EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4. ESVAC guidance on species data – State of play

ESVAC stakeholders annual meeting 2017

Presented by Claire Chauvin (Chair ESVAC species EAG) and Marian Bos (EMA/ESVAC) on 3 March 2017

Current situation in Europe

- Eight countries have data collection system in place for one or more species.
- In six more countries data collection system is under development.

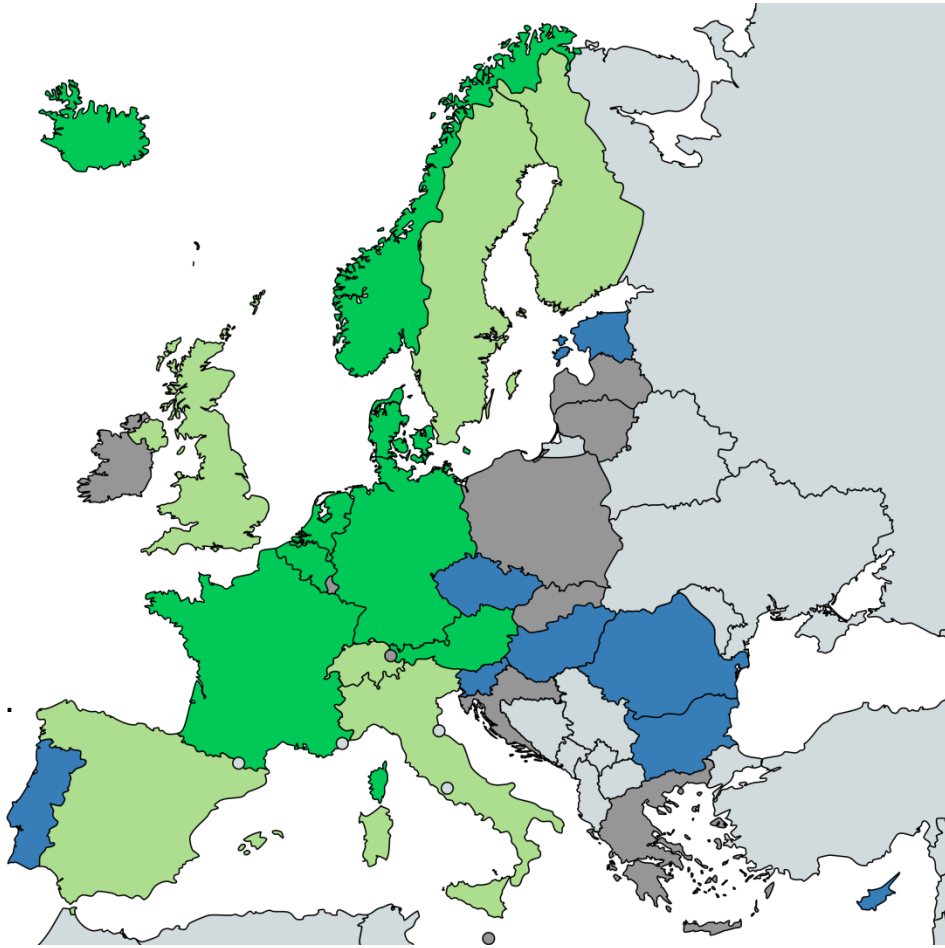
→ Included species/categories vary.

→ Coverage per species varies.

→ Initiator varies (e.g. government, industry).

→ Data sources vary.

→ Variables vary.



Guidance and legislation

- Data collection by species not mandatory in EU/EEA countries - this may change after ongoing revision of regulation on Veterinary Medicinal Products.
- Guidance sets standards for data if to be provided to EMA.
- Guidance discusses possible data collection models.
- European Commission will outline requirements in delegating/implementing acts.
- Guidance might help European Commission in setting those requirements.

Objectives of publishing guidance

- Ensure standardisation of key elements of data collection process for those already (or planning to start) collecting data by species and wanting to voluntarily provide those data to EMA.
  - Should encourage Member States to initiate collection of data by species.
  - Avoid non-harmonisation of provided data.
- Provide information for setting up data collection system for those who aim to do so.
- Prepare for meeting potential requirements (systems and procedures) for EMA and National Competent Authorities in revised regulation.

