available~~**,** and the pharmaceutical form.

Commented [MDN3]: The wording needs to be aligned with annex VI.

(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 standardised 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 **or** ~~/~~**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.

Commented [MDN4]: Should be amended to "adverse reactions".

~~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 appropriate**~~**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**e**~~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 commonly recognised European 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** ~~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**~~**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**, provided it does not promote the prescription** ~~**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 **and that it does not promote the prescription or consumption of the medicinal product**.

Commented [MDN5]: The addition is superfluous and misleading. The provision is about information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products. Consequently, it does not make sense to add: "and that it does not promote the prescription or consumption of the medicinal product". The information is not about a medicinal product. We suggest to delete the new text.

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 **comparison of quality, safety and efficacy is supported objectively by the complete** ~~demonstrated and supported by the~~ summary of product characteristics **and/or assessment reports published by competent authorities**.

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.

Commented [MDN6]: Why quality? The first part mentions "safer or more effective"?

Commented [MDN7]: When paragraph 4 is read in conjunction with recital 136, comparison in terms of safety and efficacy is only allowed if the information is listed in the summary of product characteristic (SPC) of medicinal product being advertised (not the SPC of the compared product).

We deem this approach very undesirable as relevant information on safety and efficacy may very well stem from the SPC of the compared product and thus be a combination of information in the two SPCs.

If reference to the SPC of the compared product is not allowed, it would be very difficult – and often impossible – to make comparisons about safety and efficacy in advertising to healthcare professionals. Why should it be forbidden to make such comparisons based on relevant information in the SPCs? It is common practice today and it could be useful to healthcare professionals to receive the relevant information/overview based on the SPCs.

Consequently, we suggest to amend "summary of product characteristics" to "summaries of product characteristics" and to make the necessary changes in the recital (136).

Commented [MDN8]: Does it mean that the assessment report of the compared product may be used in the comparison – but not the SPC of the compared product? It is not desirable – as the SPC is the main documentation.

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 of communication** ~~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 **or professional activity**, 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 at promotional events, h**~~H~~ospitality ~~at sales promotion events~~ shall always be strictly limited to ~~their~~ **the** main purpose **of the event and shall respect the principles laid down in paragraph 1.** ~~and~~ **The hospitality** 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.

Commented [MDN9]: The last part ("and shall respect the principles laid down in paragraph 1") of the first sentence is unclear.

How shall hospitality (e.g. meals, transport and accommodation) be "relevant to the practice of medicine or pharmacy"?

We suggest the following wording in paragraph 2:

"Hospitality being offered to healthcare professionals at promotional events shall always be strictly limited to the main purpose of the event and must not be expensive. The hospitality must not be extended to persons other than healthcare professionals."

Article 184

Hospitality at scientific events

The provisions of Article 183(1) shall **be respected when** ~~not prevent~~ hospitality **is** being offered, directly or indirectly, at events for purely professional and scientific purposes. Such hospitality **is justified only when indispensable for the fulfilment of** ~~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*** ~~***free of charge***~~

1. ~~Free s~~Samples of medicinal products shall be provided **free of charge** ~~**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. **Member States may decide that o**~~O~~n 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.

Commented [MDN10]:
Hospitality (e.g. meals and accommodation) is not "indispensable for the fulfilment of the main scientific objective of the event".

Furthermore, how shall the provisions of Article 183(1) be respected - how shall hospitality (e.g. meals, transport and accommodation) be considered "relevant to the practice of medicine or pharmacy"?

We suggest the following wording in Article 184:

"Hospitality being offered to healthcare professionals at events for purely professional and scientific purposes shall be strictly limited to the main scientific objective of the event and must not be expensive. The hospitality must not be extended to persons other than healthcare professionals."

3. Member States may also place further restrictions on the distribution of samples of certain medicinal products **free of charge** ~~**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 **intended for systemic administration,** ~~;~~ or **is an antibiotic in any pharmaceutical formulation**
   (f) contains an active substance which are
   (i) persistent, bioaccumulative and toxic, or
   (ii) very persistent and very bioaccumulative, or
   (iii) persistent, mobile and toxic, or
   (iv) 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 **(a), (b), (c), (d) and (f)**, 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.

DENMARK 2

However please find attached important comments to article D105 (4), D106 (4) og R101 (2) on Pharmacovigilance, which we hope the Presidency will take into consideration

DIRECTIVE

Chapter IX
Pharmacovigilance

Section 1
General provisions

Article 96
Member State pharmacovigilance system

1. Member States shall operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks and their participation in the Union pharmacovigilance activities.

   The pharmacovigilance system shall be used to collect information on the risks of medicinal products as regards health of the patients or the public. That information shall in particular refer to adverse reactions in human beings, arising from use of the medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, and to adverse reactions associated with occupational exposure.

2. Member States shall, by means of the pharmacovigilance system referred to in paragraph 1, evaluate all information scientifically, consider options for risk minimisation and prevention and take regulatory action concerning the marketing authorisation as necessary. They shall perform a regular audit of their pharmacovigilance system and take corrective actions if necessary.

3. Each Member State shall designate a competent authority for the performance of pharmacovigilance tasks.

4. The Commission may request the Member States to participate, under the coordination of the Agency, in international harmonisation and standardisation of technical measures in relation to pharmacovigilance.

Article 97

Member State responsibilities for pharmacovigilance activities

1. The Member States shall:
   (a) take all appropriate measures to encourage patients, doctors, pharmacists and other healthcare professionals to report suspected adverse reactions to the competent authority of the Member State and may involve organisations representing consumers, patients and healthcare professionals for those tasks where appropriate;
   (b) facilitate patient reporting through the provision of alternative reporting formats in addition to web-based formats;
   (c) take all appropriate measures to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports;
   (d) ensure that the public is given important information on pharmacovigilance concerns relating to the use of a medicinal product in a timely manner through publication on the web-portal and through other means of publicly available information as necessary;
   (e) ensure, through the methods for collecting information and where necessary through the follow-up of suspected adverse reaction reports, that all appropriate measures are taken to identify clearly any biological medicinal product prescribed, dispensed, or sold in their territory that is the subject of a suspected adverse reaction report, with due regard to the name of the medicinal product, and the batch number.

2. For the purposes of paragraph 1, points (a) and (e), the Member States may impose specific obligations on doctors, pharmacists and other healthcare professionals.

Article 98

Member State delegation of pharmacovigilance tasks

1. A Member State may delegate any of the tasks entrusted to it under this Chapter to another Member State subject to a written agreement of the latter. Each Member State may represent no more than one other Member State.

2. The delegating Member State shall inform the Commission, the Agency and all other Member States of the delegation in writing. The delegating Member State and the Agency shall make that information publicly available.

Article 99

Marketing authorisation holder pharmacovigilance system

1. Marketing authorisation holders shall operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks equivalent to the relevant Member State's pharmacovigilance system referred to in Article 96(1).

2. Marketing authorisation holders shall by means of the pharmacovigilance system referred to in Article 96(1) evaluate all information scientifically, consider options for risk minimisation and prevention and take appropriate measures as necessary.

3. Marketing authorisation holders shall perform a regular audit of their pharmacovigilance system. They shall place a note concerning the main findings of the audit on the pharmacovigilance system master file and, based on the audit findings, ensure that an appropriate corrective action plan is prepared and implemented. Once the corrective actions have been fully implemented, the note may be removed.

4. As part of the pharmacovigilance system, marketing authorisation holders shall:
   (a) have permanently and continuously at their disposal an appropriately qualified person responsible for pharmacovigilance;
   (b) maintain and make available on request by a competent authority a pharmacovigilance system master file;
   (c) operate a risk management system for each medicinal product;
   (d) monitor the outcome of risk minimisation measures that are contained in the risk management plan ~~pursuant to Article 21~~ **~~6(2)~~** or that are laid down as conditions of the marketing authorisation pursuant to Articles 44~~,~~ **(1) points (a)-(g) and point (i),** 45 and any obligations imposed in accordance with Article 87~~;~~ **(1) points (a) and (b);**
   (e) update the risk management system and monitor pharmacovigilance data to determine whether there are new risks or whether risks have changed or whether there are changes to the benefit-risk balance of medicinal products.

5. The qualified person referred to in paragraph 4, point (a), shall reside and operate in the Union and shall be responsible for the establishment and maintenance of the pharmacovigilance system. The marketing authorisation holder shall submit the name and contact details of the qualified person to the competent authority of the Member State and the Agency.

6. The marketing authorisation holder shall, on request from the competent authority of a Member State, nominate a contact person for pharmacovigilance issues in that Member State who shall report to the qualified person referred to in paragraph 4, point (a).

7. The marketing authorisation holder shall have procedures in place to ensure continued compliance with their pharmacovigilance tasks for an appropriate period after a marketing authorisation has been withdrawn or revoked to ensure patient's safety.

Commented [MDN1]: There is no marketing authorisation holder after the marketing authorisation has been withdrawn or revoked. Consequently, this legal entity (i.e. the MAH) does not exist and compliance with pharmacogivilance tasks/obligations cannot be enforced. Therefore we suggest to delete the provion.

Article 100

Risk management system

1. **Without prejudice to paragraph 2, 3 and 4,** ~~H~~**h**olders of marketing authorisations granted before 21 July 2012 shall, by way of derogation from Article 99(4), point (c), not be required to operate a risk management system for each **of these** medicinal ~~product.~~**products.**
2. The competent authority of a Member State may impose an obligation on a marketing authorisation holder of a national marketing authorisation to operate a risk management system, as referred to in Article 99(4), point (c), if there are concerns about the risks affecting the benefit-risk balance of an authorised medicinal product. In that context, the competent authority of a Member State shall also oblige the marketing authorisation holder to submit a risk management plan for the risk management system that they intend to introduce for the medicinal product concerned.

3. The obligation referred to in paragraph 2 shall be duly justified, notified in writing, and shall include the timeframe for submission of the risk management plan.

4. The competent authority of a Member State shall provide the marketing authorisation holder with an opportunity to submit written observations in response to the imposition of the obligation within a time limit which it shall specify, if the marketing authorisation holder so requests within 30 days of receipt of the written notification of the obligation.

5. On the basis of the written observations submitted by the marketing authorisation holder, the competent authority of a Member State shall withdraw or confirm the obligation. Where the competent authority of a Member State confirms the obligation, the marketing authorisation shall be varied accordingly to include **this and** the measures to be taken as part of the risk management system as conditions of the marketing authorisation referred to in Article 44~~.~~**(1),** point (a).

