Council of the European Union

Brussels, 24 May 2024
(OR. en)

9840/24

Interinstitutional Files:
2023/0132(COD)
2023/0131(COD)

LIMITE

SAN 275
PHARM 66
MI 497
COMPET 541
VETER 70
ENV 510
RECH 225
CODEC 1276
PI 65

PUBLIC

NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Revision of the pharmaceutical package *- State of play*

I INTRODUCTION

1. On 26 April 2023 the Commission adopted a proposal for the revision of the pharmaceutical legislation, consisting of a Regulation on Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency[1] and a Directive on the Union code relating to medicinal products for human use[2]. The two legislative proposals aim to adapt and simplify the current regulatory landscape, which consists of one directive and three regulations covering both general legislation and specific legislation on medicines for rare diseases and for children.

2. The proposals are based on Articles 114(1) and 168(4)(c) of the Treaty of Functioning of the European Union.

[1] 8758/23
[2] 8759/23

3. The general objectives of the two legislative proposals are ensuring the quality, safety and efficacy of medicines for EU patients and harmonising the internal market. They specifically aim to: promote innovation and ensure access to innovative and affordable medicines; improve security of supply of medicines and address shortages; support innovation and competitiveness through reduced regulatory burden and through a simplified and flexible regulatory framework; and reduce the environmental impact of the pharmaceutical lifecycle.

II STATE OF PLAY OF THE NEGOTIATIONS

4. The Belgian Presidency organised fifteen meetings of the Working Party (WP) on Pharmaceuticals and Medical Devices. Ten of the meetings focused on the 'shortages cluster', consisting of provisions in the Regulation and the Directive dealing with shortage management and security of supply of medicinal products.

5. Based on the examination of the proposals by the Commission, on written comments from delegations and building on discussions in the WP on several revised texts, the Belgian Presidency has put forward a revised text[3] on the shortages cluster to the Working Party on 21 May 2024.

6. That revised text aimed to address the main issues raised by delegations during the examination of the proposals at technical level, by:

   – introducing the possibility for Member States to establish a notification system for certain medicinal products leaving their markets and to take measures to prevent or mitigate shortages, while safeguarding free movement and the internal market, on the basis of the information available to them and with a view to guarantee a stable and safe supply of medicinal products;

   – clarifying the relationship between general notifications and notifications related to shortage management to be made by marketing authorisation holders (MAHs) and adapting certain notification deadlines;

   – further detailing, for critical medicinal products for which MAHs intend to withdraw the marketing authorisation, the procedure for offering to transfer the marketing authorisation to a third party;

[3] 9425/24

– introducing the possibility for financial penalties to be imposed by the Commission on MAHs for failure to notify a decision to permanently cease or temporarily suspend the marketing of a medicine, or permanently withdraw the marketing authorisation for a product;

– prioritising the setting up by MAHs of shortage prevention plans (SPP) for products on the Union list of critical medicines, while leaving Member States the option of requesting SPPs for further medicinal products on public health grounds;

– clarifying the responsibilities of the European Medicines Agency, the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) within the Agency and the Commission in dealing with critical shortages of Union concern;

– enhancing clarity as regards the interplay between national lists of critical medicines and the Union list of critical medicines.

7. In addition, for legal clarity, the nature, limits, and conditions for the exercise of implementing powers granted to the Commission to improve the security of supply of medicines were further framed, and the link with the internal market legal basis was reinforced.

8. Following the examination of this text at the WP of 21 May 2024, further amendments were made to reflect changes which had been broadly demanded/requested by delegations. This revised text is added as an annex to this note. Although Member States acknowledged the progress that was made and recognised the fact that the text is in an advanced state, the following issues remain outstanding and to be addressed in a later stage of the negotiations:

<u>In the Regulation</u>:

– With regard to the exemption-regime established in article 115a, it was argued that products authorised under article 205 of the revised Directive should be exempted from the provisions of article 120 paragraph 1a.

PUBLIC

– With regard to the scope of products to which the obligation to offer the marketing authorisation to an interested party in case the holder wishes to withdraw the authorisation from the market would apply, a number of Member States indicated their wish to extend the scope to include products listed on their national list of critical medicinal products. In the current text, which received broad support, the Presidency has kept the scope limited to products identified at national level according to the EU methodology referred to in Article 130 of the Regulation. This approach ensures a level of harmonisation that is balanced with national specificities, and follows the horizontal decision to separate provisions on the Union list, methodologies, actions and measures dealt with in this Regulation from national-level lists, methodologies, actions and measures which are the discretion of the Member States.