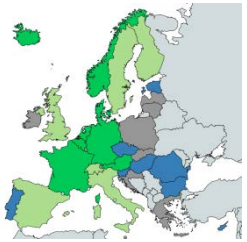
Considerations and scope for guidance

- Collecting use data by animal species is expensive.
- Some Member States might want to collect more data (on indication, more animal categories, etc.); others not for all animal categories suggested.
  - Phased approach suggested.
- Pragmatic approach needed.
- Guidance covers priority animal categories in terms of antimicrobial use.
- If MS wants to provide data to EMA, these data should follow the standards set out in guidance.

Animal categories

To be determined by MSs and/or EC

No harmonised collection of data by species



AMR monitoring (in legislation)

- Broilers
- (Fattening) turkeys
- (Fattening) pigs
- Bovine animals < 1 year

Draft guidance: AMR monitoring + other species

- Broilers
- Turkeys
- Pigs
- Bovine animals < 1 year
- Dairy cattle
- Beef cattle

Ultimate: All species

- Broilers
- Turkeys
- Pigs
- Bovine animals < 1 year
- Dairy cattle
- Beef cattle
- Companion animals
- Fish
- Horses
- Other food producing species (sheep, rabbits, etc.)

Frequency of providing data to EMA

To be determined by MSs and/or EC

Alternating years per species

AMR monitoring

2017	2018	2019	2020
Pigs Bovine < 1 yr	Broilers Turkeys	Pigs Bovine < 1 yr	Broilers Turkeys

Annually per species

(phased approach)

2017	2018	2019	2020
Pigs ...	Pigs Broilers ...	Pigs Broilers Bovine < 1 yr ...	Pigs Broilers Bovine < 1 yr Turkeys ...

EXAMPLE

Coverage of animal production

To be determined by MSs and/or EC

‘Census’

Full coverage

National=sample population

Well-designed random sampling

‘Sample survey’

Representative coverage

Sample population

Use data to be provided to EMA

- Data collection period: one calendar year.
- Antimicrobial agents:

ATCvet group	ATCvet code
Antimicrobial agents for intestinal use	QA07AA; QA07AB
Antimicrobial agents for intrauterine use	QG01AA; QG01AE; QG01BA; QG01BE; QG51AA; QG51AG
Antimicrobial agents for systemic use	QJ01
Antimicrobial agents for intramammary use	QJ51
Antimicrobial agents used as antiparasitic agents[a]	QP51AG

[a] Only sulphonamides are to be collected and reported.

- Data per species (category) per country:
  - Number of packs/VMP presentation.
  - Exploring option of providing quantity active substance/administration route.

Required variables on use

Variable	Justification
Country	To identify country which collected data
Year	To identify time period (calendar year) for collected data
Species	To identify animal species (or category where applicable) for which data are collected
Name of VMP	To identify antimicrobial veterinary medicinal product used
Form	To identify pharmaceutical form (needed for further analysis of data)
Pack size	To enable calculation of amount of active substance in each VMP presentation
Pack size unit	To enable calculation of amount of active substance in each VMP presentation
ATCvet	Only latest version of ATCvet codes should be used
Number of packs	To calculate weight of active substance sold for each VMP presentation

Animal population data to be provided to EMA

- Data collection period: one calendar year.
- Denominator: animal biomass at risk of being treated with antimicrobials.
  - Calculated by multiplying numbers of animals with standard average weight at treatment.
- Depending on animal species/category:
  - Number of slaughtered/produced animals in a country;
  - Number of living animals present in a country (e.g. sows and dairy cows).
  - Number of animals traded for fattening or slaughter within EU/EEA.
- If census: data can be collected from Eurostat and TRACES, otherwise from other (national) sources.

Final remarks

- Data by animal species/category would be presented as:
  - Mg/kg animal biomass;
  - Number of Animal Defined Daily Dose (DDDvet)/kg animal biomass;
  - Number of Animal Defined Course Dose (DCDvet)/kg animal biomass.
- DDDvet/DCDvet take into account:
  - Different dosing schedules between species;
  - Difference in potency between substances.
- ESVAC will continue to collate, analyse and report sales data per PCU.
- More detailed information on collection of data by species can be provided.

Next steps and timeline

Step	Date
Present and discuss guidance at ESVAC annual meeting	2-3 March 2017
Revise and publish guidance for public consultation on website	< 14 April 2017
Present and discuss guidance at EC workshop for MSs on ESVAC project	26 April 2017
Publish final guidance on website	Q4 2017

Call for data depends on revision of legislation (content/when into force).

Depending on available resources EMA might explore application of guidance with volunteer countries.

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Thank you for your attention

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