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ANNEXES 1 to 5

ANNEXES

to the 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

{SEC(2023) 390 final} - {SWD(2023) 192 final} - {SWD(2023) 193 final} -
{SWD(2023) 194 final}

ANNEX I

MEDICINAL PRODUCTS TO BE AUTHORISED BY THE UNION

1. Medicinal products developed by means of one of the following biotechnological processes:
 - recombinant nucleic acid technology;
 - controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells.
2. Advanced therapy medicinal products as defined in Article 2 of Regulation (EC) No 1394/2007.
3. Medicinal products for human use containing an active substance which on 20 May 2004 was not authorised in the Union, excluding allergen products or herbal medicinal products, which shall in any case not be authorised by the Union.
4. Medicinal products that are designated as orphan medicinal products pursuant to this Regulation.
5. Medicinal products authorised in accordance with a paediatric use marketing authorisation.
6. Priority antimicrobials as referred to in Article 40.

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);
- (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;
- (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;
- (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 pharmacokinetic studies in adults, except in duly justified cases, as provided for in Article 76(1).

ANNEX III

PROCEDURE AND CRITERIA GOVERNING INSPECTIONS CARRIED OUT BY THE AGENCY

Reasoned request by the competent authority

The supervisory authority may submit after consultation with the Agency, a reasoned request to the Agency to carry out an inspection or to participate with its inspectors to an inspection carried out of a site located in a third country. The reasoned request should specify:

- The precise identification of the site, the scope of the inspections and if relevant the concerned products;
- The timeline for this inspection to be completed;
- The reasons for requesting the support of the Agency, by reference to the criteria set out in this Annex.

The Agency may refuse an inspection request after consideration of the request, the scope and availability of internal inspection capacity.

Assessment by the Agency

The Agency decides whether it accepts to carry out such inspection or to participate with its inspectors in such inspection, based on the following criteria:

- The site is located in a non-EU/EEA country;
- The inspection is in the interest of the Union, when one or more of the following situations apply to ensure faster or continuous access to medicines of patients:
 - to prevent, mitigate or address shortages of medicinal products or their active substances or other supply issues;
 - to prevent, mitigate or address a possible threat to public health, a public health emergency or a major event which requires immediate action;
 - to address a suspicion of non-compliance of the manufacturing site;
 - to enable the process of granting of the marketing authorisation for centrally authorised products/emergency use authorisation and for their active substance master files;
 - to improve the oversight of medicines production worldwide;
 - to address serious challenges of an unexpected and temporary nature with inspections capacities at national level;
 - other relevant situations.

The compilation of Union procedures on inspections and exchange of information referred to in Article 3(1) of Directive 2017/1572 might be updated to cover rules applicable to situations where the Agency may be requested to carry out an inspection or to participate in a joint inspection.

In the context of inspections referred under Article 78 of Regulation (EU) 536/2014, the above criteria apply mutatis mutandis.

ANNEX IV
AVAILABILITY

Part I

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

For the purpose of the notification in accordance with Article 116(1), points (a), (b) and (c), the marketing authorisation holder shall notify the following minimum set of information:

- (1) Product details:
 - (a) Product name;
 - (b) Active substance(s) and active substance supplier(s);
 - (c) Finished product manufacturer;
 - (d) Anatomical Therapeutic Chemical (ATC)code;
 - (e) Therapeutic indication(s);
 - (f) Pharmaceutical form;
 - (g) Strength(s);
 - (h) Route(s) of administration;
 - (i) Affected pack size(s);
 - (j) Alternative, pharmaceutical form, strength, route of administration or pack size, not affected by the suspension, cessation or withdrawal;
 - (k) Details of authorisation: procedure type (national (including Member State(s) involved)/ centralised marketing authorisation) and reference;
 - (l) Member States in which the product is placed on the market.

- (2) Details of action (suspension, cessation or withdrawal):
 - (a) Category of action (suspension, cessation or withdrawal);
 - (b) Available stock up to start date of action;
 - (c) Start date of action, per Member State;
 - (d) Reason for action and information on alternative medicinal product(s), where relevant;
 - (e) Impacted EU/ EEA countries;
 - (f) Reference to pending regulatory action, Rapid Alert (quality/ safety) or Quality Defect Report related to the action, if relevant;
 - (g) Other competent authorities notified;
 - (h) Any actions completed or planned based on a request of the competent authorities of the Member State concerned.

- (3) Contact details
 - (a) Marketing authorisation holder name and address;
 - (b) Name and contact details of person notifying.

Part II

Risk assessment of impact of suspension, cessation or withdrawal

For the purpose of the request made by the competent authority concerned in accordance with Article 118(2), the marketing authorisation holder shall notify at least the following information:

- (1) Risk assessment of impact of suspension, cessation or withdrawal, including:
 - (a) Potential alternative medicinal products;
 - (b) Estimated market share per Member State in previous 12 months;
 - (c) Quantities delivered per month per Member State in previous 12 months;
 - (d) Manufacturing capacity globally per manufacturing site;
 - (e) Forecast of supply per month and per Member State until suspension, cessation or withdrawal occurs;
 - (f) Forecast of demand per month and per Member State in next 6 months;
 - (g) Impact on the supply of other medicinal products from the same marketing authorisation holder;
 - (h) Potential impact on the consumption of or demand for other medicinal products.
- (2) Any risk-mitigating measures taken by the marketing authorisation holder to address the shortage.

