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**NOTE**

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| From: | General Secretariat of the Council |
| To: | Delegations |
| Subject: | Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency<br>- Annexes to the four-column table |

Delegations will find enclosed the annexes to the four-column table on the above-mentioned Regulation. This document contains in Annex A the explanations on the layout of the table used in this document and in Annex B the text of the Commission proposal, the amendments voted by the European Parliament on 10 April 2024 and changes to the proposal approved by the Council on 4 June 2025.

**ANNEX A**

| | Commission proposal | EP amendments voted on 10 April 2024 | Text agreed by the Council on 4 June 2025 | Draft agreement |
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| | | Plain text in this column is text from the Commission proposal that the European Parliament proposes to maintain.<br><br>***Text in blue underlined bold italics in this column is text that the EP proposes to add to the Commission proposal.***<br><br>***Text in red italics ~~strikethrough~~ in this column is text that the EP proposes to delete.*** | Plain text in this column is text from the Commission proposal that Council wishes to maintain.<br><br>**Text in bold** in this column is text that Council has agreed to add.<br>Text in ~~strikethrough~~ in this column is text that Council has agreed to delete. | |

**ANNEX B**

# 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 (Text with EEA relevance)

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**Annexes**

| | Commission Proposal | EP Mandate | Council Mandate | Draft Agreement |
|---|---|---|---|---|
| Annex I | | | | |
| 1630 | Annex I | Annex I | Annex I | |
| Annex I, first paragraph | | | | |
| 1631 | MEDICINAL PRODUCTS TO BE AUTHORISED BY THE UNION | MEDICINAL PRODUCTS TO BE AUTHORISED BY THE UNION | MEDICINAL PRODUCTS TO BE AUTHORISED BY THE UNION | |

| | Commission Proposal | EP Mandate | Council Mandate | Draft Agreement |
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| Annex I, point 1. | | | | |
| 1632 | 1. Medicinal products developed by means of one of the following biotechnological processes: | 1. Medicinal products developed by means of one of the following biotechnological processes: | 1. Medicinal products developed by means of one of the following biotechnological processes: | |
| Annex I, second paragraph | | | | |
| 1633 | - recombinant nucleic acid technology; | - recombinant nucleic acid technology; | - recombinant nucleic acid technology; | |
| Annex I, -a paragraph | | | | |
| 1634 | - controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells. | - controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells. | - controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells. | |
| Annex I, point 2. | | | | |

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| 1635 | 2. Advanced therapy medicinal products as defined in Article 2 of Regulation (EC) No 1394/2007. | 2. Advanced therapy medicinal products as defined in Article 2 of Regulation (EC) No 1394/2007. | 2. Advanced therapy medicinal products as defined in Article 2 of Regulation (EC) No 1394/2007. | |
| Annex I, point 3. | | | | |
| 1636 | 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. | 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. | 3. Medicinal products for human use containing ~~an~~**a new** active substance which on ~~20 May 2004~~**[date of application of this Regulation]** was not authorised in the Union, excluding allergen **medicinal** products or herbal medicinal products~~, which shall in any case not be authorised by the Union.~~**.** | |
| Annex I, point 3a., first subparagraph | | | | |

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| 1636a | | | **3a. Medicinal products for human use containing a new active substance, which on 20 May 2004 was not authorised in the Union and which is not covered by point 3, for which the therapeutic indication is the treatment of any of the following diseases:** | |
| Annex I, point 3a., second subparagraph | | | | |
| 1636b | | | **- acquired immune deficiency syndrome,** | |
| Annex I, point 3a., third subparagraph | | | | |
| 1636c | | | **- cancer,** | |
| Annex I, point 3a., fourth subparagraph | | | | |

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| 1636d | | | **- neurodegenerative disorder,** | |
| Annex I, point 3a., fifth subparagraph | | | | |
| 1636e | | | **- diabetes,** | |
| Annex I, point 3a., sixth subparagraph | | | | |
| 1636f | | | **- auto-immune diseases and other immune dysfunctions,** | |
| Annex I, point 3a., seventh subparagraph | | | | |
| 1636g | | | **- viral diseases.** | |
| Annex I, point 4. | | | | |
| 1637 | 4. Medicinal products that are designated as orphan medicinal products pursuant to this Regulation. | 4. Medicinal products that are designated as orphan medicinal products pursuant to this Regulation. | 4. Medicinal products that are designated as orphan medicinal products pursuant to this Regulation. | |

| | Commission Proposal | EP Mandate | Council Mandate | Draft Agreement |
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| Annex I, point 5. | | | | |
| 1638 | 5. Medicinal products authorised in accordance with a paediatric use marketing authorisation. | 5. Medicinal products authorised in accordance with a paediatric use marketing authorisation. | 5. Medicinal products authorised in accordance with a paediatric use marketing authorisation. | |
| Annex I, point 6. | | | | |
| 1639 | 6. Priority antimicrobials as referred to in Article 40. | 6. Priority antimicrobials as referred to in Article 40. | 6. Priority antimicrobials as referred to in Article 40. | |
| Annex II | | | | |
| 1640 | Annex II | Annex II | Annex II | |
| Annex II, first paragraph | | | | |
| 1641 | LIST OF THE OBLIGATIONS REFERRED TO IN ARTICLE 172 | LIST OF THE OBLIGATIONS REFERRED TO IN ARTICLE 172 | LIST OF THE OBLIGATIONS REFERRED TO IN ARTICLE 172 | |

| | Commission Proposal | EP Mandate | Council Mandate | Draft Agreement |
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| Annex II, second paragraph | | | | |
| 1642 | (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; | (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; | (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; | |
| Annex II, 2 paragraph | | | | |
| 1643 | (2) the obligation to comply with conditions or restrictions included in the marketing authorisation and concerning the supply or use of the medicinal | (2) the obligation to comply with conditions or restrictions included in the marketing authorisation and concerning the supply or use of the medicinal | (2) the obligation to comply with conditions or restrictions included in the marketing authorisation and concerning the supply or use of the medicinal | |

| | Commission Proposal | EP Mandate | Council Mandate | Draft Agreement |
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| | product for human use, as referred to in Article 12 (4), point (c) and in Article 13(1) fourth subparagraph; | product for human use, as referred to in Article 12 (4), point (c) and in Article 13(1) fourth subparagraph; | product for human use, as referred to in Article 12 (4), point (c) and in Article 13(1) fourth subparagraph; | |
| Annex II, 3 paragraph | | | | |
| 1644 | (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); | (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); | (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); | |
| Annex II, 4 paragraph | | | | |
| 1645 | (4) the obligation to introduce any necessary variation to the | (4) the obligation to introduce any necessary variation to the | (4) the obligation to introduce any necessary variation to the | |

