EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

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

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An agency of the European Union

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, …

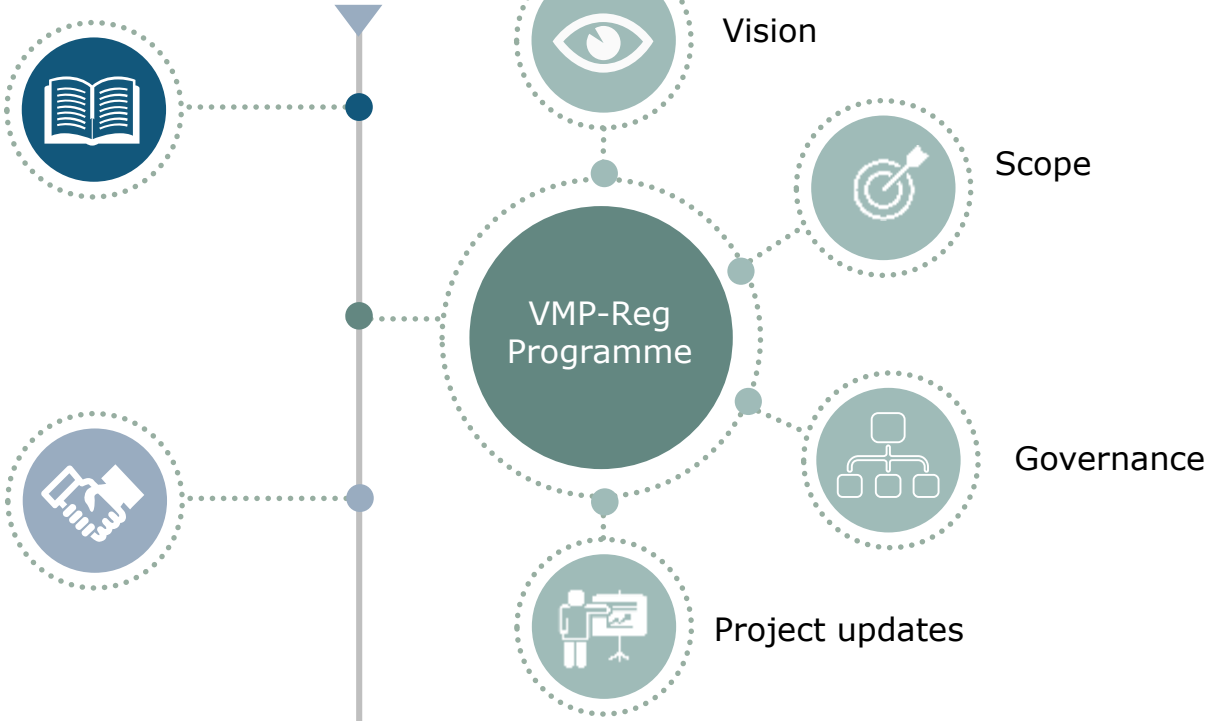
Actions on antimicrobial resistance: on request from the European Commission (ESVAC, AMEG)

Overview

The Veterinary Regulation

[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, published 7.1.2019 in OJ L 44]

Programme Change Management



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

- 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

‘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

Encourage and monitor prudent use of antimicrobials

‘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

- 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

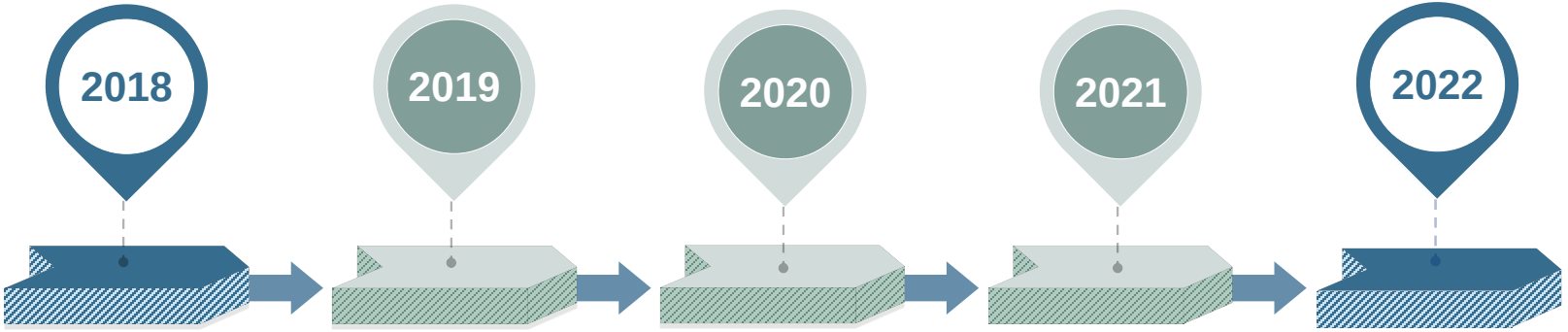
Improved information on safety profile of specific products, and a chance to get involved

