Veterinary Medicinal Products Regulation (VMP-Reg, Regulation (EU) 2019/6)

New EU rules on medicines and consequences for veterinarians, farmers and for data collection

Presented by Barbara Freischem on 3 December 2020
Head of Department Veterinary Surveillance and Regulatory Support, European Medicines Agency
Agenda

Current system regulating veterinary medicines – until January 2022

Legislative basis
Overview of existing systems

Future system regulating veterinary medicines – post January 2022

Intent of the legislation
Specific rules regarding antimicrobials
EMA actions to implement the rules

Implications for farmers and veterinarians, and for data collection
Current regulation of veterinary medicines in the EU

**Directive 2001/82/EC**

- **National marketing authorisations**
  - Decentralised system/ mutual recognition system
    - More than one MS involved
    - Relies on the assessment carried out by a Reference Member State
  - National system
    - Individual MS
    - Managed in the MS

**Regulation (EC) 726/2004**

- **Central marketing authorisations**
  - Central system
    - Authorisations issued by the EC, valid in all MS
    - Managed at EMA with the CVMP

**Shared requirements as laid down in Directive 2001/82/EC:**
Data required for authorisation, renewals after 5 years, reliance on PSURs to monitor product safety, ...

**Actions on antimicrobial resistance:** on request from the European Commission (ESVAC, AMEG)
Overview

Regulation of veterinary medicines in the EU after January 2022

The Veterinary Regulation


Programme Change Management

VMP-Reg Programme

Vision

Scope

Governance

Project updates
Regulation (EU) 2019/6 on veterinary medicinal products

Replaces Directive 2001/82/EC and part of Regulation (EC) No 726/2004 within the overall aim of achieving ‘Better Regulation’ in the EU

- **provides for a modern, innovative and fit for purpose legal framework**
- **gives incentives to stimulate innovation**
- **gives incentives to increase the availability of veterinary medicines**
- **strengthens the EU actions to fight antimicrobial resistance**
‘Better Regulation’ in veterinary medicines

- Better availability of veterinary medicines
- Accessible information on veterinary medicines available in the EU
- Reducing the risks of antimicrobial resistance
- Encouraging pharmacovigilance reporting

The Veterinary Medicines Regulation and its new rules

- Legal framework to stimulate innovation (new medicines)
- Increased flexibility of prescription cascade
- Easier import of medicines from other EU Member States; prescriptions valid throughout the EU
- Online sales (certified online pharmacies) for non-prescription medicines

Easier access to more treatment options
‘Better Regulation’ in veterinary medicines

- Better availability of veterinary medicines
- Accessible information on veterinary medicines available in the EU
- Reducing the risks of antimicrobial resistance
- Encouraging pharmacovigilance reporting

Union Product Database will provide information on all veterinary medicines authorised in any EU Member State.

Information includes, but not limited to:

- Name, active substance(s), strength
- Summary of product characteristics (SPC), package leaflet, public assessment reports (EPAR) – to give more information on the scientific background of the content of the SPC
- Dates of placing on the market in a Member State
- Information on availability for each veterinary medicinal product

Easier access to information about treatment options

The Veterinary Medicines Regulation and its new rules
‘Better Regulation’ in veterinary medicines

- Better availability of veterinary medicines
- Accessible information on veterinary medicines available in the EU
- Reducing the risks of antimicrobial resistance
- Encouraging pharmacovigilance reporting

- Certain antimicrobials to be reserved to human use
- Restrictions in use of antimicrobials under the cascade
- Preventative use prohibited, metaphylaxis only under specific conditions
- Member States to collect farm level information on the use of antimicrobials in food-producing animals & later in companion animals (phased implementation), extended sales data collection
- Imported animals/produce to comply with EU rules on growth promotion and antimicrobials reserved for human use

The Veterinary Medicines Regulation and its new rules

Encourage and monitor prudent use of antimicrobials
‘Better Regulation’ in veterinary medicines

- Improved pharmacovigilance reporting and evaluation system
- Public access to safety profile of each product, incidence of suspected adverse events reported each year (by product, animal species & type of event, incl. events humans, lack of efficacy, environmental issues)
- Possibility to impose specific requirements for veterinarians in relation to reporting of suspected adverse events
- Agency may organise meetings for groups of veterinary healthcare professionals in case of a specific need for collecting, collating or analysing specific pharmacovigilance data

The Veterinary Medicines Regulation and its new rules
Timeline

Approved on 11 December 2018

Published on 7 January 2019; effective since 27 January 2019

Becomes applicable in January 2022

3-year implementation period
20 Implementing or Delegated Acts foreseen to be developed during the implementation period
EU network collaboration to implement the new rules