– With regard to the scope of products to which the obligation to have in place a shortage prevention plan (SPP), referred to in Article 117 would apply: while the Commission proposal to demand an SPP for all medicinal products - based on the assumption that these would be based on information already available to companies as part of their 'good business practice'- was supported by a considerable number of Member States, an equally considerable number of Member States voiced concerns over the administrative burden this would imply. The current text (in which the obligations apply to products on the Union list of critical medicines, while leaving Member States the option to request SPPs for other medicinal products) represents a compromise between these two positions that has received positive feedback. However, a number of Member States are concerned about fragmentation and associated administrative burden for both companies and authorities. In order to address the issue of fragmentation, the Presidency has proposed that the MSSG could issue recommendations on the circumstances/criteria/cases in which Member States could use the option of requesting SPPs for medicinal products that are not on the Union List. It is recognised that this proposal and the proposed MSSG-role (ref. Article 123 paragraph 4a) needs further fine tuning.

PUBLIC

– With regard to the possibility for Member States to establish a notification system for certain medicinal products leaving their markets and to take measures to prevent or mitigate shortages as introduced by the Presidency in Article 120 paragraph 1a, there is broad support but room for improvement. Further clarification is needed on the relation with the TRIS-procedure.

– With regard to the identification of critical medicinal products in a Member State by using the EU methodology in accordance with Article 127 paragraph 1, and with regard to the obligation for Member States to publish a list of the products thus identified, it should be explored whether the Agency could publish a compilation of this list. This would facilitate transparency with regard to which products are identified according to the EU methodology at Member State level, and help authorisation holders to comply with obligations on these products (ref. Article 116 paragraph 3a). It should also be noted that this would increase transparency in the process of the development of the Union level list, which will be compiled through the application of a formula on the set of products identified using the EU methodology at Member State level.

– With regard to the mandate of the Agency pursuant to Article 130 paragraph 2 point (c) and paragraph 4 point (c) to request information from 'other entities', it could be clarified whether pharmacies should directly communicate with the Agency.

– With regard to the Commission role in Article 134, the Presidency notes broad recognition by Member States on the progress on framing the implementing act referred to in paragraph 2 aimed at measures to enforce the security of supply, and on reinforcing the link with the internal market legal basis. The Presidency recognises that this Article and its implications need further reflection. Although the direction of travel of this Article is broadly shared, a number of Member States emphasize the need for further limiting its scope – minimizing the impact on national competences – and designing it towards measures that 'assist' Member States.

PUBLIC

In the Directive:

– With regard to the obligation on the marketing authorisation holder to ensure appropriate stock levels and continued supply of a product placed on the market in a Member State referred to in Article 56 paragraph 3, it has been brought to the attention of the Presidency that further clarifications on what this Article could imply at national level are needed in recitals.

– With regard to obligations put on wholesale distribution authorisation holders pursuant to Article 166 paragraph 1, it has been brought to the attention of the Presidency this could be in conflict with constitutional law in specific Member States.

III CONCLUSION

9. Coreper is invited to

– take note of the latest revised text of the shortages cluster as set out in the Annex;

– take note of the current state of play and the principles discussed so far, as well as the remaining open issues listed above, with a view to continue the work on the package.

PUBLIC

ANNEX

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

Recitals

(136) Shortages of medicinal products represent a growing threat to public health, with potential serious risks to the health of patients in the Union and impacts on the right of patients to access appropriate medical treatment**, as well as risks to the smooth functioning of the internal market**. The root causes of shortages are multifactorial, with challenges identified along the entire pharmaceutical value chain, from quality **and safety risks to** ~~and~~ manufacturing problems. In particular, shortages of medicinal products can result from supply chain disruptions and vulnerabilities affecting the supply of key ingredients and components. **It can also result from a lack of coordination to measures taken at national level to adress risks to supply to cover the needs of patients in a given Member State.** ~~Therefore, all m~~**M**arketing authorisation holders should have shortage prevention plans in place **for certain products**, to prevent **or mitigate** shortages. The Agency should provide guidance to marketing authorisation holders on approaches to streamline the implementation of those plans.

(137) To achieve a better security of supply for medicinal products in the internal market and to contribute thereby to a high level of public health protection, it is appropriate to approximate the rules on monitoring and reporting of actual or potential shortages of medicinal products, including the procedures and the respective roles and obligations of concerned entities in this Regulation. It is important to ensure continued supply of medicinal products, which is often taken for granted across Europe. This is especially true for the most critical medicinal products which are essential to ensure the continuity of care, the provision of quality healthcare and guarantee a high level of public health protection ~~in Europe~~ **within the Union**.

(137a) The phenomenon of parallel trade in medicinal products concerns medicinal products traded from one Member State to another Member State or third country. While the Court of Justice has ruled that parallel trade fosters the free movement of medicinal products and is therefore beneficial to the internal market , it has also recognised that the need to ensure that a country has reliable supplies for essential medical purposes, in particular a supply of medicinal products to the public that is reliable and of good quality, may, under Article 36 TFEU, justify a restriction on trade between Member States if that objective contributes to protecting human health and human life. Therefore, it should be possible for a Member State to require, for certain medicinal products, to establish a system of notification whenever one of these products leaves the Member State in question to be distributed elsewhere. On the basis of this notification and the information at its disposal, including shortage prevention plans, the Member State should be able to take measures to prevent or mitigate shortages. These measures should also be appropriate and proportionate to such objectives and take into account that the principles of the free movement of goods are restricted only for the purpose of safeguarding public health, thus respecting the case law of the Court of Justice of the European Union and the Treaties, notably the provisions on free movement and competition. It is important to recognise that parallel import can contribute to the objective of access to medicines, notably in smaller or vulnerable markets.