Timeline

Approved on 11 December 2018

Published on 7 January 2019; effective since 27 January 2019

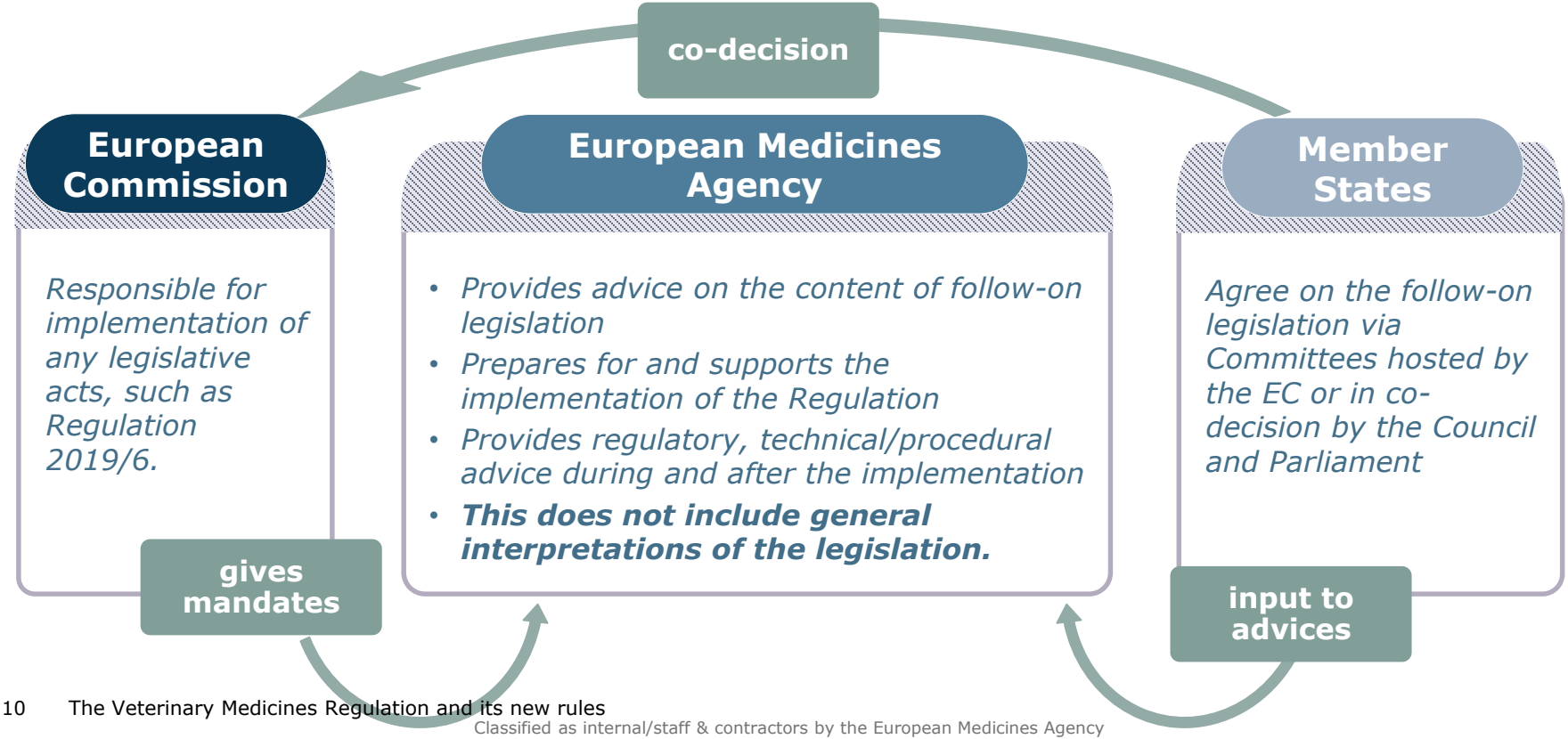
Becomes **applicable in January 2022**



3-year implementation period

20 Implementing or Delegated Acts foreseen to be developed during the implementation period

