Implementation of Regulation (EU) 2019/6

EMA Veterinary Medicines Info Day

14 March 2024

Alfonso LAS HERAS, DVM, PhD
Deputy Head of Unit – D4 Veterinary Medicines
Health and Food Safety Directorate-General

Outline

- Progress made
- Work in progress
- Final remarks

Outline

- Progress made
- Work in progress
- Final remarks

Transitional rules for packaging and labelling (Art 152)!!!!!

VMP Regulation

Amendment of the Official Controls Regulation (Art. 118)

IA Common logo for online sales

IA Union Product Database

IA List of variations not requiring assessment

DA Requirements for the collection of data on sales and use of AM

DA Criteria to designate AM reserved for humans only

DA Rules for VMPs used by oral administration

VET

IA Good Pharmacovigilance Practice & PSMF

DA Annex II

IA List of AM reserved for human use only

DA Imports of animals and products of animal origin

IA Abbreviations & pictograms for labelling

IA GDP Active substances

IA GDP VMPs

IA Format for the collection of data on sales and use of AM

IA Rules on the size of small immediate packaging units

DA Horse passport

IA Horse passport

IA amending import certificates

16+2 legal acts

European Commission

DA on oral administration

Article 106(6): Delegated acts on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed and administered by the animal keeper to food-producing animals.

- No deadline for adoption in the VMP Regulation.

✓ EMA's advice of 28/08/2020.

✓ Discussion in the Expert Group on VMPs (1/12/22 – 16/10/23)

✓ 4-week public consultation: 13/12/23 – 10/01/24

✓ Adopted by COM on 07/02/2024

European Commission

IA on abbreviations & pictograms

Article 17(2): Implementing acts to adopt a list of the abbreviations and pictograms common throughout the Union to be used for the purposes of Articles 10(2) and 11(3).

- Deadline for adoption in the VMP Regulation 29/01/2025.

✓ Discussions in the Expert Group & Standing Committee (March 23 – Feb. 24)

✓ 4-week public consultation: 17/11/23 – 17/12/23

- Meeting with stakeholders on 04/04

✓ Positive opinion SC 22/2

European Commission

IA on size of small packaging units

Article 17(3): Implementing acts on uniform rules on the size of small immediate packaging units referred to in Article 12.

- Deadline for adoption in the VMP Regulation 29/01/2025.

✓ Discussions in the Expert Group & Standing Committee (March 23 – Feb. 24)

✓ 4-week public consultation: 17/11/23 – 17/12/23

  - Meeting with stakeholders on 04/04

✓ Positive opinion SC 22/2

European Commission

Article 118 & DA 2023/905 (1/3)

Article 118(1): Article 107(2) shall apply, mutatis mutandis, to operators in third countries and those operators shall not use the designated antimicrobials referred to in Article 37(5), insofar as relevant in respect of animals or products of animal origin exported from such third countries to the Union.

- DA 2023/905 published on 4 May 2023

✓ Scope & import requirements:

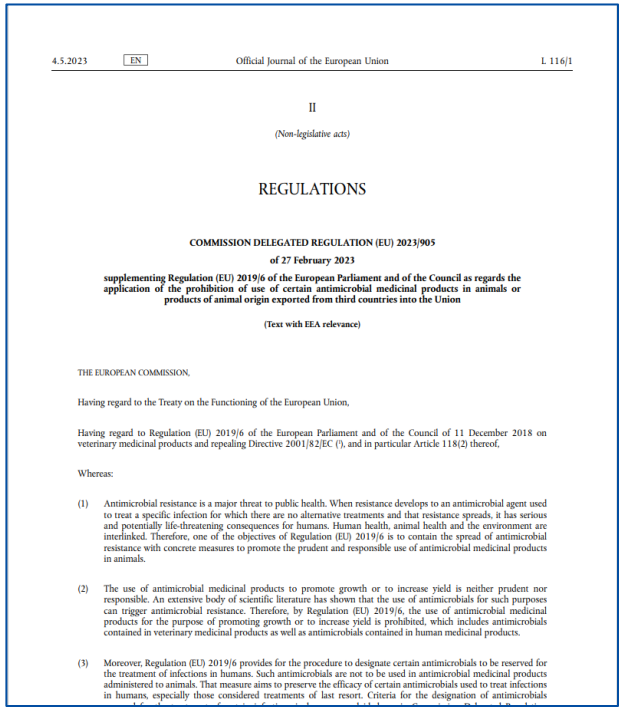
  ✓ Only from third countries in the list of approved countries;

  ✓ Official certificate attesting complies with the bans.