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| | 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); | 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); | 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); | |
| Annex II, 5 paragraph | | | | |
| 1646 | (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 | (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 | (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 | |

| | Commission Proposal | EP Mandate | Council Mandate | Draft Agreement |
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| | 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); | 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); | 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); | |
| Annex II, 6 paragraph | | | | |
| 1647 | (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); | (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); | (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); | |
| Annex II, 7 paragraph | | | | |
| 1648 | (7) the obligation to provide, at the request of the Agency, any | (7) the obligation to provide, at the request of the Agency, any | (7) the obligation to provide, at the request of the Agency, any | |

| | Commission Proposal | EP Mandate | Council Mandate | Draft Agreement |
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| | data demonstrating that the benefit-risk balance remains favourable, as provided for in Article 45(4); | data demonstrating that the benefit-risk balance remains favourable, as provided for in Article 45(4); | data demonstrating that the benefit-risk balance remains favourable, as provided for in Article 45(4); | |
| Annex II, 8 paragraph | | | | |
| 1649 | (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; | (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; | (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; | |
| Annex II, 9 paragraph | | | | |
| 1650 | (9) the obligation to comply with the conditions referred to in Article 18(1) and Article 19; | (9) the obligation to comply with the conditions referred to in Article 18(1) and Article 19; | (9) the obligation to comply with the conditions referred to in Article 18(1) and Article 19; | |

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| Annex II, 10 paragraph | | | | |
| 1651 | (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); | (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); | (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); | |
| Annex II, 11 paragraph | | | | |
| 1652 | (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 | (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 | (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 | |

| | Commission Proposal | EP Mandate | Council Mandate | Draft Agreement |
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| | 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]; | 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]; | 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]; | |
| Annex II, 12 paragraph | | | | |
| 1653 | (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); | (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); | (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); | |
| Annex II, 13 paragraph | | | | |
| 1654 | (13) the obligation to operate a risk management system as provided for in Article 22 and Article 99(2) in conjunction with | (13) the obligation to operate a risk management system as provided for in Article 22 and Article 99(2) in conjunction with | (13) the obligation to operate a risk management system as provided for in Article 22 and Article 99(2) in conjunction with | |

| | Commission Proposal | EP Mandate | Council Mandate | Draft Agreement |
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| | Article 99(4) of [revised Directive 2001/83/EC]; | Article 99(4) of [revised Directive 2001/83/EC]; | Article 99(4) of [revised Directive 2001/83/EC]; | |
| Annex II, 14 paragraph | | | | |
| 1655 | (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]; | (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]; | (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]; | |
| Annex II, 15 paragraph | | | | |
| 1656 | (15) the obligation to submit periodic safety update reports, in accordance with Article 106(2) in conjunction with 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]; | (15) the obligation to submit periodic safety update reports, in accordance with Article 106(2) in conjunction with of [revised Directive 2001/83/EC]; | |

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| Annex II, 16 paragraph | | | | |
| 1657 | (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; | (16) the obligation to conduct post-marketing studies, including post-authorisation safety studies ~~and~~, post-authorisation efficacy ***studies and post-authorisation environmental risk assessment*** studies, and to submit them for review, as provided for in Article 20; | (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; | |
| Annex II, 17 paragraph | | | | |
| 1658 | (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 | (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 | (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 | |

| | Commission Proposal | EP Mandate | Council Mandate | Draft Agreement |
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| | Articles 104 of [revised Directive 2001/83/EC]; | Articles 104 of [revised Directive 2001/83/EC]; | Articles 104 of [revised Directive 2001/83/EC]; | |
| Annex II, 18 paragraph | | | | |
| 1659 | (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); | (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); | (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); | |
| Annex II, 19 paragraph | | | | |
| 1660 | (19) the obligation to submit to the Agency an updated version of the paediatric investigation plan in | (19) the obligation to submit to the Agency an updated version of the paediatric investigation plan in | (19) the obligation to submit to the Agency an updated version of the paediatric investigation plan in | |

| | Commission Proposal | EP Mandate | Council Mandate | Draft Agreement |
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| | accordance with the agreed timing as provided for in Article 74(2) and Article 74(3); | accordance with the agreed timing as provided for in Article 74(2) and Article 74(3); | accordance with the agreed timing as provided for in Article 74(2) and Article 74(3); | |
| Annex II, 20 paragraph | | | | |
| 1661 | (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]; | (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]; | (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]; | |
| Annex II, 21 paragraph | | | | |
| 1662 | (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 | (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 | (21) the obligation to notify the Agency the intention to discontinue the placing on the market of the product no less than ~~six~~**twelve** months before the | |

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| | discontinuation as provided for in Article 60 of [revised Directive 2001/83/EC]; | discontinuation as provided for in Article 60 of [revised Directive 2001/83/EC]; | discontinuation as provided for in Article 60 of [revised Directive 2001/83/EC]; | |
| Annex II, 22 paragraph | | | | |
| 1663 | (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]; | (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]; | (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]; | |
| Annex II, 23 paragraph | | | | |
| 1664 | (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 | (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 | (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 | |

| | Commission Proposal | EP Mandate | Council Mandate | Draft Agreement |
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| | such discontinuation no less than six months before the discontinuation as provided in Article 88; | such discontinuation no less than six months before the discontinuation as provided in Article 88; | such discontinuation no less than six months before the discontinuation as provided in Article 88; | |
| Annex II, 24 paragraph | | | | |
| 1665 | (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; | (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; | (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~~**Article 94**; | |
| Annex II, 25 paragraph | | | | |
| 1666 | (25) the obligation to submit to the Agency a paediatric investigation plan with a request | (25) the obligation to submit to the Agency a paediatric investigation plan with a request | (25) the obligation to submit to the Agency a paediatric investigation plan with a request | |