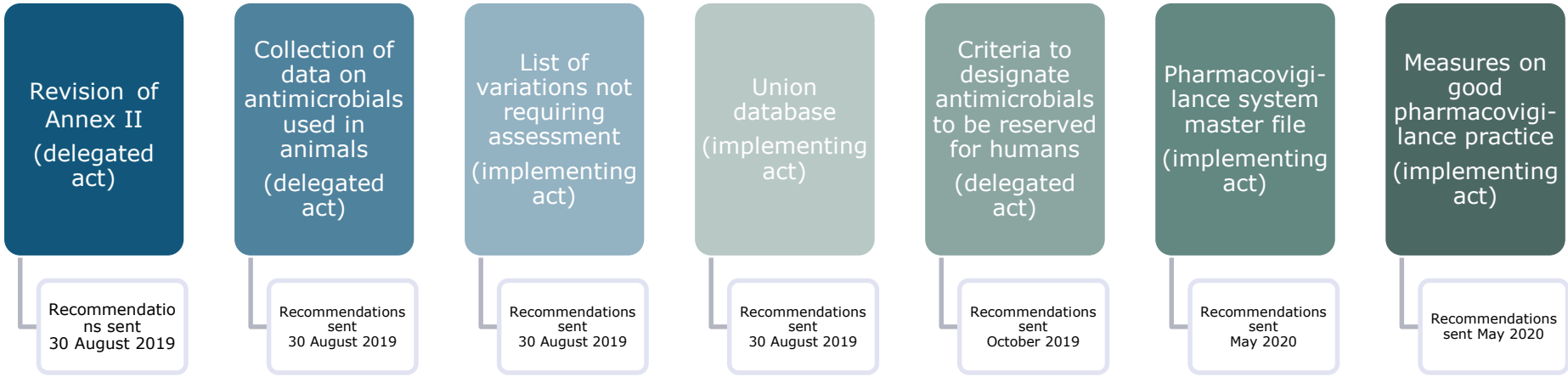
EU network collaboration to implement the new rules



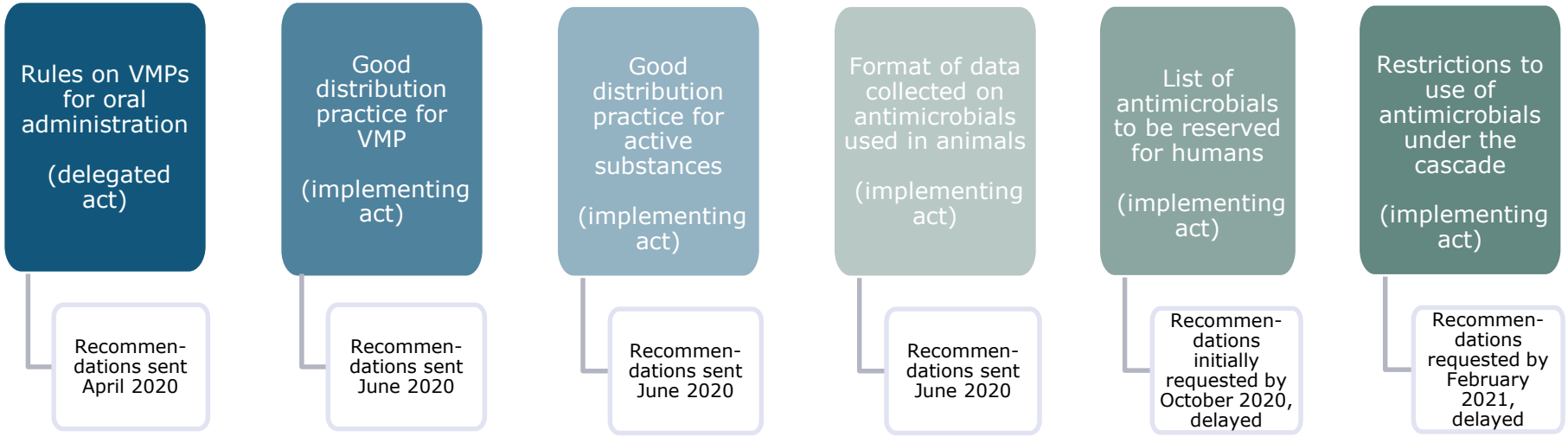
Mandates for provision of EMA scientific recommendations on implementing and delegated acts (1/3)