PUBLIC

(138) The national competent authorities should be empowered to monitor shortages of medicinal products that are authorised through both national and centralised procedures, based on notifications of marketing authorisation holders. The Agency should be empowered to monitor shortages of medicinal products that are authorised through the centralised procedure, also based on notifications of marketing authorisation holders. **To ensure continuity of supply and availability of critical medicinal products on the market, rules for the transfer of the marketing authorisation prior to the permanent marketing cessation should be laid down. Such transfer should not be considered to be a variation.** When critical shortages are identified, both national competent authorities and the Agency should work in a coordinated manner to manage those critical shortages, whether the medicinal product concerned by the critical shortage is covered by a centralised marketing authorisation or a national marketing authorisation. Marketing authorisation holders and other relevant entities ~~must~~ **should** provide the relevant information to inform the monitoring. Wholesale distributors and other persons or legal entities, including patient organisations or health care professionals, may also report a shortage of a given medicinal product marketed in the Member State concerned to the competent authority. The Executive Steering Group on Shortages and Safety of Medicinal Products ('the Medicines Shortages Steering Group' (MSSG)) already established within the Agency pursuant to Regulation (EU) 2022/123 of the European Parliament and of the Council, should adopt a list of critical shortages of medicinal products and ensure monitoring of those shortages by the Agency. The MSSG should also ~~adopt~~ **propose** a list of critical medicinal products authorised in accordance with [revised Directive 2001/83/EC] or this Regulation to ensure monitoring of the supply of those products**, to be adopted by the Commission**. The MSSG may provide recommendations on measures to be taken by marketing authorisation holders, the Member States, the Commission and other entities to resolve any critical shortage or to ensure the security of supply of those critical medicinal products to the market. Implementing acts can be adopted by the Commission to ensure that appropriate measures, including the establishment or maintenance of contingency stocks, are taken by marketing authorisation holders, wholesale distributors or other relevant entities.

PUBLIC

(138a) **Monitoring and prevention activities, together with targeted actions at national level, have at times proven to be insufficient to prevent disruption of supply within the Union of critical medicinal products. Experience has shown that difficulties in the supply chain have led to uncoordinated approaches at company and regulatory level [*example still to be inserted*], which led to restrictions in the internal market. Such restrictions are also likely to result in a suboptimal flow of access to critical medicines. It is necessary to ensure that tools for a Union approach are available to address such situations which are likely to lead to such restrictions, in specific circumstances, to ensure the free movement of medicines by safeguarding security of a safe and stable supply of them at Union level. The Commission should therefore be empowered to adopt implementing acts, after having duly identified a serious risk of disruptions and having considered the appropriateness and proportionality of the intervention, notably as regards its impact on fundamental rights, laying down measures of last resort to improve security of supply within the Union. These should be limited to ensuring appropriate contingency stock levels and appropriate supplies of medicinal products to wholesale distributors. While disruptions regarding centrally authorised products can be better addressed by different actors within the supply chain, measures concerning nationally authorised medicinal products should only be addressed to Member States.**

(139) ~~To ensure continuity of supply and availability of critical medicinal products to the market, rules on the transfer of the marketing authorisation prior to the permanent marketing cessation should be laid down. Such transfer should not be considered to be a variation.~~

PUBLIC

Articles

Article 16

Marketing authorisations

4. After a marketing authorisation has been granted, the marketing authorisation holder shall inform the Agency of the dates of actual marketing of the medicinal product for human use in the Member States, taking into account the various presentations authorised.

~~The marketing authorisation holder shall notify the Agency and the competent authority of the Member State concerned of the following:~~

~~(a) its intention to permanently cease the marketing of a medicinal product in that Member State in accordance with Article 116(1), point (a); or~~

~~(b) its intention to temporarily suspend the marketing of a medicinal product in that Member State in accordance with Article 116(1), point (c); or~~

~~(c) a potential or actual shortage in that Member State in accordance with Article 116(1), point (d); and~~

~~its reasons for such action under points (a) and (b) in accordance with Article 24, as well as any other reason relating to precautionary actions with regard to quality, safety, efficacy and the environment.~~

Upon request by the Agency, particularly in the context of pharmacovigilance, the marketing authorisation holder shall provide the Agency with all data relating to the volume of sales of the medicinal product at Union level, broken down by Member State, and any data in the marketing authorisation holder's possession relating to the volume of prescriptions in the Union and its Member States.