Article 101

Funds for pharmacovigilance activities

1. The management of funds intended for activities connected with pharmacovigilance, the operation of communication networks and market surveillance shall be under the permanent control of the competent authorities of the Member States in order to guarantee their independence in the performance of those pharmacovigilance activities.

2. Paragraph 1 shall not preclude the competent authorities of the Member States from charging fees to marketing authorisation holders for performing pharmacovigilance activities on the condition that the independence in the performance of those pharmacovigilance activities is strictly guaranteed.

Section 2

Transparency and communications

Article 102

*National **medicines** web-portal*

1. Each Member State shall set up and maintain a national medicines web-portal which shall be linked to the European medicines web-portal established in accordance with Article 104 of [revised Regulation (EC) No 726/2004]. By means of the national medicines web-portals, the Member States shall make publicly available at least the following:
   (a) public assessment reports, together with a summary thereof;
   (b) summaries of product characteristics and package leaflets;
   (c) summaries of risk management plans for medicinal products covered by a national marketing authorisation in accordance with Chapter III;
   (d) information on the different ways of reporting suspected adverse reactions to medicinal products to competent authorities of the Member States by healthcare professionals and patients, including the web-based structured forms referred to in Article 102 of [revised Regulation (EC) No 726/2004]-;
   (e) information on prescription status of medicinal products authorised in their territory.

2. The summaries referred to in paragraph ~~2~~**1**, point (c), shall include, where relevant, a description of additional risk minimisation measures.

Article 103

Publication of assessment

The Agency shall make publicly available the final assessment conclusions, recommendations, opinions and decisions referred to in Articles 107 to 116, by means of the European medicines web-portal.

Article 104

Public announcements

1. As soon as the marketing authorisation holder intends to make a public announcement relating to information on pharmacovigilance concerns in relation to the use of a medicinal product, and in any event at the same time or before the public announcement is made, they shall be required to inform the competent authorities of the Member States, the Agency and the Commission.

2. The marketing authorisation holder shall ensure that information to the public is presented objectively and is not misleading.

3. Unless urgent public announcements are required for the protection of public health, the Member States, the Agency and the Commission shall inform each other not less than 24 hours prior to a public announcement relating to information on pharmacovigilance concerns.

4. For active substances contained in medicinal products authorised in more than one Member State, the Agency shall be responsible for the coordination between competent authorities of the Member States of safety announcements and shall provide timetables for the information being made publicly available.

5. Under the coordination of the Agency, the Member States shall make all reasonable efforts to agree on a common message in relation to the safety of the medicinal product concerned and the timetables for their distribution. The Pharmacovigilance Risk Assessment Committee shall, at the request of the Agency, provide advice on those safety announcements.

6. When the Agency or competent authorities of the Member States make publicly available information referred to in paragraphs 2 and 3, any personal data or data of a commercially confidential nature shall be deleted unless its public disclosure is necessary for the protection of public health.

Section 3

Recording and reporting of suspected adverse reactions

Article 105

Recording and reporting of suspected adverse reactions by the marketing authorisation holder

1. Marketing authorisation holders shall record all suspected adverse reactions in the Union or in third countries that are brought to their attention, whether reported spontaneously by patients or healthcare professionals, or occurring in the context of a post-authorisation study including data relating to **suspected adverse reactions** ~~**related to** off-label~~ **occuring where the** ~~use of~~ the product~~.~~ **is used outside the terms of the marketing authorisation.**

   Marketing authorisation holders shall ensure that those reports are accessible at a single point within the Union.

   By way of derogation from the first subparagraph, suspected adverse reactions occurring in the context of a clinical trial shall be recorded and reported in accordance with Regulation (EU) No 536/2014.

2. Marketing authorisation holders shall not refuse to consider reports of suspected adverse reactions received electronically or by any other appropriate means from patients or healthcare professionals**, including reports from patients and healthcare professionals received in accordance with Article 105a**.

3. Marketing authorisation holders shall submit electronically to the database and data-processing network referred to in Article 101 of [revised Regulation (EC) No 726/2004] ('Eudravigilance database') information on all serious suspected adverse reactions that occur in the Union and in third countries within 15 days following the day on which the marketing authorisation holder concerned gained knowledge of the event.
Marketing authorisation holders shall submit electronically to the Eudravigilance database information on all non-serious suspected adverse reactions that occur in the Union, within 90 days following the day on which the marketing authorisation holder concerned gained knowledge of the event.

For medicinal products containing active substances referred to in the list of publications monitored by the Agency pursuant to Article 105 of [revised Regulation (EC) No 726/2004], marketing authorisation holders shall not be required to report to the Eudravigilance database the suspected adverse reactions recorded in the listed publications, but they shall monitor all other medical literature and report any suspected adverse reactions recorded therein.

~~3a. On the basis of agreements referred to in [revised Regulation (EC) No 726/2004], the Agency shall may enter into the Eudravigilance database relevant information from the relevant adverse reaction databases maintained outside the Union. The Agency shall may, in consultation with the Commission, Member States and interested parties, draw up a detailed guide regarding the monitoring these databases and the entry of relevant information into the Eudravigilance database.~~

4. Marketing authorisation holders shall establish procedures in order to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports. They shall also collect follow-up information on ~~those reports~~ and submit the updates to the Eudravigilance database. **Reports obtained from the Eudravigilance database ~~should~~shall not be re-submitted by the marketing authorisation holders to the 'Eudravigilance database', unless they contain additional information provided by the reporter.**

5. Marketing authorisation holders shall collaborate with the Agency and the competent authorities of the Member States in the detection of duplicates of suspected adverse reaction reports.

6. This Article shall apply *mutatis mutandis* to undertakings supplying medicinal products used in accordance with Article 3, paragraphs 1 or 2**.**

Article 105a

Recording and reporting of suspected adverse reactions by wholesale distributors

Wholesale distributors that supply medicinal products in accordance with Article 162(3) to (5) shall record all suspected adverse reactions with regard to those medicinal products which are brought to their attention, whether reported spontaneously by patients or by healthcare professionals, including suspected adverse reactions related to the use of the product outside the terms of the marketing authorisation. They shall transmit those reports immediately to the marketing authorisation holder ~~holding the marketing authorisation~~ in the country of origin ~~concerned~~.

Article 106

Recording and reporting of suspected adverse reactions by Member States

1. Each Member State shall record all suspected adverse reactions that occur in its territory ~~and that~~ **which** are brought to its attention from healthcare professionals and patients. This shall include all authorised medicinal products and medicinal products used in accordance with Article 3, paragraphs 1 or 2. Member States shall involve patients and healthcare professionals, as appropriate, in the follow-up of any reports they receive in order to comply with Article 97(1), points (c) and (e).

Commented [MDN2]: Why are the words, "those reports", deleted?

It is follow-up information "on those reports" the marketing authorisation holder shall collect and submit to the Eudravigilance database.

Commented [MDN3]: We assume that «shall » is the proper wording.

Commented [MDN4]: We assume that «suspected » is missing.

Commented [MDN5]: The words «holding the marketing authorisation » are superfluous.

Member States shall ensure that reports of such reactions may be submitted by means of the national medicines web-portals or by other means.

2. For reports submitted by a marketing authorisation holder, Member States on whose territory the suspected adverse reaction occurred may involve the marketing authorisation holder in the follow-up of the reports.

3. Member States shall collaborate with the Agency and the marketing authorisation holders in the detection of duplicates of suspected adverse reaction reports.

4. Member States shall, within 15 days following the receipt of the reports of serious suspected adverse reactions referred to in paragraph 1, submit the reports electronically to the Eudravigilance database.

   Member States shall, within 90 days from the receipt of the reports referred to in paragraph 1, submit reports of non-serious suspected adverse reactions electronically to the Eudravigilance database.

   Marketing authorisation holders **and marketing authorisation applicants** shall have access to the reports referred to in this paragraph through the Eudravigilance database.

5. Member States shall ensure that reports of suspected adverse reactions arising from an error associated with the use of a medicinal product that are brought to their attention are made available to the Eudravigilance database and to any authorities, bodies, organisations or institutions, responsible for patient safety within that Member State concerned. They shall also ensure that the authorities responsible for medicinal products within that Member State are informed of any suspected adverse reactions brought to the attention of any other authority within that Member State. These reports shall be appropriately identified in the forms referred to in Article 102 of [revised Regulation (EC) No 726/2004].

6. Unless there are justifiable grounds resulting from pharmacovigilance activities, Member States shall not impose any additional obligations on marketing authorisation holders for the reporting of suspected adverse reactions.

Commented [MDN6]: We suggest to delete "and marketing authorisation applicants".

The Eudravigilance database contains sensitive personal data about patients and access to the database cannot be justified because applicants do not have pharmacovigilance obligations.

Consequently, applicants should not have access to the Eudravigilance database.

Marketing authorisation holders have pharmacovigilance obligations – not applicants (furthermore, their application may be rejected if they do not comply with the requirements for a marketing authorisation).

See also our comments to REG Article 101(2) below.

Section 4
Periodic safety update reports

Article 107
Periodic safety update reports

1. Marketing authorisation holders shall submit to the Agency periodic safety update reports containing:
   (a) summaries of data relevant to the benefit-risk balance of the medicinal product, including results of all studies with a consideration of their potential impact on the marketing authorisation;
   (b) a scientific evaluation of the benefit-risk balance of the medicinal product;
   (c) all data relating to the volume of sales of the medicinal product and any data in possession of the marketing authorisation holder relating to the volume of prescriptions, including an estimate of the population exposed to the medicinal product.

   The data provided in accordance with the first subparagraph, point (c), shall differentiate between sales and volumes generated within the Union and those generated outside the Union.

2. The evaluation referred to in paragraph 1, first subparagraph, point (b), shall be based on all available data, including data from clinical trials in unauthorised ~~therapeutic~~ indications and populations.

   The periodic safety update reports shall be submitted electronically.

3. The Agency shall make available the reports referred to in paragraph 1 to the competent authorities of the Member States, the members of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use and the coordination group by means of the repository referred to in Article 103 of [revised Regulation (EC) No 726/2004].

4. By way of derogation from paragraph 1, the marketing authorisation holders for medicinal products referred to in Articles 9, or 13, ~~and the registration holders for medicinal products referred to in Articles 126 or 134(1),~~ shall only be required to submit periodic safety update reports for such medicinal products to the competent authority in the following cases:
   (a) where such obligation has been laid down as a condition in the marketing authorisation in accordance with Articles 44 or 45; or
   (b) when requested by a competent authority on the basis of concerns relating to pharmacovigilance data or due to the lack of periodic safety update reports relating to an active substance after the marketing authorisation has been granted.

