

ANNEX TBT-2: MEDICINAL PRODUCTS

Article 1: Definitions

1. For the purposes of this Annex:

- (a) “authority” means an authority of a Party as listed in Appendix A;
- (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 B;
- (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;
- (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 C.

Article 3: Objectives

With regard to the products covered the objectives of this Annex are:

- (a) to facilitate the availability of medicines in each Party’s territory;
- (b) to set out the conditions for the recognition of inspections and for the exchange and acceptance of official GMP documents between the Parties;
- (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 the other Party and shall accept official GMP documents issued by the other Party in accordance with the laws, regulations and technical guidelines listed in Appendix B.
2. An authority of a Party may in specific circumstances opt not to accept an official GMP document issued by an authority of the other Party for manufacturing facilities located in the territory of the issuing authority. 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 the other Party, that authority notifies the relevant authority of the other Party of the reasons for not accepting the document and may request clarification from the authority of the other Party. 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 the other Party for manufacturing facilities located outside the territory of the issuing authority.
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 the other Party, the authority of the other Party 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.

Article 7: Safeguards

1. Each Party has the right to conduct its own inspection of manufacturing facilities that have been certified as compliant by the other 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 other Party 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 other Party in writing at least 30 days before a proposed inspection, but may provide a shorter notice in urgent situations. The authority of the other Party may join the inspection.

Article 8 – Changes to applicable laws and regulations

1. Each Party shall notify the other Party 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 B.

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 Article 5(1) continue to exist.

3. If as a result of any of the new measures or changes referred to in paragraph 1 of this Article, a Party considers that it can no longer recognise inspections or accept official GMP documents issued by the other Party, it shall notify the other Party of its intention to apply Article 9 and the Parties shall enter into consultations within the Working Group on Medicinal Products.

4. Any notification under this Article shall be done via the designated contact points in the Working Group on Medicinal Products.

Article 9: Suspension

1. Without prejudice to Article 5(2), each Party has the right to suspend totally or partially the recognition of inspections and acceptance of official GMP documents of the other Party pursuant to Article 5(1) for all or some of the products listed in Appendix C. That right shall be exercised in an objective and reasoned manner. The Party exercising such right shall notify the other Party and provide a written justification. A Party shall continue to accept official GMP documents of the other Party 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 Article 8(3), a Party nevertheless suspends the recognition of inspections and acceptance of official GMP documents pursuant to Article 5(1), it may do so in accordance with paragraph 1 of this Article not earlier than 60 days after the commencement of the consultations. During that 60-day period, both Parties shall continue to recognise inspections and accept official GMP documents issued by an authority of the other Party.

3. Where recognition of inspections and acceptance of official GMP documents pursuant to Article 5(1) is suspended, at the request of a Party, the Parties shall discuss the matter within the Working Group on Medicinal Products 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 cooperation

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 the other Party are recognised in accordance with Article 5 and, where appropriate, to provide the opportunity to comment on such proposals, without prejudice to Article 8.

2. The Parties shall endeavour to cooperate 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.

Article 11: Amendments to appendices

The Partnership Council shall have the power to amend Appendix A in order to update the list of authorities, Appendix B in order to update list of applicable laws and regulations and technical guidelines, and Appendix C in order to update the list of covered products.

Article 12: Working Group on Medicinal Products

1. The Working Group on Medicinal Products shall assist the Trade Specialised Committee on Technical Barriers to Trade in monitoring and reviewing the implementation and ensuring the proper functioning of this Annex.

2. The functions of this Working Group shall be the following:

- (a) discussing any matter arising under this Annex at the request of a Party;
- (b) facilitating cooperation and exchanges of information for the purposes of Articles 8 and 10;
- (c) functioning as the forum for consultations and discussions for the purposes of Articles 8 (3) and 9(3)
- (d) carrying out technical discussions in accordance with Article TBT.10 [Technical discussions] of this Agreement on matters falling within the scope of this Annex; and
- (e) maintaining a list of contact points responsible for matters arising under this Annex.