**European Commission**
Responsible for implementation of any legislative acts, such as Regulation 2019/6.

**European Medicines Agency**
- Provides advice on the content of follow-on legislation
- Prepares for and supports the implementation of the Regulation
- Provides regulatory, technical/procedural advice during and after the implementation
- *This does not include general interpretations of the legislation.*

**Member States**
Agree on the follow-on legislation via Committees hosted by the EC or in co-decision by the Council and Parliament

10 The Veterinary Medicines Regulation and its new rules

*Classified as internal/staff & contractors by the European Medicines Agency*
Mandates for provision of EMA scientific recommendations on implementing and delegated acts (1/3)

- The Regulation provides for implementing legislation - 20 Implementing or Delegated Acts foreseen to be developed (on specific topics, such as pharmacovigilance, data collection on sale and use of antimicrobials)
- The Agency is requested to provide **scientific recommendations** on the basis of which the Commission will prepare delegated or implementing acts
- No stakeholder consultation will take place during this phase
- Stakeholders will be consulted on the draft delegated and implementing acts during the following phase, led by the European Commission
Mandates for provision of EMA scientific recommendations received in January 2019

1. **Revision of Annex II (delegated act)**
   - Recommendations sent 30 August 2019

2. **Collection of data on antimicrobials used in animals (delegated act)**
   - Recommendations sent 30 August 2019

3. **List of variations not requiring assessment (implementing act)**
   - Recommendations sent 30 August 2019

4. **Union database (implementing act)**
   - Recommendations sent 30 August 2019

5. **Criteria to designate antimicrobials to be reserved for humans (delegated act)**
   - Recommendations sent October 2019

6. **Pharmacovigilance system master file (implementing act)**
   - Recommendations sent May 2020

7. **Measures on good pharmacovigilance practice (implementing act)**
   - Recommendations sent May 2020
Mandates for provision of EMA scientific recommendations received in July 2019

- **Rules on VMPs for oral administration**
  - (delegated act)
  - Recommendations sent April 2020

- **Good distribution practice for VMP**
  - (implementing act)
  - Recommendations sent June 2020

- **Good distribution practice for active substances**
  - (implementing act)
  - Recommendations sent June 2020

- **Format of data collected on antimicrobials used in animals**
  - (implementing act)
  - Recommendations sent June 2020

- **List of antimicrobials to be reserved for humans**
  - (implementing act)
  - Recommendations initially requested by October 2020, delayed

- **Restrictions to use of antimicrobials under the cascade**
  - (implementing act)
  - Recommendations requested by February 2021, delayed
EMA website on Implementation ofVeterinary Medicines Regulation


Mandates, advices and other updates are published as they become available!
Overview

The Veterinary Medicines Regulation and its new rules

1. The Veterinary Regulation
2. Programme Change Management
3. Vision
4. Scope
5. Governance
6. Project updates

VMP-Reg Programme
VMP-Reg programme – vision

**Support the functioning of the Veterinary Medicines Regulation**
The regulatory processes are implemented and transferred into the business

Stable and reliable IT solutions are delivered and improved in an incremental approach.

**Support the functioning of the single market**
The IT solutions delivered provide a central point of information on the availability and safety of veterinary medicines marketed in all EU Member States

**Increased transparency**
The general public has easy access to all non-confidential data related to veterinary medicines

**Support the harmonisation of veterinary medicinal product information**
The IT solutions delivered use, as much as possible, structured data and controlled vocabularies.

Information on veterinary medicinal products undergoing harmonisation procedures can be centrally identified

**Reduced administrative burden**
Integrated IT solutions with adequate data quality and minimal duplication of data enable the revised regulatory procedures

The Veterinary Medicines Regulation and its new rules

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VMP-Reg programme – scope

**Union Product Database**
To store and make available information on different types of authorised veterinary medicinal products, at EU level.

**Union Pharmacovigilance Database**
To store and make available information on suspected adverse events for all veterinary medicinal products authorised in the Union.

**Union Database on Manufacturing and Wholesale Distribution**
To store and make available information on manufacturing and wholesale distribution data in the European Union and will support the management of the information related to manufacturing authorisations and outcomes of inspections activities.

**Collection of data on Sales and Use of Antimicrobials in Animals**
To store and make available information on the sales and use of antimicrobials.

