



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA contribution to a One Health approach addressing antimicrobial resistance

The veterinary perspective

Presented by Dr Ivo Claassen on 11 January 2021
Head of Veterinary Medicines Division

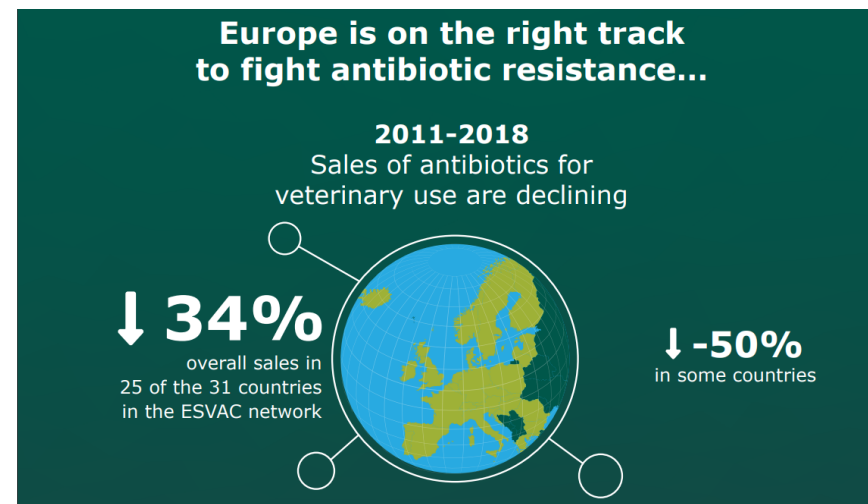
An agency of the European Union





Content

1. AMR in the European context
2. Sales data
3. Better regulation
4. Upcoming new actions for veterinary medicines – Regulation (EU) 2019/6
5. International collaboration



AMR in the European context – a One Health Approach

EU One Health Action Plan against AMR –

https://ec.europa.eu/health/antimicrobial-resistance/eu-action-on-antimicrobial-resistance_en

EU Guidelines on prudent use of antimicrobials in human health

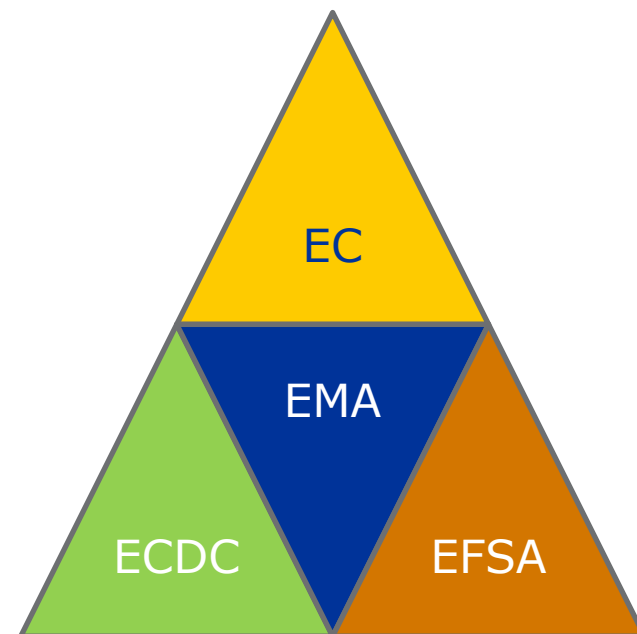
[https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52017XC0701\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52017XC0701(01))

EMA: - human and veterinary medicines authorisation
- surveillance of veterinary antimicrobial consumption (ESVAC)
- better regulation of human & veterinary medicines

ECDC: - EARS-Net – EU antimicrobial resistance surveillance (human),
- ESAC-Net – EU surveillance of a consumption (human)
- FWD-Net – EU Food- & Waterborne Diseases & Zoonoses net

EFSA: - resistance monitoring in zoonotic bacteria (veterinary)
- Scientific Network for Zoonosis Monitoring Data

EMA-ECDC-EFSA together: JIACRA reports (joint inter-agency antimicrobial consumption and resistance analysis)