Article 13 : Non-application of dispute settlement

Title I [Dispute settlement] of Part Six of this Agreement does not apply in respect of disputes regarding the interpretation and application of this Annex.

APPENDIX A – AUTHORITIES of the Parties

1) European Union:

Country	For medicinal products for human use	For medicinal products for veterinary use
Belgium	Federal agency for medicines and health products / Federaal Agentschap voor geneesmiddelen en gezondheidsproducten/ Agence fédérale des médicaments et produits de santé	See authority for medicinal products for human use
Bulgaria	Bulgarian Drug Agency / ИЗПЪЛНИТЕЛНА АГЕНЦИЯ ПО ЛЕКАРСТВАТА	Bulgarian Food Safety Agency/ Българска агенция по безопасност на храните
Czechia	State Institute for Drug Control/ Státní ústav pro kontrolu léčiv (SÚKL)	Institute for State Control of Veterinary Biologicals and Medicaments / Ústav pro státní kontrolu veterinárních biopreparátů a léčiv (ÚSKVBL)
Denmark	Danish Medicines Agency/ Laegemiddelstyrelsen	See authority for medicinal products for human use

Germany	Federal Institute for Drugs and Medical Devices / Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) Paul-Ehrlich-Institute (PEI), Federal Institute for Vaccines and Biomedicines / Paul-Ehrlich-Institut (PEI) Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel Federal Ministry of Health / Bundesministerium für Gesundheit (BMG)/ Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG) ⁹⁷	Federal Office for Consumer Protection and Food Safety / Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) Federal Ministry of Food and Agriculture, Bundesministerium für Ernährung und Landwirtschaft
Estonia	State Agency of Medicines / Ravimiamet	See authority for medicinal products for human use
Ireland	Health Products Regulatory Authority (HPRA)	See authority for medicinal products for human use
Greece	National Organisation for Medicines / Ethnikos Organismos Farmakon (EOF) - (ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΦΑΡΜΑΚΩΝ))	See authority for medicinal products for human use
Spain	Spanish Agency of Medicines and Medical Devices / Agencia Española de Medicamentos y Productos Sanitarios ⁹⁸	See authority for medicinal products for human use

⁹⁷ For the purpose of this Annex, and without prejudice to the internal division of competence in Germany on matters falling within the scope of this Annex, ZLG shall be understood as covering all the competent Länder authorities issuing GMP documents and conducting pharmaceutical inspections.

⁹⁸ For the purpose of this Annex, and without prejudice to the internal division of competence in Spain on matters falling within the scope of this Annex, Agencia Española de Medicamentos y Productos Sanitarios shall be understood as covering all the competent regional authorities issuing official GMP documents and conducting pharmaceutical inspections.

France	French National Agency for Medicines and Health Products Safety Agence nationale de sécurité du médicament et des produits de santé (ANSM)	French agency for food, environmental and occupational health safety- <i>National Agency for Veterinary Medicinal Products/</i> Agence Nationale de Sécurité Sanitaire de l'alimentation, de l'environnement et du travail- Agence Nationale du Médicament Vétérinaire (Anses-ANMV)
Croatia	Agency for Medicinal Products and Medical Devices / Agencija za lijekove i medicinske proizvode (HALMED)	Ministry of Agriculture, Veterinary and Food Safety Directorate / Ministarstvo Poljoprivrede, Uprava za veterinarstvo i sigurnost hrane
Italy	<i>Italian Medicines Agency /</i> Agenzia Italiana del Farmaco	<i>Direction General for Animal Health and Veterinary Medicinal Products</i> Ministero della Salute, Direzione Generale della Sanità Animale e dei Farmaci Veterinari
Cyprus	Ministry of Health - Pharmaceutical Services / Φαρμακευτικές Υπηρεσίες, Υπουργείο Υγείας	Ministry of Agriculture, Rural Development and Environment- Veterinary Services / Κτηνιατρικές Υπηρεσίες- Υπουργείο Γεωργίας, Αγροτικής Ανάπτυξης και Περιβάλλοντος
Latvia	State Agency of Medicines / Zāļu valsts aģentūra	Assessment and Registration Department of the Food and Veterinary Service/Pārtikas un veterinārā dienesta Novērtēšanas un reģistrācijas departaments
Lithuania	State Medicines Control Agency / Valstybinė vaistų kontrolės tarnyba	State Food and Veterinary Service / Valstybinės maisto ir veterinarijos tarnyba
Luxembourg	Ministère de la Santé, Division de la	See authority for medicinal products