✓ Official certificates already amended (Implementing Regulation (EU) 2024/399)

✓ Listing process on-going (first list - tentative - in Q3 2024)

✓ Application of the import system as from 3 September 2026



4.5.2023 EN Official Journal of the European Union L 116/1

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2023/905

of 27 February 2023

supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (1), and in particular Article 118(2) thereof,

Whereas:

(1) Antimicrobial resistance is a major threat to public health. When resistance develops to an antimicrobial agent used to treat a specific infection for which there are no alternative treatments and that resistance spreads, it has serious and potentially life-threatening consequences for humans. Human health, animal health and the environment are interlinked. Therefore, one of the objectives of Regulation (EU) 2019/6 is to contain the spread of antimicrobial resistance with concrete measures to promote the prudent and responsible use of antimicrobial medicinal products in animals.

(2) The use of antimicrobial medicinal products to promote growth or to increase yield is neither prudent nor responsible. An extensive body of scientific literature has shown that the use of antimicrobials for such purposes can trigger antimicrobial resistance. Therefore, by Regulation (EU) 2019/6, the use of antimicrobial medicinal products for the purpose of promoting growth or to increase yield is prohibited, which includes antimicrobials contained in veterinary medicinal products as well as antimicrobials contained in human medicinal products.

(3) Moreover, Regulation (EU) 2019/6 provides for the procedure to designate certain antimicrobials to be reserved for the treatment of infections in humans. Such antimicrobials are not to be used in antimicrobial medicinal products administered to animals. That measure aims to preserve the efficacy of certain antimicrobials used to treat infections in humans, especially those considered treatments of last resort. Criteria for the designation of antimicrobials

European Commission

MODEL ANIMAL HEALTH/OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION OF FRESH MEAT INTENDED FOR HUMAN CONSUMPTION, EXCLUDING MECHANICALLY SEPARATED MEAT, OF DOMESTIC BOVINE ANIMALS (MODEL BOV)

COUNTRY			Animal health/Official certificate to the EU		
Consignment	I.1 **Consignor/Exporter** Name Address Country ISO country code		I.2 **Certificate reference**	I.2a **IMSOC reference**	
			I.3 **Central Competent Authority**	**QR CODE**	
			I.4 **Local Competent Authority**		
	I.5 **Consignee/Importer** Name		I.6 **Operator responsible for the consignment** Name		

(1) (16) [**II.1.a. Attestation as regards Commission Delegated Regulation (EU) 2023/905** [Delete when the Union is not the final destination of the fresh meat]

I, the undersigned official veterinarian declare that, I am aware of the relevant requirements of Regulation (EU) 2019/6 of the European Parliament and of the Council and Commission Delegated Regulation (EU) 2023/905 and hereby certify that fresh meat of domestic bovine animals (including *Bison* and *Bubalus* species and their cross-breeds) described in Part I was produced in accordance with these requirements, and in particular, that the animals from which the meat is derived have not been administered antimicrobial medicinal products for growth promotion or yield increase or antimicrobial medicinal products containing an antimicrobial that is included in the list of antimicrobials reserved for the treatment of certain infections in humans laid down in Commission Implementing Regulation (EU) 2022/1255 as set out in Article 3 of Delegated Regulation (EU) 2023/905 and originate from a third country or region thereof listed in accordance with Article 5(2) of Delegated Regulation (EU) 2023/905.]