PUBLIC

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,~~ **T**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.

PUBLIC

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).~~

The marketing authorisation holder shall make the notification electronically and in the formats made available by the Agency. The Agency shall consult the Member States when drawing up the formats.

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 **paragraph 1**~~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].~~

PUBLIC

CHAPTER X

AVAILABILITY AND SECURITY OF SUPPLY OF MEDICINAL PRODUCTS

SECTION 1

MONITORING AND MANAGEMENT OF SHORTAGES AND CRITICAL SHORTAGES

PUBLIC

Article 115a

Derogations on the provisions of this chapter

1. Member States may waive the application of Articles 116(3a), 117~~(3) point a~~, Articles 120(2), 121(5a), 127(4), 129, 130(2) point c, 130(4) point c ~~within their territory~~, insofar as the marketing authorisation holders subject to those rules supply medicinal products for military or defence purposes or insofar as the application of such requirements imply a risk to national security and defense.

1a. Member States may exempt authorities within their territory of the obligation to communicate information in accordance with Articles 121 and 127 insofar as such requirements imply a risk to national security and defense.

2. Member States may exempt a marketing authorisation holder in possession of a marketing authorisation for a medicinal product authorised in that Member State in accordance with article 205 of [revised Directive 2001/83/EC] of the obligations set out in the articles 116, 117, 119, 125, 128 and 133.

Article 116

Marketing authorisation holder notifications

1. **In addition to the rules on notification referred to in Article 24 of this Regulation and Article 203(3) of [the revised Directive 2001/83/EC]** ~~T~~the marketing authorisation holder of a medicinal product in possession of a centralised marketing authorisation or a national marketing authorisation (**these are referred to in this chapter as**'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 temporary disruption in supply of a medicinal product in a given Member State, of an expected duration of in excess of **two weeks** ~~two weeks or,~~ based on the demand forecast of the marketing authorisation holder**, as soon as possible and in any event** no less than **three**~~six~~ months before the start of such temporary disruption of supply ~~or, if this is not possible and where duly justified, as soon as they become aware of such temporary disruption,~~ to allow the Member State to monitor any **expected** ~~potential~~ or actual shortage in accordance with Article 118(1).

PUBLIC

~~(e)~~ **By way of derogation to paragraph 1, point (d), the marketing authorisation holder shall notify the temporary disruption in supply of a medicinal product in a given Member State as soon as they become aware of such temporary disruption where exceptional circumstances, which shall be duly identified and substantiated to the competent authority concerned, prevented the marketing authorisation holder from complying with the deadlines laid down therein.**

~~(f)~~ **The marketing authorisation holder shall make the notification electronically and in the formats made available by the Agency. The Agency shall consult the Member States when drawing up the formats.**

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.

PUBLIC

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.

3a. Where the marketing authorisation holder intends to withdraw the marketing authorisation for a critical medicinal product identified using the methodology pursuant to Article 130(1), point a, the marketing authorisation holder shall, prior to the notification referred to in Article 116(1), point b:

(a) publish a declaration of its intention to offer to transfer the marketing authorisation via a dedicated webpage on its website and communicate the electronic link to such webpage to the competent authority of the Member State and the Agency. The Agency shall publish and compile a list of such electronic links.

(b) offer, on reasonable terms, to transfer the marketing authorisation to a third party that has declared its intention to place that critical medicinal product identified using the methodology pursuant to Article 130 (1), point (a) on the market, or to allow the use of the pharmaceutical non-clinical and clinical documentation contained in the file of that critical medicinal product for the purposes of submitting an application in accordance with Article 14 of [revised Directive 2001/83/EC].

(c) inform the competent authority concerned on the outcome of the negotiations with the third party.

For the purpose of this paragraph, the marketing authorisation holder shall provide as part of the notification referred to in article 116 (1) point (b) information proving that they have taken steps to make the marketing authorisation available to third parties on reasonable terms.

PUBLIC

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 **on the Union list of critical medicinal products.** ~~placed on the market.~~ 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.

The Agency, in collaboration with the working party referred to in Article 121(1), point (c), shall draw up guidance for marketing authorisation holders to put in place the shortage prevention plan. The guidance shall, in particular, indicate the relevant type and detail of information for the shortage prevention plan according to the different level of risk, including information on the relevant shortage management measures.

1a. In addition to paragraph 1, the competent authority of the Member State may, on public health grounds or ~~and~~ taking into account MSSG recommendations as referred to in Article 123 paragraph 4a, request the marketing authorisation holder of an authorised medicinal product placed on its market and which is not included in the Union list of critical medicinal products to have in place a shortage prevention plan. In such cases, the timeline referred to in paragraph 1b shall apply.

