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From:	Presidency
To:	Delegations
Subject:	Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC - <i>Exchange of views</i>

Delegations find in annex the text to be discussed at the meetings of the Working Party on Pharmaceuticals and Medical Devices on 16, 21 and 22 February 2024.

Changes compared to the Commission proposals are indicated in ~~striketrough~~ for deletions and **bold/underline** for new text.

Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006

Article 24

Suspension of marketing, withdrawal from the market of a medicinal product, withdrawal of a marketing authorisation by the marketing authorisation holder

1. In addition to the notification made pursuant to Article 116, the marketing authorisation holder shall notify the Agency without undue delay of any action they take to suspend the marketing of a medicinal product, to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation, together with the reasons for such action.

The marketing authorisation holder shall declare if such action is based on the following grounds:

- (a) the medicinal product is harmful;
- (b) it lacks therapeutic efficacy;
- (c) the benefit-risk balance is not favourable;
- (d) its qualitative and quantitative composition is not as declared;
- (e) the controls on the medicinal product or on the ingredients and the controls at an intermediate stage of the manufacturing process have not been carried out or if some other requirement or obligation relating to the grant of the manufacturing authorisation has not been fulfilled; or

- (f) a serious risk to the environment or to public health via the environment has been identified and not sufficiently addressed by the marketing authorisation holder.

Where the action referred to in the first subparagraph is to withdraw a medicinal product from the market, the marketing authorisation holder shall provide information on the impact of such withdrawal on patients who are already being treated.

The notification of the permanent withdrawal of a medicinal product from the market or of the temporary suspension of the marketing authorisation, or of the permanent withdrawal of a marketing authorisation or of the temporary disruption in supply of a medicinal product shall be made in accordance with Article 116(1).

2. The marketing authorisation holder shall make the notification pursuant to paragraph 1 if the action is taken in a third country and such action is based on any of the grounds set out in Articles 195 or 196(1) of [revised Directive 2001/83/EC].
3. In the cases referred to in paragraphs 1 and 2, the Agency shall forward the information to the competent authorities of the Member States without undue delay.
4. Where the marketing authorisation holder intends to permanently withdraw the marketing authorisation for a critical medicinal product, the marketing authorisation holder shall, prior to the notification referred to in paragraph 1, offer, on reasonable terms, to transfer the marketing authorisation to a third party that has declared its intention to place that critical medicinal product on the market, or to use the pharmaceutical non-clinical and clinical documentation contained in the file of the medicinal product for the purposes of submitting an application in accordance with Article 14 of [revised Directive 2001/83/EC].

CHAPTER X

AVAILABILITY AND SECURITY OF SUPPLY OF MEDICINAL PRODUCTS

SECTION 1

MONITORING AND MANAGEMENT OF SHORTAGES AND CRITICAL SHORTAGES

Article 116

Marketing authorisation holder notifications

1. The marketing authorisation holder of a medicinal product in possession of a centralised marketing authorisation or a national marketing authorisation ('the marketing authorisation holder') shall notify the competent authority of the Member State where the medicinal product has been placed on the market and, in addition, the Agency for a medicinal product covered by a centralised marketing authorisation (these are referred to in this Chapter as 'the competent authority concerned') of the following:
 - (a) its decision to permanently cease the marketing of a medicinal product in that Member State no less than twelve months before the last supply of that medicinal product into the market of a given Member State by the marketing authorisation holder;
 - (b) its request to permanently withdraw the marketing authorisation for that medicinal product authorised in that Member State no less than twelve months before the last supply of that medicinal product into the market of a given Member State by the marketing authorisation holder;
 - (c) its decision to temporarily suspend the marketing of a medicinal product in that Member State no less than six months before the start of the temporary suspension of supply of that medicinal product into the market of a given Member State by the marketing authorisation holder;

(d) a **foreseeable** temporary disruption in supply of a medicinal product in a given Member State, of an expected duration of in excess of **seven days** ~~two weeks or~~, based on the demand forecast of the marketing authorisation holder **as soon as possible and** no less than ~~six~~**four** months before the start of such temporary disruption of supply or, if this is not possible and where ~~duly justified~~ **unforeseeable with duly justification**, as soon as they become aware of such temporary disruption, to allow the Member State to monitor any potential or actual shortage in accordance with Article 118(1).

2. For the purposes of the notification made in accordance with paragraph 1, points (a), (b) and (c), the marketing authorisation holder shall provide the information set out in Part I of Annex IV.

For the purpose of notifications made in accordance with the paragraph 1, point (d), the marketing authorisation holder shall provide the information set out in Part III of Annex IV.

The marketing authorisation holder shall immediately notify the competent authority concerned, as appropriate, of any relevant changes to the information provided according to this paragraph.