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| | 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). | 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). | for agreement or an application for a waiver from it, ~~not later than upon completion of the human pharmaco-kinetic~~**before the initiation of safety and efficacy clinical** studies ~~in adults~~, except in duly justified cases, as provided for in Article 76(1)~~.~~**;** |
| Annex II, 26 paragraph | | | | |
| 1666a | | | **26. the obligation to notify in accordance with Article 116, paragraph 1, points (a), (b), (c) and (d).** | |
| Annex II, 25 paragraph a | | | | |
| 1666b | | ***(25a) the obligations related to the availability and supply of*** | | |

| | Commission Proposal | EP Mandate | Council Mandate | Draft Agreement |
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| | | ***medicinal products as laid down in Chapter X;*** | | |
| Annex II, 25 paragraph b | | | | |
| 1666c | | ***(25b) the obligations to report on financial support and research and development costs as laid down in Article 57 of [revised Directive 2001/83/EC].*** | | |
| Annex III | | | | |
| 1667 | Annex III | Annex III | Annex III | |
| Annex III, first paragraph | | | | |
| 1668 | PROCEDURE AND CRITERIA GOVERNING INSPECTIONS CARRIED OUT BY THE AGENCY | PROCEDURE AND CRITERIA GOVERNING INSPECTIONS CARRIED OUT BY THE AGENCY | ~~PROCEDURE AND CRITERIA GOVERNING~~ INSPECTIONS ~~CARRIED OUT BY THE~~ | |

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| | | | ~~AGENCY~~**IN THE INTEREST OF THE UNION** | |
| Annex III, second paragraph | | | | |
| 1669 | Reasoned request by the competent authority | Reasoned request by the competent authority | ~~Reasoned request by the competent authority~~ | |
| Annex III, third paragraph | | | | |
| 1670 | 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 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 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:~~ | |
| Annex III, fourth paragraph | | | | |

| | Commission Proposal | EP Mandate | Council Mandate | Draft Agreement |
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| 1671 | - The precise identification of the site, the scope of the inspections and if relevant the concerned products; | - The precise identification of the site, the scope of the inspections and if relevant the concerned products; | - ~~The precise identification of the site, the scope of the inspections and if relevant the concerned products;~~ | |
| Annex III, -a paragraph | | | | |
| 1672 | - The timeline for this inspection to be completed; | - The timeline for this inspection to be completed; | - ~~The timeline for this inspection to be completed;~~ | |
| Annex III, -a paragraph | | | | |
| 1673 | - The reasons for requesting the support of the Agency, by reference to the criteria set out in this Annex. | - The reasons for requesting the support of the Agency, by reference to the criteria set out in this Annex. | - ~~The reasons for requesting the support of the Agency, by reference to the criteria set out in this Annex.~~ | |
| Annex III, -a paragraph | | | | |
| 1674 | The Agency may refuse an inspection request after | The Agency may refuse an inspection request after | ~~The Agency may refuse an inspection request after~~ | |

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| | consideration of the request, the scope and availability of internal inspection capacity. | consideration of the request, the scope and availability of internal inspection capacity. | ~~consideration of the request, the scope and availability of internal inspection capacity.~~ | |
| Annex III, -b paragraph | | | | |
| 1675 | Assessment by the Agency | Assessment by the Agency | ~~Assessment by the Agency~~ | |
| Annex III, -c paragraph | | | | |
| 1676 | 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 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 Agency decides whether it accepts to carry out such inspection or to participate with its inspectors in such inspection, based on the following criteria:~~ | |
| Annex III, -Ca paragraph | | | | |
| 1677 | - The site is located in a non-EU/EEA country; | - The site is located in a non-EU/EEA country; | - ~~The site is located in a non-EU/EEA country;~~ | |

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| Annex III, -a paragraph | | | | |
| 1678 | - 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: | - 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: | - ~~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:~~ | |
| Annex III, -a paragraph | | | | |
| 1679 | - to prevent, mitigate or address shortages of medicinal products or their active substances or other supply issues; | - to prevent, mitigate or address shortages of medicinal products or their active substances or other supply issues; | - ~~to prevent, mitigate or address shortages of medicinal products or their active substances or other supply issues;~~ | |
| Annex III, -a paragraph | | | | |
| 1680 | - to prevent, mitigate or address a possible threat to public health, a public health emergency | - to prevent, mitigate or address a possible threat to public health, a public health emergency | - ~~to prevent, mitigate or address a possible threat to public health, a public health emergency~~ | |

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| | or a major event which requires immediate action; | or a major event which requires immediate action; | ~~or a major event which requires immediate action;~~ | |
| Annex III, -a paragraph | | | | |
| 1681 | - to address a suspicion of non-compliance of the manufacturing site; | - to address a suspicion of non-compliance of the manufacturing site; | - ~~to address a suspicion of non-compliance of the manufacturing site;~~ | |
| Annex III, -a paragraph | | | | |
| 1682 | - 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 enable the process of granting of the marketing authorisation for centrally authorised products/emergency use authorisation and for their active substance master files; | - ~~to enable the process of granting of the marketing authorisation for centrally authorised products/emergency use authorisation and for their active substance master files;~~ | |
| Annex III, -a paragraph | | | | |

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| 1683 | - to improve the oversight of medicines production worldwide; | - to improve the oversight of medicines production worldwide; | - ~~to improve the oversight of medicines production worldwide;~~ | |
| Annex III, -a paragraph | | | | |
| 1684 | - to address serious challenges of an unexpected and temporary nature with inspections capacities at national level; | - to address serious challenges of an unexpected and temporary nature with inspections capacities at national level; | - ~~to address serious challenges of an unexpected and temporary nature with inspections capacities at national level;~~ | |
| Annex III, -a paragraph | | | | |
| 1685 | - other relevant situations. | - other relevant situations. | - ~~other relevant situations.~~ | |
| Annex III, -a paragraph | | | | |
| 1686 | The compilation of Union procedures on inspections and exchange of information referred to in Article 3(1) of Directive | The compilation of Union procedures on inspections and exchange of information referred to in Article 3(1) of Directive | ~~The compilation of Union procedures on inspections and exchange of information referred to in Article 3(1) of Directive~~ | |

