Informal CVO, Prague, 30.9. 2022

Data collection on sales and use of antimicrobials

Questionnaire to understand the MSs needs

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We don`t want MSs to say what we expect to hear - we expect to hear what MSs want to say …

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The questionnaire main objectives:

- Identify the WP interest in **being updated with** developments **of** building the system for data collection and use **of such data**

- Identify areas more urgent **or of higher CVOs´ interest**

- Gather views on certain **strategic** issues within the CVOs´ competence

Step by step to gain the opinion on 5 areas of importance

Questionnaire sections:

A) Involvement of the Chief Veterinary Officers

B) Quality of collected data and prospects for their use at the EU and global levels

C) Use of data at national level

D) Reference animal population – biomass ("denominator")

E) Miscellaneous

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Involvement of Chiefs of Veterinary Officers

- The responsibility for data collection lies with the MS
- The system of data collection and assessment as such goes beyond the competence of medicine agencies
  - *number of stakeholders / national bodies to be involved*
- In a number of MSs, veterinary administrations directly involved in the process
- Outputs from the data collection and analysis expected to directly impact veterinary authorities
  - AMR risks assessment and management, antimicrobial policies
  - Animal health / welfare / farming practices (e.g. biosecurity)
  - Food safety / consumer protection
  - International trade / standards
  - Issues of availability of veterinary medicinal products

Quality of collected data and prospects for their use at the EU and global levels

Purposes and rules for collection and reporting of the data on Antimicrobial Sales and Use (ASU) formed by

- Framework in legislation (R 2019/6, CDR 2021/578, CIR 2022/209)

- Current practice at EU and national levels

- Use of data at International/global level – WOAH (OIE), FAO (Codex Alimentarius), WHO

- The continuous progress in the fight against AMR (One Health Platform, WOAH...) bringing new accents and themes

Now the basic parts of a long-term data collection system setup are still under development – still time for strategic look-up!!!

- Cost – benefit (sustainability / robustness / stability) – essential part of our considerations

  - properties of the data

  - priority areas for use of the data at various levels

  - addressing priorities regarding areas impacted indirectly

Use of the data at the national level

National concepts – inspiration but also co-determinant for system settings

Mapping of MSs´ activities to:

- Share experiences
- Promote discussion with all stakeholders needed for building up, implementing and use of the system
- Indicate the level of a broader use of the data collected
  (nationally, regionally, at holding levels …)

The overview obtained could be useful both

at the implementation of the EU system and at EU level,
and

at the coordination of activities at national levels

Reference animal population – biomass ("denominator")

Not only volumes of antimicrobials sold/used matters ...

- Legislation attention to data on animal population/biomass << medicines !!!

- Publicly available sources prioritized (in practice EUROSTAT, TRACES) ...
  BUT these data come from MSs as well !

- Questions arise:

  - medicinal data legislative requirements x current practice of population data reporting

  - quality of reported data x influence of final analyses and their outcomes

  - acceptable variation among Member States, animal species/categories for

    - data availability / quality

    - data retrieval methodology ?

Data availability

Data quality

Comparability ?!

Implementation lessons:
mayor impacts on the interpretation and utilisation of the data on antimicrobials

Various other comments of importance:

Regulation (EU) No 2019/6 on VMPs brings new challenges:

- till **now** only antimicrobial VMP <u>sales</u> **collected**, reported (to EMA), analysed and aggregated/commented results published/communicated in ESVAC

- **newly, the** <u>use</u> of antimicrobial medicinal products = VMPs + HMPs in animal species/categories to be collected, reported, analysed and published/communicated

PRES considers benefitial to collect comments on

- **Expectations ref cooperation between the EMA and the Member States** (both numerator and animal population/biomass agenda)

- **Approach to the 1st report of the datasets gained according the new system**

- **Specific challenges: collection – validation - reporting**

Note: ASU data collection and reporting ("numerator") has been recently consulted with the MS based on the EMA questionnaire therefore only limited attention has been paid to this area in our material

If you feel the questionnaire as very long ...

- 23 questions - BUT 💡
    - 7 (only ☺) questions are obligatory
    - 14 questions closed – just clicking ...
    - 5 queries completely free – just if you want to express more...

We hope in

- promotion of internal discussions in MSs.

- opening the horizon beyond January 1st to stakeholders.

- turning the sights from the operational level to **the final use and complex benefits**

Many thanks therefore for your efforts !

Important timings

Questionnaire release:
30. September 2022

Questionnaire return to PRES:
before 31. October 2022

Horse expert committee on denominator ☺

Thank you for your attention!

Informal CVO meeting
PRAGUE 30. 9. 2022

Questions ? Comments ?

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