3. The Commission is empowered to adopt delegated acts, in accordance with Article 175 in order to amend Annex IV as regards the information to be provided in case of a temporary disruption of supply, information to be provided in case of a suspension or cessation of marketing of a medicinal product or withdrawal of the marketing authorisation of a medicinal product, or the content of the shortage prevention plan referred to in Article 117.

Article 117

The shortage prevention plan

1. The marketing authorisation holder as defined in Article 116(1) shall have in place and keep up to date a shortage prevention plan for any medicinal product placed on the market **or a common shortage prevention plan for medicinal products with similar product details.** To put in place the shortage prevention plan, the marketing authorisation holder shall include the minimum set of information set out in Part V of Annex IV and take into account the guidance drawn up by the Agency according to paragraph 2.

2. The Agency, in collaboration with the working party referred to in Article 121(1), point (c), shall draw up guidance to marketing authorisation holders as defined in Article 116(1) to put in place the shortage prevention plan. **The guidance shall include specific requirements for critical medicinal products listed in the Union list of critical medicinal products or in a national list. The guidance shall also cover the common shortage prevention plans for products with similar product details.**
- 2a. The competent authority of the Member State may at any time ask the marketing authorisation holder to submit the shortage prevention plan. The marketing authorisation holder shall submit that copy at the latest seven days after receipt of the request.**
3. Where relevant, the marketing authorisation holder as defined in Article 116(1) shall update the shortage prevention plan to include additional information, based on recommendations of **the competent authority of the Member State, or of** the Executive Steering Group on Shortages and Safety of Medicinal Products (also referred to as the Medicine Shortages Steering Group – ‘MSSG’, established in Article 3(1) of Regulation (EU) 2022/123, in accordance with Articles 123(4) and 132(1).

Article 118

Shortage monitoring by the competent authority of the Member State or the Agency

1. Based on the reports referred to in Articles 120(1) and 121(1), point (c), information referred to in Articles 119, 120(2) and 121 and the notification made pursuant to Article 116(1), points (a) to (d), the competent authority concerned as referred to in Article 116(1) shall continuously monitor any potential or actual shortage of those medicinal products.

The Agency shall carry out that monitoring in collaboration with the relevant competent authority of the Member State when those medicinal products are authorised under this Regulation.

2. For the purposes of paragraph 1, the competent authority concerned as defined in Article 116(1) may request any additional information from the marketing authorisation holder as defined in Article 116(1). In particular, it may request the marketing authorisation holder to submit a shortage mitigation plan in accordance with Article 119(2), a risk assessment of impact of suspension, cessation or withdrawal in accordance with Article 119(3), or the shortage prevention plan referred to in Article 117. The competent authority concerned may set a deadline for the submission of the information requested.

Article 2

Definitions

- (14) ‘shortage’ means a situation in which the supply of a medicinal product that is authorised and placed on the market in a Member State does not meet the demand for that medicinal product in that Member State.

Article 119

Obligations on the marketing authorisation holder

1. The marketing authorisation holder as defined in Article 116(1) shall:
- (a) submit the information requested in accordance with Article 118(2), ~~or~~ Article 124(2), point (b), **or Article 117(2a)** to the competent authority concerned as defined in Article 116(1), without undue delay, using the tools, methods of and criteria for the monitoring and reporting established pursuant to Article 122(4), point (b), by the deadline set by that competent authority;
 - (b) provide updates to the information provided in accordance with point (a), where necessary;
 - (c) justify any failure to provide any of the requested information;
 - (d) where necessary, submit a request to the competent authority concerned as defined in Article 116(1) for an extension of the deadline set by that competent authority in accordance with point (a), and

- (e) indicate whether the information provided in accordance with point (a) contains any commercially confidential information, identify the relevant parts of that information having a commercially confidential nature and explain why that information is of such nature.
2. To prepare the shortage mitigation plan referred to in Article 118(2), the marketing authorisation holder as defined in Article 116(1) shall include the minimum set of information set out in Part IV of Annex IV and take into account the guidance drawn up by the Agency according to Article 122(4), point (c).
 3. To prepare a risk assessment of impact of suspension, cessation or withdrawal referred to in Article 118(2), the marketing authorisation holder as defined in Article 116(1) shall include the minimum set of information set out in Part II of Annex IV and take into account the guidance drawn up by the Agency according to Article 122(4), point (c).
 4. The marketing authorisation holder as defined in Article 116(1) shall be responsible for providing correct, not misleading, and complete information as requested by the competent authority concerned.
 5. The marketing authorisation holder as defined in Article 116(1) shall cooperate with that competent authority and disclose, on their own motion, any relevant information to that authority and update the information as soon as new information becomes available.