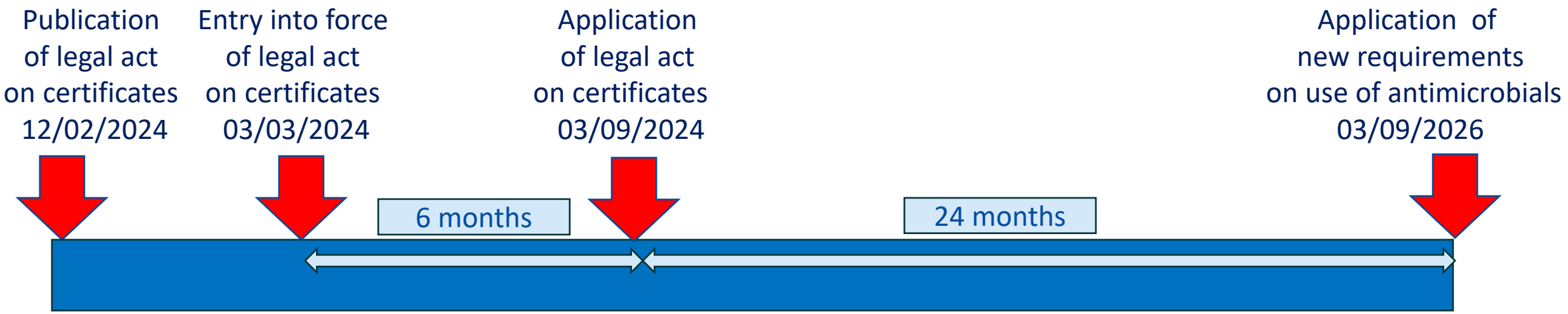
(1) Delete if not applicable.

(16) Applicable to consignments entering the Union as from 3 September 2026.

Article 118 & DA 2023/905 (3/3)

Commission Implementing Regulation (EU) 2024/399

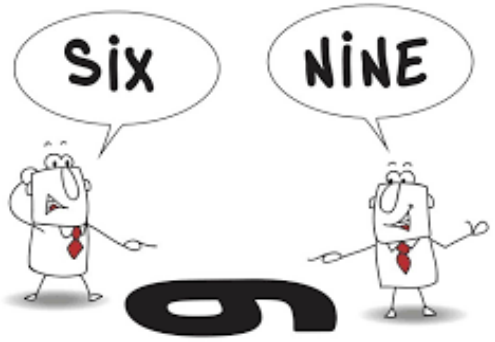
Date of application – 3 September 2026



European Commission

Guidance to applicants

- Published on 14 February 2024
- ✓ Informative session on 26 March



Official Journal of the European Union

EN
C series

C/2024/1443

14.2.2024

COMMISSION NOTICE

Guidance to Applicants - Veterinary Medicinal Products

(Text with EEA relevance)

(C/2024/1443)

Contents

Official Journal of the European Union

EN
C series

C/2024/90009

23.2.2024

Corrigendum to Commission Notice - Guidance to Applicants - Veterinary Medicinal Products

(Official Journal of the European Union C, C/2024/1443, 14 February 2024)

Notice C/2024/1443 should read as follows:

'**COMMISSION NOTICE**

Guidance to Applicants - Veterinary Medicinal Products

(Text with EEA relevance)

(C/2024/1443)

