Concept paper on guidance for the collection of data on antimicrobial consumption by species from national data collection systems

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Agreed by European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) species Expert Advisory Group	4 July 2016
Start of public consultation	13 July 2016
End of consultation (deadline for comments)	30 September 2016

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Comments should be provided using this template. The completed comments form should be sent to vet-guidelines@ema.europa.eu

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1. Introduction

The European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) activity work stream on the collection of antimicrobial consumption data by animal species aims to foster the collection of harmonised and standardised data in the European Union/European Economic Area (EU/EEA). One of the objectives of this work stream is to provide guidance on the collection of antimicrobial consumption data per animal species.

The guidance will outline the required data that an EU/EEA country should collect, and provide to ESVAC, on the consumption of antimicrobials by species for those countries that are currently, or might wish to start, collecting such data and would like to provide those data to ESVAC in the future. The scope of the guidance will be the three major groups of food-producing animals (pigs, poultry and cattle) but the guidance should be adaptable to other species as well.

The guidance will be developed in conjunction with the ESVAC species Expert Advisory Group (EAG). The lessons learnt during the trial on the collection of antimicrobial consumption data from pig farms in 2014[1] will be taken into account. The guidance is intended to ensure the collection of harmonised and standardised data at a supranational level and should therefore be applicable in all EU/EEA countries.

The collection of antimicrobial consumption data by animal species is one of the three work streams of the ESVAC project; the outcome of the public consultation of the Draft ESVAC Vision and Strategy 2016-2020 (EMA/326299/2015) will be taken into account during the preparation of the guidance. This guidance does not intend to prescribe if or how countries should set up systems for collection of data on antimicrobial consumption in animals.

2. Problem statement

To enable development of the guidance the following needs to be established and defined:

1. antimicrobial consumption data per species (numerator), including minimum required variables to be provided to ESVAC, data source, calculations, etc.;

2. animal population at risk of treatment with antimicrobials (denominator), including minimum required variables to be provided to ESVAC, data source, calculations, etc.

3. Discussion (on the problem statement)

The consumption data (numerator) can be obtained from prescriptions/vet practice records, health records/treatment log books, delivery notes and invoices, which could be collected from farm, veterinarian or pharmacy records. The consumption data collected per observation can be the number of packages per VMP (or VMP presentation), or the dosing regimen (including number of animals treated) for a treatment with a VMP or medicated feed, or the total quantity of a VMP or medicated feed. These data sources and types of consumption data may not deliver the same information; therefore the potential impact on the numerator would need to be addressed.

Collection of the so-called 'raw' data should allow for the necessary quality control of the data by the country and further analysis (e.g. calculation of total amount of the active substance used in a certain animal species), but before providing the required data to ESVAC a country would have to aggregate the observations for one species. The guidance needs to provide details on the level of aggregation of those data.

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[1] See for full report: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/05/WC500206990.pdf

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49 The animal population at risk for treatment with antimicrobials (i.e. the denominator), or a proxy
50 thereof, will be used to normalise the numerator and therefore it is important to assess which
51 denominator is the most suitable. The denominator should be based on population data that are
52 transparent and validated, preferably publicly available (e.g. Eurostat). The population data should
53 preferably be similar to those used to report ESVAC sales data[2].

54 To allow for comparison of data collected from a representative sample to data collected from
55 practically the whole animal population for the species in question, a denominator for the farms
56 included in the sample has to be established as well. It needs to be explored during the development
57 of the guidance if data at farm level provide for similar/comparable categories of animals as those used
58 to derive the denominator at national level; if not, if a comparable denominator should be obtained.

59 In order to identify the required data that need to be collected and provided to ESVAC if providing data
60 by animal species, two major data collection models should be explored during the development of the
61 guidance; a 'census' model, involving the consumption during a year in practically all farms or the
62 whole animal population in an animal species/sector in a country, and a 'sample survey' model,
63 involving the consumption during a year in a representative sample of the animal population in an
64 animal species/sector in a country. An assessment of how these models can deliver the required data
65 should be attempted.

4. Recommendation

67 It is recommended to draft guidance on the collection of data on antimicrobial consumption per species
68 and on the animal population at risk for treatment with antimicrobials, with the following objective:

69 *"To define the type and format of data to be provided to EMA/ESVAC from national data collection*
70 *systems collecting antimicrobial consumption data, in order for ESVAC to collate, analyse and report*
71 *harmonised and standardised data on antimicrobial consumption per species per country."*

72 Guidance should, in the first instance, be created for three major groups of food-producing animals:
73 pigs, poultry and cattle, but might be adapted to other animal species at a later stage.

74 It is recommended that guidance refers to the collection of data per species on a national level for the
75 provision of those data to ESVAC; it will not cover reporting consumption per farm (e.g. for
76 benchmarking purposes), which remains for the countries' own consideration.

5. Proposed timetable

78 The concept paper will be released for consultation in July 2016. The deadline for comments will be
79 September 2016.

80 The draft guidance for public consultation is intended to be released by December 2016. The deadline
81 for comments will be March 2017. The expected date for adoption of the guidance is June 2017.

6. Resource requirements for preparation

83 The guidance will be prepared by the ESVAC species EAG in collaboration with the ESVAC team. One
84 physical meeting will take place in 2016 and Adobe Connect meetings will be organised as required.

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[2] See
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jsp&mid=WC
0b01ac0580153a00&jsenabled=true

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7. Impact assessment (anticipated)

To clarify the requirements for collection of harmonised antimicrobial consumption data by animal species, facilitating the setup of those systems.

8. Interested parties

Livestock producers, veterinarians, risk assessors, farmers' and veterinarians' associations, policy makers, veterinary medicine authorities, etc.

9. References to literature, guidelines, etc.

Information on the ESVAC activity:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jsp&mid=WC0b01ac0580153a00