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| | 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. | 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. | ~~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.~~ | |
| Annex III, -b paragraph | | | | |
| 1687 | In the context of inspections referred under Article 78 of Regulation (EU) 536/2014, the above criteria apply mutatis mutandis. | In the context of inspections referred under Article 78 of Regulation (EU) 536/2014, the above criteria apply mutatis mutandis. | ~~In the context of inspections referred under Article 78 of Regulation (EU) 536/2014, the above criteria apply mutatis mutandis.~~ | |
| Annex III, -b paragraph a | | | | |
| 1687a | | | **An inspection is in the interest of the Union when there is a need to ensure faster or continous access to medicines for patients** | |

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| | | | **and when the inspection is justified based on at least one of the following grounds:** | |
| Annex III, -b paragraph a, point (a) | | | | |
| 1687b | | | **(a) to prevent, mitigate or address shortages of medicinal products, or their active substances or other supply issues, or** | |
| Annex III, -b paragraph a, point (b) | | | | |
| 1687c | | | **(b) to prevent, mitigate or address a possible threat to public health, a public health emergency or a major event which requires immediate action, or** | |

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| Annex III, -b paragraph a, point (c) | | | | |
| 1687d | | | **(c) to address a suspicion of non-compliance of the manufacturing site, or** | |
| Annex III, -b paragraph a, point (d) | | | | |
| 1687e | | | **(d) to enable the process of granting the marketing authorisation for centrally authorised products/emergency use authorisation and for their active substance master files.** | |
| Annex IV | | | | |
| 1688 | Annex IV | Annex IV | Annex IV | |
| Annex IV, first paragraph | | | | |

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| 1689 | AVAILABILITY | AVAILABILITY | AVAILABILITY | |
| Annex IV, Part I | | | | |
| 1690 | Part I Part I | Part I Part I | Part I Part I | |
| Annex IV, second paragraph | | | | |
| 1691 | 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 | 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 | 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 | |
| Annex IV, third paragraph | | | | |
| 1692 | For the purpose of the notification in accordance with Article 116(1), points (a), (b) and (c), the marketing authorisation holder | For the purpose of the notification in accordance with Article 116(1), points (a), (b) and (c), the marketing authorisation holder | For the purpose of the notification in accordance with Article 116(1), points (a), (b) and (c), the marketing authorisation holder | |

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| | shall notify the following minimum set of information: | shall notify the following minimum set of information: | shall notify the following minimum set of information: | |
| Annex IV, fourth paragraph | | | | |
| 1693 | (1) Product details: | (1) Product details: | (1) Product details: | |
| Annex IV, fourth paragraph, point (a) | | | | |
| 1694 | (a) Product name; | (a) Product name; | (a) Product name; | |
| Annex IV, fourth paragraph, point (b) | | | | |
| 1695 | (b) Active substance(s) and active substance supplier(s); | (b) Active substance(s) and active substance supplier(s); | (b) Active substance(s) and active substance supplier(s); | |
| Annex IV, fourth paragraph, point (c) | | | | |
| 1696 | (c) Finished product manufacturer; | (c) Finished product manufacturer; | (c) Finished product manufacturer; | |

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| Annex IV, fourth paragraph, point (d) | | | | |
| 1697 | (d) Anatomical Therapeutic Chemical (ATC)code; | (d) Anatomical Therapeutic Chemical (ATC)code; | (d) Anatomical Therapeutic Chemical (ATC)code; | |
| Annex IV, fourth paragraph, point (e) | | | | |
| 1698 | (e) Therapeutic indication(s); | (e) Therapeutic indication(s); | (e) Therapeutic indication(s); | |
| Annex IV, fourth paragraph, point (f) | | | | |
| 1699 | (f) Pharmaceutical form; | (f) Pharmaceutical form; | (f) Pharmaceutical form; | |
| Annex IV, fourth paragraph, point (g) | | | | |
| 1700 | (g) Strength(s); | (g) Strength(s); | (g) Strength(s); | |
| Annex IV, fourth paragraph, point (h) | | | | |
| 1701 | (h) Route(s) of administration; | (h) Route(s) of administration; | (h) Route(s) of administration; | |

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| Annex IV, fourth paragraph, point (i) | | | | |
| 1702 | (i) Affected pack size(s); | (i) Affected pack size(s); | (i) Affected pack size(s); | |
| Annex IV, fourth paragraph, point (j) | | | | |
| 1703 | (j) Alternative, pharmaceutical form, strength, route of administration or pack size, not affected by the suspension, cessation or withdrawal; | (j) Alternative, pharmaceutical form, strength, route of administration or pack size, not affected by the suspension, cessation or withdrawal; | (j) Alternative, pharmaceutical form, strength, route of administration or pack size, not affected by the suspension, cessation or withdrawal; | |
| Annex IV, fourth paragraph, point (k) | | | | |
| 1704 | (k) Details of authorisation: procedure type (national (including Member State(s) involved)/ centralised marketing authorisation) and reference; | (k) Details of authorisation: procedure type (national (including Member State(s) involved)/ centralised marketing authorisation) and reference; | (k) Details of authorisation: procedure type (national (including Member State(s) involved)/ centralised marketing authorisation) and reference; | |

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| Annex IV, fourth paragraph, point (l) | | | | |
| 1705 | (l) Member States in which the product is placed on the market. | (l) Member States in which the product is placed on the market. | (l) Member States in which the product is placed on the market. | |
| Annex IV, 2 paragraph | | | | |
| 1706 | (2) Details of action (suspension, cessation or withdrawal): | (2) Details of action (suspension, cessation or withdrawal): | (2) Details of action (suspension, cessation or withdrawal): | |
| Annex IV, 2 paragraph, point (a) | | | | |
| 1707 | (a) Category of action (suspension, cessation or withdrawal); | (a) Category of action (suspension, cessation or withdrawal); | (a) Category of action (suspension, cessation or withdrawal); | |
| Annex IV, 2 paragraph, point (b) | | | | |