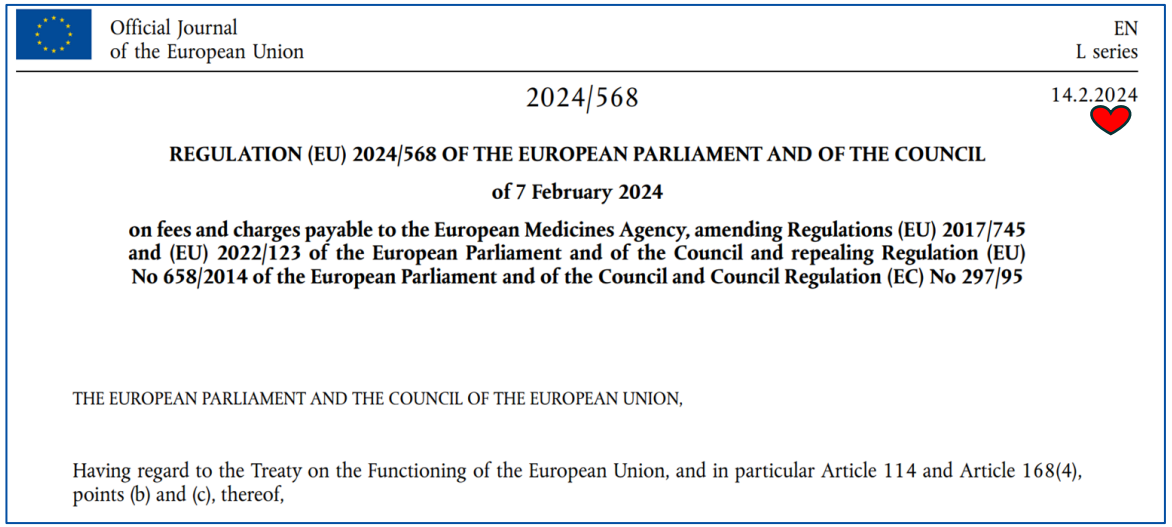
Contents

European Commission

Revision of the EMA Fee system

- Commission proposal (13/12/2022)
- Regulation (EU) 2024/568 published on 14/02/2024
- Co-legislators recognised the specificities of the VMP sector

  → fee amounts updated only by 50% of the inflation rate



Official Journal of the European Union — EN L series

2024/568 — 14.2.2024

REGULATION (EU) 2024/568 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 7 February 2024

on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), points (b) and (c), thereof,

- EC to monitor inflation → annual update
- EMA to monitor cost data → special report to EC (first report + every 3 years)
- EC may adapt fees by means of delegated acts

European Commission

Outline

- Progress made
- Work in progress
- Final remarks

VMP Regulation

Work in progress: 5 legal acts

IA List of AM not to be used outside terms of the MA

IA GMPs VMPs & active substances

EMA's scientific advice completed

IA: List of authorised third countries for imports into the Union

IA List of substances essential for equine species

IA List of substances for food-producing aquatic species

Mandates sent to EMA

No legal deadline for adoption

IA Model format for prescriptions

IA Rules for the functioning of the worksharing procedure

DA Procedures for financial penalties for CAs VMP

IA Uniform rules on the identification code

European Commission

Work in progress – Listing of third countries

Article 5(2) of Regulation (EU) 2023/905: The list referred to in Article 4(1), point (a), is to be established by means of an implementing act adopted by the Commission in accordance with Article 127 of Regulation (EU) 2017/625.

- Written guarantees requested to 98 third countries (TCs) in May 2023 (6 months)
- Guarantees provided by TCs under assessment; if satisfactory, the third country is listed
- Discussion of the draft IA with MSs (PAFF Section controls & import conditions)
- Notification of the draft Regulation to the WTO/SPS
- Two-step process:
  - A first list: certainty, transparency for TCs having provided the guarantees
  - A revised list to be published before the application date (i.e. 3/09/26)

European Commission

Work in progress – IA on Article 107(6) list

Article 107(6): Implementing acts to establish a list of antimicrobials which (a) shall not be used in accordance with Articles 112, 113 and 114; or (b) shall only be used in accordance with Articles 112, 113 and 114 subject to certain conditions.

- No deadline for adoption in the VMP Regulation
- Mandate sent to EMA on 17/02/2020
- SA sent to Commission on 15/06/23 & presented to SC on 26/06/24
- On-going discussions with MSs at the SC meetings
- Step-wise approach – consistency with other lists under Articles 113(4) and 115(5)

  → equine and aquatic species not included in the first list

European Commission

Work in progress – IAs on GMPs

Article 93(2): Implementing acts on good manufacturing practice for veterinary medicinal products and active substances used as starting materials, referred to in point (j) of paragraph 1 of this Article.