Pharmacie et Médicaments	des	for human use
Hungary	Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet / National Institute of Pharmacy and Nutrition	National Food Chain Safety Office, Directorate of Veterinary Medicinal Products / Nemzeti Élelmiszerlánc- biztonsági Hivatal, Állatgyógyászati Termékek Igazgatósága (ÁTI)
Malta	Medicines Regulatory Authority	Veterinary Medicines Section of the National Veterinary Laboratory (NVL) within The Animal Health and Welfare Department (AHWD)
Netherlands	Healthcare and Youth Inspectorate / Inspectie Gezondheidszorg en Youth (IGJ)	Medicines Evaluation Board / Bureau Diergeneesmiddelen, College ter Beoordeling van Geneesmiddelen (CBG)
Austria	Austrian Agency for Health and Food Safety / Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH	See authority for medicinal products for human use
Poland	The Main Pharmaceutical Inspectorate / Główny Inspektorat Farmaceutyczny (GIF) /	See authority medicinal products for human use
Portugal	National Authority of Medicines and Health Products / INFARMED, I.P Autoridade Nacional do Medicamento e Produtos de Saúde, I.P	General Directorate of Food and Veterinary / DGAV - Direção Geral de Alimentação e Veterinária (PT)
Romania	National Agency for Medicines and Medical Devices /	National Sanitary Veterinary and Food Safety Authority / Autoritatea Națională Sanitară Veterinară și

Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia / Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP)	See authority for medicinal products for human use
Slovakia	State Institute for Drug Control / Štátny ústav pre kontrolu liečiv (ŠÚKL)	Institute for State Control of Veterinary Biologicals and Medicaments / Ústav štátnej kontroly veterinárnych biopreparátov a liečiv (USKVBL)
Finland	Finnish Medicines Agency /	See authority for medicinal products for human use
Sweden	Lääkealan turvallisuus- ja kehittämiskeskus (FIMEA) Medical Products Agency / Läkemedelsverket	See authority for medicinal products for human use

2) United Kingdom

Medicines and Healthcare Products Regulatory Agency

Veterinary Medicines Directorate

APPENDIX B – List of applicable laws, regulations and technical guidelines relating to Good Manufacturing Practice

(1) For the European Union:

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;⁹⁹

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;¹⁰⁰

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;¹⁰¹

Regulation (EU) 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC;¹⁰²

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;¹⁰³

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;¹⁰⁴

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;¹⁰⁵

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products;¹⁰⁶

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;¹⁰⁷

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;¹⁰⁸

⁹⁹ OJ L 311, 28.11.2001, p. 67.

¹⁰⁰ OJ L 311, 28.11.2001, p. 1.

¹⁰¹ OJ L 121, 1.5.2001, p. 34.

¹⁰² OJ L 158, 27.5.2014, p. 1.

¹⁰³ OJ L 136, 30.4.2004, p. 1.

¹⁰⁴ OJ L 324, 10.12.2007, p. 121.

¹⁰⁵ OJ L 262, 14.10.2003, p. 22.

¹⁰⁶ OJ L 228, 17.8.1991, p. 70.

¹⁰⁷ OJ L 238, 16.9.2017, p. 44.

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;¹⁰⁹

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.

(2) For the United Kingdom:

The Human Medicines Regulations 2012 (SI 2012/1916)

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

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

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

¹⁰⁸ OJ L 337, 25.11.2014, p. 1.

¹⁰⁹ OJ L 238, 16.9.2017, p. 12.

APPENDIX C – 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,
- investigational medicinal products.