- 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



Mandates for provision of EMA scientific recommendations received in July 2019

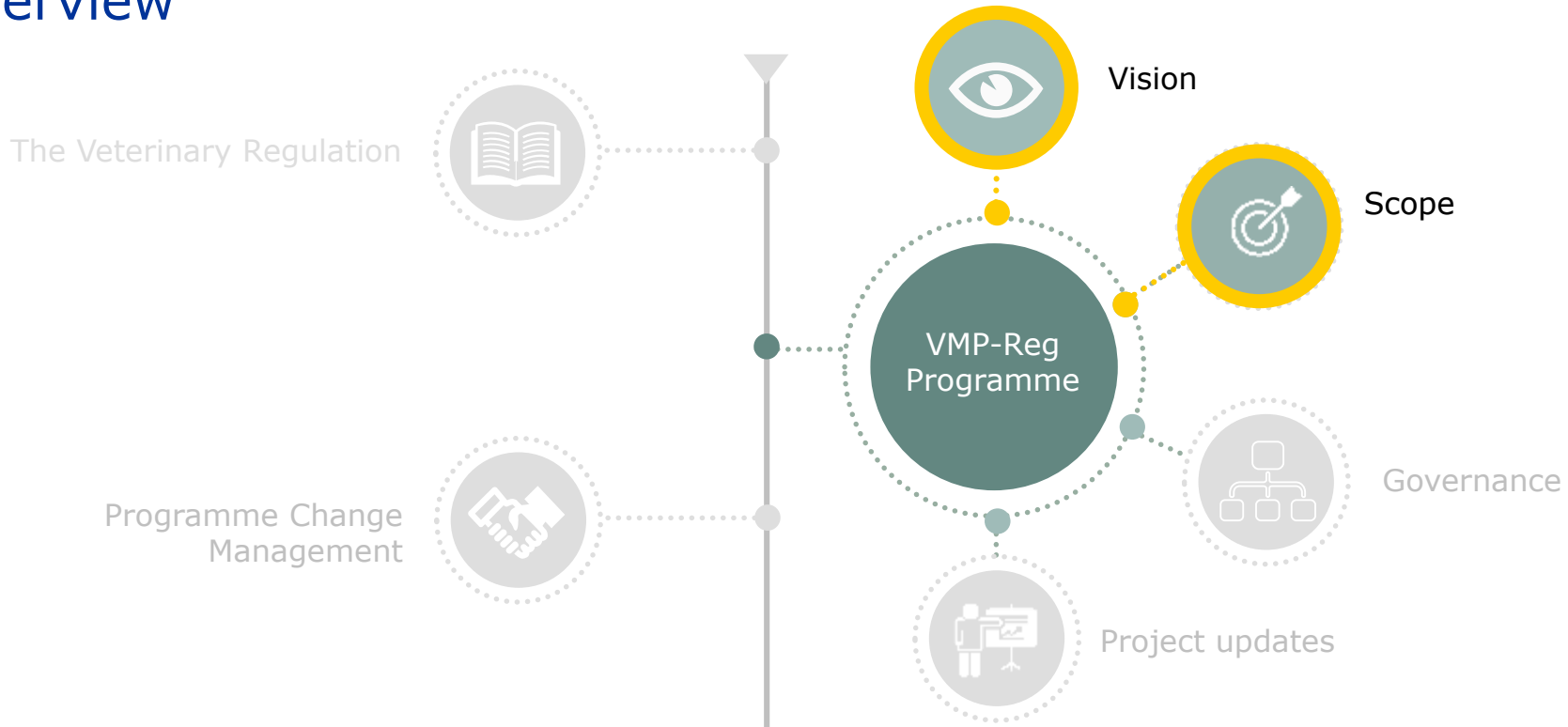


EMA website on Implementation of Veterinary Medicines Regulation

https://www.ema.europa.eu/en/veterinary-regulatory/overview/implementation-new-veterinary-medicines-regulation

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

Overview



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

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.

