Update from the Commission on the VMP-Reg and secondary legislation

EMA Info day- 16 February 2023

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Outline


7.1.2019 EN Official Journal of the European Union L 4/43

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

(Text with EEA relevance)

- Intro
- Progress made
- Work in progress
- Final remarks

European Commission

Outline

- Intro
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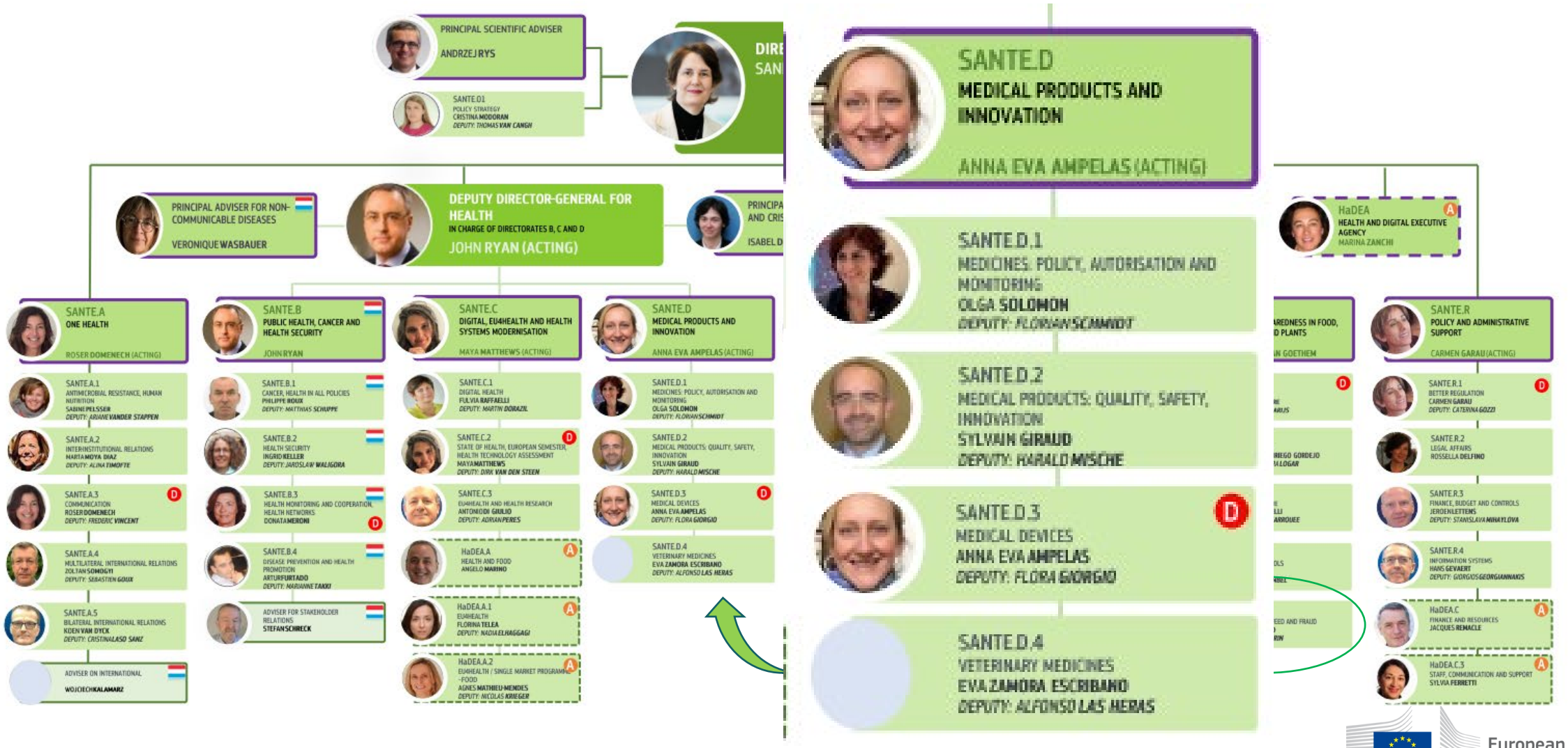
European Commission