Article 120

Obligations on other actors

1. Wholesale distributors and other persons or legal entities that are authorised or entitled to supply medicinal products authorised to be placed on the market of a Member State pursuant to Article 5 of [revised Directive 2001/83/EC] to the public may report a shortage of a given medicinal product marketed in the Member State concerned to the competent authority in that Member State.

1a. A wholesale distributor that is not the marketing authorisation holder and whose intention it is to obtain a medicinal product from a Member State ('source Member State') and to distribute this medicinal product in another Member State ('destination Member State') shall notify the competent authority of the source Member State of this intention. This notification shall include:

(a) The name of the medicinal product;

(b) Active substance(s);

(c) Therapeutic indication(s);

(d) Pharmaceutical form;

(e) Strength;

(f) Route of administration;

(g) Destination Member State

(h) Pack size

(i) The quantity of the medicinal product obtained/which shall be obtained in the source Member State;

2. For the purposes of Article 118(1), where relevant, upon request from the competent authority concerned as defined in Article 116(1), entities including other marketing authorisation holders as defined in Article 116(1), importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public shall provide any information requested in a timely manner.

Article 121

Role of the competent authority of the Member State

1. The competent authority of the Member State shall:
 - (a) assess the merits of each confidentiality claim made by the marketing authorisation holder as defined in Article 116(1) in accordance with Article 119(1), point (e), and shall protect information which that competent authority considers to be commercially confidential against unjustified disclosure;
 - (b) publish information on actual shortages of medicinal products, in cases in which that competent authority has assessed the shortage, on a publicly available website;
 - (c) report to the Agency, through the single point of contact working party referred to in Article 3(6) of Regulation (EU) 2022/123, any shortage of a medicinal product that it identifies as a critical shortage in that Member State to the Agency without undue delay.
2. Following the reporting referred to in paragraph 1, point (c), and to facilitate the monitoring referred to in Articles 118(1), the competent authority of the Member State shall, through the working party referred to in paragraph 1, point (c):
 - (a) submit to the Agency the information referred to in Articles 122(1) or 124(2), point (a), using the tools, methods of and criteria for the monitoring and reporting established pursuant to Article 122(4), point (b), by the deadline set by the Agency;
 - (b) where necessary, provide updates to the information provided in accordance with point (a) to the Agency;
 - (c) justify any failure to provide any of the information referred to in point (a) to the Agency;
 - (d) where necessary, submit a request to the Agency to extend the deadline set by the Agency referred to in point (a);

- (e) indicate whether the marketing authorisation holder as defined in Article 116(1) has indicated the existence of any commercially confidential information and provide the marketing authorisation holder's explanation of why that information is of a commercially confidential nature, in accordance with Article 119(1), point (e);
 - (f) inform the Agency of any actions foreseen or taken by that Member State to mitigate the shortage at national level.
3. Where the competent authority of the Member State has any information in addition to the information to be provided pursuant to this Article, it shall immediately provide such information to the Agency through the working party referred to in paragraph 1, point (c).
4. Following the addition of a medicinal product on the list of critical shortages of medicinal products referred to in Article 123(1), the competent authority of the Member State shall, through the working party referred to in paragraph 1, point (c), provide any information requested pursuant to Article 124(2), point (a), to the Agency.
5. Following any MSSG recommendations provided in accordance with Article 123(4), the competent authority of the Member State shall, through the working party referred to in paragraph 1, point (c):
- (a) report to the Agency on any information received from the marketing authorisation holder as defined in Article 116(1) of the medicinal product concerned or from other actors pursuant to Article 120(2);
 - (b) comply and coordinate with any measures taken by the Commission pursuant to Article 126(1), point (a);
 - (c) take into account any MSSG recommendations referred to in Article 123(4);
 - (d) inform the Agency of any actions foreseen or taken by that Member State in accordance with points (b) and (c) and report on any other actions taken to mitigate or resolve the critical shortage in the Member State, as well as the results of these actions.

5a. National competent authorities may require wholesale distributors and other persons or legal entities that are authorised or entitled to supply medicinal products authorised to be placed on the market of a Member State pursuant to Article 5 of [revised Directive 2001/83/EC] to the public to report a shortage of a given medicinal product marketed in the Member State concerned to the competent authority in that Member State.

