



1 5 November 2020  
2 EMA/222040/2020  
3 Veterinary Medicines Division

4 **Concept paper on the reporting of antimicrobial sales and**  
5 **use in animals at the EU level**

6 Draft

Agreed by European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) ad hoc expert group on revision of indicators and denominator (written approval)	October 2020
Adopted by ESVAC network via written procedure for release for consultation	4 November 2020
Start of public consultation	12 November 2020
End of consultation (deadline for comments)	31 January 2021

7  
8

Comments should be provided using this [template](#). The completed comments form should be sent to [vet\\_guidelines@ema.europa.eu](mailto:vet_guidelines@ema.europa.eu)

9  
10

11 **1. Introduction**

12 As outlined in the Article 57 of the Regulation (EU) 2019/6, a mandatory reporting of the sales and on  
13 the use of antimicrobial medicinal products used in animals is required to enable the direct or indirect  
14 evaluation of the use of such products in food-producing animals. The Article 57 states that, the  
15 European Medicines Agency (EMA) shall cooperate with Member States and with other European Union  
16 agencies to analyse antimicrobial sales and use data and shall publish an annual report. It is requested  
17 that the EMA should take into account those data when adopting any relevant guidelines and  
18 recommendations.

19 The EMA advice on implementing measures under Article 57(3) of the Regulation (EU) 2019/6 on  
20 veterinary medicinal products – “Report on specific requirements for the collection on antimicrobial  
21 medicinal products used in animals” ([EMA/CVMP/131097/2019](#)) - recommends conducting a scientific  
22 assessment on different denominators and indicators for analysing use data.



## 23 **2. Problem statement**

24 In the context of the Regulation (EU) 2019/6 and its future delegated and implementing acts, there is  
25 a need to further develop standards, amongst others, in terms of the denominator and main indicators  
26 for the reporting of veterinary antimicrobial sales and use data.

27 The work performed in the ESVAC project constitutes a good basis for the development of such  
28 guidance.

29 When reporting data on antimicrobial sales and on use by animal species it is necessary to take into  
30 account data relating to the animal population that could potentially be treated with antimicrobials. The  
31 methodology for calculation of the current ESVAC sales denominator - the population correction unit  
32 (PCU) - has now been in place for several years. ESVAC participating countries have indicated that this  
33 denominator for sales data reporting, i.e. including animal categories to be included and weights of  
34 animals used for calculation of the sales PCU, should be revisited.

35 The EMA advice on implementing measures under Article 57(3) of the Regulation (EU) 2019/6 on  
36 veterinary medicinal products includes, amongst others, recommendations for denominators and  
37 indicators for reporting of the data. The advice also recommends conducting a scientific assessment of  
38 different denominators for reporting of use data.

39 Of note is that, until an assessment of different denominators and indicators has been conducted, the  
40 PCU will continue to be used as a denominator when reporting sales data.

41 Assessment and proposals for the denominator for sales and use data is considered as a priority task.  
42 This assessment should take into account international guidelines and recent publications worldwide  
43 concerning the reporting of antimicrobial consumption in animals.

44 Recommendations on the main indicators to present quantification of antimicrobial sales and use data  
45 are also to be established. The effects on the presentation of the quantification of antimicrobial sales  
46 data should be evaluated.

47 The overall assessment of the denominator and main indicators should provide key recommendations  
48 for description of sales and use data by country, at EU level, by animal species, as appropriate.

49 Finally, it is necessary to determine activities to accommodate the recommendations resulting from  
50 this review exercise of indicators and denominators for reporting antimicrobial sales and use in animals  
51 at the EU level.

## 52 **3. Discussion (on the problem statement)**

53 To enable development of the guideline the following elements needs to be prepared:

- 54 • Assessment of the current denominator used for reporting ESVAC sales data;
- 55 • Assessment of a suitable denominator and main indicators for describing antimicrobial use data by  
56 animal species, including assessment of applicability of PCU for reporting use data;
- 57 • Proposals for indicators for reporting antimicrobial sales;
- 58 • Proposals for ESVAC sales denominator and use data denominator per animal species;
- 59 • Proposals for indicators for reporting antimicrobial use data in animal species, prioritising according  
60 to the requirements of the Reg. 2019/6;

61 • Assessment of the tasks for the EMA and Member States to accommodate the recommendations  
62 for the analysis of antimicrobial use data at European level.

63 The guideline should take into consideration the impact on the work performed within the ESVAC  
64 activity in consideration of analysis of antimicrobial consumption in animals at European level.

#### 65 **4. Recommendation**

66 It is recommended to draft a guideline for presenting antimicrobial sales data and use data of  
67 antimicrobial medicinal products used in animals in Europe.