1b. When a product is added to the Union list of critical medicinal products pursuant to Article 131, paragraph 3, the marketing authorisation holder shall put in place the shortage prevention plan within 12 months from the addition of that product to the Union list of critical medicinal products. The shortage prevention plan shall be drawn up in accordance with paragraph 1.

PUBLIC

1c~~b~~. Whenever a medicinal product is subject to a shortage prevention plan in accordance with this Article, the competent authority of the Member State may request the marketing authorisation holder to submit that shortage prevention plan at any time. The marketing authorisation holder shall submit that copy at the latest two days after receipt of such request.

~~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.~~

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~~ **taking into account** recommendations of **the competent authority of the Member State in case of a nationally authorized medicinal product, 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).

PUBLIC

ANNEX IV

Part V

The shortage prevention plan

PUBLIC

The Shortage Prevention Plan referred to in Article 117 shall contain the following minimum set of information:

(1) Product details:

(a) Product name;

(b) Active substance(s) and active substance manufacturer(s);

(c) Finished product manufacturer;

(d) ATC code;

(e) Therapeutic indication(s);

(f) Pharmaceutical form;

(g) Strength(s);

(h) Route(s) of administration;

(i) Pack size(s);

(j) Details of authorisation: procedure type (national (including Member State(s) involved)/ centralised marketing authorisation) and reference;

(k) Member States in which the product is placed on the market.

(2) Shortage prevention measures and supply chain risk assessment:

(a) **Patient impact of potential supvesply disruptions, considering therapeutic indication and a**~~A~~lternative marketed medicinal products **and estimated market share by Member states in the previous 12 months**;

(b) Supply chain **risk assessment** ~~map, with risk identification and analysis with particular attention to supply chain vulnerabilities;~~**, to include:**

(i) Supply chain map, with particular attention to supply chain vulnerabilities;

(ii) A record of root causes of resolved shortages and mitigation measures taken for those shortages;

(ba) Final risk classification (low, medium, high).

(2a)~~(c)~~ Shortage management measures, to include:

(a)~~(i)~~ a risk control strategy in place, to include information on strategies to minimise risks of shortages and how these are implemented;

(b)~~(ii)~~ a process for the detection and notification of supply disruptions and

(c)~~(iii)~~ a record of root causes of resolved shortages and mitigation measures taken for those shortages.

(2b)~~(d)~~ Process for check of effectiveness, review and update of the shortage prevention plan.

(3) Contact details

(a) Marketing authorisation holder name and address;

(b) Name and details of contact person.

PUBLIC

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) **and 120(1a)**, the competent authority concerned as referred to in Article 116(1) shall continuously monitor any **expected** ~~potential~~ or actual shortage of those medicinal products. **In addition, the competent authority concerned may use information contained in the repositories in Article 67(2), second subparagraph, point (e), of [revised Directive 2001/83/EC] or in a national repository.**

   The Agency shall carry out that monitoring in collaboration with the relevant competent authority of the Member State whe**re**~~n~~ 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(1), 2nd subparagraph** 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).

PUBLIC

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. Member States may require for centrally or nationally authorised medicinal products, that a~~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 ~~or third country~~ ('destination Member State) or third country notifies the competent authority of the source Member State of this intention. This notification shall include:

(a) The name of the medicinal product and authorisation number;

(b) Active substance(s);

(c) Pharmaceutical form;

(d) Strength;

(e) Pack size

PUBLIC

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

(g) Destination Member State or third country of destination.

Based on the notification referred to in this paragraph and on the information available pursuant to this Chapter, the source Member State may take measures to prevent or to mitigate shortages in the source member state.

The measures referred to in this paragraph adopted by the source Member State for medicinal products intended for distribution to a destination Member State shall, 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.

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~~ **within the timeframe specified by the competent authority concerned**.

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);

PUBLIC

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

6. The Member States may request that the MSSG provide further recommendations **pursuant to**~~, 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 a significant impact on the healthcare system of a Member State or 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 **critical shortages of Union concern.**~~the medicinal products for which the shortage cannot be resolved without EU coordination.~~

PUBLIC

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 **of Union concern** 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 **of Union concern** 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~~ **while avoiding** duplication of reporting.

PUBLIC

Article 123

*Role of the MSSG and the list of critical shortages **of Union concern** 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 Union concern** 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 **of Union concern**').

2. The MSSG shall review the status of the critical shortage **of Union concern** whenever necessary and shall update the list when it considers that a medicinal product needs to be added or that the critical shortage **of Union concern** 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 **of Union concern**, in accordance with the methods referred to in Article 122(4), point (d), to relevant marketing authorisation holders, the Member States, the Commission, **the Agency,** the representatives of healthcare professionals or other entities.

4a. The MSSG may also provide recommendations to Member States regarding the possibility, pursuant to article 117 paragraph 1a, to require a shortage prevention plan for a medicinal product that is not on the Union list of critical medicinal products.