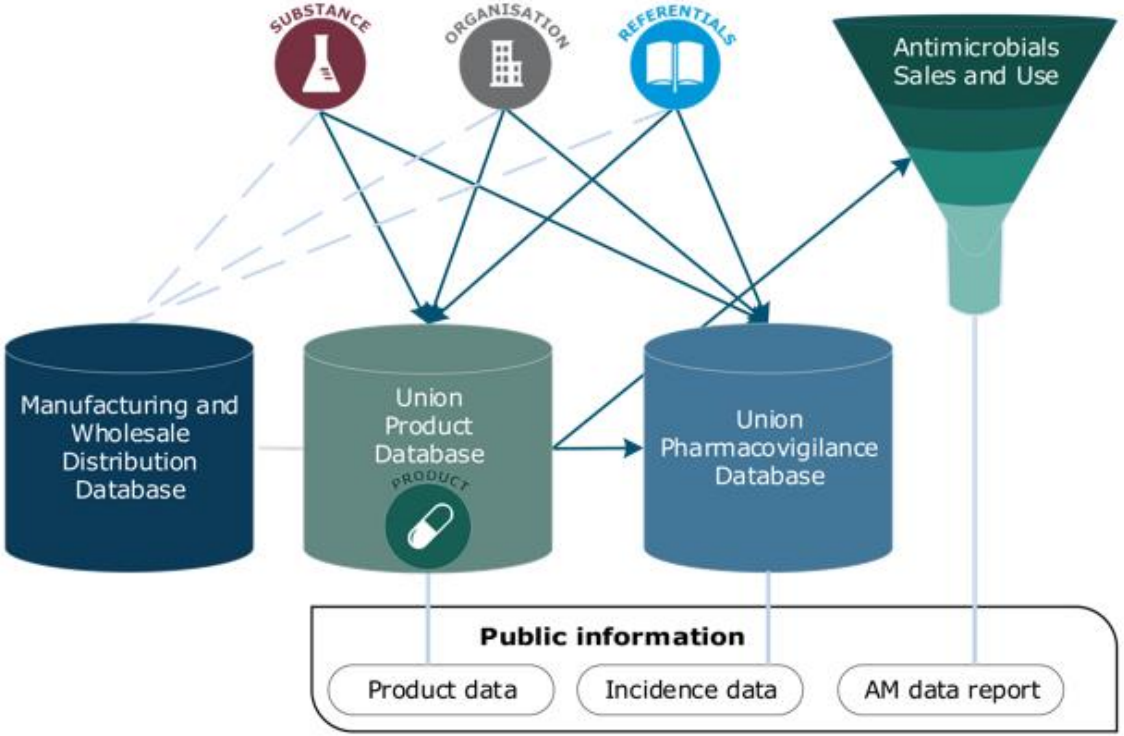
Collection of data on Sales and Use of Antimicrobials in Animals

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

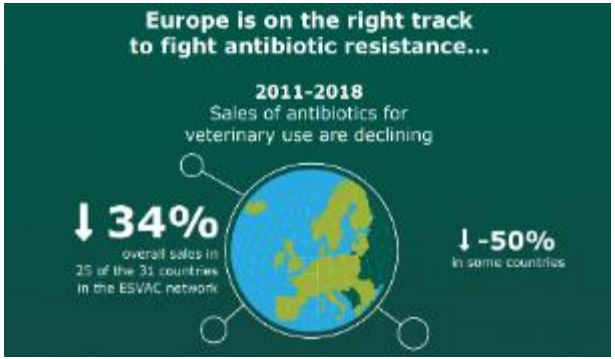
VMP-Reg programme – IT systems overview



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

Delegated act

Mandatory resp. voluntary sales and use data on antimicrobials

Data as no of packs/presentation

Timelines

Quality control requirements

Considerations on availability of animal numbers

Continuous (semi)automated data collection system **or** other appropriate systems that enable direct or indirect evaluation of use at farm level