- Deadline for adoption in the VMP Regulation 28/01/2025
- Mandate sent to EMA on 28/07/2022
- Adoption of SA at the Dec 23 CVMP meeting
- Targeted stakeholder consultation: 19 December 2023 - 31 January 2024
- Presentation of EMA's SA (+ outcome stakeholders' consultation) at the February SC meeting
- Two IAs: one for VMPs and one for active substances

European Commission

Work in progress – S.A. essential substances

Article 115(5): Implementing acts establish a list of substances which are essential for the treatment of equine species, or which bring added clinical benefit compared to other treatment options available for equine species and for which the withdrawal period for equine species shall be six months.

- Deadline for adoption in the VMP Regulation 29/01/2025
- Mandate sent to EMA on 9/02/23
- 2-month stakeholder consultation (until 30/06/23): new substances for addition; existing substances for revision
- Scientific advice due by 31 March 2024 → extension until 31/07/2024
- Work in progress

European Commission

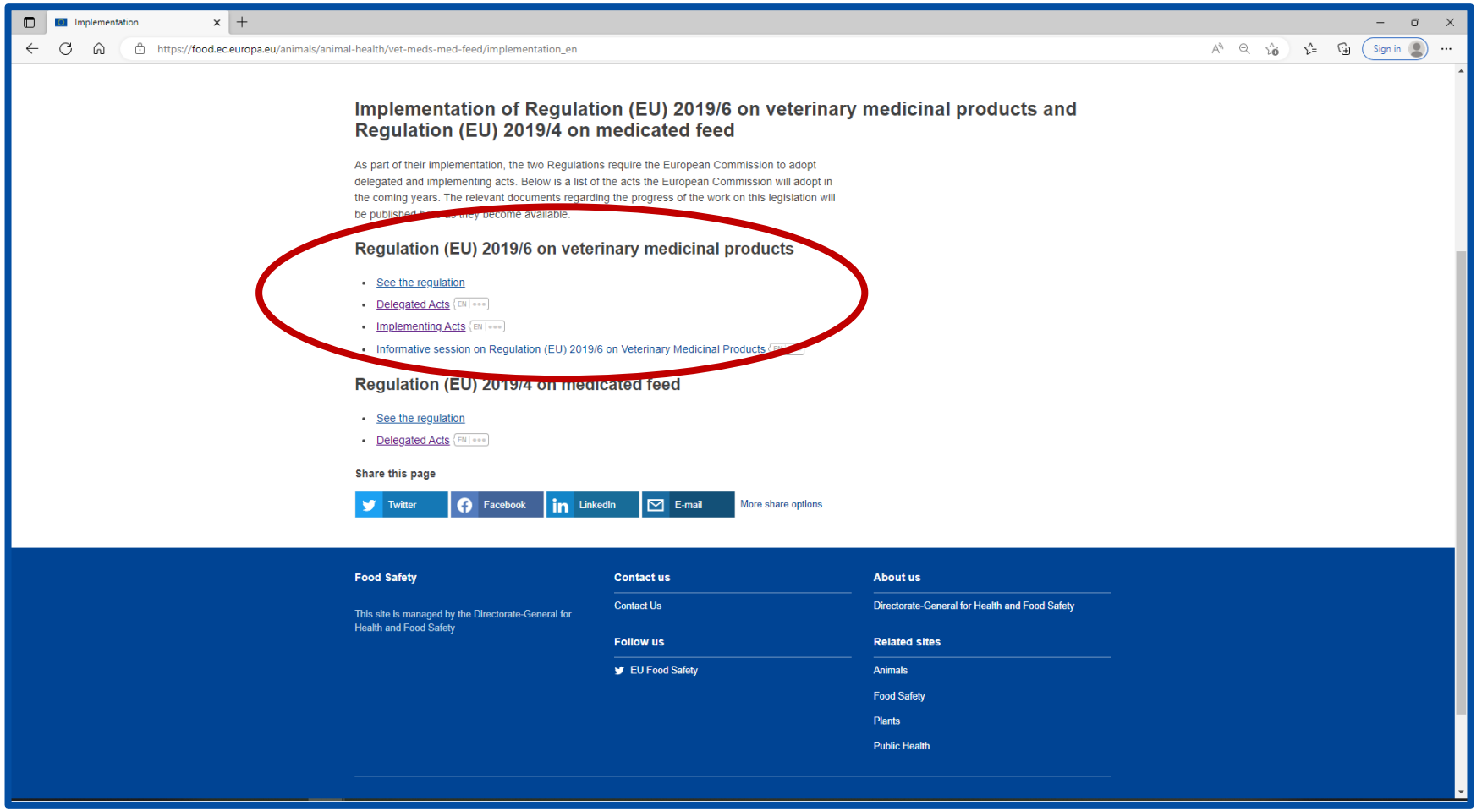
Work in progress - S.A. list aquatics