PUBLIC

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 **of Union concern***

1. Following the addition of a medicinal product to the list of critical shortages **of Union concern** 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 **concerned**, shall continuously monitor the critical shortage **of Union concern** of that medicinal product.

2. For the purposes of paragraph 1, ~~where that information is not already available to the Agency~~, the Agency may**, if that information is not already available to the Agency,** request relevant information on that critical shortage **of Union concern** 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.

PUBLIC

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 Union concern** 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 ***of Union concern***

1. Following the addition of a medicinal product to the list of critical shortages **of Union concern** 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) **take into account the actions taken by the Commission pursuant to Article 126 (1)** ~~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 **and the competent authority of the Member State** of the end date of the critical shortage **of Union concern**.

PUBLIC

Article 126

Role of the Commission

1. The Commission**:** ~~shall, where it considers it appropriate and necessary:~~

   (a) **shall** take into account the MSSG recommendations ~~and implement relevant measures~~;

   (aa) shall take any necessary actions, within the limits of the powers conferred on the Commission, to address critical shortages of Union concern;

   (b) **shall** inform the MSSG of those **actions** ~~measures~~ taken **pursuant to letter (aa).** ~~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. **For the purposes of establishing the Union list of critical medicinal products referred to in Article 131 (1),** ~~T~~**t**he competent authority of the Member State shall **identify** ~~identify~~ critical medicinal products **in that Member State** ~~in that Member State, using~~ **using** the methodology set out in Article 130(1), point (a). **The Member State shall make public a list of the critical medicinal products identified pursuant to this subparagraph.**

In addition to the first subparagraph, the Member State may establish a national list of critical medicinal products using a national methodology or 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** ~~identified~~ pursuant to the paragraph 1, **first subparagraph,** 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 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).~~ **For the purposes of the identification of critical medicinal products referred to in paragraph 1, first subparagraph, the competent authority of the Member State may request relevant information from the marketing authorisation holder.**

4. For the purposes of the **identification of critical medicinal products referred to in paragraph 1, first subparagraph** ~~identification~~ of ~~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:

PUBLIC

(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 **actions** ~~measures~~ taken by the Commission pursuant to Article 134(1), point (a);

PUBLIC

(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).~~

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.~~ **within the timeframe specified by the competent authority concerned.**

PUBLIC

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.

PUBLIC

The Agency, in consultation with the working party referred to in Article 121(1), ~~-~~point (c), 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).

PUBLIC

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 **the** coordinated Union level action **foreseen in this chapter** is necessary ("the Union list of critical medicinal products").

2. The MSSG may propose updates to the Union list of critical medicin**al**~~es~~ **products** to the Commission, where necessary.

   The first revision and possible update shall take place no later than one year after the date of entry into application of this Regulation.

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.

PUBLIC

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**, the Agency** or other entities. Such measures may include**, inter alia,** recommendations on diversification of suppliers**,** ~~and~~ inventory management **and regulatory flexibilities**.

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 **following** 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~~ **take into account the** ~~any measures~~ **actions** 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) **shall** take into account the MSSG recommendations ~~and implement the relevant measures;~~

(aa) shall ~~may~~ **take any necessary** ~~relevant~~ ~~non-binding~~ **actions within the limits of the powers conferred on the Commission, including the development of guidelines to improve the security of supply;**

(ab) may foster coordination of Member State measures aimed at ensuring security of supply within their territories.

(b) **shall** inform the MSSG of those ~~measures~~ **actions** taken by the Commission.

(c) **may** request the MSSG to provide information or an opinion or further recommendations referred to in Article 132(1).

PUBLIC

2. The Commission, taking into consideration the **recommendations** ~~information or the opinion,~~ referred to in paragraph 1, ~~or MSSG recommendations,~~ may ~~decide to~~ adopt an implementing act to **improve security of supply within the Union, with a view to ensure the good functioning of the internal market. These measures shall be limited to cases where the Commission identifies a likely disruption of the internal market due to severe risk of disruption of the security of supply within the Union that cannot be resolved through existing instruments or actions and that is liable to affect the security of supply of medicinal products on the Union list of critical medicinal products. For nationally authorised products, these measures shall be addressed at Member States.** ~~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.~~

The implementing act shall be limited to measures aimed at ensuring appropriate stock levels, such as requirements of contingency stocks, and ensuring approriate supplies of medicinal products to wholesale distributors, pharmacies or persons authorised to supply medicinal products. These measures shall be proportionate and necessary to the objective pursued, with due regard to the protection of fundamental rights.

2a. The implementing powers referred to in paragraph 2 of this article shall not affect measures adopted by the Member States, the Council or the Commission pursuant to [EMA revised mandate, HERA Regulation, CBHT] concerning supply of critical countermeasures during a major event or a public health emergency at Union level.

3. The implementing act referred to in paragraph 2 shall be adopted in accordance with the examination procedure referred to in Article 173(2).

PUBLIC

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 **regarding centrally authorised medicinal products**.