By way of derogation from paragraph 1, the registration holders for medicinal products referred to in Articles 126 or 134(1), shall only be required to submit periodic safety update reports for such medicinal products when requested by a competent authority on the basis of concerns relating to pharmacovigilance data.

The assessment reports of the periodic safety update reports referred to in the first subparagraph shall be communicated by the competent authority to the Pharmacovigilance Risk Assessment Committee, which shall consider whether there is a need for a single assessment report for all marketing authorisations for medicinal products containing the same active substance and which shall inform the coordination group or the Committee for Medicinal Products for Human Use accordingly, in order to apply the procedures laid down in Articles 108(4) and 110.

Article 108

Frequency of periodic safety update reports

1. The frequency with which the periodic safety update reports are to be submitted shall be specified in the marketing authorisation.

   The dates of submission according to the specified frequency shall be calculated from the date when then marketing authorisation was granted.

2. Holders of marketing authorisations which have been granted before 21 July 2012, and for which the frequency and dates of submission of the periodic safety update reports are not laid down as a condition to the marketing authorisation, shall submit the periodic safety update reports in accordance with the second subparagraph ~~**point (b)**~~ until another frequency or other dates of submission of the reports are laid down in the marketing authorisation or determined in accordance with the paragraphs 4, 5 and 6.

   Periodic safety update reports shall be submitted to the competent authorities immediately upon request **or in accordance with the following**:

   (a) where a medicinal product has not yet been placed on the market, at least every six months following the marketing authorisation and until the placing on the market;

   (b) where a medicinal product has been placed on the market, ~~at least every six months~~ **once a year** during the first ~~two~~ **five** years following the initial placing on the market, ~~once a year for the following two years~~ and ~~at~~**a** three-yearly intervals **for the subsequent six years and with a five years interval** thereafter.

3. Paragraph 2 shall also apply to medicinal products that are authorised only in one Member State and for which paragraph 4 does not apply.

4. Where medicinal products that are subject to different marketing authorisations contain the same active substance or the same combination of active substances, the frequency and dates of submission of the periodic safety update reports resulting from the application of the paragraphs 1 and 2 may be amended and harmonised to enable a single assessment to be made in the context of a periodic safety update report work-sharing procedure and to set a Union reference date from which the submission dates to be calculated.

   The harmonised frequency for the submission of the reports and the Union reference date may be determined, after consultation of the Pharmacovigilance Risk Assessment Committee, by one of the following:

   (a) the Committee for Medicinal Products for Human Use, where at least one of the marketing authorisations for the medicinal products containing the active substance concerned has been granted in accordance with the centralised procedure provided for in Article 3 of [revised Regulation (EC) No 726/2004];

(b) the coordination group, in other cases than those referred to in point (a).

The harmonised frequency for the submission of the reports determined pursuant to the first and second subparagraphs shall be made publicly available by the Agency. Marketing authorisation holders shall submit an application for a variation of the marketing authorisation accordingly.

5. For the purposes of paragraph 4, the Union reference date for medicinal products containing the same active substance or the same combination of active substances shall be one of the following:
   (a) the date when the first marketing authorisation was granted in the Union for a medicinal product containing that active substance or that combination of active substances;
   (b) if the date referred to in point (a) cannot be ascertained, the earliest of the known dates of the marketing authorisations for a medicinal product containing that active substance or that combination of active substances.

6. Marketing authorisation holders shall be allowed to submit requests to the Committee for Medicinal Products for Human Use or the coordination group, as appropriate, to determine Union reference dates or to change the frequency of submission of periodic safety update reports on one of the following grounds:
   (a) for reasons relating to public health;
   (b) in order to avoid a duplication of the assessment;
   (c) in order to achieve international harmonisation.

   Such requests shall be submitted in writing and shall be duly justified. The Committee for Medicinal Products for Human Use or the coordination group shall, following the consultation with the Pharmacovigilance Risk Assessment Committee, either approve or deny such requests. Any change in the dates or the frequency of submission of periodic safety update reports shall be made publicly available by the Agency. The marketing authorisation holders shall submit an application for a variation of the marketing authorisation accordingly.

7. The Agency shall make public a list of Union reference dates and frequency of submission of periodic safety update reports by means of the European medicines web-portal.

Any change to the dates of submission and frequency of periodic safety update reports specified in the marketing authorisation as a result of the application of the paragraphs 4, 5 and 6 shall take effect four months after the date of the publication referred to in the first subparagraph.

Article 109

Assessment of periodic safety update reports

The competent authorities of the Member State shall assess periodic safety update reports to determine whether there are new risks or whether risks have changed or whether there are changes to the benefit-risk balance of medicinal products.

Article 110

Single assessment of periodic safety update reports

1. A single assessment of periodic safety update reports shall be performed for medicinal products authorised in more than one Member State and, in the cases referred to in Article 108, paragraphs 4, 5 and 6, for all medicinal products containing the same active substance or the same combination of active substances and for which a Union reference date and a frequency of periodic safety update reports has been established.

The single assessment shall be conducted by either of the following:

(a) a Member State appointed by the coordination group where none of the marketing authorisations concerned has been granted in accordance with the centralised procedure provided for in Article 3 of [revised Regulation (EC) No 726/2004];

(b) a rapporteur appointed by the Pharmacovigilance Risk Assessment Committee, where at least one of the marketing authorisations concerned has been granted in accordance with the centralised procedure provided for in Article 3 of [revised Regulation (EC) No 726/2004].

When selecting the Member State in accordance with the second subparagraph, point (a), the coordination group shall take into account whether any Member State is acting as a reference Member State, in accordance with Chapter III, Sections 3 and 4.

2. The Member State or rapporteur, as appropriate, shall prepare an assessment report within 60 days of receipt of the periodic safety update report and send it to the Agency and to the Member States concerned. The Agency shall send the report to the marketing authorisation holder.

   Within 30 days of receipt of the assessment report, the Member States and the marketing authorisation holder may submit comments to the Agency and to the rapporteur or Member State. **Where the report includes questions to the marketing authorisation holder, the holder shall provide answers within those 30 days.**

3. Following the receipt of the comments referred to in paragraph 2, the rapporteur or Member State shall within 15 days update the assessment report taking into account any comments submitted, and forward it to the Pharmacovigilance Risk Assessment Committee. The Pharmacovigilance Risk Assessment Committee shall adopt the assessment report with or without further changes at its next meeting and issue a recommendation. The recommendation shall mention any divergent positions with the grounds on which they are based. The Agency shall include the adopted assessment report and the recommendation in the repository set up under Article 103 of [revised Regulation (EC) No 726/2004] and forward them to the marketing authorisation holder.

Article 111

Regulatory action on periodic safety update reports

Following the assessment of periodic safety update reports referred to in Article ~~107~~ **109**, the competent authorities of the Member States shall consider whether any action concerning the marketing authorisation for the medicinal product concerned is necessary and shall maintain, vary, suspend or revoke the marketing authorisation as appropriate.

Article 112

Procedure for regulatory action on periodic safety update reports

1. In the case of a single assessment of periodic safety update reports in accordance with Article 110(1) which recommends action concerning more than one marketing authorisation that does not include any centralised marketing authorisation, the coordination group shall, within 30 days of receipt of the assessment report of the Pharmacovigilance Risk Assessment Committee, consider the assessment report and reach a position on the maintenance, variation, suspension or revocation of the marketing authorisations concerned, including a timetable for the implementation of the agreed position.

2. If, within the coordination group, the Member States represented reach an agreement on the action to be taken by consensus, the chairperson shall record the agreement and send it to the marketing authorisation holder and the Member States. The Member States shall adopt necessary measures to maintain, vary, suspend or revoke the marketing authorisations concerned in accordance with the timetable for implementation determined in the agreement. In the event of a variation, the marketing authorisation holder shall submit to the competent authorities of the Member States an appropriate application for a modification, including an updated summary of product characteristics and an updated package leaflet within the determined timetable for implementation.

   If an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall be forwarded to the Commission which shall apply the procedure laid down in Article 42.

   Where the agreement reached by the Member States represented within the coordination group or the position of the majority of Member States differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the coordination group shall attach to the agreement or the majority position a detailed explanation of the scientific grounds for the differences together with the recommendation.

3. In the case of a single assessment of periodic safety update reports in accordance with Article 110(1) that recommends action concerning more than one marketing authorisation that includes at least one centralised marketing authorisation, the Committee for Medicinal Products for Human Use shall, within 30 days of receipt of the report of the Pharmacovigilance Risk Assessment Committee, consider the report and adopt an opinion on the maintenance, variation, suspension or revocation of the marketing authorisations concerned, including a timetable for the implementation of the opinion.

4. Where the opinion of the Committee for Medicinal Products for Human Use referred to in paragraph 3 differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use shall attach to its opinion a detailed explanation of the scientific grounds for the differences together with the recommendation.

5. On the basis of the opinion of the Committee for Medicinal Products for Human Use referred to in paragraph 3, the Commission shall, by means of implementing acts:
   (a) adopt a decision addressed to the Member States concerning the measures to be taken in respect of marketing authorisations granted by the Member States and concerned by the procedure provided for in this section; and
   (b) where the opinion states that regulatory action concerning the marketing authorisation is necessary, adopt a decision to vary, suspend or revoke the centralised marketing authorisations ~~and~~ concerned by the procedure provided for in this section.

6. Article 42 shall apply to the adoption of the decision referred to in paragraph 5, point (a), and to its implementation by the Member States.

7. Article 13 of [revised Regulation (EC) No 726/2004] shall apply to the decision referred to in paragraph 5, point (b). Where the Commission adopts such decision, it may also adopt a decision addressed to the Member States pursuant to Article ~~55~~ **57** of [revised Regulation (EC) No 726/2004].

Section 5
Signal detection

Article 113

Signal monitoring and detection

1. Regarding medicinal products authorised in accordance with Chapter III, competent authorities of the Member States shall in collaboration with the Agency, take the following measures:
   (a) monitor the outcome of risk minimisation measures contained in risk management plans and of the conditions referred to in Articles 44~~,~~ **(1) points (a)-(g) and point (i),** 45 and any obligations imposed in accordance with Article 87~~,~~ **(1) points (a) and (b);**
   (b) assess updates to the risk management system;
   (c) monitor the data in the Eudravigilance database to determine whether there are new risks or whether risks have changed and whether those risks impact on the benefit-risk balance.

Commented [MDN7]: The new point (ba) in Article 87(1) should be inserted.

