

ANNEX IX

**REFERRED TO IN PARAGRAPH 3 OF ARTICLE 2.22 (SCOPE) OF
SECTION 2.2 (TECHNICAL BARRIERS TO TRADE) OF
CHAPTER 2 (TRADE IN GOODS)**

ANNEX IX

MEDICINAL PRODUCTS

REFERRED TO IN PARAGRAPH 3 OF ARTICLE 2.22 (SCOPE) OF SECTION 2.2 (TECHNICAL BARRIERS TO TRADE) OF CHAPTER 2 (TRADE IN GOODS)

ARTICLE 1

Definitions

1. For the purposes of this Annex:
 - (a) “authority” means an authority of a Party as listed in Appendix 1;
 - (b) “Good Manufacturing Practice” or “GMP” means that part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use and as required by the applicable marketing authorisation or product specifications, as listed in Appendix 2;
 - (c) “inspection” means an evaluation of a manufacturing facility to determine whether such manufacturing facility is operating in compliance with Good Manufacturing Practice and/or commitments made as part of the approval to market a product, which is conducted in accordance with the laws, regulations and administrative provisions of the relevant Party, and includes pre-marketing and post-marketing inspection; and
 - (d) “official GMP document” means a document issued by an authority of a Party following the inspection of a manufacturing facility, including, for example, inspection reports, certificates attesting the compliance of a manufacturing facility with GMP, or a GMP non-compliance statement.

ARTICLE 2

Scope

The provisions of this Annex apply to medicinal products as listed in Appendix 3.

ARTICLE 3

Objectives

1. With regard to the products covered by this Annex as outlined in Article 2, the objectives of this Annex are:
 - (a) to facilitate the availability of medicines within each Party;
 - (b) to set out the conditions for the recognition of inspections and for the exchange and acceptance of official GMP documents between the Parties; and
 - (c) to promote public health by safeguarding patient safety and animal health and welfare, as well as to protect high levels of consumer and environmental protection, where relevant, by promoting regulatory approaches in line with the relevant international standards.

ARTICLE 4

International Standards

The relevant standards for the products covered by this Annex shall ensure a high level of protection of public health in line with standards, practices and guidelines developed by the World Health Organization (WHO), the Organization for Economic Cooperation and Development (OECD), the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), and the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

ARTICLE 5

Recognition of Inspections and Acceptance of Official GMP Documents

1. A Party shall recognise inspections carried out by another Party and shall accept official GMP documents issued by another Party in accordance with the laws, regulations and technical guidelines listed in Appendix 2.
2. An authority of a Party may in specific circumstances opt not to accept an official GMP document issued by an authority of another Party for manufacturing facilities located within the issuing authority's Party. Examples of such circumstances include the indication of material inconsistencies or inadequacies in an inspection report, quality defects identified in post-market surveillance or other specific evidence of serious concern in relation to product quality or patient safety. Each Party shall ensure that where an authority of a Party opts not to accept an official GMP document issued by an authority of another Party, that authority notifies the

relevant authority of the Party concerned of the reasons for not accepting the document and may request clarification from the authority of the Party concerned. The relevant Party shall ensure that its authority endeavours to respond to the request for clarification in a timely manner.

3. A Party may accept official GMP documents issued by an authority of another Party for manufacturing facilities located outside the issuing authority's Party.
4. Each Party may determine the terms and conditions under which it accepts official GMP documents issued under paragraph 3.

ARTICLE 6

Exchange of Official GMP Documents

1. Each Party shall ensure that if an authority of a Party requests an official GMP document from the authority of another Party, the authority of the Party concerned shall endeavour to transmit the document within 30 calendar days of the date of the request.
2. Each Party shall treat the information in a document obtained pursuant to paragraph 1 as confidential. This shall not prevent disclosure of such information which may be required under national law.

ARTICLE 7

Safeguards

1. Each Party has the right to conduct its own inspection of manufacturing facilities that have been certified as compliant by another Party.
2. Each Party shall ensure that, prior to conducting an inspection under paragraph 1, the authority of the Party that intends to conduct the inspection notifies the relevant authority of the Party concerned of the inspection in writing, stating the reasons for conducting its own inspection. The authority of the Party that intends to conduct the inspection shall endeavour to notify the authority of the Party concerned in writing at least 30 days before a proposed inspection, but may provide a shorter notice in urgent situations. The authority of the Party concerned may join the inspection.

ARTICLE 8

Changes to Applicable Laws and Regulations

1. Each Party shall notify the other Parties at least 60 days before adopting any new measures or changes relating to Good Manufacturing Practice concerning any of the relevant laws, regulations and technical guidelines listed in Appendix 2.
2. The Parties shall exchange all the necessary information, including changes to their respective laws, regulations, technical guidelines or inspection procedures relating to Good Manufacturing Practice so that each Party can consider whether the conditions for the recognition of inspections and acceptance of official GMP documents pursuant to paragraph 1 of Article 5 (Recognition of Inspections and Acceptance of Official GMP Documents) continue to exist.
3. If as a result of any of the new measures or changes referred to in paragraph 1, a Party considers that it can no longer recognise inspections or accept official GMP documents issued by another Party, it shall notify the Party concerned of its intention to apply Article 9 (Suspension) and the Parties shall enter into consultations via the Sub-Committee on Technical Barriers to Trade.
4. Any notification under this Article shall be done via the designated contact.