DG SANTE | Directorate-General For Health & Food Safety

COMMISSIONER : STELLA KYRIAKIDES

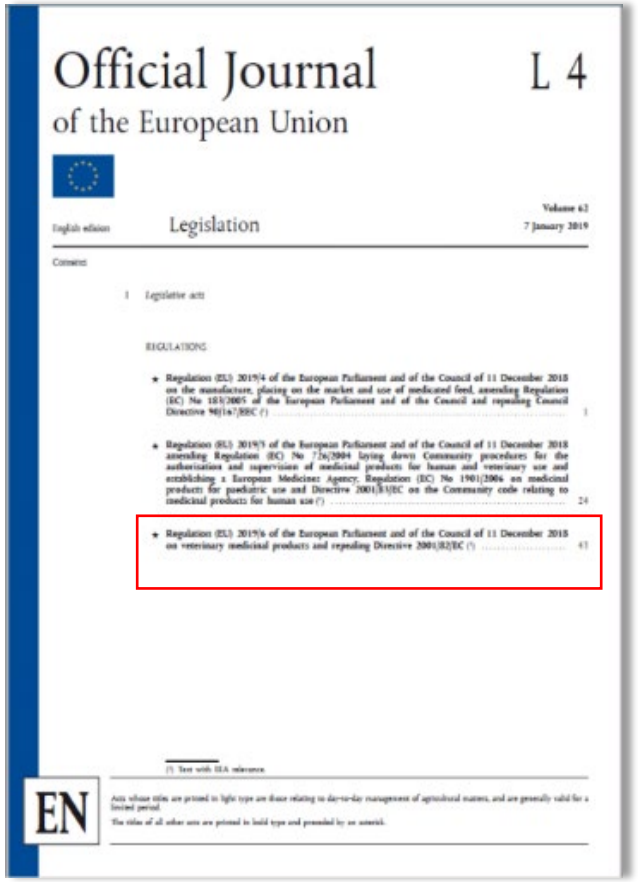


European Commission

The Implementation Challenge

VMP Regulation empowerments:

- 13 before or by the date of application
- 6 by 2025
- 1 by 2027
- 6 no legal deadline


Official Journal of the European Union L 4

Legislation

EN

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The implementation challenge

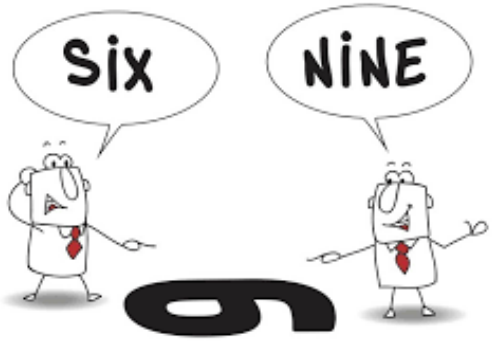
VMP Regulation empowerments:

- Implementation of new provisions
- 6 by 2025
- 1 by 2027
- 6 no legal deadline

&

- Fixing errors

- Matters of interpretation



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VMP Regulation

Transitional rules for packaging and labelling (Art. 152)

Amendment of the Official Controls Regulation (Art. 118)

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

Report to EP & Council on ERA monographs

VET

IA Good Pharmacovigilance Practice & PSMF

DA Annex II

IA List of AM reserved for human use only

IA Common logo for online sales

IA GDP Active substances

IA GDP VMPs

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

AHL

DA Horse passport

IA Horse passport

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Legal acts already published (1/3)

1. Commission Implementing Regulation (EU) 2021/16 **(Union product database)**	✓
2. Commission Implementing Regulation (EU) 2021/17 **(list of variations not requiring assessment)**	✓
3. Commission Delegated Regulation (EU) 2021/578 **(Methods for AM data gathering)**	✓
4. Commission Delegated Regulation (EU) 2021/577 **(Medication record in the Horse Passport)**	✓
5. Commission Delegated Regulation (EU) 2021/805 **(Annex II)**	✓
6. Commission Implementing Regulation (EU) 2021/963 **(Horse Passport)**	✓

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Legal acts already published (2/3)

7. Commission Implementing Regulation (EU) 2021/1281 **(Good PhV practice & PSMF)**	✓
8. Commission Implementing Regulation (EU) 2021/1280 **(Good distribution practice (GDP) for active substances)**	✓
9. Commission Delegated Regulation (EU) 2021/1248 **(Good distribution practice (GDP) for veterinary medicinal products)**	✓
10. Commission Delegated Regulation (EU) 2021/ 1760 **(criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans)**	✓
11. Regulation(EU) 2021/1756 of the EP and of the Council **(official controls on animals and products of animal origin exported from third countries to the Union in order to ensure compliance with the prohibition of certain uses of antimicrobials)**	✓