2. The Pharmacovigilance Risk Assessment Committee shall perform the initial analysis and prioritisation of signals of new risks or risks that have changed or changes to the benefit-risk balance. Where it considers that follow-up action may be necessary, the assessment of those signals and agreement on any subsequent action concerning the marketing authorisation shall be conducted in a timescale commensurate with the extent and seriousness of the issue. **Where appropriate, the assessment of those signals may be included in a pending assessment of a periodic safety update report or a pending procedure in accordance with Articles 92 to 95 and 114-116 of this Directive or Article 55 of [revised Regulation].**

3. The Agency and competent authorities of the Member States and the marketing authorisation holder shall inform each other in the event of new risks or risks that have changed or changes to the benefit-risk balance being detected.

4. Member States shall ensure that marketing authorisation holders inform the Agency and competent authorities of the Member State in the event of new risks or risks that have changed or when changes to the benefit-risk balance have been detected.

Section 6
Urgent Union procedure

Article 114

Initiation of an urgent Union procedure

1. A Member State or the Commission, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities, initiate the procedure provided for in this Section (the 'urgent Union procedure') by informing the other Member States, the Agency and the Commission where:
   (a) it considers suspending or revoking a marketing authorisation;
   (b) it considers prohibiting the supply of a medicinal product;
   (c) it considers refusing the renewal of a marketing authorisation; or
   (d) it is informed by the marketing authorisation holder that, on the basis of safety concerns, the marketing authorisation holder has interrupted the placing on the market of a medicinal product or has taken action to have a marketing authorisation withdrawn, or intends to take such action or has not applied for the renewal of a marketing authorisation.

2. A Member State or the Commission, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities, inform the other Member States, the Agency and the Commission where it considers that a new contraindication, a reduction in the recommended dose or a restriction to the ~~therapeutic~~ indications of a medicinal product is necessary. The information shall outline the action considered and the reasons therefore.

   Any Member State or the Commission, as appropriate, shall, when urgent action is considered necessary in any of the cases referred to in the first subparagraph, initiate the urgent Union procedure.

Where the urgent Union procedure is not initiated, for medicinal products authorised in accordance with Chapter III, Sections 3 and 4, the case shall be brought to the attention of the coordination group.

Article 95 shall apply where the interests of the Union are involved.

3. Where the urgent Union procedure is initiated, the Agency shall verify whether the safety concern relates to medicinal products other than the one covered by the information, or whether the safety concern is common to all medicinal products belonging to the same range or therapeutic class.

Where the medicinal product involved is authorised in more than one Member State, the Agency shall without undue delay inform the initiator of the urgent Union procedure of the outcome of the verification, and the procedures laid down in Articles 115 and 116 shall apply. Otherwise, the safety concern shall be addressed by the Member State concerned. The Agency or the Member State, as applicable, shall make the information that the urgent Union procedure has been initiated available to marketing authorisation holders.

4. Without prejudice to paragraphs 1 and 2, and Articles 115 and 116, a Member State may, where urgent action is necessary to protect public health, suspend the marketing authorisation and prohibit the use of the medicinal product concerned on its territory until a definitive decision is adopted in the urgent Union procedure. It shall inform the Commission, the Agency and the other Member States no later than the following working day of the reasons for its action.

5. At any stage of the procedure laid down in Articles 115 and 116, the Commission may request a Member State in which the medicinal product is authorised to take temporary measures immediately.

Where the scope of the procedure, as determined in accordance with paragraphs 1 and 2, includes medicinal products covered by centralised marketing authorisations, the Commission may, at any stage of the urgent Union procedure, take temporary measures immediately in relation to those marketing authorisations.

6. The information referred to in this Article may relate to individual medicinal products or to a range of medicinal products or a therapeutic class.

If the Agency identifies that the safety concern relates to more medicinal products than those that are covered by the information or that the safety concern is common to all medicinal products belonging to the same range or therapeutic class, it shall extend the scope of the procedure accordingly.

Where the scope of the urgent Union procedure concerns a range of medicinal products or therapeutic class, medicinal products covered by the centralised marketing authorisation, that belong to that range or class shall also be included in the procedure.

7. At the time the information referred to in paragraphs 1 and 2 is provided, the Member State shall make available to the Agency all relevant scientific information that it has at its disposal and any assessment by the Member State.

Article 115

Urgent Union procedure scientific assessment

1. Following receipt of the information referred to in Article 114, paragraphs 1 and 2, the Agency shall publicly announce the initiation of the urgent Union procedure by means of the European medicines web-portal. In parallel, Member States may publicly announce the initiation of the procedure on their national medicines web-portals.

The announcement shall specify the matter submitted to the Agency in accordance with Article 114, and the medicinal products and, where applicable, the active substances concerned. It shall contain information on the right of the marketing authorisation holders, healthcare professionals and the public to submit to the Agency information relevant to the procedure and it shall state how such information may be submitted.

2. The Pharmacovigilance Risk Assessment Committee shall assess the matter that has been submitted to the Agency in accordance with Article 114. The rapporteur, as referred to in Article 152 of [revised Regulation (EC) No 726/2004], shall closely collaborate with the rapporteur appointed by the Committee for Medicinal Products for Human Use and with the reference Member State for the medicinal products concerned.

For the purposes of the assessment referred to in the first subparagraph, the marketing authorisation holder may submit comments in writing.

Where the urgency of the matter permits, the Pharmacovigilance Risk Assessment Committee may hold public hearings, where it considers that this is appropriate on justified grounds particularly with regard to the extent and seriousness of the safety concern. The hearings shall be held in accordance with the modalities specified by the Agency and shall be announced by means of the European medicines web-portal. **In the hearing due regard shall be given to the therapeutic effect of the medicinal product.** The announcement shall specify the modalities of participation.

The Agency shall, in consultation with the parties concerned, draw up Rules of Procedure on the organisation and conduct of public hearings, in accordance with Article 163 of [revised Regulation (EC) No 726/2004].

Where a marketing authorisation holder or another person intending to submit information, has confidential data relevant to the subject matter of the procedure, they may request permission to present that data to the Pharmacovigilance Risk Assessment Committee in a non-public hearing.

3. Within 60 days of the submission of the information, the Pharmacovigilance Risk Assessment Committee shall make a recommendation, stating the reasons on which it is based, having due regard to the therapeutic effect of the medicinal product. The recommendation shall mention any divergent positions and the grounds on which they are based. In the case of urgency, and on the basis of a proposal by its chairperson, the Pharmacovigilance Risk Assessment Committee may agree to a shorter deadline. The recommendation shall include any or a combination of the following conclusions:
   (a) no further evaluation or action is required at Union level;
   (b) the marketing authorisation holder should conduct further evaluation of data and carry out a follow-up of the results of that evaluation;
   (c) the marketing authorisation holder should sponsor a post-authorisation safety study and carry out a follow up evaluation of the results of that study;
   (d) the Member States or marketing authorisation holder should implement risk minimisation measures;
   (e) the marketing authorisation should be suspended, revoked or not renewed;
   (f) the marketing authorisation should be varied.

4. For the purposes of paragraph 3, point (d), the recommendation shall specify the risk minimisation measures recommended and any conditions or restrictions to which the marketing authorisation should be made subject, including the timeline for implementation.

5. For the purposes of paragraph 3, point (f), where it is recommended to change or add information in the summary of product characteristics or the labelling or package leaflet, the recommendation shall suggest the wording of such changed or added information and shall indicate where in the summary of product characteristics, the labelling or package leaflet such wording should be placed.

Article 116

Follow-up of recommendation made in the framework of the urgent Union procedure

1. Where the scope of the urgent Union procedure, as determined in accordance with Article 114(6), does not include any centralised marketing authorisation, the coordination group shall, within 30 days of receipt of the recommendation of the Pharmacovigilance Risk Assessment Committee, consider the recommendation and reach a position on the maintenance, variation, suspension, revocation or refusal of the renewal of the marketing authorisation concerned, including a timetable for the implementation of the agreed position. Where an urgent adoption of the position is necessary, the coordination group may, on the basis of a proposal by its chairperson, agree to a shorter deadline.

2. If, within the coordination group, the Member States represented reach an agreement on the action to be taken by consensus, the chairperson shall record the agreement and send it to the marketing authorisation holder and the Member States. The Member States shall adopt necessary measures to maintain, vary, suspend, revoke or refuse renewal of the marketing authorisation concerned in accordance with the implementation timetable determined in the agreement.

   In the event that a variation is agreed upon, the marketing authorisation holder shall submit to the competent authorities of the Member States an appropriate application for a variation, including an updated summary of product characteristics and an updated package leaflet within the determined timetable for implementation.

   If an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall be forwarded to the Commission which shall apply the procedure laid down in Article 42.

Where the agreement reached by the Member States represented within the coordination group or the position of the majority of the Member States represented within the coordination group differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the coordination group shall attach to the agreement or majority position a detailed explanation of the scientific grounds for the differences together with the recommendation.

3. Where the scope of the procedure, as determined in accordance with Article 114(6), includes at least one centralised marketing authorisation, the Committee for Medicinal Products for Human Use shall, within 30 days of receipt of the recommendation of the Pharmacovigilance Risk Assessment Committee, consider the recommendation and adopt an opinion on the maintenance, variation, suspension, revocation or refusal of the renewal of the marketing authorisations concerned. Where an urgent adoption of the opinion is necessary, the Committee for Medicinal Products for Human Use may, on the basis of a proposal by its chairperson, agree to a shorter deadline.

   Where the opinion of the Committee for Medicinal Products for Human Use differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use shall attach to its opinion a detailed explanation of the scientific grounds for the differences together with the recommendation.

4. On the basis of the opinion of the Committee for Medicinal Products for Human Use referred to in paragraph 3, the Commission shall, by means of implementing acts:
   (a) adopt a decision addressed to the Member States concerning the measures to be taken in respect of marketing authorisations that are granted by the Member States and that are subject to the urgent Union procedure;
   (b) where the opinion states that regulatory action concerning the marketing authorisation is necessary, adopt a decision to vary, suspend, revoke or refuse the renewal of the centralised marketing authorisations ~~and~~ concerned by the procedure provided for in this section.

5. Article 42 shall apply to the adoption of the decision referred to in paragraph 4, point (a), and to its implementation by the Member States.

6. Article 13 of [revised Regulation (EC) No 726/2004] shall apply to the decision referred to in paragraph 4, point (b). Where the Commission adopts such decision, it may also adopt a decision addressed to the Member States pursuant to Article ~~55~~ **57** of [revised Regulation (EC) No 726/2004].