6. The Member States may request that the MSSG provide further recommendations, referred to in Article 123(4).

Article 2

Definitions

- (15) ‘critical shortage in the Member State’ means a shortage of a medicinal product **which results in harm or risk of harm to patients and for which** there is no appropriate alternative medicinal product available **in sufficient quantities** on the market in that Member State, ~~and that shortage cannot be resolved.~~

Article 122

Role of the Agency concerning shortages

1. For the purposes of Article 118(1), the Agency may request additional information from the competent authority of the Member State, through the working party referred to in Article 121(1), point (c). The Agency may set a deadline for the submission of the information requested.
2. On the basis of Article 118(1), the Agency, in collaboration with the working party referred to in Article 121(1), point (c), shall identify the medicinal products for which ~~the shortage cannot be resolved without EU coordination~~ **coordinated Union level action is considered necessary to resolve that shortage in accordance with this Regulation.**
3. The Agency shall inform the MSSG of the shortages of the medicinal products that have been identified pursuant to paragraph 2.

4. For the purposes of fulfilling the tasks referred to in Articles 118(1), 123 and 124, the Agency shall ensure the following, in consultation with the working party referred to in Article 121(1), point (c):
- (a) set the criteria to adopt and review the list of critical shortages referred to in Article 123(1);
 - (b) specify the tools, including the European Shortages Monitoring Platform ('ESMP'), established by Regulation (EU) 2022/123, once the scope is expanded pursuant to paragraph 6, the methods of and criteria for the monitoring and reporting provided for in Articles 119(1), point (a), and 121(2), point (a);
 - (c) draw up guidance to allow marketing authorisation holders as defined in Article 116(1) to put in place the risk assessment of impact of suspension, cessation or withdrawal and the shortage mitigation plan as referred to in Article 118(2);
 - (d) specify the methods for the provision of recommendations referred to in Article 123(4);
 - (e) publish information covered by points (a) to (d) on a dedicated webpage on its web-portal referred to in Article 104.
5. For the duration of the critical shortage and until the MSSG considers it to be resolved, the Agency shall regularly report on the results of the monitoring referred to in Article 124 to the Commission and the MSSG, and in particular, it shall report any event that is likely to lead to a major event, as defined in Article 2 of Regulation (EU) 2022/123. Where a public health emergency is recognised in accordance with Regulation (EU) 2022/2371 or an event is recognised as a major event, in accordance with Regulation (EU) 2022/123, that Regulation applies.
6. For the purposes of implementing this Regulation, the Agency shall expand the scope of the ESMP. The Agency shall ensure that, where relevant, data is interoperable between the ESMP, Member States' IT systems and other relevant IT systems and databases, without duplication of reporting.

Article 123

Role of the MSSG and the list of critical shortages of medicinal products

1. Based on the monitoring referred to in Article 118(1), and following consultation with the Agency and the working party referred to in Article 121(1), point (c), the MSSG shall adopt a list of critical shortages of medicinal products authorised to be placed on the market of a Member State pursuant to Article 5 of [revised Directive 2001/83/EC] and for which co-ordinated Union level action is necessary ('the list of critical shortages of medicinal products').
2. The MSSG shall review the status of the critical shortage whenever necessary and shall update the list when it considers that a medicinal product needs to be added or that the critical shortage has been resolved based on the report pursuant to Article 122(5).
3. In addition, the MSSG shall amend its rules of procedure, and the rules of procedure of the working party referred to in Article 121(1), point (c), in accordance with the roles set out in this Regulation.
4. The MSSG may provide recommendations on measures to resolve or to mitigate the critical shortage, in accordance with the methods referred to in Article 122(4), point (d), to relevant marketing authorisation holders, the Member States, the Commission, the representatives of healthcare professionals or other entities.

Article 2

Definitions

- (16) 'critical shortage **of Union concern**' means a critical shortage in the Member State **that cannot be resolved at Member State level and** for which coordinated Union level action is considered necessary to resolve that shortage in accordance with this Regulation.

Article 124

Management of the critical shortage

1. Following the addition of a medicinal product to the list of critical shortages pursuant to Article 123, paragraphs 1 and 2, and based on the continuous monitoring carried out in accordance with Article 118(1), the Agency, in coordination with the competent authority of the Member State, shall continuously monitor the critical shortage of that medicinal product.
2. For the purposes of paragraph 1, where that information is not already available to the Agency, the Agency may request relevant information on that critical shortage from:
 - (a) the competent authority of the Member State concerned through the working party referred to in Article 121(1), point (c);
 - (b) the marketing authorisation holder as defined in Article 116(1);
 - (c) the other actors listed in Article 120(2).

For the purposes of this paragraph, the Agency may set a deadline for the submission of the information requested.

3. The Agency shall establish within its web-portal referred to in Article 104 a publicly available webpage that provides information on actual critical shortages of medicinal products in cases in which the Agency has assessed the shortage and has provided recommendations to healthcare professionals and patients. This webpage shall also provide references to the lists of actual shortages published by the competent authorities of the Member State pursuant to Article 121(1), point (b).