Article 172

Union penalties

1. The Commission may impose financial penalties in the form of fines or periodic penalty payments on the marketing authorisations holder granted under this Regulation if they fail to comply with any of the obligations laid down in Annex II in connection with the marketing authorisations.

2. The Commission may, insofar as specifically provided for in the delegated acts referred to in paragraph 10, point (b), impose the financial penalties referred to in paragraph 1 on a legal entity or legal entities other than the marketing authorisation holder provided that such entities form part of the same economic entity as the marketing authorisation holder and that such other legal entities:
   (a) exerted a decisive influence over the marketing authorisation holder; or
   (b) were involved in, or could have addressed, such failure to comply with the obligation by the marketing authorisation holder.

3. Where the Agency or a competent authority of a Member State is of the opinion that a marketing authorisation holder has failed to comply with any of the obligations, referred to in paragraph 1, it may request the Commission to investigate whether to impose financial penalties pursuant to that paragraph.

4. In determining whether to impose a financial penalty and in determining its appropriate amount, the Commission shall be guided by the principles of effectiveness, proportionality and dissuasiveness and take into consideration, where relevant, the seriousness and the effects of the failure to comply with the obligations.

5. For the purposes of paragraph 1, the Commission shall take into account:
   (a) any infringement procedure initiated by a Member State against the same marketing authorisation holder on the basis of the same legal grounds and the same facts;
   (b) any sanctions, including penalties, already imposed on the same marketing authorisation holder on the basis of the same legal grounds and the same facts.

6. Where the Commission finds that the marketing authorisation holder has failed, intentionally or negligently, to comply with its obligations, as referred to in paragraph 1, it may adopt a decision imposing a fine not exceeding 5 % of the marketing authorisation holder's Union turnover in the business year preceding the date of that decision.

   Where the marketing authorisation holder continues to fail to comply with its obligations referred to in paragraph 1, the Commission may adopt a decision imposing periodic penalty payments per day not exceeding 2,5 % of the marketing authorisation holder's average daily Union turnover in the business year preceding the date of that decision.

   Periodic penalty payments may be imposed for a period running from the date of notification of the relevant Commission's decision until the failure to comply with the obligation by the marketing authorisation holder, as referred to in paragraph 1, has been brought to an end.

PUBLIC

7. When conducting the investigation on a failure to comply with any of the obligations referred to in paragraph 1, the Commission may cooperate with competent authorities of the Member States and rely on resources provided by the Agency.

8. Where the Commission adopts a decision imposing a financial penalty, it shall publish a concise summary of the case, including the names of the marketing authorisation holders involved and the amounts of and reasons for the financial penalties imposed, having regard to the legitimate interest of the marketing authorisation holders for the protection of their business secrets.

9. The Court of Justice of the European Union shall have unlimited jurisdiction to review decisions whereby the Commission has imposed financial penalties. The Court of Justice of the European Union may cancel, reduce or increase the fine or periodic penalty payment imposed by the Commission.

10. The Commission is empowered to adopt delegated acts in accordance with Article 175 in order to supplement this Regulation by laying down:
    (a) procedures to be applied by the Commission when imposing fines or periodic penalty payments, including rules on the initiation of the procedure, measures of inquiry, rights of the defence, access to file, legal representation and confidentiality;
    (b) further detailed rules on the imposition by the Commission of financial penalties on legal entities other than the marketing authorisation holder;
    (c) rules on duration of procedure and limitation periods;
    (d) elements to be taken into account by the Commission when setting the level of and imposing fines and periodic penalty payments, as well as the conditions and methods for their collection.

PUBLIC

ANNEX II

LIST OF THE OBLIGATIONS REFERRED TO IN ARTICLE 172

(1) the obligation to submit complete and accurate particulars and documentation in an application for marketing authorisation submitted to the Agency or in response to obligations laid down in this Regulation to the extent that the failure to comply with the obligation concerns a material particular;

(2) the obligation to comply with conditions or restrictions included in the marketing authorisation and concerning the supply or use of the medicinal product for human use, as referred to in Article 12 (4), point (c) and in Article 13(1) fourth subparagraph;

(3) the obligation to comply with conditions or restrictions included in the marketing authorisation with regard to the safe and effective use of the medicinal product for human use as referred to in Article 12(4), points (b), (d), (e), (f) and (g) and in Article 13(1);

(4) the obligation to introduce any necessary variation to the terms of the marketing authorisation to take account of technical and scientific progress and enable the medicinal products for human use to be manufactured and checked by means of generally accepted scientific methods, as provided for in Article 45(1);

(5) the obligation to supply any new information which may entail a variation to the terms of the marketing authorisation, to notify any prohibition or restriction imposed by the competent authorities of any country in which the medicinal product for human use is marketed, or to supply any information that may influence the evaluation of the risks and benefits of the product, as provided for in Article 45(2);