Section 7

Supervision of post-authorisation safety studies

Article 117

Non-interventional post-authorisation safety studies

1. This Section applies to non-interventional post-authorisation safety studies that are initiated, managed or financed by the marketing authorisation holder voluntarily or pursuant to obligations imposed in accordance with Articles 44 or 87, and that involve the collection of safety data from patients or healthcare professionals.

2. This Section is without prejudice to Member States and Union requirements for ensuring the well-being and rights of participants in non-interventional post-authorisation safety studies.

3. The studies shall not be performed where the act of conducting the study promotes the use of a medicinal product.

4. Payments to healthcare professionals for participating in non-interventional post-authorisation safety studies shall be restricted to the compensation for time and expenses incurred.

5. The competent authority of the Member State may require the marketing authorisation holder to submit the protocol and the progress reports to the competent authorities of the Member States in which the study is conducted.

6. The marketing authorisation holder shall send the final report of the study to the competent authorities of the Member States in which the study was conducted within 12 months of the end of data collection.

7. While a study is being conducted, the marketing authorisation holder shall monitor the data generated and consider its implications for the benefit-risk balance of the medicinal product concerned.

   Any new information that might influence the evaluation of the benefit-risk balance of the medicinal product shall be communicated to the competent authorities of the Member State in which the medicinal product has been authorised in accordance with Article 90.
   The obligation laid down in the second subparagraph is without prejudice to the information on the results of studies that the marketing authorisation holder shall make available by means of the periodic safety update reports as laid down in Article 107.

8. Articles 118 to 121 shall apply exclusively to studies referred to in paragraph 1 that are conducted pursuant to an obligation imposed in accordance with Articles 44 or 87.

Article 118

Agreement of a protocol for a non-interventional post-authorisation safety study

1. Before a study is conducted, the marketing authorisation holder shall submit a draft protocol to the Pharmacovigilance Risk Assessment Committee, except for studies to be conducted in only one Member State that requests the study in accordance with Article 87. For such studies, the marketing authorisation holder shall submit a draft protocol to the competent authority of the Member State in which the study is conducted.

2. Within 60 days of the submission of the draft protocol referred to in paragraph 1 the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate, shall issue:
   (a) a letter endorsing the draft protocol;

(b) a letter of objection, which shall set out in detail the grounds for the objection, where:
   (i) it considers that the conduct of the study promotes the use of a medicinal product;
   (ii) it considers that the design of the study does not fulfil the study objectives; or
(c) a letter notifying the marketing authorisation holder that the study is a clinical trial falling under the scope of Regulation (EU) No 536/2014.

3. The study may commence only when the written endorsement from the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate, has been issued.

Where a letter of endorsement of the draft protocol as referred to in paragraph 2, point (a), has been issued, the marketing authorisation holder shall forward the protocol to the competent authorities of the Member States in which the study is to be conducted and may thereafter commence the study according to the endorsed protocol.

Article 119

Update of a protocol for a non-interventional post-authorisation safety study

After a study has been commenced, any substantial amendments to the protocol shall be submitted, before their implementation, to the competent authority of the Member State or to the Pharmacovigilance Risk Assessment Committee, as appropriate. The competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate, shall assess the amendments and inform the marketing authorisation holder of its endorsement or objection. Where applicable, the marketing authorisation holder shall inform the Member States in which the study is conducted.

Article 120

Final study report on a non-interventional post-authorisation safety study

1. Upon completion of the study, a final study report shall be submitted to the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee within 12 months of the end of data collection unless a written waiver has been granted by the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate.

2. The marketing authorisation holder shall evaluate whether the results of the study have an impact on the marketing authorisation and shall, if necessary, submit to the competent authorities of the Member States an application to vary the marketing authorisation.

3. Together with the final study report, the marketing authorisation holder shall electronically submit an abstract of the study results to the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee.

Article 121

Recommendations following the submission of a final study report on non-interventional post-authorisation safety studies

1. Based on the results of the study and after consultation of the marketing authorisation holder, the Pharmacovigilance Risk Assessment Committee may make recommendations concerning the marketing authorisation, stating the reasons on which they are based. The recommendations shall mention any divergent positions and the grounds on which they are based.

2. When recommendations for the variation, suspension or revocation of a national marketing authorisation are made, the Member States represented within the coordination group shall agree on a position on the matter taking into account the recommendation referred to in paragraph 1 and shall include a timetable for the implementation of the agreed position.

If, within the coordination group, the Member States represented reach an agreement on the action to be taken by consensus, the chairperson shall record the agreement and send it to the marketing authorisation holder and the Member States. The Member States shall adopt necessary measures to vary, suspend or revoke the marketing authorisation concerned in accordance with the implementation timetable determined in the agreement.

In the event that a variation is agreed upon, the marketing authorisation holder shall submit to the competent authorities of the Member State an appropriate application for a variation, including an updated summary of product characteristics and an updated package leaflet within the determined timetable for implementation.

The agreement shall be made publicly available on the European medicines web-portal established in accordance with Article 104 of [revised Regulation (EC) No 726/2004].

3. If an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group, **with a detailed description of the matters on which the other Member States have been unable to reach an agreement and of all the divergent positions of Member States presented** shall be forwarded to the Commission, which shall apply the procedure laid down in Article 42.

4. Where the agreement reached by the Member States represented within the coordination group or the position of the majority of Member States differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the coordination group shall attach to the agreement or majority position a detailed explanation of the scientific grounds for the differences together with the recommendation.

Section 8
Implementation, guidance and reporting

Article 122

Implementing measures related to pharmacovigilance activities

1. In order to harmonise the performance of the pharmacovigilance activities provided for in this Directive, the Commission shall adopt implementing measures in the following areas for which pharmacovigilance activities are provided for in Annex I, Articles 96, 99, 100, 105 to 107, 113, 118 and 120 by setting out:
   (a) the content and the rules on the maintenance of the pharmacovigilance system master file kept by the marketing authorisation holder;
   (b) minimum requirements for the quality system for the performance of pharmacovigilance activities by the competent authorities of the Member States and the marketing authorisation holder;
   (c) rules on the use of internationally agreed terminology, formats and standards for the performance of pharmacovigilance activities;
   (d) minimum requirements for the monitoring of data in the Eudravigilance database to determine whether there are new risks or whether risks have changed;
   (e) the format and content of the electronic transmission of suspected adverse reactions by Member States and the marketing authorisation holder;
   (f) the format and content of electronic periodic safety update reports and risk management plans;
   (g) the format of protocols, abstracts and final study reports for the post-authorisation safety studies.

2. Those measures shall take account of the work on international harmonisation carried out in the area of pharmacovigilance~~.~~ **and shall, where necessary, be revised to take account of technical and scientific progress.** Those measures shall be adopted in accordance with the regulatory procedure referred to in Article 214(2).

Article 123

Guidance to facilitate the performance of pharmacovigilance activities

The Agency shall, in cooperation with competent authorities of the Member States and other interested parties, draw up:

(a) guidance on good pharmacovigilance practices for both competent authorities and marketing authorisation holders;

(b) scientific guidance on post-authorisation efficacy studies.

Article 124

Reporting on pharmacovigilance tasks

The Agency shall make public a report on the performance of pharmacovigilance tasks by the Member States and the Agency every three years. The first report shall be made public by [three years after application date of [revised Regulation (EC) No 726/2004].

REGULATION

CHAPTER VIII
PHARMACOVIGILANCE

Article 99
Pharmacovigilance

1. The obligations of marketing authorisation holders laid down in Articles 99 and 100(1) of [revised Directive 2001/83/EC] shall apply to marketing authorisation holders for medicinal products for human use authorised in accordance with this Regulation.

2. The Agency may impose an obligation on a holder of a centralised marketing authorisation to operate a risk management system, as referred to in Article 99(4), point (c) of [revised Directive 2001/83/EC], if there are concerns about the risks affecting the benefit-risk balance of an authorised medicinal product. In that context, the Agency shall also oblige the marketing authorisation holder to submit a risk management plan for the risk-management system that they intend to introduce for the medicinal product concerned.

   The obligation ~~referred to in paragraph 2~~ shall be duly justified, notified in writing, and shall include the timeframe for submission of the risk-management plan.

3. The Agency shall provide the marketing authorisation holder with an opportunity to submit written observations in response to the imposition of the obligation **referred to in paragraph 2** within a time limit which it shall specify, if the marketing authorisation holder so requests within 30 days of receipt of the written notification of the obligation.

   On the basis of the written observations submitted by the marketing authorisation holder, the Agency shall review its opinion.

4. Where the opinion of the Agency confirms the obligation **referred to in paragraph 2** and unless the Commission returns the opinion to the Agency for further consideration, the marketing authorisation shall be varied accordingly by the Commission in accordance with the procedure set out in Article 13, to:
   (a) include the obligation as a condition of the marketing authorisation and the risk management system shall be updated accordingly.
   (b) include the measures to be taken as part of the risk management system as conditions of the marketing authorisation referred to in Article 12(4), point (e).

Article 100

Safety announcements

The obligations of marketing authorisation holders laid down in Article 104, **paragraphs 1 and 2** ~~(1)~~ of [revised Directive 2001/83/EC], and the obligations of the Member States, the Agency and the Commission laid down in paragraphs ~~2,~~ 3 and 4 of that Article shall apply to the safety announcements referred to in Article 138(1), point (f), of this Regulation concerning medicinal products for human use authorised in accordance with this Regulation.

Article 101

Eudravigilance database

1. The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a database and data processing network ('Eudravigilance database') to collate pharmacovigilance information regarding medicinal products authorised in the Union and to allow competent authorities to access that information simultaneously and to share it.

   ~~In justified cases,~~ ~~t~~**T**he Eudravigilance database ~~may~~ **shall** include pharmacovigilance information with regard to medicinal products used under compassionate use referred to in Article 26 or early access schemes.

The Eudravigilance database shall contain information on suspected adverse reactions in human beings arising from use of the medicinal product within the terms of the marketing authorisation as well as from uses outside the terms of the marketing authorisation, and on those occurring in the course of post-authorisation studies with the medicinal product or associated with occupational exposure.

2. The Agency shall, in collaboration with the Member States and the Commission, draw up the functional specifications for the Eudravigilance database, together with a timeframe for their implementation.

The Agency shall prepare an annual report on the Eudravigilance database and send it to the European Parliament, the Council and the Commission.

Any substantial change to the Eudravigilance database and the functional specifications shall take into account the recommendations of the Pharmacovigilance Risk Assessment Committee.