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Legal acts already published (3/3)

12. Commission Implementing Regulation (EU) 2021/1904 **(the design of a common logo for the retail of veterinary medicinal products at a distance)** ✓

13. Commission Implementing Regulation (EU) 2022/209 **(format of the data to be collected and reported in order to determine the volume of sales and the use of antimicrobial medicinal products in animals)** ✓

14. Commission Delegated regulation (EU) 2022/524 **(correcting Delegated Regulation (EU) 2021/577 - Medication record in the horse passport)** ✓

15. Regulation (EU) 2022/839 of the EP and of the **Council (transitional rules for the packaging and labelling of veterinary medicinal products)** ✓

16. Commission Implementing Regulation (EU) 2022/1255 **(antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans)** ✓

17. Commission Delegated Regulation (EU) 2023/183 **(amending Annex II to Regulation (EU) 2019/6 as regards the requirements on compliance with GLPs)** ✓

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Transitional rules packaging & labelling (Art.152)

- Regulation of the EP and of the Council laying down transitional rules for the packaging and labelling of veterinary medicinal products authorised or registered in accordance with Directive 2001/82/EC and Regulation (EC) No 726/2004
- Issue:
  - MAHs not able to comply, by 28 January 2022 with the requirements set out in Articles 10 to 16 of Regulation (EU) 2019/6.
  - CAs are not in a position to process all the **necessary variations** to ensure compliance with Articles 10 to 16 of Regulation (EU) 2019/6 in a timely manner
- Solution to ensure the continued availability of VMPs in the Union and to establish legal certainty

European Commission

Transitional rules packaging & labelling (Art.152)

- VMPs which were authorised or registered in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 and which comply with Articles 58 to 64 of Directive 2001/82/EC, as applicable on 27 January 2022, can be placed on the market **until 29 January 2027**, even if their labelling and, where applicable, package leaflet are not in compliance with Articles 10 to 16 of Regulation (EU) 2019/6.
- One year is already over → Need to ensure a well-planned submission of the relevant variations (to implement the new QDR template) in order to avoid an unintended situation at the end of the transition period

→ NO extension

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Report on ERA monographs

“Yes”… but not yet:

- VMP Regulation implementation still on-going; very demanding for EC, EMA, NCAs & Industry
- Reflections on the human medicines side – common approach (OSOA)

EUROPEAN COMMISSION

Brussels, 13.1.2023
COM(2023) 9 final

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on a feasibility study of an active-substance-based review system (‘monographs’) and other potential alternatives for the environmental risk assessment of veterinary medicinal products

https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1673881860414&uri=CELEX%3A52023DC0009

EN EN

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VMP Regulation

No legal deadline for adoption

IA Model format for prescriptions

IA Rules for the functioning of the work-sharing procedure

DA Procedures for financial penalties for CAs VMP

IA Uniform rules on the identification code

Work in progress

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

IA GMPs VMPs & active substances

IA List of substances for food-producing aquatic species

DA Rules for VMP oral administration via drinking water or top dressing

DA Imports of animals and products of animal origin

IA: Certificates

IA List of substances essential for equine species

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

Work to be started in 2023

IA Rules on the size of small immediate packaging units

IA Abbreviations and pictograms for labelling

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VMP Regulation

IA List of AM not to be used outside terms of MA	No deadline for adoption in the VMP Regulation. EMA advice in preparation.
IA List of substances for food-producing aquatic species	Deadline by 28/01/2027 - Draft mandate in preparation
IA List of substances essential for equine species	Deadline 29/01/2025 - Mandate sent to EMA – Scientific advice due by 31 March 2024.

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VMP Regulation

Deadline 29/01/2025 – Mandate sent to EMA on 28/07/2022 – Expert group work in progress (15 meetings so far).