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| 1708 | (b) Available stock up to start date of action; | (b) Available stock up to start date of action; | (b) Available stock up to start date of action; | |
| Annex IV, 2 paragraph, point (c) | | | | |
| 1709 | (c) Start date of action, per Member State; | (c) Start date of action, per Member State; | (c) Start date of action, per Member State; | |
| Annex IV, 2 paragraph, point (d) | | | | |
| 1710 | (d) Reason for action and information on alternative medicinal product(s), where relevant; | (d) Reason for action and information on alternative medicinal product(s), where relevant; | (d) Reason for action and information on alternative medicinal product(s), where relevant; | |
| Annex IV, 2 paragraph, point (e) | | | | |
| 1711 | (e) Impacted EU/ EEA countries; | (e) Impacted EU/ EEA countries; | (e) Impacted EU/ EEA countries; | |
| Annex IV, 2 paragraph, point (f) | | | | |

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| 1712 | (f) Reference to pending regulatory action, Rapid Alert (quality/ safety) or Quality Defect Report related to the action, if relevant; | (f) Reference to pending regulatory action, Rapid Alert (quality/ safety) or Quality Defect Report related to the action, if relevant; | (f) Reference to pending regulatory action, Rapid Alert (quality/ safety) or Quality Defect Report related to the action, if relevant; | |
| Annex IV, 2 paragraph, point (g) | | | | |
| 1713 | (g) Other competent authorities notified; | (g) Other competent authorities notified; | (g) Other competent authorities notified; | |
| Annex IV, 2 paragraph, point (h) | | | | |
| 1714 | (h) Any actions completed or planned based on a request of the competent authorities of the Member State concerned. | (h) Any actions completed or planned based on a request of the competent authorities of the Member State concerned. | (h) Any actions completed or planned based on a request of the competent authorities of the Member State concerned. | |
| Annex IV, 3 paragraph | | | | |
| 1715 | (3) Contact details | (3) Contact details | (3) Contact details | |

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| Annex IV, 3 paragraph, point (a) | | | | |
| 1716 | (a) Marketing authorisation holder name and address; | (a) Marketing authorisation holder name and address; | (a) Marketing authorisation holder name and address; | |
| Annex IV, 3 paragraph, point (b) | | | | |
| 1717 | (b) Name and contact details of person notifying. | (b) Name and contact details of person notifying. | (b) Name and contact details of person notifying. | |
| Annex IV, Part II | | | | |
| 1718 | Part II Part II | Part II Part II | Part II Part II | |
| Annex IV, 4 paragraph | | | | |
| 1719 | Risk assessment of impact of suspension, cessation or withdrawal | Risk assessment of impact of suspension, cessation or withdrawal | Risk assessment of impact of suspension, cessation or withdrawal | |
| Annex IV, 5 paragraph | | | | |

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| 1720 | 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: | 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: | 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: | |
| Annex IV, 6 paragraph | | | | |
| 1721 | (1) Risk assessment of impact of suspension, cessation or withdrawal, including: | (1) Risk assessment of impact of suspension, cessation or withdrawal, including: | (1) Risk assessment of impact of suspension, cessation or withdrawal, including: | |
| Annex IV, 6 paragraph, point (a) | | | | |
| 1722 | (a) Potential alternative medicinal products; | (a) Potential alternative medicinal products; | (a) Potential alternative medicinal products; | |
| Annex IV, 6 paragraph, point (b) | | | | |

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| 1723 | (b) Estimated market share per Member State in previous 12 months; | (b) Estimated market share per Member State in previous 12 months; | (b) Estimated market share per Member State in previous 12 months; | |
| Annex IV, 6 paragraph, point (c) | | | | |
| 1724 | (c) Quantities delivered per month per Member State in previous 12 months; | (c) Quantities delivered per month per Member State in previous 12 months; | (c) Quantities delivered per month per Member State in previous 12 months; | |
| Annex IV, 6 paragraph, point (d) | | | | |
| 1725 | (d) Manufacturing capacity globally per manufacturing site; | (d) Manufacturing capacity globally per manufacturing site; | (d) Manufacturing capacity globally per manufacturing site; | |
| Annex IV, 6 paragraph, point (e) | | | | |
| 1726 | (e) Forecast of supply per month and per Member State until suspension, cessation or withdrawal occurs; | (e) Forecast of supply per month and per Member State until suspension, cessation or withdrawal occurs; | (e) Forecast of supply per month and per Member State until suspension, cessation or withdrawal occurs; | |

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| Annex IV, 6 paragraph, point (f) | | | | |
| 1727 | (f) Forecast of demand per month and per Member State in next 6 months; | (f) Forecast of demand per month and per Member State in next 6 months; | (f) Forecast of demand per month and per Member State in next 6 months; | |
| Annex IV, 6 paragraph, point (g) | | | | |
| 1728 | (g) Impact on the supply of other medicinal products from the same marketing authorisation holder; | (g) Impact on the supply of other medicinal products from the same marketing authorisation holder; | (g) Impact on the supply of other medicinal products from the same marketing authorisation holder; | |
| Annex IV, 6 paragraph, point (h) | | | | |
| 1729 | (h) Potential impact on the consumption of or demand for other medicinal products. | (h) Potential impact on the consumption of or demand for other medicinal products. | (h) Potential impact on the consumption of or demand for other medicinal products. | |
| Annex IV, 2 paragraph | | | | |

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| 1730 | (2) Any risk-mitigating measures taken by the marketing authorisation holder to address the shortage. | (2) Any risk-mitigating measures taken by the marketing authorisation holder to address the shortage. | (2) Any risk-mitigating measures taken by the marketing authorisation holder to address the shortage. | |
| Annex IV, Part III | | | | |
| 1731 | Part III Part III | Part III Part III | Part III Part III | |
| Annex IV, 3 paragraph | | | | |
| 1732 | Information to be provided in case of a temporary disruption of supply (to monitor potential or actual shortage) | Information to be provided in case of a temporary disruption of supply (to monitor potential or actual shortage) | Information to be provided in case of a temporary disruption of supply (to monitor potential or actual shortage) | |
| Annex IV, 4 paragraph | | | | |
| 1733 | For the purpose of the notification in accordance with Article 116(1), point (d) the marketing | For the purpose of the notification in accordance with Article 116(1), point (d) the marketing | For the purpose of the notification in accordance with Article 116(1), point (d) the marketing | |