The Eudravigilance database shall be fully accessible to the competent authorities of the Member States and to the Agency and the Commission. It shall also be accessible to marketing authorisation holders **and marketing authorisation applicants** to the extent necessary for them to comply with their pharmacovigilance obligations.

The Agency shall ensure that healthcare professionals and the public have appropriate levels of access to the Eudravigilance database, and that personal data is protected. The Agency shall work together with all stakeholders, including research institutions, healthcare professionals, and patient and consumer organisations, in order to define the 'appropriate level of access' for healthcare professionals and the public to the Eudravigilance database.

Commented [MDN8]: We suggest to delete «and marketing authorisation applicants».

The Eudravigilance database contains sensitive personal data about patients and access to the database cannot be justified because the applicants do not have pharmacovigilance obligations.

Consequently, applicants should not have access to the Eudravigilance database.

Marketing authorisation holders have pharmacovigilance obligations – not applicants (furthermore, their application may be rejected if they do not comply with the requirements for a marketing authorisation).

The data held on the Eudravigilance database shall be made publicly available in an aggregated format together with an explanation of how to interpret the data.

3. The Agency shall, in collaboration either with the marketing authorisation holder or with the Member State that submitted an individual suspected adverse reaction report to the Eudravigilance database, be responsible for operating procedures that ensure the quality and integrity of the information collected in the Eudravigilance database.

4. Individual suspected adverse reaction reports and follow-ups submitted to the Eudravigilance database by marketing authorisation holders**, marketing authorisation applicants or undertakings supplying medicinal products used in accordance with Article 3, paragraphs 1 or 2 of [revised Directive 2001/83/EC]** shall be transmitted electronically upon receipt to the competent authority of the Member State where the reaction occurred.

Article 102

Forms for reporting suspected adverse reactions

The Agency shall, in collaboration with the Member States, develop standard web-based structured forms for the reporting of suspected adverse reactions by healthcare professionals and patients in accordance with the provisions referred to in Article 106 of [revised Directive 2001/83/EC].

Article 103

Periodic safety update reports repository

The Agency shall, in collaboration with the competent authorities of the Member States and the Commission, set up and maintain a repository for periodic safety update reports ('repository') and the corresponding assessment reports regarding medicinal products authorised in the Union so that they are fully and permanently accessible to the Commission, the competent authorities of the Member States, the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use and the coordination group referred to in Article 37 of [revised Directive 2001/83/EC] ('coordination group').

The Agency shall, in collaboration with the competent authorities of the Member States and the Commission, and after consultation with the Pharmacovigilance Risk Assessment Committee, draw up the functional specifications for the repository.

Any substantial change to the repository and the functional specifications shall always take into account the recommendations of the Pharmacovigilance Risk Assessment Committee.

Article 104

European medicines web-portal ~~and register of studies for environmental risk assessment~~

1. The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a European medicines web-portal for the dissemination of information on medicinal products authorised or to be authorised in the Union. By means of that portal, the Agency shall make public the following:
   (a) the names of members of the Committees referred to in Article 142, points (d) and (e), and the members of the coordination group, together with their professional qualifications and with the declarations referred to in Article 147(2);
   (b) agendas and minutes from each meeting of the Committees referred to in Article 142, points (d) and (e), and of the coordination group as regards pharmacovigilance activities;
   (c) a summary of the risk management plans **including a description of any additional risk minimisation measures** for medicinal products authorised in accordance with this Regulation;
   (d) ~~a list of the locations in the Union where pharmacovigilance system master files are kept and contact information for pharmacovigilance enquiries, for all medicinal products authorised in the Union;~~
   (e) information about how to report to competent authorities of the Member States suspected adverse reactions to medicinal products and the standard structured forms referred to in Article 102 for their web-based reporting by patients and healthcare professionals, including links to national websites;
   (f) Union reference dates and frequency of submission of periodic safety update reports established in accordance with Article 108 of [revised Directive 2001/83/EC];

(g) protocols and public abstracts of results of the post-authorisation safety studies referred to in Articles ~~108~~ **118** and 120 of [revised Directive 2001/83/EC];

(h) the initiation of the procedure provided for in Article 41~~(2),~~ and Articles 114~~, 115 and~~ 116 of [revised Directive 2001/83/EC~~],~~**] and Article 55,** the active substances or medicinal products concerned and the issue being addressed, any public hearings pursuant to that procedure and information on how to submit information and to participate in public hearings;

(i) conclusions of assessments, recommendations, opinions, approvals and decisions taken by the Agency and its Committees under this Regulation and [revised Directive 2001/83/EC], unless it is required that this information is made public by the Agency by other means;

(j) conclusions of assessments, recommendations, opinions, approvals and decisions taken by the coordination group, the competent authorities of the Member States and the Commission in the framework of the procedures set out in Articles 16, 106, 107 and 108 of this Regulation and of Chapter IX, Sections 3 and 7 of [revised Directive 2001/83/EC].

~~The summaries referred to in point (c) shall include a description of any additional risk minimisation measures.~~

2. In the development and review of the web portal, the Agency shall consult relevant stakeholders, including patient and consumer groups, healthcare professionals and industry representatives.

Article 104a

European register of studies for environmental risk assessment

~~3.~~ The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a register of environmental risk assessment studies conducted for the purpose of supporting an environmental risk assessment for medicinal products authorised in the Union, unless such information is made public in the Union by different means.

Information in such register shall be publicly available, unless restrictions are necessary to protect commercially confidential information. For the purpose of setting up such register, the Agency may request marketing authorisation holders and competent authorities to submit results of any such study already completed for products authorised in the Union within [*OP please add the date = 24 months after the date of application of this Regulation*].

Article 105

Literature monitoring

1. The Agency shall monitor selected medical literature for reports of suspected adverse reactions to medicinal products containing certain active substances. It shall publish the list of active substances being monitored and the medical literature subject to this monitoring.

2. The Agency shall enter into the Eudravigilance database relevant information from the selected medical literature.

3. The Agency shall, in consultation with the Commission, Member States and interested parties, draw up a detailed guide regarding the monitoring of medical literature and the entry of relevant information into the Eudravigilance database.

Article 106

Monitoring of safety of medicinal products

1. The obligations of marketing authorisation holders and of Member States laid down in Article 105 and Article 106 of [revised Directive 2001/83/EC] shall apply to the recording and reporting of suspected adverse reactions for medicinal products for human use authorised in accordance with this Regulation.

2. The obligations of marketing authorisation holders laid down in Article 107 of [revised Directive 2001/83/EC] and the procedures under Articles 107 and 108 of that Directive shall apply to the submission of periodic safety update reports, the establishment of Union reference dates and changes to the frequency of submission of periodic safety update reports for medicinal products for human use authorised in accordance with this Regulation.

The provisions applicable to the submission of periodic safety update reports laid down in the of Article 108(2), second subparagraph, of that Directive shall apply to marketing authorisation holders of marketing authorisations which were granted before 2 July 2012 and for which the frequency and dates of submission of the periodic safety update reports are not laid down as a condition to the marketing authorisation until such time as another frequency or other dates of submission of the reports are laid down in the marketing authorisation or are determined in accordance with Article 108 of that Directive.

3. The assessment of the periodic safety update reports shall be conducted by a rapporteur appointed by the Pharmacovigilance Risk Assessment Committee. The rapporteur shall closely collaborate with the rapporteur appointed by the Committee for Medicinal Products for Human Use or the Reference Member State for the medicinal products concerned.

The rapporteur shall prepare an assessment report within 60 days of receipt of the periodic safety update report and send it to the Agency and to the members of the Pharmacovigilance Risk Assessment Committee. The Agency shall send the report to the marketing authorisation holder.

Within 30 days of receipt of the assessment report, the marketing authorisation holder and the members of the Pharmacovigilance Risk Assessment Committee may submit comments to the Agency and to the rapporteur.

Following the receipt of the comments referred to in the third subparagraph, the rapporteur shall within 15 days update the assessment report taking into account any comments submitted, and forward it to the Pharmacovigilance Risk Assessment Committee. The Pharmacovigilance Risk Assessment Committee shall adopt the assessment report with or without further changes at its next meeting and issue a recommendation. The recommendation shall mention the divergent positions with the grounds on which they are based. The Agency shall include the adopted assessment report and the recommendation in the repository set up under Article 103, and forward both to the marketing authorisation holder.

4. In the case of an assessment report that recommends any action concerning the marketing authorisation, the Committee for Medicinal Products for Human Use shall, within 30 days of receipt of the report by the Pharmacovigilance Risk Assessment Committee, consider the report and adopt an opinion on the maintenance, variation, suspension or revocation of the marketing authorisation concerned, including a timetable for the implementation of the opinion. Where this opinion of the Committee for Medicinal Products for Human Use differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use shall attach to its opinion a detailed explanation of the scientific grounds for the differences together with the recommendation.

   Where the opinion states that regulatory action concerning the marketing authorisation is necessary, the Commission shall adopt a decision, by means of implementing acts, to vary, suspend or revoke the marketing authorisation in accordance with Article 13. Where the Commission adopts such a decision, it may also adopt a decision addressed to the Member States pursuant to Article 57.

5. In the case of a single assessment of periodic safety update reports concerning more than one marketing authorisation in accordance with Article 110(1) of [revised Directive 2001/83/EC] which includes at least one marketing authorisation granted in accordance with this Regulation, the procedure laid down in Article ~~107~~**110** and Article ~~109~~**112** of that Directive shall apply.

6. The final recommendations, opinions and decisions referred to in paragraphs 3, 4 and 5 shall be made public by means of the European medicines web-portal referred to in Article 104.

Article 107

Agency pharmacovigilance related activities

1. Regarding medicinal products for human use authorised in accordance with this Regulation, the Agency shall, in collaboration with the Member States, take the following measures:
   (a) monitor the outcome of risk minimisation measures contained in risk management plans and of conditions referred to in Article 12, paragraph 4, points (d) to (g), or in Article 20, paragraph 1, points (a) and (b), and in Articles 18(1) and 19;
   (b) assess updates to the risk management system;
   (c) monitor the data in the Eudravigilance database to determine whether there are new risks or whether risks have changed and whether those risks impact on the benefit-risk balance.

2. The Pharmacovigilance Risk Assessment Committee shall perform the initial analysis and prioritisation of signals of new risks or risks that have changed or changes to the benefit-risk balance. Where it considers that follow-up action may be necessary, the assessment of those signals and agreement on any subsequent action concerning the marketing authorisation shall be conducted in a timescale commensurate with the extent and seriousness of the issue. Where appropriate, the assessment of those signals may be included in a pending assessment of a periodic safety update report or a pending procedure in accordance with Articles 95 and 114-**116** of [revised Directive 2001/83/EC] or Article 55 of this Regulation.