ARTICLE 9

Suspension

1. Without prejudice to paragraph 2 of Article 5 (Recognition of Inspections and Acceptance of Official GMP Documents), each Party has the right to suspend totally or partially the recognition of inspections and acceptance of official GMP documents of another Party pursuant to paragraph 1 of Article 5 for all or some of the products listed in Appendix 3. That right shall be exercised in an objective and reasoned manner. The Party exercising such right shall notify the Party concerned and provide a written justification. A Party shall continue to accept official GMP documents of the Party concerned issued prior to such suspension, unless the Party decides otherwise on the basis of health or safety considerations.
2. Where, following consultations referred to in paragraph 3 of Article 8 (Changes to Applicable Laws and Regulations), a Party nevertheless suspends the recognition of inspections and acceptance of official GMP documents pursuant to paragraph 1 of Article 5 (Recognition of Inspections and Acceptance of Official GMP Documents), it may do so in accordance with paragraph 1 not earlier than 60 days after the commencement of the consultations. During that 60-day period, the Parties shall continue to

recognise inspections and accept official GMP documents issued by an authority of the Party concerned.

3. Where recognition of inspections and acceptance of official GMP documents pursuant to paragraph 1 of Article 5 (Recognition of Inspections and Acceptance of Official GMP Documents) is suspended, at the request of a Party, the Parties shall discuss the matter via the Sub-Committee on Technical Barriers to Trade and they shall make every effort to consider possible measures that would enable the recognition of inspections and acceptance of official GMP documents to be restored.

ARTICLE 10

Regulatory Co-operation

1. The Parties shall endeavour to consult one another, as permitted by their respective law, on proposals to introduce significant changes to technical regulations or inspection procedures, including those that affect how documents from another Party are recognised in accordance with Article 5 (Recognition of Inspections and Acceptance of Official GMP Documents) and, where appropriate, to provide the opportunity to comment on such proposals, without prejudice to Article 8 (Changes to Applicable Laws and Regulations).
2. The Parties shall endeavour to co-operate with a view to strengthening, developing and promoting the adoption and implementation of internationally agreed scientific or technical guidelines including, where feasible, through the presentation of joint initiatives, proposals and approaches in the relevant international organisations and bodies referred to in Article 4 (International Standards).

ARTICLE 11

Amendments to Appendices

The Joint Committee shall have the power to amend Appendix 1 in order to update the list of authorities, Appendix 2 in order to update list of applicable laws and regulations and technical guidelines, and Appendix 3 in order to update the list of covered products.

ARTICLE 12

Non-Application of Dispute Settlement

Chapter 16 (Dispute Settlement) of this Agreement does not apply in respect of disputes regarding the interpretation and application of this Annex.

APPENDIX 1

AUTHORITIES OF THE PARTIES

ICELAND AND NORWAY

Country	For medicinal products for human use	For medicinal products for veterinary use
Norway	The Norwegian Medicines Agency. Statens legemiddelverk.	The Norwegian Medicines Agency. Statens legemiddelverk.
Iceland	The Icelandic Medicines Agency. Lyfjastofnun.	The Icelandic Medicines Agency. Lyfjastofnun.

UNITED KINGDOM

Medicines and Healthcare Products Regulatory Agency Veterinary.

Medicines Directorate.

APPENDIX 2

LIST OF APPLICABLE LAWS, REGULATIONS AND TECHNICAL GUIDELINES RELATING TO GOOD MANUFACTURING PRACTICE

FOR ICELAND AND NORWAY:

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use;¹

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products;²

Directive 2001/20/EC of European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use;³

Regulation (EU) 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC;⁴

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;⁵

Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004;⁶

¹ OJ L 311, 28.11.2001, p. 67.
² OJ L 311, 28.11.2001, p. 1.
³ OJ L 121, 1.5.2001, p. 34.
⁴ OJ L 158, 27.5.2014, p. 1.
⁵ OJ L 136, 30.4.2004, p. 1
⁶ OJ L 324, 10.12.2007, p. 121.

Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use;⁷

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products;⁸

Commission Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use;⁹

Commission Delegated Regulation (EU) 1252/2014 of 28 May 2014 of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use;¹⁰

Commission Delegated Regulation (EU) 2017/1569 of 23 May 2017 supplementing Regulation (EU) No 536/2014 of the European Parliament and of the Council by specifying principles of and guidelines for good manufacturing practice for investigational medicinal products for human use and arrangements for inspections;¹¹

Current version of the Guide to good manufacturing practice contained in volume IV of Rules governing medicinal products in the European Union and compilation of the community procedures on inspections and exchange of information; and

For Norway, all legal acts are implemented into Act of 4 December 1992 nr. 192 on Medicinal Products and Regulation 2 November 2004 nr. 1441

⁷ OJ L 262, 14.10.2003, p. 22.

⁸ OJ L 228, 17.8.1991, p. 70.

⁹ OJ L 238, 16.9.2017, p. 44.

¹⁰ OJ L 337, 25.11.2014, p. 1.

¹¹ OJ L 238, 16.9.2017, p. 12.

on Manufacturing and Import of Medicinal Products.

FOR THE UNITED KINGDOM:

The Human Medicines Regulations 2012 (SI 2012/1916);

The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI2004/1031);

The Veterinary Medicines Regulations 2013 (SI 2013/2033);

Regulations on good manufacturing practice made under regulation B17, and guidelines on good manufacturing practice published pursuant to regulation C17, of the Human Medicines Regulations 2012; and

The principles and guidelines on good manufacturing practice applicable for the purposes of Schedule 2 to the Veterinary Medicines Regulations 2013.

APPENDIX 3

COVERED PRODUCTS

MEDICINAL PRODUCTS FOR HUMAN USE AND VETERINARY USE:

- marketed medicinal products for human or veterinary use, including marketed biological and immunological products for human and veterinary use;
 - advanced therapy medicinal products;
 - active pharmaceutical ingredients for human or veterinary use; and
 - investigational medicinal products.
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