European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)

- Launched in 09/2009 by the EMA as a project mandated by the EC with 9 countries
- 2020: 10th report, 31 countries (EU 27 plus CH, IS, NO, UK)
- Between 2011 and 2018, sales have reduced by:
 - ↓ 34% for **overall** sales;
 - ↓ 24% for third and fourth generation **cephalosporins**;
 - ↓ 70% for **polymyxins**;
 - ↓ 4% for **fluoroquinolones**;
 - ↓ 74% for other **quinolones**.
- Mixed picture across the EU, even increase over time in a few countries

Spatial distribution of overall sales of all antimicrobials for food-producing animals, in mg/PCU, for 31 countries, for 2018



3. Better regulation of veterinary medicines

The Committee's for Veterinary Medicinal Products CVMP strategy on antimicrobials ([2021-2025 in development](#))

CVMP guidelines on

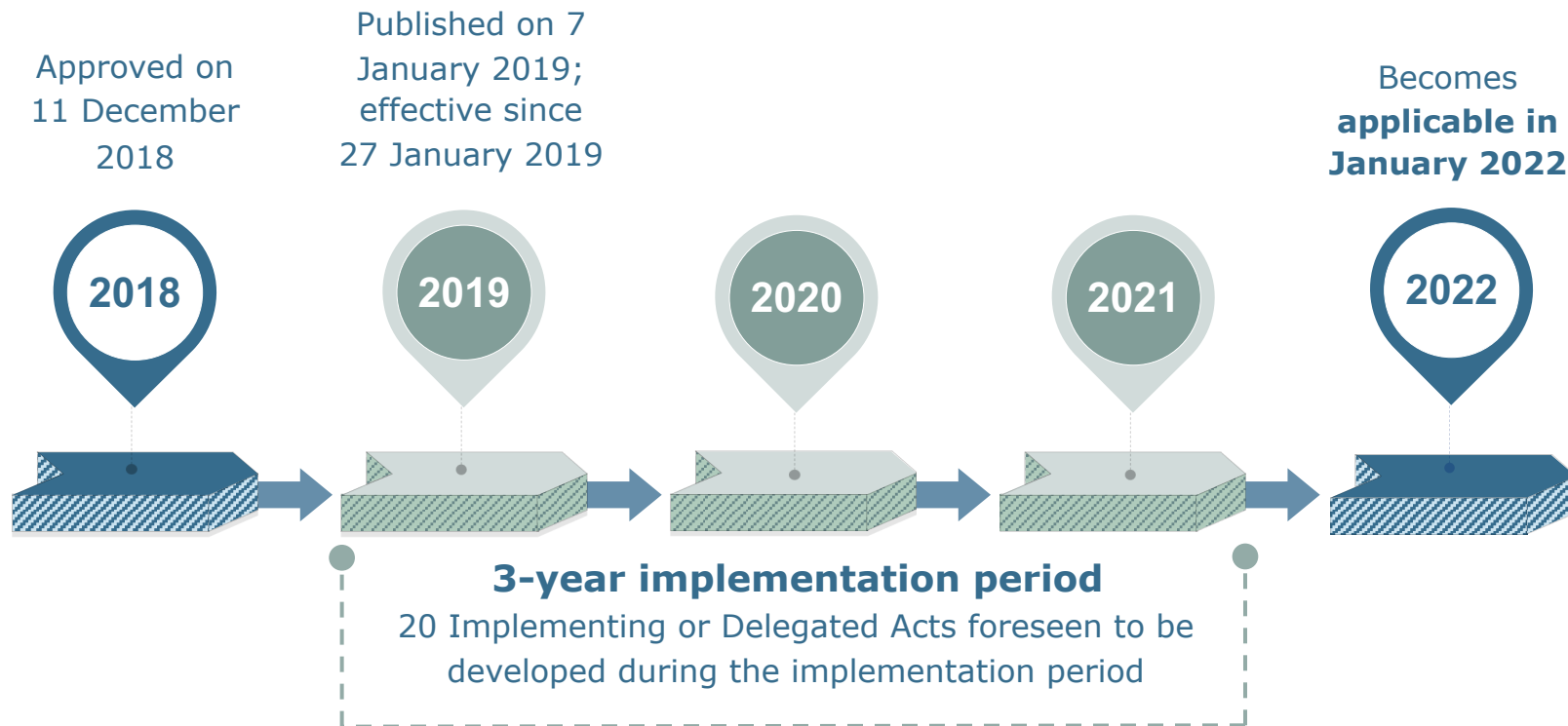
- [Efficacy of antimicrobial VMPs](#)
- [AMR public health risk assessment](#)
- [SPC of antimicrobial VMPs](#)