Article 125

Obligations on the marketing authorisation holder in case of a critical shortage

1. Following the addition of a medicinal product to the list of critical shortages of medicinal products in accordance with Article 123, paragraphs 1 and 2, or recommendations provided in accordance with Article 123(4), the marketing authorisation holder as defined in Article 116(1) and subject to those recommendations shall:

- (a) provide any additional information that the Agency may request;
- (b) provide additional relevant information to the Agency;
- (c) take into account the recommendations referred to in Article 123(4);
- (d) comply with any measures taken by the Commission pursuant to Article 126(1), point (a), or actions taken by the Member State pursuant to Article 121(5), point (d);
- (e) inform the Agency of any measures taken pursuant to points (c) and (d) and the report on results of such measures;
- (f) inform the Agency of the end date of the critical shortage.

Article 126

Role of the Commission

1. The Commission shall, where it considers it appropriate and necessary:
 - (a) take into account the MSSG recommendations and implement relevant measures;
 - (b) inform the MSSG of those measures taken by the Commission.
2. The Commission may request the MSSG to provide recommendations referred to in Article 123(4).

SECTION 2

SECURITY OF SUPPLY

Article 127

Identification and management of critical medicinal products by the competent authority of the Member State

1. The competent authority of the Member State shall ~~identify~~ **establish a national list of** critical medicinal products ~~in that Member State.~~ **The Member State may use** using the methodology set out in Article 130(1), point (a).

2. The competent authority of the Member State acting through the working party referred to in Article 121(1), point (c), shall report to the Agency the critical medicinal products in that Member State identified pursuant to the paragraph 1, as well as the information received from the marketing authorisation holder as defined in Article 116(1).
3. For the purposes of the identification of ~~critical medicinal products referred to in paragraph 1,~~ **the national list of critical medicinal products and its adaptation** the competent authority of the Member State may request relevant information including the shortage prevention plan referred to in Article 117 from the marketing authorisation holder as defined in Article 116(1).
4. For the purposes of the identification of **the national list of critical medicinal products and its adaptation** ~~critical medicinal products referred to in paragraph 1,~~ the competent authority of the Member State may request relevant information from other entities including other marketing authorisation holders, importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public.
5. The competent authority of the Member State shall assess the merits of each confidentiality claim made by the marketing authorisation holder pursuant to Article 128(1), point (e), and shall protect any information that is commercially confidential against unjustified disclosure.
6. For the purposes of the adoption of the Union list of critical medicinal products pursuant to Article 131, each Member State shall, through the competent authority of the Member State concerned:
 - (a) submit to the Agency the information referred to in Article 130(2), point (a), using the tools, methods of and criteria for the monitoring and reporting established pursuant to Article 130(1), point (c), by the deadline set by the Agency;
 - (b) provide any relevant information to the Agency, including information on measures that have been taken by the Member State to strengthen the supply of that medicinal product;

- (c) provide updates to the information provided in accordance with points (a) and (b) to the Agency where necessary;
- (d) justify any failure to provide any of the requested information;
- (e) indicate the existence of any commercially confidential information reported as such by the marketing authorisation holder pursuant to Article 128(1), point (e), and provide the marketing authorisation holder's explanation of why that information is of a commercially confidential nature.

Where necessary, the competent authority of the Member State may request an extension of the deadline set by the Agency to comply with the request for information in accordance with point (a) of the first subparagraph.

7. Following the addition of a medicinal product to the Union list of critical medicinal products in accordance with Article 131 or any recommendations provided in accordance with Article 132(1), the Member States shall:
 - (a) provide any additional information that the Agency may request;
 - (b) provide additional relevant information to the Agency;
 - (c) comply and coordinate with any measures taken by the Commission pursuant to Article 134(1), point (a);
 - (d) take into account any MSSG recommendations referred to in Article 132(1);
 - (e) inform the Agency of any actions foreseen or taken in accordance with point (c) and (d) by that Member State, as well as the results of these actions.
8. Member States that take an alternative course of action in respect of paragraph 7, points (c) and (d), shall share the reasons for doing so with the Agency in a timely manner.

Article 2

Definitions

- (13) ‘critical medicinal product’ means a medicinal product for which insufficient supply results in serious harm or risk of serious harm to patients and identified using the methodology pursuant to Article 130(1), point (a) **or a national methodology**.