No deadline for adoption in the VMP Regulation. EMA's advice of 28/08/2020. Preparatory work on-going:

- First discussion in the Expert Group VMPs on 1/12/2022
- Upcoming discussion in March (date tbc)

IA GMPs
VMPs & active substances

DA Rules for VMP oral administration via drinking water or top dressing

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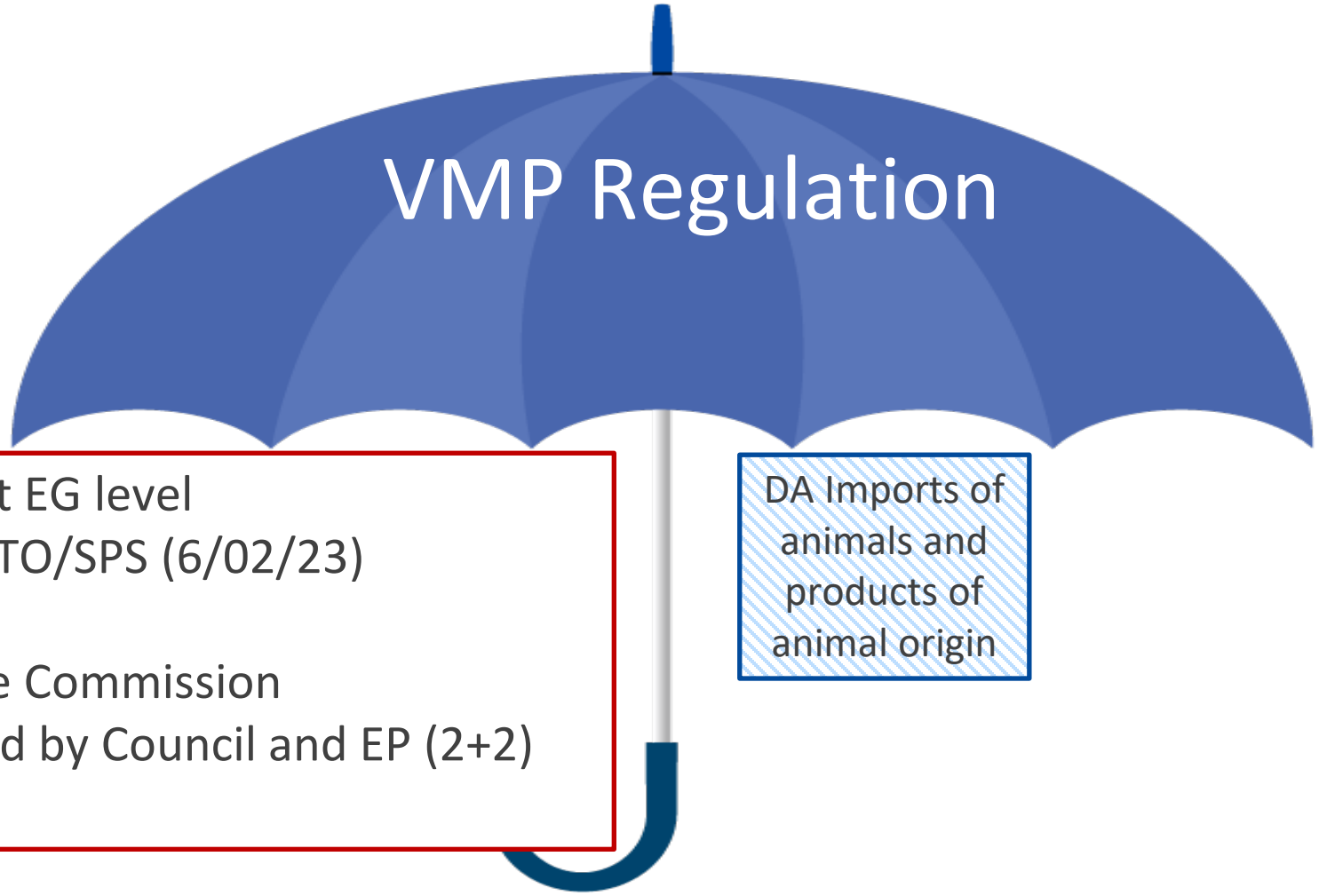
VMP Regulation



Draft DA agreed at EG level
OPC (3/01/23); WTO/SPS (6/02/23)
Next steps:
- Adoption by the Commission
- Objection period by Council and EP (2+2)
- Publication

DA Imports of animals and products of animal origin

Preparatory work on-going
Next steps after the publication of the delegated act (after objection period)