Implementing act

Specific formats for the data to be submitted on

- Sales of veterinary antimicrobials
- Use of antimicrobials in animals

Table 2. Categories and ATC/ATCvet codes[10] 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)

Categories of veterinary antimicrobial agents	SALES ATCvet codes		USE ATCvet and ATC codes
Antidiarrheals, intestinal anti-inflammatory / antiinfective agents	**QA07AA** **QA07AB** **QA07AX03** **QA07AX04**	Included in current ESVAC sales	**QA07AA /A07AA** **QA07AB** **QA07AX03 / A07AX03** **QA07AX04 / A07AX04**
Gynaecological antiinfectives and antiseptics	**QG01AA** **QG01AE** **QG01BA** **QG01BE**		**QG01AA/G01AA** **QG01AE/G01AE** **QG01BA/G01BA** **QG01BE/G01BE**
Antiinfectives and antiseptics for intrauterine use	**QG51AA** **QG51AG**		**QG51AA**
Antibacterials for systemic use	**QJ01**		**QJ01/J01**
Antibacterials for intramammary use	**QJ51**		**QJ51**
Antiprotozoals (with antibacterial effect)	**QP51AG**		**QP51AG**

Categories of veterinary antimicrobial agents	SALES ATCvet codes		USE ATCvet and ATC codes
Antibiotics and chemotherapeutics for dermatological use	**QD06**	Not included in current ESVAC sales	*QD06 /D06*
Other nasal preparations	**QR01AX06, QR01AX08**		*QR01AX06 / R01AX06, QR01AX08 / R01AX08*
Antimycobacterials for intramammary use	**QJ54**		*QJ54*
Ophthalmological antiinfectives	**QS01AA, QS01AB, QS01AD, QS01AE, QS01CA, QS01CC**		*QS01AA, QS01AB, QS01AD, QS01AE QS01CA, QS01CC / S01AA, S01AB, S01AD, S01AE, S01CA, S01CC*
Otological antiinfectives	**QS02AA, QS02CA, QS03AA, QS03CA**		*QS02AA, QS02CA, QS03AA, QS03CA/ S02AA, S02CA, S03AA, S03CA*
Antiprotozoals (other than QP51AG)	*QP51*	Not Included in current ESVAC sales	*QP51 /P01*
Antifungals for topical use	*QD01A*		*QD01A /D01A*
Antifungals for systemic use	*QD01B*		*QD01B/D01B*
Antimycotics for systemic use	*QJ02*		*QJ02 /J02*
Antimycobacterials	*QJ04*		*QJ04/J04*
Antivirals for systemic use	*QJ05*		*QJ05 /J05*

Stepwise approach to use data collection (1)

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

By 2024	By 2027	By 2030	Data source for animal population (biomass produced farmed fish)
Cattle All production categories, and specifying use in bovines < 1 year[(a)]	**Cattle** All production categories, and specifying use in bovines < 1 year[(a)]	**Cattle** All production categories, and specifying use in bovines < 1 year[(a)]	Eurostat
Pigs	**Pigs**	**Pigs**	Eurostat
Poultry • **Chickens** • **Turkeys** All production categories or stages for each species, including breeders, layers, broilers for chickens, and fattening turkeys	**Poultry** • **Chickens** • **Turkeys** • **Ducks** • **Geese** All production categories or stages for each species	**Poultry** • **Chickens** • **Turkeys** • **Ducks** • **Geese** All production categories or stages for each species	Eurostat or national data for species or categories where production level is <10 000 tonnes slaughtered per year (e.g. geese, fattening turkeys)

Stepwise approach to use data collection (2)

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By 2024	By 2027	By 2030	Data source for animal population (biomass produced farmed fish)
	Sheep	**Sheep**	Eurostat
	Goats	**Goats**	Eurostat
	Finfish	**Finfish**	Eurostat or national data
	Horses – both food-producing and non-food-producing	**Horses** – both food-producing and non-food-producing	National data[(b)]
	Rabbits (food-producing)	**Rabbits** (food-producing)	National data
	Any **other food-producing animals**[(c)]	Any **other food-producing animals**[(d)]	National data
		Dogs	National data[(d)]
		Cats	National data[(d)]
		Fur animals • **Minks** • **Foxes**	National data[(d)]

[(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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