Additional resources:

- EMA and EFSA Joint Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety ([RONAFA](#))
- Updated [AMEG categorisation of antibiotics](#)
- CVMP Reflection paper on authorisation of [Alternatives to Antibiotics](#)
- AMEG advice on [preliminary risk profiling](#) for new veterinary antimicrobials

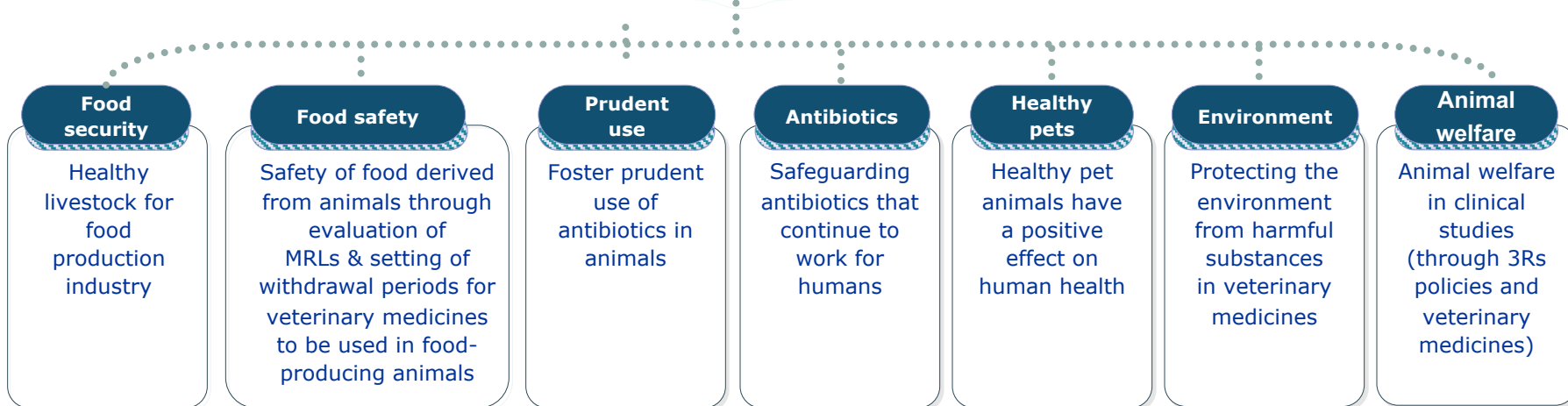
4. Regulation (EU) 2019/6 on VMPs

Timeline



4. Regulation (EU) 2019/6 on VMPs

We must increase awareness of the social and economic relevance of the activities related to veterinary medicines – **most of what we do has an effect on people.**



Specific actions for AMR



Extended collection of antimicrobial sales data



Collection of data on use of antimicrobials in animals (stepwise approach)



List of antimicrobials reserved for human use based on specific criteria (under development)



Restriction of legally allowed use outside the terms of the marketing authorisation for certain antimicrobials



5. International collaboration

[Limited during the implementation for Regulation (EU) 2019/6]

VICH

Codex Alimentarius TFAMR

TATFAR

OIE Antimicrobials Working Group



Any questions?

Further information

ivo.claassen@ema.europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Telephone +31 (0)88 781 6000

Send us a question Go to www.ema.europa.eu/contact

Follow us on  **@EMA_News**