3. The Agency and competent authorities of the Member States and the marketing authorisation holder shall inform each other in the event of new risks or risks that have changed or changes to the benefit-risk balance **having been** ~~being~~ detected.

Article 108

Non-interventional post-authorisation safety studies

1. For non-interventional post-authorisation safety studies concerning medicinal products for human use authorised in accordance with this Regulation which have been imposed in accordance with Articles 13 and 20, the procedure provided for in Article 117, paragraphs 3 to 7, Articles 118, 119, 120 and 121(1) of [revised Directive 2001/83/EC] shall apply.

2. Where, in accordance with the procedure referred to in paragraph 1, the Pharmacovigilance Risk Assessment Committee issues recommendations for the variation, suspension or revocation of the marketing authorisation, the Committee on Medicinal Products for Human Use shall adopt an opinion taking into account the recommendation, and the Commission shall adopt a decision in accordance with Article 13.

Where the opinion of the Committee for Medicinal Products for Human Use differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use shall attach to its opinion a detailed explanation of the scientific grounds for the differences, together with the recommendation.

Article 109

Exchange of information with other organisations

1. The Agency shall collaborate with the World Health Organization in matters of pharmacovigilance and shall take the necessary steps to submit to it, promptly, appropriate and adequate information regarding the measures taken in the Union which could have a bearing on public health protection in third countries.

The Agency shall make available promptly all suspected adverse reaction reports occurring in the Union to the World Health Organization.

2. The Agency and the European Monitoring Centre for Drugs and Drug Addiction shall exchange information that they receive on the abuse of medicinal products including information related to illicit drugs.

Article 110

International collaboration

At the request of the Commission, the Agency shall participate in collaboration with the Member States in international harmonisation and standardisation of technical measures in relation to pharmacovigilance.

Article 111

Cooperation with Member States

The Agency and the Member States shall cooperate to continuously develop pharmacovigilance systems capable of achieving high standards of public health protection for all medicinal products, regardless of the routes of marketing authorisation, including the use of collaborative approaches, to maximise use of resources available within the Union.

Article 112

Reports on pharmacovigilance tasks

The Agency shall perform regular independent audits of its pharmacovigilance tasks and report the results to its Management Board on a 2-yearly basis. The results shall be subsequently published.

FRANCE

In English :

The French authorities are not opposed to the proposed compromise. However, they would like to make a number of comments, which do not constitute blocking points, to improve the text:

- **Concerning the "Labeling" section**, the French authorities would like to propose an amendment relating to unit packaging in articles 66 and 17 (see appendix);

  Also, in article 72, the French authorities consider that the possibility of adding symbols and pictograms on the box, at national level, still seems necessary to support our national particularities, in particular the driving or pregnancy pictograms, the triman logo, etc... The reinstatement of the last point (the "e" which could become an "f") seems important.

- **Concerning the "Advertising" section**, the French authorities consider that the amendment made to article 175 is not appropriate, as the addition of the words "and that it does not promote the prescription or consumption of the medicinal product." at the end of paragraph 2 d) seems neither relevant nor desirable (and was not previously discussed in the group).

  Indeed, with the proposed addition, information relating to human health or a disease will be requalified as advertising if two conditions are met: reference, even indirect, to a medicinal product and it does not promote the prescription or consumption of such products. Under current law, a single reference, even indirect, to a drug prevents the issuer from bringing his document within the scope of this exception. With the proposed addition, pharmaceutical companies would be able to demonstrate that their document, although containing an indirect reference to a drug, does not encourage the prescription or consumption of that drug.

  Moreover, the definition of advertising and the case law of the CJEU are quite clear, and today make it "easy" to requalify a document distributed by a laboratory claiming the application of this exception.

- **Concerning public financial support**, in article 57, the French authorities maintain that the management of this information does not necessarily fall within the remit of the MA authorities, and that the text should take into account the diversity of national organizations; one solution might be to propose that the entity locally responsible for transmitting this information should be designated (at a later date) by each Member State.

FR Proposal Article 66 / Article 17 :

unit doses for antimicrobials

Article 66 :

We propose to add a paragraph 4

1. The particulars laid down in Annex IV shall appear on immediate packagings other than those referred to in the paragraphs 2, and 3 **and 4.**

…

"4. On request of a Member state as laid down in Article 17.4, the following particulars at least shall appear on each single dose of an immediate packaging :

(a) the name of the medicinal product followed by its strength ;
b) the batch number;
c) the expiry date;"

Article 17 :

We propose to add a paragraph 4

"4. A Member states may require for antimicrobials an immediate packaging with unit dose with the labelling particulars laid down in article art 66. 4. , "

Rationale

In an overall context of proper use, combating antibiotic resistance, reducing waste and in the event of shortages (in order to limit the quantities dispensed to those strictly necessary), it is important to make more medicines available in unit packs.

Each unit dose must meet minimum labelling requirements to ensure patient safety, particularly as regards identification of the medicinal product, dosage, batch number and expiry date.

We propose adding a new paragraph 4 to Article 66 and Article 17 along these lines

These amendments make it optional for Member States to require such packaging in unit doses.

- - -

FR :

Dans un contexte global de bon usage, de lutte contre la résistance aux antibiotiques, de réduction des déchets et en cas de pénurie (afin de limiter les quantités délivrées aux quantités strictement nécessaires), il est important de rendre disponible plus de médicaments en conditionnement unitaire.

Chaque dose unitaire doit répondre à des exigences minimales d'étiquetage pour assurer la sécurité du patient, notamment en ce qui concerne l'identification du médicament, le dosage, le numéro de lot et la date de péremption.

Nous proposons d'ajouter un nouveau paragraphe 4 à l'article 66 et à l'article 17 en ce sens

Par ces amendements, il est facultatif pour les États membres de demander un tel conditionnement en doses unitaires

GREECE

We would like to thank the Presidency for the latest compromise on Labelling cluster, which we generally support although we would like to see further changes in three points (see article 63.3a, 66.2a,176.4)

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 the packaging in paper format and electronically in accordance with the specifications, standards and format specified by the implementing act pursuant to paragraph 6. The competent authorities shall make publicly available the electronic package leaflet on their websites.**

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~~ from paragraph 1,** Member States may decide that the package leaflet shall be made available **by the marketing authorisation holder for specific categories of medicinal products or for all medicinal products,** ~~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 both preparing the electronic leaflet and ~~shall be responsible for providing~~ ensuring that the printed version of the package leaflet is readily available to the patient. If a Member State decides that the package leaflet shall be only made available electronically, it shall not preclude the marketing authorisation holder from providing the package leaflet in paper format in addition to the electronic format on a voluntary basis.**

3a. **The obligation ~~to make available~~ of providing the paper leaflet into the packaging ~~the package leaflet in paper format~~ in a Member State shall not constitute a reason for the marketing authorisation holder to refuse to supply the medicinal product on the market in that Member State.**

Commented [REV1]: Different meaning

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**:**

(a) establish common standards and formats for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies;

(b) establish criteria for the provision of such information through secure digital platforms of the competent authorities~~;~~

(c) set the necessary processes to validate the electronic version of the package leaflet and make it available to patients;

(d) specify mandatory information on the packaging on how to access the electronic version of the package leaflet;

(e) the details of implementing commonly recognised European antimicrobial symbol.

~~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 **to maintain the paper package leaflet in parallel to**~~on~~ the adoption of measures enabling the electronic provision of product information**. It is necessary to** ~~while~~ ensur**e**~~ing~~ 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 **providing product information only in** electronic **format** ~~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' 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 162

Wholesale distribution of medicinal products

4. In the case of medicinal products covered by a national marketing authorisation, the notification referred to in paragraph 3 to the competent authority of the Member State shall be without prejudice to additional procedures provided for in the legislation of that Member State and to fees payable to the competent authority of the Member State for examining the notification. **A Member State may require that the imported medicinal product is labelled in accordance with Article 74. The Member State may also require that the electronic product information is provided in accordance with Article 63(3).**

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 **packages that are also multi-lingual**.

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 appropriate~~ ~~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~~appropriate, 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;**

Commented [REV2]: General comment
For public health reasons it is essential for the patient to be informed about the strength of the medicinal product used, while the pharmaceutical form is evident

~~(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**, if not already evident from the name or pharmaceutical form of the ~~of the~~ medicinal product**;

(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 ~~**manufacturing**~~ **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, as well as to assess the general supply situation to avoid shortages,** use the information contained in the repositories system referred to paragraph 2, second subparagraph, point (e).

Commented [REV3]: We strongly support the provision

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 ~~radio~~activity per dose or per vial and the number of capsules, or, for liquids, the number of millilitres in the container.

3. **In addition to the requirements of Article 66, ~~T~~t**he 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 ~~radio~~activity 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 beginning of** 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”)~~ **and** ~~with~~ information on antimicrobial resistance and the appropriate use and disposal of antimicrobials.

In the case of electronic version of the package leaflet, the information referred to in the previous subparagraph shall be made available to patients electronically in a distinct and immediately visible way.

~~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~~appropriate, and pharmaceutical form, if ~~applicable~~appropriate, ~~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 **free of charge** 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) the identity of the medicinal product in accordance with national requirements, including for statistical reasons.
   ~~(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** 6~~5~~**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**, as well as in the English language in the electronic version of the package leaflet**.

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 ~~,~~**or 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 ~~,~~**or multi-country** package is marketed.

Recital:

(130) The use of multi-language~~,~~ **or 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~~,~~ **or**~~,~~ **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~~,~~ **or 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~~**multi-language or multi-country** 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~~**appropriate (including in Braille),** and pharmaceutical form **(including in Braille, if appropriate)**, 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;**

Commented [REV4]: Why not for all medicinal products

(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 standardised 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 **or** ~~/~~**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 appropriate**~~**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**e**~~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 commonly recognised European 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** ~~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**~~**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**, provided it does not promote the prescription** ~~**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 **and that it does not promote the prescription or consumption of the medicinal product**.

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~~ **~~comparison of quality, safety and efficacy is supported objectively by the complete~~** ~~demonstrated and supported by the summary of product characteristics~~ **~~and/or assessment reports published by competent authorities~~**.

Commented [REV5]: We don't support the current changes.