Article 128

Obligations of the marketing authorisation holder with regard to critical medicinal products

1. For the purposes of Article 127, paragraphs 1 and 3, and Article 131(1), the marketing authorisation holder as defined in Article 116(1) shall:
 - (a) submit the information requested in accordance with Articles 127(3), 130(2), point (b), and 130(4), point (b), to the competent authority concerned as defined in Article 116(1), without undue delay, using the tools, methods of and criteria for the monitoring and reporting established pursuant to Article 130(1), point (c), by the deadline set by that competent authority concerned;
 - (b) provide updates to the information provided in accordance with point (a) where necessary;
 - (c) justify any failure to provide any of the requested information;
 - (d) where necessary, submit a request to the competent authority concerned as defined in Article 116(1) for an extension of the deadline set by that competent authority in accordance with point (a), and
 - (e) indicate whether the information provided in accordance with point (a) contain any commercially confidential information, identify the relevant parts of that information having a commercially confidential nature and explain why that information is of such nature.

2. The marketing authorisation as defined in Article 116(1) authorisation shall be responsible for providing correct, not misleading, and complete information as requested by the competent authority concerned as defined in Article 116(1) and shall have the duty to cooperate and to disclose on their own motion any relevant information without undue delay to that competent authority and to update the information as soon as that information becomes available.

Article 129

Obligations on other actors

For the purposes of Article 127(4) and Article 130(2), point (c), and Article 130(4), point (c), where relevant, upon request from the competent authority concerned as defined in Article 116(1), entities including other marketing authorisation holders as defined in Article 116(1), importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public shall provide any information requested in a timely manner.

Article 130

Role of the Agency

1. The Agency shall, in collaboration with the working party referred to in Article 121(1), point (c), ensure the following:
 - (a) develop a common methodology to identify critical medicinal products, including the evaluation of vulnerabilities with respect to the supply chain of those medicines, in consultation, where appropriate, with relevant stakeholders;
 - (b) specify the procedures and criteria for establishing and reviewing the Union list of critical medicinal products referred to in Article 131;
 - (c) specify the tools, methods of and criteria for the monitoring and reporting provided for in Articles 127(6), point (a), and 128(1), point (a);
 - (d) specify the methods for the provision and review of MSSG recommendations referred to in Article 132, paragraphs 1 and 3.

The Agency shall publish the information referred to in points (b), (c) and (d) on a dedicated webpage on its web-portal.

2. Following the reports and information provided by the Member States and marketing authorisation holders in accordance with Article 127, paragraphs 2 and 6, and Article 128(1), the Agency, may request the relevant information from:
 - (a) the competent authority of the Member State concerned;
 - (b) the marketing authorisation holder of the medicinal product, including the shortage prevention plan, referred to in Article 117;
 - (c) other entities including other marketing authorisation holders, importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public.

The Agency, in consultation with the working party referred to in Article 121(1), ~~point (c), and based on the methodology set out in article 130(1), point (a)-,~~ shall report the information referred to in Article 127, paragraphs 2 and 6, and Article 128(1) to the MSSG.

3. For the purposes of Article 127(6), point (e), and Article 128(1), point (e), the Agency shall assess the merits of each confidentiality claim and protect commercially confidential information against unjustified disclosure.
4. Following the adoption of the Union list of critical medicinal products in accordance with Article 131, the Agency may request additional information from:
 - (a) the competent authority of the Member State concerned;
 - (b) the marketing authorisation holder as defined in Article 116(1);
 - (c) other entities including other marketing authorisation holders, importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public.

5. Following the adoption of the Union list of critical medicinal products in accordance with Article 131, the Agency shall report to the MSSG on any relevant information received from the marketing authorisation holder pursuant to Article 133 and the competent authority of the Member State in accordance with Article 127, paragraphs 7 and 8.
6. The Agency shall make publicly available via the web-portal referred to in Article 104 the MSSG recommendations referred to in Article 132(1).

Article 131

The Union List of Critical Medicinal Products

1. Following the reporting referred to in Article 130, paragraph 2, second subparagraph, and Article 130(5), the MSSG shall consult the working party referred to in Article 121(1), point (c). Based on this consultation, the MSSG shall propose a Union list of critical medicinal products authorised to be placed on the market of a Member State pursuant to Article 5 of [revised Directive 2001/83/EC] and for which coordinated Union level action is necessary (“the Union list of critical medicinal products”).
2. The MSSG may propose updates to the Union list of critical medicines to the Commission, where necessary.
3. The Commission, taking into account the proposal of the MSSG, shall adopt and update the Union list of critical medicinal products by means of an implementing act and communicate the adoption of the list and any updates to the Agency and the MSSG. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 173(2).
4. Following the adoption of the Union list of critical medicinal products in accordance with paragraph 3, the Agency shall immediately publish this list and any updates to this list on its web-portal referred to in Article 104.

