“Regulatory tools in the VMP Regulation”

B-THENET SATELLITE EVENT:
Availability of Veterinary Medicinal Products for use in beekeeping in the EU

Brussels, 29 November 2023

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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)

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

After transmission of the draft legislative act to the national parliaments,

After consulting the Committee of the Regions,

Whereas:

Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products

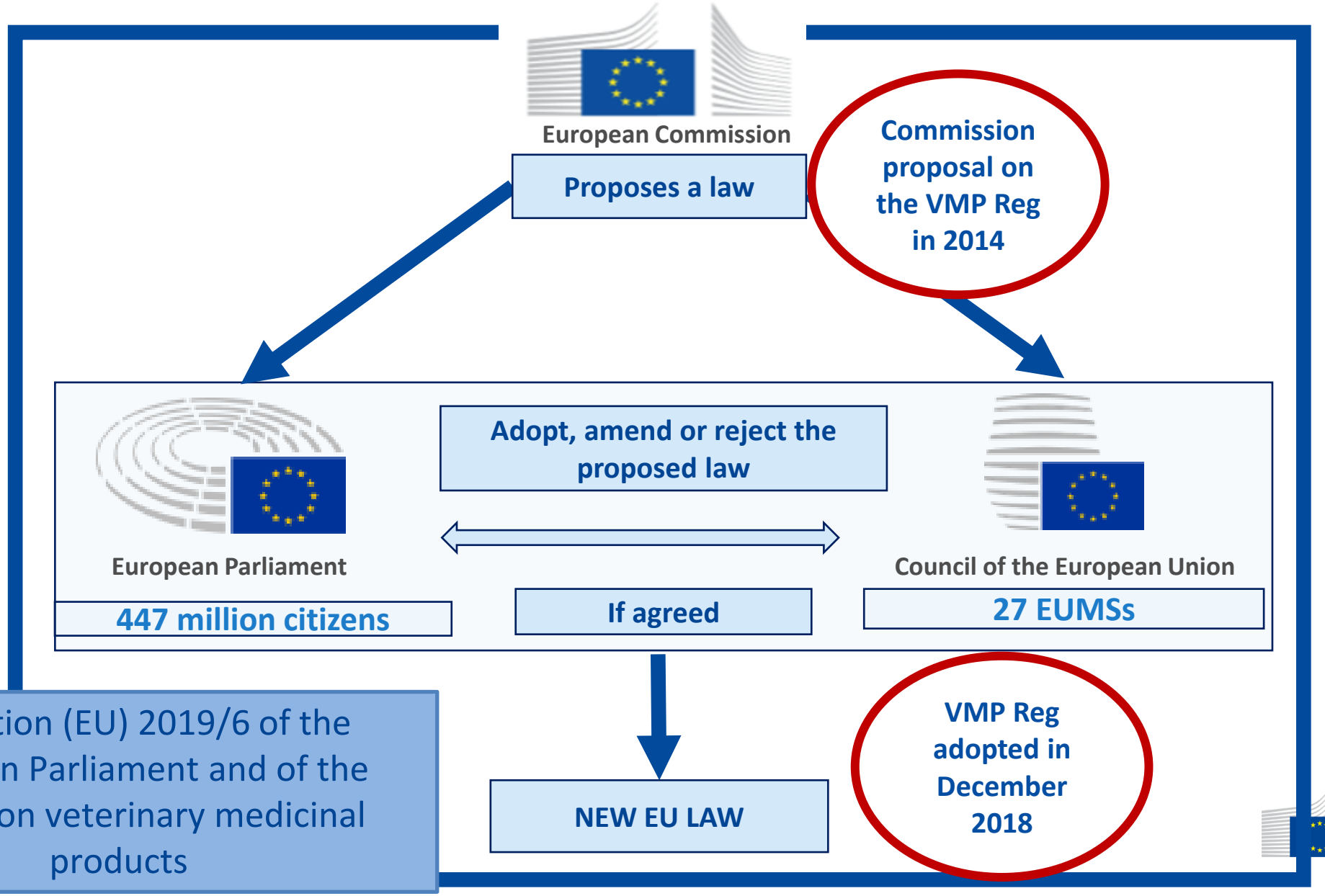
Repealing Directive 2001/82

Published on 7 January 2019

Applicable since 28 January 2022

European Commission

EU Legislative process

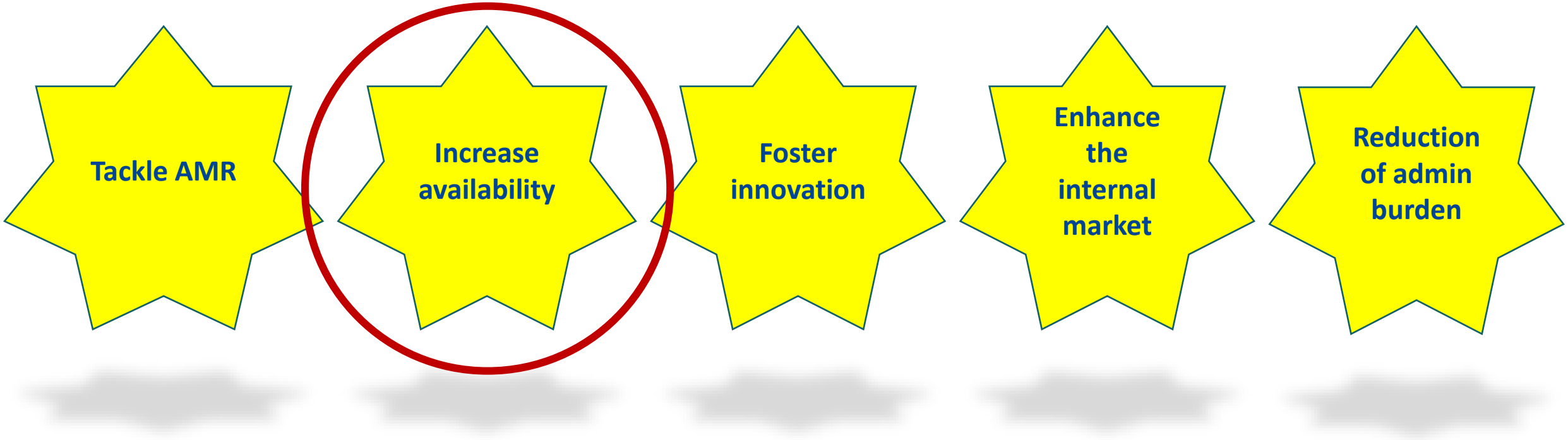


Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products

European Commission

Objectives of the Regulation on VMPs

Safeguarding public- and animal health and environmental protection +



European Commission

Initial remarks

1. “Availability” is a multifaceted issue, involving different actors & matters:
    1. Market needs (and market size)
    2. Innovation → Authorisation and placing on the market → Distribution and retailing → Veterinary prescription and use
    3. Affordability
    4. Unexpected circumstances (e.g. shortages)
2. The VMP Regulation provides for further harmonization at EU level…
3. … but Member States may still develop national rules in some areas (e.g. retail of VMPs, implementation of the “cascade” articles)

Regulatory tools to increase availability
Authorisation procedures

- **Article 39(1)(c)** - Protection period of the technical documentation of 18 years specific for VMPs for bees
- **Article 23(1)** - Possibility for an application for limited market, allowing to deviate from the safety and efficacy documentation
- ***[Article 25** - Possibility for an application under exceptional circumstances related to animal or public health; immediate availability outweighs the risk the incomplete application**]**.*

Regulatory tools to increase availability
Authorisation procedures

- **Article 7(2)** - Increased possibilities for multilingual-packs; increases the economical viability to produce batches for smaller markets
- **Articles 10, 11 & 12** - Use of uniform pictograms and abbreviations contribute to the possibilities of multilingual packs (*work on-going*)
- **Article 53** - Subsequent recognition allows for a fast-track authorisation of an MRP/DCP authorised VMP in other MSs (CMDv is publishing each year a list of VMPs authorised for bees in all EU MSs)

Regulatory tools to increase availability
Authorisation procedures

Beyond the VMP Regulation - **Fee waivers:**

- EMA fee regulation for SMEs and Limited markets, both for scientific advices and applications throughout the centralized procedure
- NCAs may also foresee fee waivers for authorisations of VMPs for bees (in some MSs there is a “zero-fee” policy)

Regulatory tools to increase availability
Wholesale distribution