Article 114(3): implementing acts establish a list of substances used in veterinary medicinal products authorised in the Union for use in food-producing terrestrial animal species or substances contained in a medicinal product for human use authorised in the Union in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004, which may be used in food-producing aquatic species in accordance with paragraph 1 of this Article.

- Deadline for adoption in the VMP Regulation 28/01/2027
- Mandate sent to EMA on 12/04/23
- Scientific advice due by 30 November 2024
- Work in progress

European Commission

Follow our work progress on Tertiary Legislation



https://food.ec.europa.eu/animals/animal-health/vet-meds-med-feed/implementation_en

European Commission

Work in progress - SMP actions - studies

Article 158: report to the EP and Council on the situation as regards the treatment with medicinal products of animals of the equine species

- Deadline for transmission of the report: 29/01/2025
- On-going study; data gathering exercise by contractor with MSs & stakeholders
- Final report to be delivered by July 2024; delays expected

Article 157: Commission report on traditional herbal products used to treat animals

- Deadline 29/01/2027
- Study supporting the report included in the 2024 work programme

European Commission

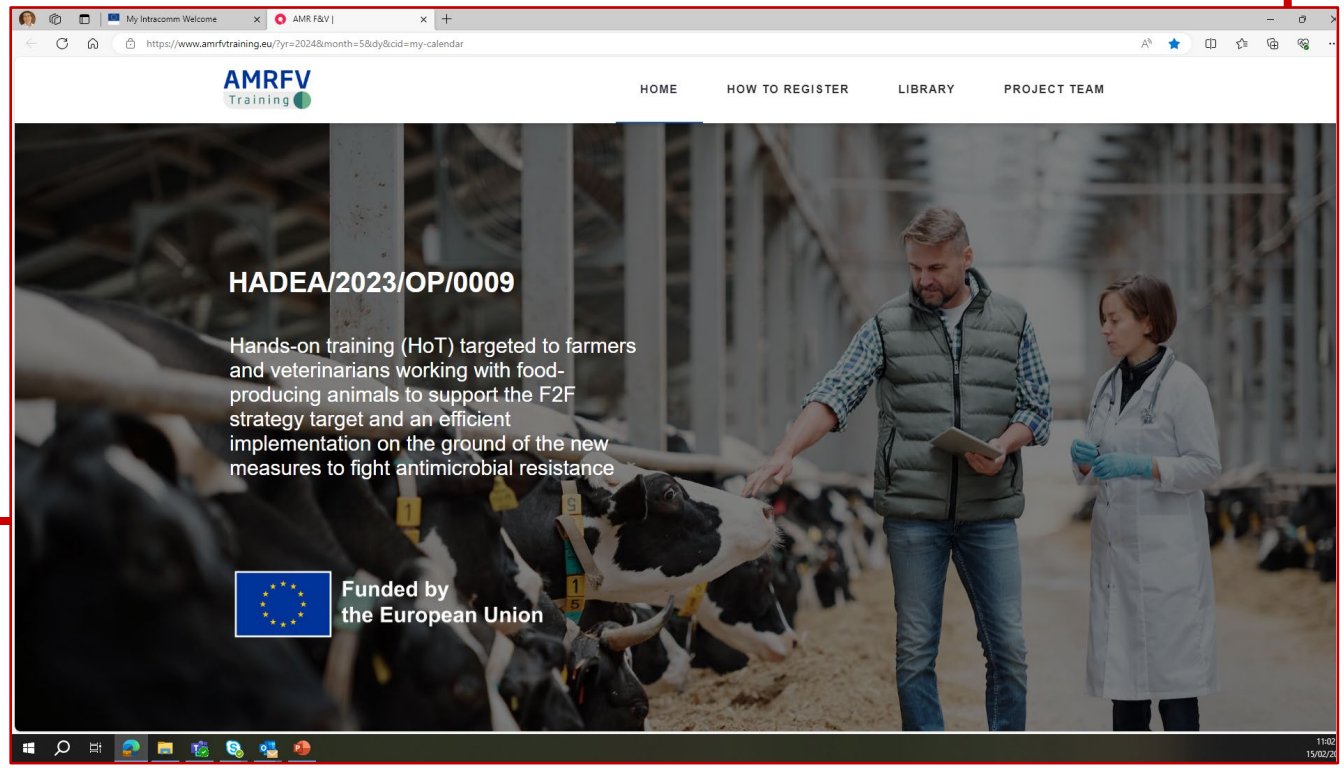
Work in progress - SMP actions - training