Article 132
Role of the MSSG

1. Following the adoption of the Union list of critical medicinal products pursuant to Article 131(3), in consultation with the Agency and the working party referred to in Article 121(1), point (c), the MSSG may provide recommendations, in accordance with the methods referred to in Article 130(1), point (d), on appropriate security of supply measures to marketing authorisation holders as defined in Article 116(1), the Member States, the Commission or other entities. Such measures may include recommendations on diversification of suppliers and inventory management.
2. The MSSG shall amend its rules of procedure, and the rules of procedure of the working party referred to in Article 121(1), point (c), in accordance with the tasks set out in this section.
3. Following the report pursuant to Article 130(5), the MSSG shall review its recommendations in accordance with the methods referred to in Article 130(1), point (d).
4. The MSSG may request the Agency to request further information from the Member States or marketing authorisation holder of the medicinal product as defined in Article 116(1) and included on the Union list of critical medicinal products or other relevant entities referred to in Article 129.

Article 133

Obligations on the marketing authorisation holder after the MSSG recommendations

Following the addition of a medicinal product to the Union list of critical medicinal products in accordance with Article 131(3) or any recommendations provided in accordance with Article 132(1), the marketing authorisation holder as defined in Article 116(1) of a medicinal product on that list or subject to those recommendations shall:

- (a) provide any additional information that the Agency may request;
- (b) provide additional relevant information to the Agency;
- (c) take into account the recommendations referred to in Article 132(1);

- (d) comply with any measures taken by the Commission in accordance with Article 134(1), point (a), or by the Member State pursuant to Article 127(7), point (e);
- (e) inform the Agency of any measures taken and report on the results of such measures.

Article 134

Role of the Commission

1. The Commission may, where it considers it appropriate and necessary:
 - (a) take into account the MSSG recommendations and implement the relevant measures;
 - (b) inform the MSSG of those measures taken by the Commission.
 - (c) request the MSSG to provide information or an opinion or further recommendations referred to in Article 132(1).
2. The Commission, taking into consideration the information or the opinion, referred to in paragraph 1, or MSSG recommendations, may decide to adopt an implementing act to improve security of supply. The implementing act may impose contingency stock requirements of active pharmaceutical ingredient or finished dosage forms, or other relevant measures required to improve security of supply, on marketing authorisation holders, wholesale distributors or other relevant entities.
3. The implementing act referred to in paragraph 2 shall be adopted in accordance with the examination procedure referred to in Article 173(2).

CHAPTER XII

GENERAL PROVISIONS

Article 171

Penalties at national level

1. Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.
2. Member States shall inform the Commission immediately of any litigation instituted for infringement of this Regulation.

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.

Chapter XII

Wholesale distribution and sale at a distance

Article 162

Wholesale distribution of medicinal products

1. Without prejudice to Article 5, Member States shall take all appropriate action to ensure that only medicinal products in respect of which a marketing authorisation has been granted in accordance with Union law are distributed on their territory.

2. In the case of wholesale distribution including storage, medicinal products shall be covered by either a centralised marketing authorisation or by a national marketing authorisation.
3. Distributors who intend to import a medicinal product from another Member State shall notify the marketing authorisation holder and the competent authority of the Member State to which the medicinal product is to be imported of their intention to import that medicinal product.
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.
5. In the case of medicinal products covered by a centralised marketing authorisation, the distributor shall submit the same notification referred to in paragraph 3 to the Agency which will be in charge of checking that the conditions laid down in Union law on medicinal products and in the marketing authorisations are observed. For this check, a fee shall be payable to the Agency.

Article 166

Obligations of the wholesale distribution authorisation holder

1. Member States shall ensure that wholesale distribution authorisation holders shall:
 - (a) have at their disposal the services of staff who comply with the legal requirements existing in the Member State as regards wholesale distribution;
 - (b) allow the official representatives of the competent authority of the Member State access to their premises, installations and equipment referred to in Article 164(2), point (a), at all times;
 - (c) obtain, including by financial transactions, their supplies of medicinal products only from persons who are themselves in possession of a wholesale distribution authorisation in the Union or a manufacturing authorisation referred to in Article 163(3);

- (d) supply, including by financial transaction, medicinal products only to persons who are themselves wholesale distribution authorisation holders or who are authorised or entitled to supply medicinal products to the public;
- (e) verify that the medicinal products received are not falsified by checking the safety features on the outer packaging, in accordance with the requirements laid down in the delegated acts adopted pursuant to Article 67(2), second subparagraph;
- (f) have an emergency plan that ensures effective implementation of any recall from the market ordered by the competent authorities or carried out in cooperation with the manufacturer or marketing authorisation holder for the medicinal product concerned;
- (g) keep records giving, for any medicinal products received, dispatched or brokered, at least the following information:
 - (i) the date of receipt, dispatch or brokering of the medicinal product,
 - (ii) the name of the medicinal product,
 - (iii) the quantity of the medicinal product received, supplied or brokered,
 - (iv) the name and address of the supplier of the medicinal product or the consignee, as appropriate,
 - (v) the batch number of the medicinal products, at least for medicinal products bearing the safety features referred to in Article 67;
- (h) keep the records referred to in point (g) available to the competent authorities of the Member States, for inspection purposes, for a period of five years;
- (i) comply with the principles of good distribution practices for medicinal products laid down in Article 160;
- (j) maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities;

