ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

Decision No 2536/2023 of the Joint Sectoral Committee established under Article 14 of the United States – European Union amended Sectoral Annex for pharmaceutical good manufacturing practices (GMPs) (the 'Annex') on including veterinary products within the product coverage of the Annex

of 11 May 2023 [2023/1044]

THE JOINT SECTORAL COMMITTEE,

Whereas Article 20 of the Annex requires the Joint Sectoral Committee to consider whether to include veterinary products within the product coverage of the Annex,

Whereas the Joint Sectoral Committee has duly considered to include veterinary products, as defined in Appendix 3, paragraph 6, within the product coverage of the Annex,

Taking into account that Article 4(2) of the Annex expressly excludes veterinary immunologicals from the product coverage of the Annex,

Recognizing that any decision to include veterinary products within the product coverage of the Annex can be implemented only after successful mutual assessments of each Party's authorities in accordance with Article 5 and Appendix 4 of the Annex,

Recognizing that to this end the Parties have agreed that each Party will complete the assessment of the other party regulatory authorities as set out in Attachment A to this Decision,

Recognizing that the Food and Drug Administration ('FDA') has completed the assessment of 14 authorities of the Member States of the European Union ('EU') competent for veterinary products (of which five are competent for veterinary products only, and considering that at least one capability assessment of those five authorities of the EU Member States, is favorable) in accordance with paragraph II.A of Appendix 4,

Recognizing that the EU has completed the assessment of the FDA in accordance with paragraph II.B of Appendix 4,

Recognizing that the FDA addressed the outstanding observations resulting from the audit in accordance with paragraph II. B (i) of Appendix 4,

Recognizing that FDA has already satisfied paragraph II.B (ii) of Appendix 4 as part of the EU's assessment of the FDA for human pharmaceuticals.

Confirming that Article 9 of the Annex does not apply to veterinary products, *mutatis mutandis,* until the date on which all authorities of the Member States of the EU competent for veterinary products listed in Appendix 2 have been recognized by the FDA,

Considering that the List of Authorities in Appendix 2 of the Annex need to be updated,

HAS DECIDED AS FOLLOWS:

1. Veterinary products, as defined in Appendix 3, paragraph 6, are included within the product coverage of the Annex.

   FDA shall complete the capability assessment of the authorities of all the Member States of the EU according to Attachment A to this Decision,

   FDA has addressed the outstanding observations resulting from the audit in accordance with paragraph II.B (i) of Appendix 4.

Article 9 of the Annex will apply to veterinary products on the date on which all EU Member State authorities competent for veterinary products listed in Appendix 2, have been recognized by the FDA.

2. The text of Appendix 2 of the Annex is replaced with the text of the Appendix 2 in Attachment B to this Decision.

Attachment A: Schedule for Assessment of Member State Authorities for Veterinary Products

Attachment B: Appendix 2 List of Authorities

This Decision, done in duplicate, shall be signed by the co-chairs of the Joint Sectoral Committee as referred to in Article 14(2) of the Annex. This Decision shall be effective from the date of the later of these signatures.

On behalf of the United States of America	*On behalf of the European Union*
Mark ABDOO	Sylvain GIRAUD
Signed in Silver Spring, MD, on 5 May 2023	Signed in Brussels, on 11 May 2023

ATTACHMENT A

Schedule for Assessment of Member State Authorities for Veterinary Products

1. Member States authorities for veterinary products listed in Appendix 2 of the Annex shall submit complete capability assessment packages containing the information specified in Appendix 4 of the Annex according to the following schedule:
   - No later than 1 December 2022: capability assessment packages from nineteen Member States authorities;
   - No later than 1 June 2023: capability assessment packages from four additional Member States authorities;
   - No later than 1 December 2023: capability assessment packages from four additional Member State authorities;
   - No later than 1 February 2024: any remaining capability assessment packages (due to FDA's determination that a full capability assessment is needed for a dual human and veterinary competence authority of a Member State)

2. The FDA shall complete the capability assessments of Member States authorities for veterinary products listed in Appendix 2 of the Annex and as set out in Appendix 4 of the Annex, according to the following schedule, provided that the FDA receives complete capability assessment packages for such authorities containing the information specified in Appendix 4 of the Annex according to the schedule set out in paragraph 1:
   - 31 December 2022: seventeen capability assessments
   - 31 December 2023: five additional capability assessments
   - 31 July 2024: five additional capability assessments

3. For each Member State authority:
   (a) The EU shall submit a final audit report to the FDA no later than 60 days before the due date of the capability assessment package for the Member State authority.
   (b) The FDA shall provide a finalized capability assessment package checklist to the Member State authority no later than 20 days after the FDA receives the audit report.
   (c) The Member State authority shall submit the capability assessment package to FDA no later than 40 days after that Member State authority receives the capability assessment package checklist.

4. The deadline for delivering capability assessment packages will be automatically extended by 3 months, if these cannot be completed in time due to repercussions of measures related to the COVID-19 pandemic or similar disruptive event, such as travel restrictions, quarantine measures, sick leaves and resource shortages arising thereof. The EU shall inform the FDA in a timely manner of relevant delays and shall propose an updated timeline for agreement in the Joint Sectoral Committee.

