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Draft ESVAC Vision and Strategy 2016-2020

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ESVAC Vision and Strategy 2016-2020

1. Background

The ESVAC (European Surveillance of Veterinary Antimicrobial Consumption) activity started in September 2009. Since then ESVAC has become a worldwide leading activity on collecting data on veterinary antimicrobial consumption at supra-national level. So far, ESVAC has collected and published data on sales from up to 26 European countries; the report to be published in 2016 will include data from 29 countries.

Currently, ESVAC relies on voluntary participation of the countries. However, the proposal for a new regulation governing veterinary medicinal products (VMPs) adopted by the European Commission in September 2014 (COM(2014) 558 final) includes in Art. 54 a requirement for European Union/European Economic Area (EU/EEA) countries to collect and supply to the European Medicines Agency (EMA) data on sales and use of antimicrobials. In the period 2016-2020 a major driver for ESVAC activities will therefore be to put in place the systems and procedures necessary to manage this anticipated future legal requirement for both national competent authorities (NCAs) and the European Medicines Agency ("the Agency"). It is currently envisaged that the regulation will be adopted in 2017 to come into force two years later. Whilst the detailed provisions of the regulation cannot be predicted in advance of the outcome of the co-decision procedure, there is widespread consensus that the collection of data on sales and use of veterinary antimicrobials will form an important part of the new legislation.

ESVAC currently has three work streams ongoing: collection of overall sales data, development of systems for collection of data on consumption by animal species and establishment of technical units of measurement. Taking into account the knowledge gained to date from the ongoing work streams, the extremely resource-demanding nature of work to collect data by animal species and the proposed changes in the legislative framework, and in order to define the financial and human resources that need to be allocated by the Agency and NCAs to ESVAC, there is a need to re-define the vision and strategy for ESVAC for the next five years.

This document seeks to define the vision and strategy for the ESVAC activity for the period 2016-2020. Once finalised, this strategy will be used as the basis for the successor to the current ESVAC project plan 2013-2016 (EMA/42322/2013). The EU Medicines Agencies Network Strategy to 2020 (EMA/MB/151414/2015) includes support for ESVAC as an important element within Theme 2, Objective 4 'Focus on key public and animal health priorities including antimicrobial resistance'. Activities within the Network Strategy, including ESVAC, will be delivered through inclusion within the multi-annual work plans of both the Agency and the Heads of Medicines Agencies (HMA).

2. Mission

The ESVAC mission is *"to develop a harmonised approach for the collection and reporting of data based on national sales figures combined with estimations of usage in at least major groups of species (poultry, pigs, veal, other ruminants, pets and fish)"*.

This mission originates from the request from the Commission to the Agency to take the lead in collecting data on the use of antimicrobials in animals, and thus to develop an approach for the

collection and reporting of harmonised data on the use of antimicrobial agents in animals in the Member States (SANCO/E2/KDS/rz D(2008) 520915).

3. Strategic importance of ESVAC

Antimicrobial resistance (AMR) is an increasingly important and urgent concern for both human health and animal health. In order to enable policy makers to develop policies to fight AMR effectively, there is a need for reliable data on antimicrobial consumption and on AMR from all sectors (human and veterinary). ESVAC currently provides a consolidated set of harmonised data and reports on the sales of veterinary antimicrobial agents, collected and reported in a standardised format on an annual basis. ESVAC thereby provides policy makers with objective data on, for example, trends over time in the sales of veterinary antimicrobials in participating countries.

By collecting sales data from most EU/EEA countries, ESVAC has played an important role in terms of increasing awareness on the challenges from AMR. Furthermore, publication of the collated sales data is thought to have been one of the stimulators behind campaigns to promote responsible use of antimicrobials and other AMR-related management activities in some EU/EEA countries. Some of these activities have resulted in significant decreases of veterinary antimicrobial consumption. Some countries that have reduced veterinary antimicrobial consumption have as a consequence reduced the prevalence of resistance to antimicrobials in zoonotic (and commensal) bacteria, thereby reducing the risk to man from food-borne infections.

4. Achievements 2009-2015 and objectives 2016-2020

Based on the ESVAC mission and on the terms of reference from the European Commission, the achievements of ESVAC to date and the objectives for the next period are summarised in the following sections.

4.1. Overall sales data

Since 2009 ESVAC has produced annual reports on sales of antimicrobials by country, taking into account a proxy for the biomass of food-producing animals ‘at risk of treatment’ in each country (the ‘population correction unit’; PCU). The number of countries participating has increased from 9 in 2009 to 26 in 2012. In 2013, it was possible for the first time to show a trend of a decrease in overall sales of veterinary antimicrobials in the majority of countries reporting for a period of three consecutive years. In 2015, ESVAC developed and launched a web-based reporting tool enabling EU/EEA countries to submit their data online and through that system facilitating the quality assurance of the submitted data. The system also provides analytical facilities and tools to produce tables and graphs automatically based on the collated data.

In the period 2016-2020, ESVAC intends to continue collecting and publishing overall sales data from as many EU/EEA countries as possible. The 26 countries included in the 2013 ESVAC report covered approximately 95% of the food-producing animal population in the EU/EEA area. Since then, Croatia and Romania have also provided sales data. Therefore, the objective to collate data from all EU/EEA countries is close to being achieved. In addition, Switzerland has provided sales data in accordance with the ESVAC system, which will be included in the report to be published in 2016. The collection of data from the EU/EEA countries and the production of the report are subject to continuous improvement. An ESVAC Sales Expert Advisory Group (EAG) was established in 2015 and will continue to provide the expertise required, ensuring that best practice in collection and reporting of sales data is further developed in line with developments in the field.