68 The objectives of this guideline are:

- 69 1. To assess adequate denominators and indicators of antimicrobial consumption at EU level;
- 70 2. To define the methodology, including animal categories and weights assigned, of the denominator  
71 to be used for sales and use data;
- 72 3. To recommend denominator(s) and indicator(s) that should be used for reporting on sales and on  
73 the use of antimicrobial medicinal products used in animals at European level to guaranty the  
74 fulfilment of the requirements and obligations set by the Article 57 of the Regulation 2019/6.

#### 75 **5. Proposed timetable**

76 The concept paper will be released for consultation in November 2020. The deadline for comments is  
77 January 2021.

78 The draft guideline for public consultation is intended to be released by June 2021. The deadline for  
79 comments will be September 2021. The expected date for adoption of the guideline is December 2021.

#### 80 **6. Resource requirements for preparation**

81 The guideline will be prepared by the ESVAC Denominator and Indicators Review Ad Hoc Expert Group  
82 in collaboration with the ESVAC secretariat. Virtual meetings will be held every 4 weeks (or as  
83 required).

#### 84 **7. Impact assessment (anticipated)**

85 To describe the reporting of data on antimicrobial sales and use in a harmonised manner, as noted in  
86 the recital 50 and as per requirements of Article 57 of Regulation (EU) 2019/6. To assist Member  
87 States and EMA providing standards for quantifying antimicrobial consumption in animals in Europe. To  
88 perform necessary analysis of antimicrobial sales and use at European level as per requirements of  
89 Article 57 of Regulation (EU) 2019/6.

#### 90 **8. Interested parties**

91 Veterinarians, policy makers, veterinary medicine authorities, national competent authorities  
92 responsible for collection and analysis of antimicrobial sales and use data, organisations liable for  
93 developing policies for antimicrobial consumption reduction, offices for animal population statistics etc.

## 94 **9. References to literature, guidelines, etc.**

- 95 AACTING, 2019. 'Guidelines for collection, analysis and reporting of farm-level antimicrobial use, in the  
96 scope of antimicrobial stewardship',  
97 [https://aacting.org/swfiles/files/AACTING\\_Guidelines\\_V1.2\\_2019.07.02\\_54.pdf](https://aacting.org/swfiles/files/AACTING_Guidelines_V1.2_2019.07.02_54.pdf);
- 98 ECDC/EFSA/EMA, 2017. 'Joint Scientific Opinion on a list of outcome indicators as regards surveillance  
99 of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals',  
100 [https://www.ema.europa.eu/en/documents/report/ecdc-efsa-ema-joint-scientific-opinion-list-outcome-  
101 indicators-regards-surveillance-antimicrobial\\_en.pdf](https://www.ema.europa.eu/en/documents/report/ecdc-efsa-ema-joint-scientific-opinion-list-outcome-<br/>101 indicators-regards-surveillance-antimicrobial_en.pdf);
- 102 EMA, 2018a. 'Guidance on collection and provision of national data on antimicrobial use by animal  
103 species/categories (EMA/489035/2016)', [https://www.ema.europa.eu/en/documents/scientific-  
104 guideline/guidance-collection-provision-national-data-antimicrobial-use-animal-  
105 species/categories\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-<br/>104 guideline/guidance-collection-provision-national-data-antimicrobial-use-animal-<br/>105 species/categories_en.pdf);
- 106 EMA/CVMP, 2019. 'Advice on implementing measures under Article 57(3) of Regulation (EU) 2019/6 on  
107 veterinary medicinal products - Report on specific requirements for the collection of data on  
108 antimicrobial medicinal products used in animals (EMA/CVMP/131097/2019)',  
109 [https://www.ema.europa.eu/en/documents/report/advice-implementing-measures-under-article-573-  
110 regulation-eu-2019/6-veterinary-medicinal-products-report-specific-requirements-collection-data-  
111 antimicrobial-medicinal\\_en.pdf](https://www.ema.europa.eu/en/documents/report/advice-implementing-measures-under-article-573-<br/>110 regulation-eu-2019/6-veterinary-medicinal-products-report-specific-requirements-collection-data-<br/>111 antimicrobial-medicinal_en.pdf);
- 112 FDA, 2017. 'FDA's Proposed Method for Adjusting Data on Antimicrobials Sold or Distributed for Use in  
113 Food-Producing Animals, Using a Biomass Denominator',  
114 <https://www.fda.gov/media/106826/download>;
- 115 Góchez, D., M. Raicek, J. Pinto Ferreira, M. Jeannin, G. Moulin, and E. Erlacher-Vindel, 2019. 'OIE  
116 Annual Report on Antimicrobial Agents Intended for Use in Animals: Methods Used', *Frontiers in  
117 veterinary science*, Vol. 6 p.317., <https://www.frontiersin.org/articles/10.3389/fvets.2019.00317/full>