IA: Certificates

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

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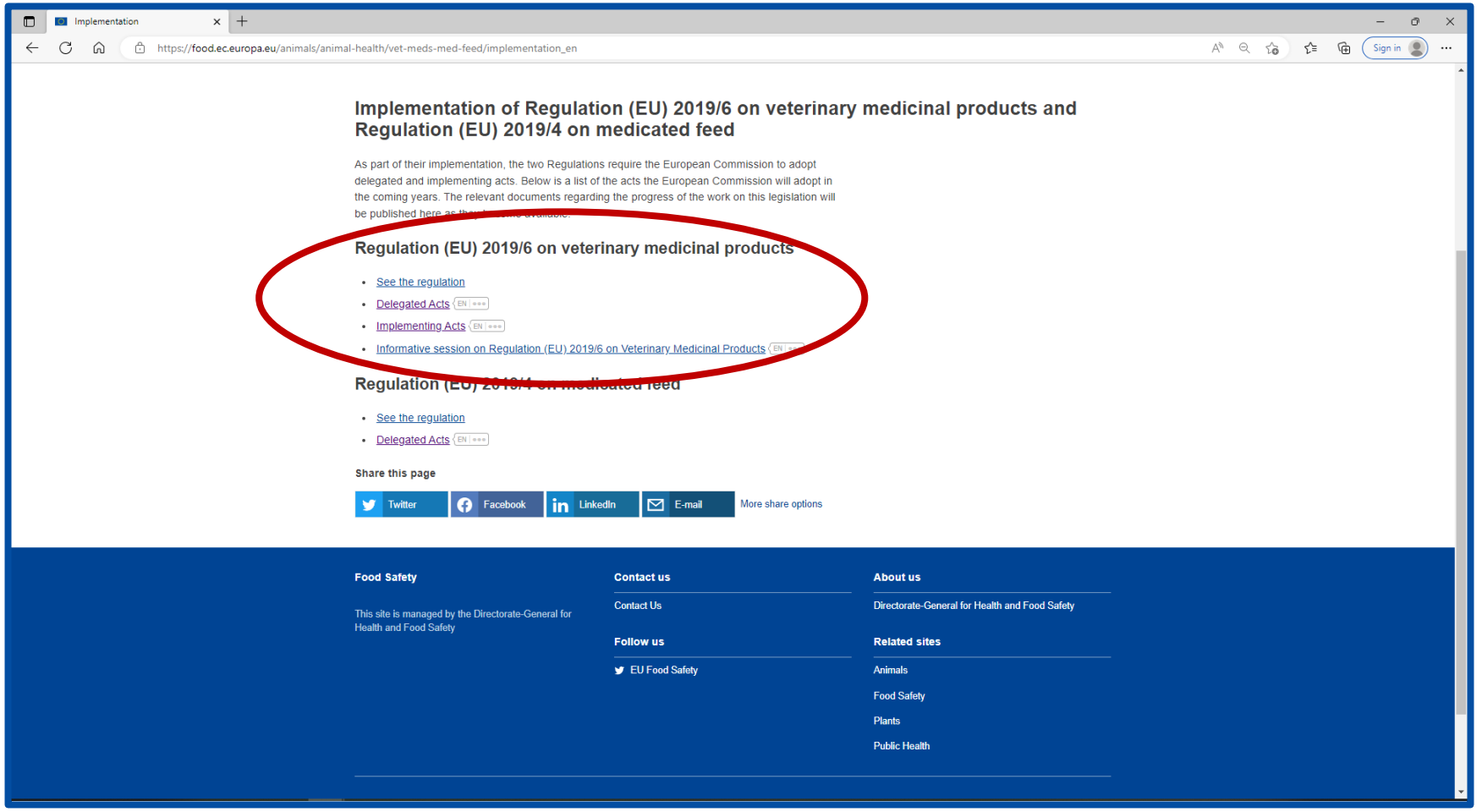
Follow our work progress on Tertiary Legislation



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

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Other non-legislative actions/Implementation

Report to the European Parliament and to the Council on assessment of situation as regards the treatment with medicinal products of Equidae and their exclusion from the food chain, including regarding third country imports (Article 158)

Due by 2025

- 1st step: Study to support the Commission report
    - Start of initiative planned for early 2023….
    - Study planned to last about a year after awarding it

Other non-legislative actions/Implementation

Support actions under the Single Market Programme-Food strand in the area of AMR :

- Data collection: financial support (grants) to Member States for data collection on sales and use of antimicrobials.
- Responsible use: hands-on training targeted to farmers and veterinarians working with food-producing animals to support the ‘F2F’ strategy target and an efficient implementation on the ground of the new measures to fight AMR (procurement – call for tenders).