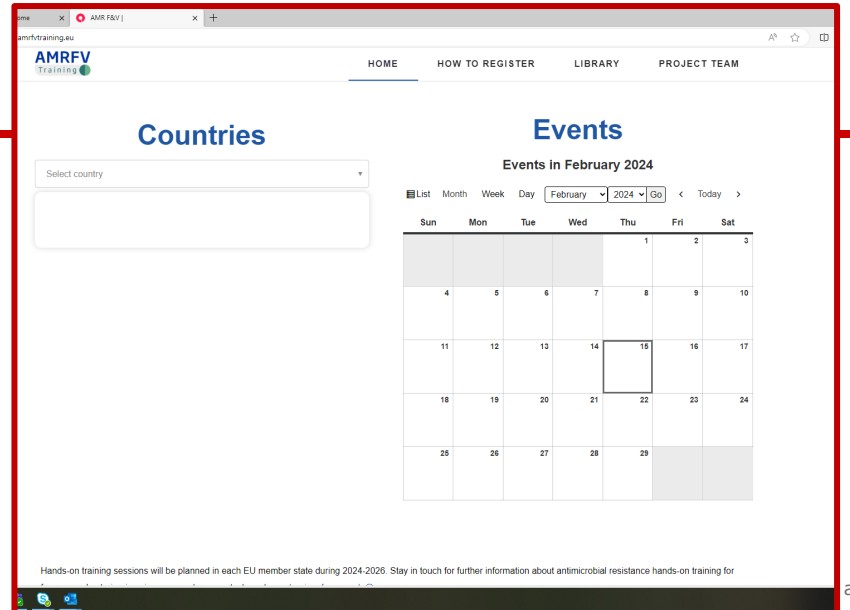
Hands-on training targeted to farmers and veterinarians working with food-producing animals (fight AMR)

- Budget EUR 3.090.000
- First trainings have started (MT)

  → First tentative dates at

  AMR F&V | (amrfvtraining.eu)