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| | authorisation holder shall notify the following information: | authorisation holder shall notify the following information: | authorisation holder shall notify the following information: | |
| Annex IV, 5 paragraph | | | | |
| 1734 | (1) Product details | (1) Product details | (1) Product details | |
| Annex IV, 5 paragraph, point (a) | | | | |
| 1735 | (a) Product name; | (a) Product name; | (a) Product name; | |
| Annex IV, 5 paragraph, point (b) | | | | |
| 1736 | (b) Active substance(s) and active substance manufacturer(s); | (b) Active substance(s) and active substance manufacturer(s); | (b) Active substance(s) and active substance manufacturer(s); | |
| Annex IV, 5 paragraph, point (c) | | | | |
| 1737 | (c) Finished product manufacturer; | (c) Finished product manufacturer; | (c) Finished product manufacturer; | |

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| Annex IV, 5 paragraph, point (d) | | | | |
| 1738 | (d) Therapeutic indication(s); | (d) Therapeutic indication(s); | (d) Therapeutic indication(s); | |
| Annex IV, 5 paragraph, point (e) | | | | |
| 1739 | (e) ATC code; | (e) ATC code; | (e) ATC code; | |
| Annex IV, 5 paragraph, point (f) | | | | |
| 1740 | (f) Pharmaceutical form; | (f) Pharmaceutical form; | (f) Pharmaceutical form; | |
| Annex IV, 5 paragraph, point (g) | | | | |
| 1741 | (g) Strength(s); | (g) Strength(s); | (g) Strength(s); | |
| Annex IV, 5 paragraph, point (h) | | | | |
| 1742 | (h) Route(s) of administration; | (h) Route(s) of administration; | (h) Route(s) of administration; | |

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| Annex IV, 5 paragraph, point (i) | | | | |
| 1743 | (i) Affected pack size; | (i) Affected pack size; | (i) Affected pack size; | |
| Annex IV, 5 paragraph, point (j) | | | | |
| 1744 | (j) Alternative, pharmaceutical form, strength, route of administration or pack size, not affected by the supply disruption; | (j) Alternative, pharmaceutical form, strength, route of administration or pack size, not affected by the supply disruption; | (j) Alternative, pharmaceutical form, strength, route of administration or pack size, not affected by the supply disruption; | |
| Annex IV, 5 paragraph, point (k) | | | | |
| 1745 | (k) Details of authorisation: procedure type (national (including Member State(s) involved)/ centralised marketing authorisation) and reference; | (k) Details of authorisation: procedure type (national (including Member State(s) involved)/ centralised marketing authorisation) and reference; | (k) Details of authorisation: procedure type (national (including Member State(s) involved)/ centralised marketing authorisation) and reference; | |
| Annex IV, 5 paragraph, point (l) | | | | |

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| 1746 | (l) Member States in which the product is placed on the market. | (l) Member States in which the product is placed on the market. | (l) Member States in which the product is placed on the market. | |
| Annex IV, 2 paragraph | | | | |
| 1747 | (2) Details of supply disruption | (2) Details of supply disruption | (2) Details of supply disruption | |
| Annex IV, 2 paragraph, point (a) | | | | |
| 1748 | (a) Shortage status (actual, potential); | (a) Shortage status (actual, potential); | (a) Shortage status (actual, potential); | |
| Annex IV, 2 paragraph, point (b) | | | | |
| 1749 | (b) Available stock per month | (b) Available stock per month | (b) Available stock per month | |
| Annex IV, 2 paragraph, point (c) | | | | |

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| 1750 | (c) Expected start date of shortage by Member State; | (c) Expected start date of shortage by Member State; | (c) Expected start date of shortage by Member State; | |
| Annex IV, 2 paragraph, point (d) | | | | |
| 1751 | (d) Expected end date of shortage by Member State; | (d) Expected end date of shortage by Member State; | (d) Expected end date of shortage by Member State; | |
| Annex IV, 2 paragraph, point (e) | | | | |
| 1752 | (e) Reason for shortage; | (e) Reason for shortage~~;~~ ***providing, where applicable, information on:*** | (e) Reason for shortage; | |
| Annex IV, 2 paragraph, point (e)(i) | | | | |
| 1752a | | ***(i) raw material disruption;*** | | |
| Annex IV, 2 paragraph, point (e)(ii) | | | | |
| 1752b | | ***(ii) API disruption;*** | | |

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| Annex IV, 2 paragraph, point (e)(iii) | | | | |
| 1752c | | ***(iii) excipient disruption;*** | | |
| Annex IV, 2 paragraph, point (e)(iv) | | | | |
| 1752d | | ***(iv) production problems;*** | | |
| Annex IV, 2 paragraph, point (e)(v) | | | | |
| 1752e | | ***(v) quality problems;*** | | |
| Annex IV, 2 paragraph, point (e)(vi) | | | | |
| 1752f | | ***(vi) production capacity;*** | | |
| Annex IV, 2 paragraph, point (e)(vii) | | | | |
| 1752g | | ***(vii) logistics problems;*** | | |
| Annex IV, 2 paragraph, point (e)(viii) | | | | |

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| 1752h | | ***(viii) distribution problems;*** | | |
| Annex IV, 2 paragraph, point (e)(ix) | | | | |
| 1752i | | ***(ix) inventory and storage practices;*** | | |
| Annex IV, 2 paragraph, point (e)(x) | | | | |
| 1752j | | ***(x) increase in demand;*** | | |
| Annex IV, 2 paragraph, point (e)(xi) | | | | |
| 1752k | | ***(xi) commercial reasons; and*** | | |
| Annex IV, 2 paragraph, point (e)(xii) | | | | |
| 1752l | | ***(xii) any other reasons;*** | | |
| Annex IV, 2 paragraph, point (f) | | | | |

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| 1753 | (f) Impacted EU/ EEA countries and where available other impacted countries; | (f) Impacted EU/ EEA countries and where available other impacted countries; | (f) Impacted EU/ EEA countries and where available other impacted countries; | |
| Annex IV, 2 paragraph, point (g) | | | | |
| 1754 | (g) Reference to pending regulatory action, Rapid Alert (quality/ safety) or Quality Defect Report related to the action, if relevant; | (g) Reference to pending regulatory action, Rapid Alert (quality/ safety) or Quality Defect Report related to the action, if relevant; | (g) Reference to pending regulatory action, Rapid Alert (quality/ safety) or Quality Defect Report related to the action, if relevant; | |
| Annex IV, 2 paragraph, point (h) | | | | |
| 1755 | (h) Other competent authorities notified; | (h) Other competent authorities notified; | (h) Other competent authorities notified; | |
| Annex IV, 2 paragraph, point (i) | | | | |
| 1756 | (i) Any actions completed or planned based on a request of | (i) Any actions completed or planned based on a request of | (i) Any actions completed or planned based on a request of | |