Tentative planning

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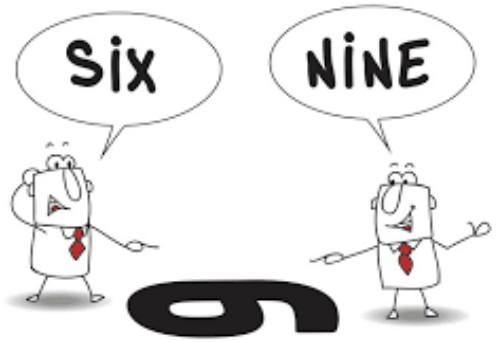
Other non-legislative actions/Implementation



"**Guidance to applicants**":

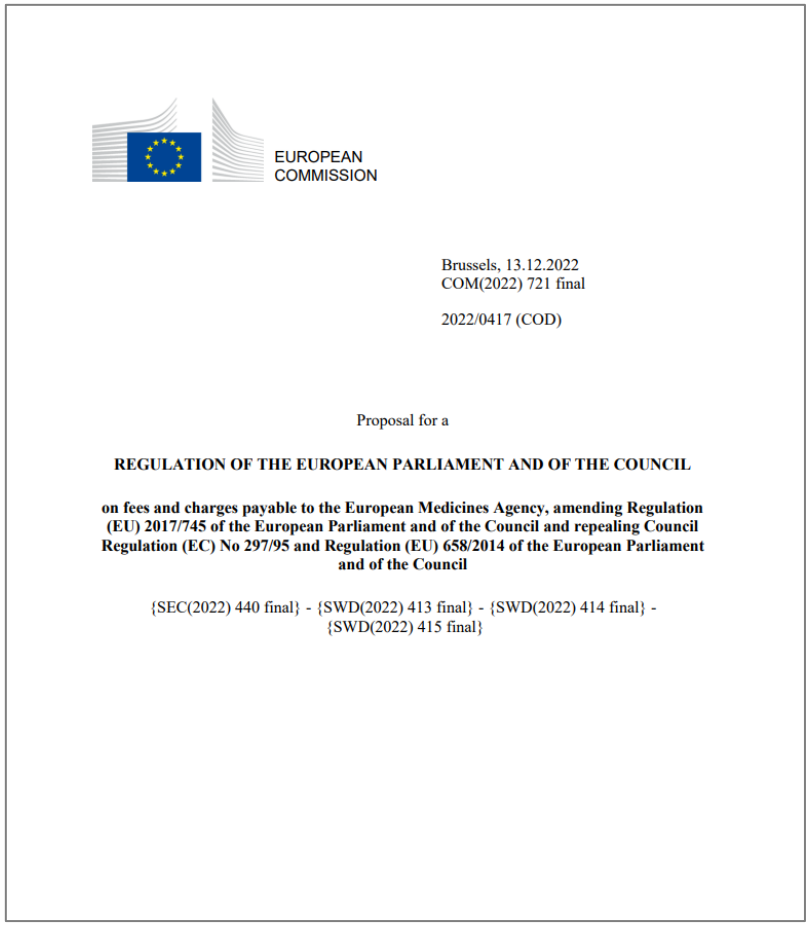
- Sub-Group on Guidance to Applicants established under the Expert Group on VMPs – support COM in the development of interpretative documents regarding the VMPs legislation

- 4 meetings held so far; good progress achieved, adjusting the old Notice to Applicants to the new framework, as well as addressing new issues such as new obligations of marketing authorisation holders or new requirements in the VMP Regulation.

Ongoing Revision of the EMA Fee system

- Commission proposal adopted on 13/12/2022
- First discussions in the Council working party on-going
- More info at:

  https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/european-medicines-agencys-ema-fee-system-impact-assessment-and-commission-proposal_en



EUROPEAN
COMMISSION

Brussels, 13.12.2022
COM(2022) 721 final

2022/0417 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

{SEC(2022) 440 final} - {SWD(2022) 413 final} - {SWD(2022) 414 final} - {SWD(2022) 415 final}

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Final remarks

1. Implementation work still on-going; key priority for the Commission in order to put in place all the relevant instruments necessary to achieve the objectives of the VMP Regulation
2. “T.T.T.” (*things take time*) – adaptation to a new system by all actors (EC, EMA, NCAs, stakeholders…)
3. “Practical implementation” may reveal elements that could be subject to improvement/optimisation.
4. We are confident to reach the full potential of the VMP Regulation in the upcoming years and deliver in its key policy objectives

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

Thank you

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