**Required interconnections**

**Any required changes to business processes that are not related to IT solutions, within the Agency**
VMP-Reg programme – IT systems overview

Manufacturing and Wholesale Distribution Database

Union Product Database

Union Pharmacovigilance Database

Antimicrobials Sales and Use

Public information
- Product data
- Incidence data
- AM data report
Implications of Regulation (EU) 2019/6 - Data collection for antimicrobials

**Current system - ESVAC**

- Data collection on sales of veterinary antimicrobials under ESVAC voluntary
- Participation of the EMA in JIACRA at the request of the Commission

**Future system - Regulation (EU) 2019/6**

- **Mandatory** collection of sales data for veterinary antimicrobials, supplemented by voluntary data collection
- **Mandatory** collection of use data for antimicrobials in animals supplemented by voluntary data in a phased approach
- JIACRA reports become a core activity of the EMA (Regulation (EU) 2019/5)
Implications of Regulation (EU) 2019/6
- Data collection for antimicrobials

<table>
<thead>
<tr>
<th>Delegated act</th>
<th>Specific formats for the data to be submitted on</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandatory resp. voluntary sales and use data on antimicrobials</td>
<td>• Sales of veterinary antimicrobials</td>
</tr>
<tr>
<td>Data as no of packs/presentation</td>
<td>• Use of antimicrobials in animals</td>
</tr>
<tr>
<td>Timelines</td>
<td></td>
</tr>
<tr>
<td>Quality control requirements</td>
<td></td>
</tr>
<tr>
<td>Considerations on availability of animal numbers</td>
<td></td>
</tr>
<tr>
<td>Continuous (semi)automated data collection system or other appropriate systems that enable direct or indirect evaluation of use at farm level</td>
<td></td>
</tr>
</tbody>
</table>
### Table 2. Categories and ATC/ATCvet codes and names of antimicrobial medicinal categories for which collection and reporting of sales and use data is **mandatory** (ATC and ATCvet codes in bold) and for which it is **voluntary** (ATC and ATCvet codes in italic)

<table>
<thead>
<tr>
<th>Categories of veterinary antimicrobial agents</th>
<th>SALES ATCvet codes</th>
<th>USE ATCvet and ATC codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antidiarrheals, intestinal anti-inflammatory / antiinfective agents</td>
<td>QA07AA QA07AB QA07AX03 QA07AX04</td>
<td>QA07AA/A07AA QA07AB QA07AX03/QA07AX04</td>
</tr>
<tr>
<td>Gynaecological antiinfectives and antiseptics</td>
<td>QG01AA QG01AE QG01BA QG01BE</td>
<td>QG01AA/G01AA QG01AE/G01AE QG01BA/G01BA QG01BE/G01BE</td>
</tr>
<tr>
<td>Antiinfectives and antiseptics for intrauterine use</td>
<td>QG51AA QG51AG</td>
<td>Included in current ESVAC sales</td>
</tr>
<tr>
<td>Antibacterials for systemic use</td>
<td>QJ01</td>
<td>QJ01/J01</td>
</tr>
<tr>
<td>Antibacterials for intramammary use</td>
<td>QJ51</td>
<td>QJ51</td>
</tr>
<tr>
<td>Antiprotozoals (with antibacterial effect)</td>
<td>QP51AG</td>
<td>QP51AG</td>
</tr>
<tr>
<td>Categories of veterinary antimicrobial agents</td>
<td>SALES</td>
<td>USE</td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>-------</td>
<td>-----</td>
</tr>
<tr>
<td>Antibiotics and chemotherapeutics for dermatological use</td>
<td>QD06</td>
<td>Not included in current ESVAC sales</td>
</tr>
<tr>
<td>Other nasal preparations</td>
<td>QR01AX06, QR01AX08</td>
<td>Not included in current ESVAC sales</td>
</tr>
<tr>
<td>Antimycobacterials for intramammary use</td>
<td>QJ54</td>
<td>QS01AA, QS01AB, QS01AD, QS01AE, QS01CA, QS01CC</td>
</tr>
<tr>
<td>Ophthalmological antiinfectives</td>
<td>QS02AA, QS02CA, QS03AA, QS03CA</td>
<td>QS02AA, QS02CA, QS03AA, QS03CA/ S02AA, S02CA, S03AA, S03CA</td>
</tr>
<tr>
<td>Otological antiinfectives</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antiproteozoals (other than QP51AG)</td>
<td>QP51</td>
<td>QP51 /P01</td>
</tr>
<tr>
<td>Antifungals for topical use</td>
<td>QD01A</td>
<td>QD01A /D01A</td>
</tr>
<tr>
<td>Antifungals for systemic use</td>
<td>QD01B</td>
<td>QD01B/D01B</td>
</tr>
<tr>
<td>Antimycotics for systemic use</td>
<td>QJ02</td>
<td>QJ02 /J02</td>
</tr>
<tr>
<td>Antimycobacterials</td>
<td>QJ04</td>
<td>QJ04/J04</td>
</tr>
<tr>
<td>Antivirals for systemic use</td>
<td>QJ05</td>
<td>QJ05 /J05</td>
</tr>
</tbody>
</table>
### Stepwise approach to use data collection (1)

**Table 3.** Animal species, including fish, for which antimicrobial use data are to be provided and data sources for animal population data