5. The communication of the recognition of Member States authorities assessed shall be done promptly following the conclusion of the capability assessment (on a rolling basis) and in line with Article 7 of the Annex.

ATTACHMENT B

Appendix 2 List of Authorities

United States:

The Food and Drug Administration

European Union:

Country	For medicinal products for human use	For veterinary medicinal products
Austria	Austrian Agency for Health and Food Safety / *Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH*	See responsible authority for medicinal products for human use
Belgium	Federal Agency for Medicines and Health Products – FAMHP / *Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten – FAGG / Agence fédérale des médicaments et des produits de santé – AFMPS*	See responsible 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*
Croatia	Agency for Medicinal Products and Medical Devices / *Agencija za lijekove i medicinske proizvode (HALMED)*	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*
Cyprus	Ministry of Health – Pharmaceutical Services / *Φαρμακευτικές Υπηρεσίες, Υπουργείο Υγείας*	Ministry of Agriculture, Rural Development and Environment – Veterinary Services / *Υπουργείο Γεωργίας, Αγροτικής Ανάπτυξης και Περιβάλλοντος – Κτηνιατρικές Υπηρεσίες*
Czechia	State Institute for Drug Control / *Státní ústav pro kontrolu léčiv (SÚKL)*	Institute for State Control of Veterinary Biologicals and Medicines / *Ústav pro státní kontrolu veterinárních biopreparátů a léčiv (ÚSKVBL)*
Denmark	Danish Medicines Agency / *Lægemiddelstyrelsen*	See responsible authority for medicinal products for human use
Estonia	State Agency of Medicines / *Ravimiamet*	See responsible authority for medicinal products for human use
Finland	Finnish Medicines Agency / *Lääkealan turvallisuus- ja kehittämiskeskus (FIMEA)*	See responsible authority for medicinal products for human use
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 – French Agency for Veterinary Medicinal Products / *Agence Nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail – Agence Nationale du Médicament Vétérinaire (Anses-ANMV)*

Country	For medicinal products for human use	For veterinary medicinal products
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)* Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices / *Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG* ([1])	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*
Greece	National Organisation for Medicines / *Ethnikos Organismos Farmakon (EOF) – (Εθνικός Οργανισμός Φαρμάκων))*	See responsible authority for medicinal products for human use
Hungary	National Institute of Pharmacy and Nutrition / *Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet*	National Food Chain Safety Office, Directorate of Veterinary Medicinal Products / *Nemzeti Élelmiszerlánc-biztonsági Hivatal, Állatgyógyászati Termékek Igazgatósága (ÁTI)*
Ireland	Health Products Regulatory Authority (HPRA)	See responsible authority for medicinal products for human use
Italy	Italian Medicines Agency / *Agenzia Italiana del Farmaco*	Ministry of Health, Direction General for Animal Health and Veterinary Medicinal Products / *Ministero della Salute, Direzione Generale della Sanità Animale e dei Farmaci Veterinari*
Latvia	State Agency of Medicines / *Zāļu valsts aģentūra*	Food and Veterinary Service / *Pārtikas un veterinārais dienests*
Lithuania	State Medicines Control Agency / *Valstybinė vaistų kontrolės tarnyba*	State Food and Veterinary Service / *Valstybinė maisto ir veterinarijos tarnyba*
Luxembourg	Ministry of Health, Division of Pharmacy and Medicines / *Ministère de la Santé, Division de la Pharmacie et des Médicaments*	See responsible authority for medicinal products for human use
Malta	Malta Medicines Authority (MMA)	The Animal Health and Welfare Department (AHWD)
Netherlands	Healthcare and Youth Care Inspectorate, Ministry of Health, Welfare and Sport / *Inspectie Gezondheidszorg en Jeugd (IGJ), Ministerie van Volksgezondheid, Welzijn en Sport*	Medicines Evaluation Board (MEB) / *College ter Beoordeling van Geneesmiddelen (CBG)* Veterinary Medicinal Products Unit / *Bureau Diergeneesmiddelen*
Poland	Chief Pharmaceutical Inspectorate / *Główny Inspektorat Farmaceutyczny (GIF)*	See responsible authority for medicinal products for human use

Country	For medicinal products for human use	For veterinary medicinal products
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 / *Direção-Geral de Alimentação e Veterinária (DGAV)*
Romania	National Agency for Medicines and Medical Devices of Romania / *Agenția Națională a Medicamentului şi a Dispozitivelor Medicale din România*	National Sanitary Veterinary and Food Safety Authority / *Autoritatea Națională Sanitară Veterinară şi pentru Siguranța Alimentelor*
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)*
Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia / *Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP)*	See responsible authority for medicinal products for human use
Spain	Spanish Agency of Medicines and Medical Devices / *Agencia Española de Medicamentos y Productos Sanitarios* ([2])	See responsible authority for medicinal products for human use
Sweden	Swedish Medical Product Agency / *Läkemedelsverket*	See responsible authority for medicinal products for human use

([1]) 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 coordinating authority for all competent Laender authorities issuing GMP documents and conducting pharmaceutical inspections.

([2]) 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 GMP documents and conducting pharmaceutical inspections.