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| | competent authorities of Member State concerned. | competent authorities of Member State concerned. | competent authorities of Member State concerned. | |
| Annex IV, 3 paragraph | | | | |
| 1757 | (3) Contact details | (3) Contact details | (3) Contact details | |
| Annex IV, 3 paragraph, point (a) | | | | |
| 1758 | (a) Marketing authorisation holder name and address; | (a) Marketing authorisation holder name and address; | (a) Marketing authorisation holder name and address; | |
| Annex IV, 3 paragraph, point (b) | | | | |
| 1759 | (b) Name and contact details of person notifying. | (b) Name and contact details of person notifying. | (b) Name and contact details of person notifying. | |
| Annex IV, Part IV | | | | |
| 1760 | Part IV Part IV | Part IV Part IV | Part IV Part IV | |

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| Annex IV, 4 paragraph | | | | |
| 1761 | The Shortage Mitigation Plan | The Shortage Mitigation Plan | The Shortage Mitigation Plan | |
| Annex IV, 5 paragraph | | | | |
| 1762 | 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: | 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: | 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: | |
| Annex IV, 6 paragraph | | | | |
| 1763 | 1. Shortage mitigation plan, detailing the risk assessment of impact of shortage, including, where available: | 1. Shortage mitigation plan, detailing the risk assessment of impact of shortage, including, where available: | 1. Shortage mitigation plan, detailing the risk assessment of impact of shortage, including, where available: | |
| Annex IV, 6 paragraph, point (a) | | | | |

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| 1764 | (a) Potential alternative medicinal products; | (a) Potential alternative medicinal products; | (a) Potential alternative medicinal products; | |
| Annex IV, 6 paragraph, point (b) | | | | |
| 1765 | (b) Estimated market share by Member State in previous 12 months; | (b) Estimated market share by Member State in previous 12 months; | (b) Estimated market share by Member State in previous 12 months; | |
| Annex IV, 6 paragraph, point (c) | | | | |
| 1766 | (c) Quantities delivered per month per Member State, in previous 12 months; | (c) Quantities delivered per month per Member State, in previous 12 months; | (c) Quantities delivered per month per Member State, in previous 12 months; | |
| Annex IV, 6 paragraph, point (d) | | | | |
| 1767 | (d) Manufacturing capacity globally per manufacturing site; | (d) Manufacturing capacity globally per manufacturing site; | (d) Manufacturing capacity globally per manufacturing site; | |
| Annex IV, 6 paragraph, point (e) | | | | |

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| 1768 | (e) Forecast of supply per month and per Member State for the duration of the shortage, | (e) Forecast of supply per month and per Member State for the duration of the shortage, | (e) Forecast of supply per month and per Member State for the duration of the shortage, | |
| Annex IV, 6 paragraph, point (f) | | | | |
| 1769 | (f) Forecast of demand 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; | (f) Forecast of demand per month and per Member State for the duration of the shortage; | |
| Annex IV, 6 paragraph, point (g) | | | | |
| 1770 | (g) Impact on the supply of other medicinal products from the same marketing authorisation holder; | (g) Impact on the supply of other medicinal products from the same marketing authorisation holder; | (g) Impact on the supply of other medicinal products from the same marketing authorisation holder; | |
| Annex IV, 6 paragraph, point (h) | | | | |

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| 1771 | (h) Potential impact on the consumption of or demand for other medicinal products; | (h) Potential impact on the consumption of or demand for other medicinal products; | (h) Potential impact on the consumption of or demand for other medicinal products; | |
| Annex IV, 6 paragraph, point (i) | | | | |
| 1772 | (i) Any risk-mitigating measures taken or planned by the marketing authorisation holder to address the shortage. | (i) Any risk-mitigating measures taken or planned by the marketing authorisation holder to address the shortage. | (i) Any risk-mitigating measures taken or planned by the marketing authorisation holder to address the shortage. | |
| Annex IV, Part V | | | | |
| 1773 | Part V Part V | Part V Part V | Part V Part V | |
| Annex IV, 2 paragraph | | | | |
| 1774 | The shortage prevention plan | The shortage prevention plan | The shortage prevention plan | |
| Annex IV, 3 paragraph | | | | |

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| 1775 | The Shortage Prevention Plan referred to in Article 117 shall contain the following minimum set of information: | The Shortage Prevention Plan referred to in Article 117 shall contain the following minimum set of information: | The Shortage Prevention Plan referred to in Article 117 shall contain the following minimum set of information: | |
| Annex IV, 4 paragraph | | | | |
| 1776 | (1) Product details: | (1) Product details: | (1) Product details: | |
| Annex IV, 4 paragraph, point (a) | | | | |
| 1777 | (a) Product name; | (a) Product name; | (a) Product name; | |
| Annex IV, 4 paragraph, point (b) | | | | |
| 1778 | (b) Active substance(s) and active substance manufacturer(s); | (b) Active substance(s) and active substance manufacturer(s); | (b) Active substance(s) and active substance manufacturer(s); | |
| Annex IV, 4 paragraph, point (c) | | | | |

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| 1779 | (c) Finished product manufacturer; | (c) Finished product manufacturer; | (c) Finished product manufacturer; | |
| Annex IV, 4 paragraph, point (d) | | | | |
| 1780 | (d) ATC code; | (d) ATC code; | (d) ATC code; | |
| Annex IV, 4 paragraph, point (e) | | | | |
| 1781 | (e) Therapeutic indication(s); | (e) Therapeutic indication(s); | (e) Therapeutic indication(s); | |
| Annex IV, 4 paragraph, point (f) | | | | |
| 1782 | (f) Pharmaceutical form; | (f) Pharmaceutical form; | (f) Pharmaceutical form; | |
| Annex IV, 4 paragraph, point (g) | | | | |
| 1783 | (g) Strength(s); | (g) Strength(s); | (g) Strength(s); | |
| Annex IV, 4 paragraph, point (h) | | | | |