European Commission

as public by the European Medicines Agency

Work in progress - SMP actions - training

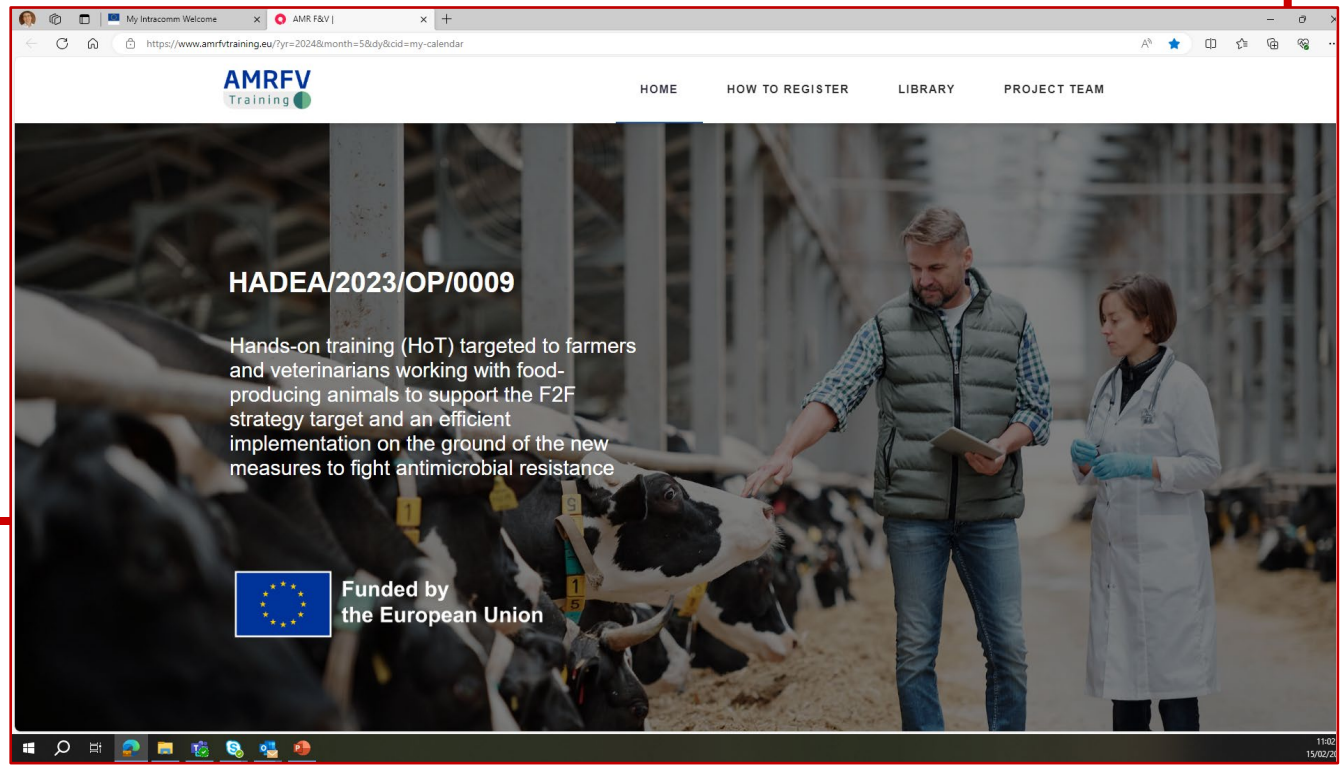
Hands-on training targeted to farmers and veterinarians working with food-producing animals (fight AMR)

- Budget EUR 3.090.000
- First trainings have started (MT)

  → First tentative dates at

  AMR F&V | (amrfvtraining.eu)

  - ✓ MT: 7-8/03
  - HU: 19-20/03
  - EE: 10-11/04
  - RO: 9-10/04
  - HR: 16-17/05
  - CY: 6-7/06
  - PT: 13-14/06
  - SK: 21/06
  - PL: 24-25/10



European Commission

Work in progress
G.I. 18 variations (QRD-9 update)

Article 152 & Regulation (EU) 2022/839 (DDL 29/01/2027)

Time is of the essence

→ Applications must be submitted

→ Process should be made as efficient as possible

Outline

- Progress made
- Work in progress
- Final remarks

Final remarks

1. Good progress has been made in the development of tertiary legislation as a result of a collective effort: thanks to all involved!
2. With most legal instruments in place, it is time now for implementation.
3. Continuous dialogue between involved parties will help to facilitate the day-to-day practical implementation.
4. Efficient implementation will be crucial for the VMP Regulation to deliver in its key policy objectives.

European Commission

We count on your continued commitment to make the implementation of the VMP Regulation our common success

Thank you

European Commission