(6) the obligation to keep product information up to date with current scientific knowledge, including the conclusions of the assessment and recommendations made public on the European medicines web-portal, as provided for in Article 45(3);

(7) the obligation to provide, at the request of the Agency, any data demonstrating that the benefit-risk balance remains favourable, as provided for in Article 45(4);

PUBLIC

(8) the obligation to place the medicinal product for human use on the market in accordance with the content of the summary of product characteristics and the labelling and package leaflet as contained in the marketing authorisation;

(9) the obligation to comply with the conditions referred to in Article 18(1) and Article 19;

(10) the obligation to notify the Agency of the dates of actual marketing and of the date when the medicinal product for human use ceases to be on the market, and to provide to the Agency data relating to the volume of sales and the volume of prescriptions of the medicinal product for human use, as provided in Article 16(4);

(11) the obligation to operate a comprehensive pharmacovigilance system for the fulfilment of pharmacovigilance tasks, including the operation of a quality system, maintenance of a pharmacovigilance system master file and performance of regular audits, in accordance with Article 99 in conjunction with Article 99 of [revised Directive 2001/83/EC];

(12) the obligation to submit, at the request of the Agency, a copy of the pharmacovigilance system master file, as provided for in Article 45(4);

(13) the obligation to operate a risk management system as provided for in Article 22 and Article 99(2) in conjunction with Article 99(4) of [revised Directive 2001/83/EC];

(14) the obligation to record and report suspected adverse reactions for medicinal products for human use, in accordance with Article 106 (1) in conjunction with Article 105 of [revised Directive 2001/83/EC];

(15) the obligation to submit periodic safety update reports, in accordance with Article 106(2) in conjunction with of [revised Directive 2001/83/EC];

(16) the obligation to conduct post-marketing studies, including post-authorisation safety studies and post-authorisation efficacy studies, and to submit them for review, as provided for in Article 20;

PUBLIC

(17) the obligation to ensure that public announcements relating to information on pharmacovigilance concerns are presented objectively and are not misleading and to notify them to the Agency, as provided for in Articles 104 of [revised Directive 2001/83/EC];

(18) the obligation to comply with the time limits for initiating or completing measures specified in the Agency's decision on deferral following the initial marketing authorisation of the medicinal product for human use concerned and in accordance with the definitive opinion referred to in Article 81(2);

(19) the obligation to submit to the Agency an updated version of the paediatric investigation plan in accordance with the agreed timing as provided for in Article 74(2) and Article 74(3);

(20) the obligation to place the medicinal product for human use on the market within two years of the date on which the paediatric indication is authorised, as provided for in Article 59 of [revised Directive 2001/83/EC];

(21) the obligation to notify the Agency the intention to discontinue the placing on the market of the product no less than six months before the discontinuation as provided for in Article 60 of [revised Directive 2001/83/EC];

(22) the obligation to transfer the marketing authorisation or to allow a third party to use documentation contained in the file of the medicinal product, as provided for in Article 60 of [revised Directive 2001/83/EC];

(23) the obligation to notify the Agency of the intention to discontinue the conduct of an agreed paediatric investigation plan and provide the reasons for such discontinuation no less than six months before the discontinuation as provided in Article 88;

(24) the obligation to submit paediatric studies to the Agency or to the Member States, including the obligation to enter information on third country clinical trials into the European database, as provided for in Articles 91;

PUBLIC

(25) the obligation to submit to the Agency a paediatric investigation plan with a request for agreement or an application for a waiver from it, not later than upon completion of the human pharmaco-kinetic studies in adults, except in duly justified cases, as provided for in Article 76(1)~~.~~**;**

(26) the obligation to notify in accordance with ~~a~~Article 116, paragraph 1, points (a), (b), (c) and (d) ~~a decision to permanently cease or temporarily suspend the marketing of a medicinal product, or permanently withdraw the marketing authorisation for that medicinal product.~~

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

Chapter V

Obligations and liability of the marketing authorisation holder

Article 56

General obligations

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 **stock levels** 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.

Chapter XII

Wholesale distribution and sale at a distance

Article 162

Wholesale distribution of medicinal products

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.

PUBLIC

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;

PUBLIC

(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.

PUBLIC

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.

PUBLIC

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.

PUBLIC

Chapter XVI

General provisions

Article 203

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

PUBLIC

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).~~

The marketing authorisation holder shall notify the national competent authority 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 notified action is based on any of the grounds set out in Articles 195 or 196(1) and specify the grounds for such action.

2a. **~~If a marketing authorisation holder submits a notification pursuant to Article 116(1) of [revised Regulation (EC) No 726/2004], it shall concomitantly notify, without undule delay, in accordance with paragraph 2 [where that notification is also based on any of the grounds listed in paragraph 2].~~**

The marketing authorisation holder shall make the notification electronically and in the formats made available by the Agency. The Agency shall consult the Member States when drawing up the formats.

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.

PUBLIC