- **Article 58(2)** – Obligation of the marketing authorisation holder to ensure appropriate and continued supplies of its VMPs

- **Article 99(3)** - Wholesale distribution authorisations shall be valid throughout the Union.

  → The Union manufacturing and wholesale distribution database (Article 91) will help retailers to identify distributors in the whole EU

- **Article 102** - Parallel trade in veterinary medicinal products (*only if the product is authorized in the two Member States*)

Regulatory tools to increase availability
Prescription & use

- **Article 113(1) & (2)** - possibility to use VMPs from other MSs and from 3rd countries (if no VMP available in the Union)

  → The Union product database (**Article 55**) will help vets & beekeepers to identify products available in the whole EU

Search medicines

Active substance

Choose some options

Medicine name

Choose some options

Authorised in

Choose some options

Target species

× Honey bee

Route of administration

256 results

Sort by Alphabetic order

Applied filters:

- Authorisation status : Valid ×
- Target species : Honey bee ×

AB VAR C

Active substance:	Coumaphos
Route of administration:	In-hive use
Pharmaceutical form:	Tablet

https://medicines.health.europa.eu/veterinary/en/search?f%5B0%5D=authorisation_status%3A8207&f%5B1%5D=target_species%3A9926

Target species

× Honey bee

Route of administration

Choose some options

Authorisation status

× Valid

ATCvet code

Choose some options

Pharmaceutical form

Choose some options

- Bee-hive dispersion
- Bee-hive gel
- Bee-hive solution
- Bee-hive strip
- Bee smoke stick

Clear filters

AB VAR C

Active substance: Coumaphos

Route of administration: In-hive use

Pharmaceutical form: Tablet

Target species: Honey bee

Product status: Authorised

Compare

Apiguard gel

Active substance: Timols

Route of administration: In-hive use

Pharmaceutical form: Gel

Target species: Honey bee

Product status: Authorised

Compare

Bayvarol Strips

Active substance: Flumetrīns

Route of administration: In-hive use

Compare medicines

0 Medicine selected (3 max.) Compare

12:27
29/11/2023

Regulatory tools to increase availability
Prescription & use

- **Article 113(1) & (2)** - possibility to use VMPs from other MSs and from 3rd countries (if no VMP available in the Union)

  → The Union product database (**Article 55**) will help vets & beekeepers to identify products available in the whole EU

- **Article 115(4)** - more flexibility for determining an appropriate withdrawal period for honey compared to the old legislative framework

Final remarks

1. “Availability” is a multifaceted issue, so cooperation between the sector, CAs and other stakeholders is key
2. The VMP Regulation provides for further harmonised rules at EU level aiming at increasing the availability of VMPs (for bees)
3. Close cooperation at Member State level remains crucial to identify and address critical, limiting factors that might be country-specific

Thank you

European Commission