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 of communication** ~~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 **or professional activity**, 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 at promotional events, h**~~H~~ospitality ~~at sales promotion events~~ shall always be strictly limited to ~~their~~ **the** main purpose **of the event and shall respect the principles laid down in paragraph 1.** ~~and~~ **The hospitality** 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 **be respected when** ~~not prevent~~ hospitality **is** being offered, directly or indirectly, at events for purely professional and scientific purposes. Such hospitality **is justified only when indispensable for the fulfilment of** ~~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*** ~~***free of charge***~~

1. ~~Free s~~**S**amples of medicinal products shall be provided **free of charge** ~~**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. **Member States may decide that o**~~O~~n 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** ~~**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 **intended for systemic administration,** ~~;~~ or **is an antibiotic in any pharmaceutical formulation**
   (f) contains an active substance which are
   (i) persistent, bioaccumulative and toxic, or
   (ii) very persistent and very bioaccumulative, or
   (iii) persistent, mobile and toxic, or
   (iv) 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 **(a), (b), (c), (d) and (f)**, 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**~~.

Commented [REV6]: We prefer the previous wording, as it becomes complicated; if para 4 is included, para 2 and 6 should also be included. Otherwise, para 4 of Article 51 should be deleted from Article 52.

~~*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**.

Commented [REV7]: The consequences of not compliance with the obligation to submit a variation should be provided. We propose that the member state may impose this variation by unilateral act.

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.

IE Comments on Labelling, advertising and prescriptions and Pharmacovigilance cluster-25/4/25

Product information, advertising and prescriptions cluster

Legislative text – 16.04.25	IE suggested adaptions to the text	IE comments
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.	1. The marketing authorisation holders shall establish, within ~~their~~ **its** undertaking ~~or not-for-profit entities~~, a scientific service in charge of information about the medicinal products that they place on the market.	We had sought a change to this wording, which at the last meeting COM signalled they were open to because it was not their intention that a MAH could choose to establish their scientific service in a separate not-for-profit entity. They had added the reference to a not-profit-entity solely in case the MAH itself was a not-for-profit entity. The proposed text as originally worded could have the unintended consequence of allowing MAHs to establish their scientific service in a separate not-for-profit entity. We wish to ensure that any such services are established within the MAH's own

		undertaking. We do not consider it necessary to refer to not-for-profit entities here as it is accepted that the MAH could itself be a not-for-profit entity. The proposed wording would be consistent with Art 98 of the existing directive which has not led to any issues that we are aware of. As an alternative to 'undertaking' if needed we could accept organisation. The reference to 'not for profit entities' should also be deleted from para 2 points (a), (b) and (c)
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.		

Pharmacovigilance Cluster

Legislative text – 16.04.25	IE suggested adaptions to the text	IE comments
Article 99 *Marketing authorisation holder pharmacovigilance system*		
1. Marketing authorisation holders shall operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks equivalent to the relevant Member State's pharmacovigilance system referred to in Article 96(1).		
2. Marketing authorisation holders shall by means of the pharmacovigilance system referred to in Article 96(1) evaluate all information scientifically, consider options for risk minimisation and prevention and take appropriate measures as necessary.		
3. Marketing authorisation holders shall perform a regular audit of their pharmacovigilance system. They shall place a note concerning the main findings of the audit on the pharmacovigilance system master file and, based on the audit findings, ensure that an		

appropriate corrective action plan is prepared and implemented. Once the corrective actions have been fully implemented, the note may be removed.		
4. As part of the pharmacovigilance system, marketing authorisation holders shall: (a) have permanently and continuously at their disposal an appropriately qualified person responsible for pharmacovigilance; (b) maintain and make available on request by a competent authority a pharmacovigilance system master file; (c) operate a risk management system for each medicinal product; (d) monitor the outcome of risk minimisation measures that are contained in the risk management plan ~~pursuant to Article 21~~ **~~6(2)~~** or that are laid down as conditions of the marketing authorisation pursuant to Articles 44, **(1) points (a)-(g) and point (i)**, 45 and any obligations imposed in accordance with Article 87; **(1) points (a) and (b)**;		

(e) update the risk management system and monitor pharmacovigilance data to determine whether there are new risks or whether risks have changed or whether there are changes to the benefit-risk balance of medicinal products.		
5. The qualified person referred to in paragraph 4, point (a), shall reside and operate in the Union and shall be responsible for the establishment and maintenance of the pharmacovigilance system. The marketing authorisation holder shall submit the name and contact details of the qualified person to the competent authority of the Member State and the Agency.		
6. The marketing authorisation holder shall, on request from the competent authority of a Member State, nominate a contact person for pharmacovigilance issues in that Member State who shall report to the qualified person referred to in paragraph 4, point (a).		
7. The marketing authorisation holder shall have procedures in place to ensure continued	**7. The marketing authorisation holder shall have procedures in place to**	This relates to a comment we made seeking to ensure that MAH's would continue to fulfil relevant

compliance with their pharmacovigilance tasks for an appropriate period after a marketing authorisation has been withdrawn or revoked to ensure patient's safety.	**ensure continued compliance with their pharmacovigilance and other post marketing tasks, to ensure patient's safety, for an appropriate period after a marketing authorisation has been withdrawn or revoked.~~to ensure patient's safety.~~**	obligations in the event that a medicine is voluntarily withdrawn but stock released prior to the withdrawal remains on the market. We think that the wording is better if it is re-ordered as it is not clear whether the the revocation is due to the patient safety or whether the requirement to continue pharmacovigilance is due to patient safety. We believe it is the latter. We also think that post withdrawal re-calls etc should also be a requirement.

Input Netherlands on Pharmacovigilance and Labelling

Pharmacovigilance

DIR Article 99(7): We support the inclusion of this new PARA, to make clear that MAH still have the responsibility to monitor their medicinal products after the marketing authorisation has been withdrawn. However, the current legal text now obliges the MAH comply to all pharmacovigilance tasks. We do not see the need for this, for example PSURs should not be necessary. We therefore propose different wording and allow to develop guidance to specify for MAHs which tasks they still need to comply to.

7. The marketing authorisation holder shall have procedures in place to ensure continued compliance with their pharmacovigilance tasks that are neccessary to ensure patients's safety for an appropriate period after a marketing authorisation has been withdrawn or revoked ~~to ensure patient's safety~~.

Technical comments
DIR Article 102: we note that depending on the outcomes of the incentives cluster, a reference should be made to include the given data protection period in the national medicines web-portal.

REG Article 107(2): In line with DIR article 113, reference should be made to articles 92 to 95 and 114-116.

2. The Pharmacovigilance Risk Assessment Committee shall perform the initial analysis and prioritisation of signals of new risks or risks that have changed or changes to the benefit-risk balance. Where it considers that follow-up action may be necessary, the assessment of those signals and agreement on any subsequent action concerning the marketing authorisation shall be conducted in a timescale commensurate with the extent and seriousness of the issue. Where appropriate, the assessment of those signals may be included in a pending assessment of a periodic safety update report or a pending procedure in accordance with Articles 92 to 95 and 114-**116** of [revised Directive 2001/83/EC] or Article 55 of this Regulation.

Labelling

DIR article 51(1)(f) : During the CWP we discussed the properties of these substances in relation to the prescription status. For The Netherlands, it was important that this provision would not be hazard based (properties of a substance itself, not linked to its effect on the environment), but risk based (the effect the substance has on the environment). The Commission clarified that the second part of this provision, starting from "and" covers the necessity that these substances should be prescription status based on risk. This part of the provision should therefore be applicable for all four subparagraphs. In the current text it could be interpreted that this is only applicable for para (iv).

(f) contains an active substance which is

(i) persistent, bioaccumulative and toxic, or
(ii) very persistent and very bioaccumulative, or
(iii) persistent, mobile and toxic, or
(iv) 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.

SWEDEN COMMENTS
Labelling

Art. 63.3 D

SE propose an addition (a subparagraph) to paragraph 3 in this article. We predict situations where it could be deemed necessary to make exemptions from the requirement to provide a printed copy of the package leaflet to the patient. There is a risk that smaller countries (markets) will not get access to some medicinal products if this requirement must be upheld in all situations. It should be possible for Member States to make exemptions in justified cases.

Proposal:

Member States may, in justified cases when there is no risk to patient safety, make an exception from the patients right to a printed copy of the package leaflet.

Art. 74 D

SE supports the addition in paragraph 1 but is of the opinion that it needs to be clarified in transitional provisions when the requirement of electronic versions of the package leaflet in English is effective.

Today there are about 2000 medicinal products on the Swedish market without package leaflets in English since the products are approved nationally. There must be sufficient time for both pharmaceutical companies to provide the package leaflets in English and for the national competent authorities to assess them.

Art. 75 D

Art. 75 provides a list of possible exemptions from requirements for labelling and package leaflet. SE have on several occasions proposed an additional possible exemption (letter f). The proposal is justified since it's important that we conserve resources for environmental reasons. This exemption can for example be applicable to avoid destruction of packages and whole batches of a medicinal product when there are minor printing errors in the labelling or the package leaflet *that does not affect patient safety*.

Annex V

SE propose an addition (p. 13) to this annex. The concept 'risk to the environment' is defined in EMA guidelines. This information in the SmPC can help persons who can prescribe medicinal products to make environmentally friendly choices in cases where there is a possibility to choose between medicinal products.

Proposal

(13) information about any substantial risks to the environment that are caused by the medicinal product.

Annex VI

Information on how to dispose used medicines and packaging material should be included for all medicinal products and not just antimicrobials. Information on package material have been requested by patients and industry with the purpose of correctly disposals according to national systems. It is for example important for patients to know how to dispose inhalators and blister packs. A similar proposal has been made by DE on working group meetings.

Proposal

(8) information on special precautions for disposal of a used medicinal product and brief information regarding package materials, and for antimicrobials, a warning that improper use and disposal of the medicinal product contributes to antimicrobial resistance and the commonly recognised European antimicrobial symbol.

Marketing

Art. 176.4

SE is opposed to the second addition in art. 176.4. The addition entails an unwanted exemption from the principal rule that all parts of advertising of a medicinal product must comply with the particulars listed in the summary of product characteristics (paragraph 2). The summary of product characteristics contains the relevant information about a medicinal product. Assessment reports can include argumentative parts, for example regarding studies, that advertising should not be based on. If a pharmaceutical company has conducted relevant comparative studies, the results of these studies would be reflected in the summary of product characteristics. In our opinion there is no need to base any advertising on any other data than what is covered in the summary of product characteristics. Also, if the addition is kept, the wording 'assessment reports' is too wide and can include different kinds of reports. If the intention is to make a reference to the European public assessment report, this should be clearly stated.

To clarify, the wording of paragraph 4 should be:

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.