Part III

Information to be provided in case of a temporary disruption of supply (to monitor potential or actual shortage)

For the purpose of the notification in accordance with Article 116(1), point (d) the marketing authorisation holder shall notify the following information:

- (1) Product details
 - (a) Product name;
 - (b) Active substance(s) and active substance manufacturer(s);
 - (c) Finished product manufacturer;
 - (d) Therapeutic indication(s);
 - (e) ATC code;
 - (f) Pharmaceutical form;
 - (g) Strength(s);
 - (h) Route(s) of administration;
 - (i) Affected pack size;

- (j) Alternative, pharmaceutical form, strength, route of administration or pack size, not affected by the supply disruption;
 - (k) Details of authorisation: procedure type (national (including Member State(s) involved)/ centralised marketing authorisation) and reference;
 - (l) Member States in which the product is placed on the market.
- (2) Details of supply disruption
- (a) Shortage status (actual, potential);
 - (b) Available stock per month
 - (c) Expected start date of shortage by Member State;
 - (d) Expected end date of shortage by Member State;
 - (e) Reason for shortage;
 - (f) Impacted EU/ EEA countries and where available other impacted countries;
 - (g) Reference to pending regulatory action, Rapid Alert (quality/ safety) or Quality Defect Report related to the action, if relevant;
 - (h) Other competent authorities notified;
 - (i) Any actions completed or planned based on a request of competent authorities of Member State concerned.
- (3) Contact details
- (a) Marketing authorisation holder name and address;
 - (b) Name and contact details of person notifying.

Part IV

The Shortage Mitigation Plan

For the purpose of the request made by the competent authority concerned in accordance with Article 118(2), the marketing authorisation holder shall notify at least the following information:

1. Shortage mitigation plan, detailing the risk assessment of impact of shortage, including, where available:
 - (a) Potential alternative medicinal products;
 - (b) Estimated market share by Member State in previous 12 months;
 - (c) Quantities delivered per month per Member State, in previous 12 months;
 - (d) Manufacturing capacity globally per manufacturing site;
 - (e) Forecast of supply per month and per Member State for the duration of the shortage,
 - (f) Forecast of demand per month and per Member State for the duration of the shortage;

- (g) Impact on the supply of other medicinal products from the same marketing authorisation holder;
- (h) Potential impact on the consumption of or demand for other medicinal products;
- (i) Any risk-mitigating measures taken or planned by the marketing authorisation holder to address the shortage.

Part V

The shortage prevention plan

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) Alternative marketed medicinal products;
 - (b) Supply chain map, with risk identification and analysis with particular attention to supply chain vulnerabilities;
 - (c) Shortage management measures, to include:
 - (i) a risk control strategy in place, to include information on strategies to minimise risks of shortages and how these are implemented;
 - (ii) a process for the detection and notification of supply disruptions and
 - (iii) a record of root causes of resolved shortages and mitigation measures taken for those shortages.
 - (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.

ANNEX V
CORRELATION TABLE

Regulation (EC) No 726/2004	Directive 2001/83/EC	Regulation (EC) No 141/2000	Regulation (EC) No 1901/2006	This Regulation
Art. 1				Art. 1
Art. 2		Art. 2	Art. 2	Art. 2
Art. 3(1)				Art. 3(1)
Art. 3(2), point (b)				Art. 3(2), introductory sentence and point (a)
				Art. 3(2), point (b)
Art. 4(2)				Art. 3(4)
Art. 3(3), introductory sentence, points (a) and (b)				Art. 4
Art. 2, 4th subparagraph				Art. 5(1)

				Art. 5(2-7)
Art. 6(1)				Art. 6(1)
				Art. 6(2)
Art. 6(1), 2nd subparagraph				Art. 6(3)
				Art. 6(4) and (5)
Art. 6(3)				Art. 6(6)
Art. 14(9)				Art. 6(7)
Art. 14(9), 1st subparagraph, 2nd sentence				Art. 6(7), 1st subparagraph
Art. 14(9), 2nd subparagraph				Art. 6(7), 2nd subparagraph
				Art. 7
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Art. 7				Art. 10, paragraph 1, points (a) and (b)
				Art. 10, paragraph 2
Art. 8(1)				Art. 11(1)
Art. 8(2), 1st and 2nd subparagraph				Art. 11(2), 1st and 2nd subparagraph
				Art. 11(2), 3rd subparagraph
Art. 9(1)				Art. 12(1)
Art. 9(2), 1st subparagraph				Art. 12(2), 1st subparagraph
Art. 62(1), 5th subparagraph, 2nd sentence				Art. 12(2), 2nd subparagraph
Art. 9(2), 2nd subparagraph				Art. 12(2), 3rd subparagraph
Art. 9(3)				Art. 12(3)

Art. 9(4)				Art. 12(4)
Art. 14(10)				Art. 12(5)
Art. 10(1)				Art. 13(1)
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				Art. 24(1), 2nd subparagraph
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				Art. 24(4)
Art. 82(1)				Art. 25(1), 1st and 2nd subparagraph

				Art. 25(1), 3rd subparagraph
Art. 82(2) and (3)				Art. 25(2) and (3)
Art. 83(1)				Art. 26(1)
				Art. 26(1), 2nd sentence
Art. 83(2-3)				Art. 26(2) and (3)
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				Art. 26(4), 2nd to 4th subparagraph
Art. 83(5) to (9)				Art. 26(5) to (9)
				Art. 26(10)
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