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| 1784 | (h) Route(s) of administration; | (h) Route(s) of administration; | (h) Route(s) of administration; | |
| Annex IV, 4 paragraph, point (i) | | | | |
| 1785 | (i) Pack size(s); | (i) Pack size(s); | (i) ~~Pack size(s);~~ | |
| Annex IV, 4 paragraph, point (j) | | | | |
| 1786 | (j) Details of authorisation: procedure type (national (including Member State(s) involved)/ centralised marketing authorisation) and reference; | (j) Details of authorisation: procedure type (national (including Member State(s) involved)/ centralised marketing authorisation) and reference; | (j) Details of authorisation: procedure type (national (including Member State(s) involved)/ centralised marketing authorisation) and ~~reference~~**marketing authorisation number**; | |
| Annex IV, 4 paragraph, point (k) | | | | |

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| 1787 | (k) Member States in which the product is placed on the market. | (k) Member States in which the product is placed on the market. | (k) Member States in which the product is placed on the market. | |
| Annex IV, 2 paragraph | | | | |
| 1788 | (2) Shortage prevention measures and supply chain risk assessment: | (2) Shortage prevention measures and supply chain risk assessment: | (2) Shortage prevention measures and supply chain risk assessment: | |
| Annex IV, 2 paragraph, point (a) | | | | |
| 1789 | (a) Alternative marketed medicinal products; | (a) Alternative marketed medicinal products; | (a) **Patient impact of potential supply disruptions, considering therapeutic indication and** alternative marketed medicinal products **and estimated market share by Member States in the previous 12 months**; | |

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| Annex IV, 2 paragraph, point (b) | | | | |
| 1790 | (b) Supply chain map, with risk identification and analysis with particular attention to supply chain vulnerabilities; | (b) Supply chain map, with risk identification and analysis with particular attention to supply chain vulnerabilities; | (b) Supply chain ~~map, with risk identification and analysis with particular attention to supply chain vulnerabilities;~~**risk assessment , to include:** | |
| Annex IV, 2 paragraph, point (b)(i) | | | | |
| 1790a | | | **(i) Supply chain map, with particular attention to supply chain vulnerabilities;** | |
| Annex IV, 2 paragraph, point (b)(ii) | | | | |
| 1790b | | | **(ii) A record of root causes of resolved shortages and mitigation measures taken for those shortages;** | |

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| Annex IV, 2 paragraph, point (ba) | | | | |
| 1790c | | | **(ba) Final risk classification (low, medium, high) covering both the risk of shortage and its public health impact, with separate risk classification if necessary.** | |
| Annex IV, 2 paragraph, point (c) | | | | |
| 1791 | (c) Shortage management measures, to include: | (c) Shortage management measures, to include: | ~~(c)~~**(2a)** Shortage management measures, to include: | |
| Annex IV, 2 paragraph, point (c)(i) | | | | |
| 1792 | (i) a risk control strategy in place, to include information on strategies to minimise risks of shortages and how these are implemented; | (i) a risk control strategy in place, to include information on strategies to minimise risks of shortages and how these are implemented; | ~~(i)~~**(a)** a risk control strategy in place, to include information on strategies to minimise risks of shortages and how these are implemented; | |

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| Annex IV, 2 paragraph, point (c)(ii) | | | | |
| 1793 | (ii) a process for the detection and notification of supply disruptions and | (ii) a process for the detection and notification of supply disruptions and | ~~(ii)~~**(b)** a process for the detection and notification of supply disruptions and | |
| Annex IV, 2 paragraph, point (c)(iii) | | | | |
| 1794 | (iii) a record of root causes of resolved shortages and mitigation measures taken for those shortages. | (iii) a record of root causes of resolved shortages and mitigation measures taken for those shortages. | ~~(iii)~~**(c)** a record of root causes of resolved shortages and mitigation measures taken for those shortages. | |
| Annex IV, 2 paragraph, point (d) | | | | |
| 1795 | (d) Process for check of effectiveness, review and update of the shortage prevention plan. | (d) Process for check of effectiveness, review and update of the shortage prevention plan. | ~~(d)~~**(2b)** Process for check of effectiveness, review and update of the shortage prevention plan. | |
| Annex IV, 2 paragraph, point (da) | | | | |

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| 1795a | | ***(da) methodology for establishing the demand forecast;*** | | |
| Annex IV, 3 paragraph | | | | |
| 1796 | (3) Contact details | (3) Contact details | (3) Contact details | |
| Annex IV, 3 paragraph, point (a) | | | | |
| 1797 | (a) Marketing authorisation holder name and address; | (a) Marketing authorisation holder name and address; | (a) Marketing authorisation holder name and address; | |
| Annex IV, 3 paragraph, point (b) | | | | |
| 1798 | (b) Name and details of contact person. | (b) Name and details of contact person. | (b) Name and details of contact person. | |
| Annex IV, Part Va | | | | |
| 1798a | | ***Part Va*** | | |

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| Annex IV, 3 paragraph a | | | | |
| 1798b | | ***For the purposes of reporting in accordance with Article 118(1) and for the early detection of supply shortages, wholesalers shall provide the following information in a timely manner:*** | | |
| Annex IV, point 1. | | | | |
| 1798c | | ***1. Product availability information:*** | | |
| Annex IV, 3 paragraph b | | | | |
| 1798d | | ***Product availabilities shall be reported per warehouse and shall be indexed as yes/no.*** | | |
| Annex IV, point 2. | | | | |

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| 1798e | | ***2. Service level information:*** | | |
| Annex IV, 3 paragraph c | | | | |
| 1798f | | ***Service level information which captures the level of fulfilment of wholesale orders by marketing authorisation holders and suppliers shall be reported. Such information involves comparing the quantity ordered with the quantity actually received at the product level. The resulting difference describes the service level.*** | | |
| Annex V | | | | |
| 1799 | Annex V | Annex V | Annex V | |
| Annex V, first paragraph | | | | |

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| 1800 | CORRELATION TABLE | CORRELATION TABLE | CORRELATION TABLE | |