<table>
<thead>
<tr>
<th>By 2024</th>
<th>By 2027</th>
<th>By 2030</th>
<th>Data source for animal population (biomass produced farmed fish)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cattle</strong></td>
<td><strong>Cattle</strong></td>
<td><strong>Cattle</strong></td>
<td>Eurostat</td>
</tr>
<tr>
<td>All production categories, and specifying use in bovines &lt; 1 year&lt;sup&gt;a&lt;/sup&gt;</td>
<td>All production categories, and specifying use in bovines &lt; 1 year&lt;sup&gt;a&lt;/sup&gt;</td>
<td>All production categories, and specifying use in bovines &lt; 1 year&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td><strong>Pigs</strong></td>
<td><strong>Pigs</strong></td>
<td><strong>Pigs</strong></td>
<td>Eurostat</td>
</tr>
<tr>
<td><strong>Poultry</strong></td>
<td><strong>Poultry</strong></td>
<td><strong>Poultry</strong></td>
<td>Eurostat or national data for species or categories where production level is &lt;10,000 tonnes slaughtered per year (e.g. geese, fattening turkeys)</td>
</tr>
<tr>
<td>- Chickens</td>
<td>- Chickens</td>
<td>- Chickens</td>
<td></td>
</tr>
<tr>
<td>- Turkeys</td>
<td>- Turkeys</td>
<td>- Turkeys</td>
<td></td>
</tr>
<tr>
<td>All production categories or stages for each species, including breeders, layers, broilers for chickens, and fattening turkeys</td>
<td>All production categories or stages for each species</td>
<td>All production categories or stages for each species</td>
<td></td>
</tr>
</tbody>
</table>
## Stepwise approach to use data collection (2)

<table>
<thead>
<tr>
<th>By 2024</th>
<th>By 2027</th>
<th>By 2030</th>
<th>Data source for animal population (biomass produced farmed fish)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sheep</td>
<td>Sheep</td>
<td></td>
<td>Eurostat</td>
</tr>
<tr>
<td>Goats</td>
<td>Goats</td>
<td></td>
<td>Eurostat</td>
</tr>
<tr>
<td>Finfish</td>
<td>Finfish</td>
<td></td>
<td>Eurostat or national data</td>
</tr>
<tr>
<td>Horses – both food-producing and non-food-producing</td>
<td>Horses – both food-producing and non-food-producing</td>
<td>National data(b)</td>
<td></td>
</tr>
<tr>
<td>Rabbits (food-producing)</td>
<td>Rabbits (food-producing)</td>
<td>National data</td>
<td></td>
</tr>
<tr>
<td>Any other food-producing animals(c)</td>
<td>Any other food-producing animals(d)</td>
<td>National data</td>
<td></td>
</tr>
<tr>
<td>Dogs</td>
<td></td>
<td></td>
<td>National data(d)</td>
</tr>
<tr>
<td>Cats</td>
<td></td>
<td></td>
<td>National data(d)</td>
</tr>
<tr>
<td>Fur animals</td>
<td></td>
<td></td>
<td>National data(d)</td>
</tr>
<tr>
<td>• Minks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Foxes</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(a) For Member States where production is more than 10 000 tonnes slaughtered/year in line with Commission Implementing Decision 2013/652/EU
(b) For some countries based on estimates obtained through sample surveys performed at regular intervals
(c) Specifying the species reported; may vary per Member State.
Implications of Regulation (EU) 2019/6
- Data format

• Same requirements for mandatory and voluntary data

• Builds on experience gained with the ESVAC project

• Separate but congruent specification of format for sales and use data

3.1. Format of sales data

The reporting of data on the volume of sales of antimicrobial medicinal products used in animals to the Agency should include the following components (variables) per each product presentation. These variables should be reported also for antimicrobial sales data that can be submitted on voluntary basis.

3.1.1. Variables to be submitted

1. ISO Country code
   - Description: 2 letter code (alpha-2 code), according to the International Standard for country codes (ISO, 2013).
   - Purpose: To identify country for which sales data are reported.

2. Year
   - Description: Four-digit number.
   - Purpose: To identify the calendar year for which sales data were collected and submitted.
Implications of Regulation (EU) 2019/6
- Transparency on veterinary medicinal products

- Authorised products across the EU
- => Identification of treatment alternatives
- Availability of products
- Adverse events reported after use
- Incidence of adverse reactions
Implications for farmers, veterinarians and on data collection

**Farmers**
- Better information on vet meds
- Better availability
- Better feedback on adverse events
- Active role in data collection
- Restrictions re AMs apply internationally

**Veterinarians**
- Better information on vet meds
- Better availability
- Better feedback on adverse events
- Expanded cascade rules – better therapeutic options, though restrictions on certain AMs
- Active role in data collection

**Data collection**
- Mandatory and voluntary sales data collection (Antibacterials included in ESVAC = mandatory)
- Implementation of (farm level) use data collection for antimicrobials (incl. human medicines)
Any questions?

Further information

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