- (k) immediately inform the competent authority of the Member State and, where applicable, the marketing authorisation holder, of medicinal products they receive or are offered that they identify as falsified or suspect to be falsified;
 - (l) continuously guarantee the appropriate and continued supply of an adequate range of medicinal products to meet the requirements of a specific geographical area, and deliver the supplies requested over the whole of the area in question, within a reasonable timeframe, which shall be defined in the national legislation;
 - (m) cooperate with marketing authorisation holders and competent authorities of the Member States on the security of supply.
2. Where the medicinal product is obtained from another wholesale distributor, the wholesale distribution authorisation holders obtaining the product shall verify compliance with the principles of good distribution practices by the supplying wholesale distributor. This includes verifying whether the supplying wholesale distributor holds a wholesale distribution authorisation, or a manufacturing authorisation referred to in Article 163(3).
 3. Where the medicinal product is obtained from a manufacturer or importer, wholesale distribution authorisation holders shall verify that the manufacturer or importer holds a manufacturing authorisation.
 4. Where the medicinal product is obtained through brokering of medicinal products, wholesale distribution authorisation holders shall verify that the person brokering the medicinal product fulfils the requirements set out in Article 171.

Article 167

Obligation of supply of medicinal products

1. With regard to the supply of medicinal products to pharmacists and persons authorised or entitled to supply medicinal products to the public, Member States shall not impose upon the wholesale distribution authorisation holder that has been granted by another Member State any obligation, in particular public service obligations, more stringent than those they impose on persons whom they have themselves authorised to engage in equivalent activities.

2. The wholesale distributors of a medicinal product placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.
3. The arrangements for implementing this Article 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.

Chapter XIV

Supervision and controls

SECTION 1

SUPERVISION

Article 188

System of supervision and inspections

1. Where the competent authority of the Member State considers it necessary, in particular where there are grounds for suspecting non-compliance with the rules of this Directive, including with the principles of good manufacturing practice and good distribution practices, referred to in Articles 160 and 161, it may have its official representatives carry out the measures referred to in paragraph 1, second subparagraph at the premises or on the activities of:
 - (a) manufacturers or importers of medicinal products applying for a manufacturing import authorisation or wholesale distributors applying for a wholesale distribution authorisation;
 - (b) manufacturers of active substance applying for a registration or manufacturing sites applying for a registration as decentralised sites;
 - (c) marketing authorisation holders;

- (d) distributors of medicinal products or active substances located in third countries;
- (e) manufacturers of excipients, functional excipients, starting materials or intermediate products located in its territory or in a third country;
- (f) importers of excipients, functional excipients, starting materials or intermediate products located in its territory;
- (g) persons brokering medicinal products located in its territory.

Chapter XVI

General provisions

Article 203

Information on prohibition of supply or other action on a marketing authorisation

1. Each Member State shall take all the appropriate measures to ensure that decisions granting marketing authorisation, refusing or revoking a marketing authorisation, cancelling a decision refusing or revoking a marketing authorisation, prohibiting supply, or withdrawing a product from the market, together with the reasons on which such decisions are based, are brought to the attention of the Agency without undue delay.
2. In addition to the notification made pursuant to Article 116 of [revised Regulation (EC) No 726/2004], the marketing authorisation holder shall declare without undue delay if such notified action is based on any of the grounds set out in Articles 195 or 196(1).
3. The marketing authorisation holder shall also make the notification pursuant to paragraph 2 in cases where the action is taken in a third country and where such action is based on any of the grounds set out Articles 195 or 196(1).
4. The marketing authorisation holder shall furthermore notify the Agency where the action referred to in paragraphs 2 or 3 is based on any of the grounds referred to in Articles 195 or 196(1).
5. The Agency shall forward notifications received in accordance with paragraph 4 to all Member States without undue delay.

6. Member States shall ensure that appropriate information about action taken pursuant to paragraphs 1 and 2 that may affect the protection of public health in third countries is without undue delay brought to the attention of the World Health Organization, with a copy to the Agency.
 7. Each year, the Agency shall make public a list of the medicinal products for which marketing authorisations have been refused, revoked or suspended in the Union, whose supply has been prohibited or that have been withdrawn from the market, including the reasons for such action.
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