The production of the sales data report is being changed from a project-based activity to an annual activity with a substantial element of continuous improvement. Over the next period, training will continue to be given to national ESVAC contact points to reduce the resources needed for quality checking of the data by ESVAC staff. The process of analysing the data and the production of tables and graphs for the annual report has been automated using IT tools which will be further optimised to produce enhanced reports. Currently, ESVAC relies on its own database developed for the purpose of collecting and storing sales of antimicrobial VMPs. As part of a wider programme to prepare for the implementation of the revised veterinary medicines legislation, this database will be linked to the Common EU Database of VMPs that is being progressively developed over the period 2015-2019. In turn, the ESVAC database of antimicrobial VMPs will ultimately form part of the wider EMA SPOR data repository (Substances, Products, Organisations and Referentials).

4.2. Collection of consumption data by species

The objective of this work stream is to foster the collection of harmonised and standardised data in the EU/EEA countries on the consumption of antimicrobials per species for the three major food-producing animal species; cattle, pigs and poultry. These data should allow for the analysis of trends in use of antimicrobials over time and for the comparison of use of antimicrobials per species between countries. The data should be submitted in a form that allows for analysis using the standardised units of measurement (DDDvet and DCDvet) that have been established and assigned by ESVAC. This work stream should further support the preparation of countries for the requirements of the revised legislation on veterinary medicinal products (and the 'Animal Health Law') as it relates to the collection and supply of data on antimicrobial consumption.

To achieve these objectives ESVAC will:

1. Act as the networking hub within the EU/EEA area, bringing together the best technical expertise on collection and analysis of consumption data per species. This will be a key activity in preparing for the new veterinary regulation by enabling the Agency and NCAs to provide advice to the European Commission in preparing the necessary delegated and implementing acts;

2. Develop, in consensus with the ESVAC Species EAG and the ESVAC network, guidance (including methodology) for the collection of harmonised and standardised data on consumption per species and, when applicable, on animal population 'at risk of treatment' that allow ESVAC to collate data at a European level;

3. Foster the conduct by EU/EEA countries of studies to ensure applicability of the guidance throughout the EU/EEA area and promote the uptake at national level.

ESVAC has developed a protocol and templates for collection of harmonised and standardised data on use of antimicrobials in pigs, as well as data on the pig population-at-risk. A trial was conducted in 2014-2015 in ten Member States (MSs) to test this protocol and the templates, for which the results will be published on the Agency's website in 2016. Furthermore, a revised version of the protocol and templates will be published in 2016 as guidance providing the minimum required variables for data collection.

In 2015, there was an insufficient level of support expressed by EU/EEA countries for ESVAC to conduct a pilot study on collection of data on use of antimicrobials in pigs involving twenty pig farms per country. Reasons expressed for not participating included factors such as the high cost of on-farm surveys, the lack of a legal basis or source of funding, the complexity of the project planning process

due to multiple involved parties, and the fact that several EU/EEA countries are already carrying out national surveys of use and do not wish to repeat the same activity in a different context.

Based on the findings and experience of the above mentioned trial, the highly resource demanding *'manual'* collection of data on consumption per species at national level suggests that it would not be a sustainable approach in the long term. Therefore, the focus for ESVAC will be on automated or semi-automated data collection, preferably covering all farms or, alternatively, from a representative number of farms.

Over the next period, based on the experience and findings from the test, ESVAC will produce guidance/protocols for collection of harmonised and standardised data from MSs on the use of antimicrobials and, when applicable, on the animal population-at-risk, for use in cattle, pigs and poultry. The guidance will provide the minimum required variables to initially collect consumption data per species for the harmonised ESVAC data collection as well as a template for providing those data to ESVAC that EU/EEA countries can populate either using data expressly collected for this purpose or data collected as part of (existing) national surveillance schemes.

The guidance will be developed and approved in conjunction with the ESVAC EAG on collection of data per animal species, with the objective that the collected harmonised and standardised data eventually allow for an integrated analysis with data on use of antimicrobials in humans, and on resistance in animals, humans and food. The analysis will be used as part of the Joint Interagency Antimicrobial Consumption and Resistance Analysis Report (JIACRA), which is prepared at the request of the European Commission in conjunction with the European Food Safety Authority and the European Centre for Disease Prevention and Control[1]. As part of this objective, the Expert Advisory Group will provide support for the investigation and decision making on which indicators for reporting consumption data per species at EU level are both feasible and useful for analysis and reporting of data.

The guidance to be developed should be applicable for the establishment at EU level of schemes for collection of electronic prescriptions or delivery records (automated continuous collection of data) which will considerably simplify and reduce the cost for EU/EEA countries of supplying data on use of antimicrobials per species (farm level) to the ESVAC project (as this information is contained within the records). The ESVAC work stream would therefore have to ensure that those schemes produce data that are harmonised and compatible with the EMA databases.

Collecting data from a representative sample of farms is perceived as an alternative option for those countries that do not currently collect data from electronic prescriptions or delivery records from all farms (automated continuous collection of data). Once the guidance on automated continuous collection of data is drafted, as a next step, EMA will draft guidance/protocols on collecting data from a representative sample of farms per species using manual or (semi-)automated methods.

4.2.1. Stratification of sales data

Experience from countries collecting data per species and initial work conducted by the Agency/ESVAC in the period 2014-2015 has highlighted the limitations that currently exist in terms of resources and legal basis for EU/EEA countries to collect data on antimicrobial consumption by species and for EMA to analyse and report these in a standardised and harmonised manner. It has become apparent that it will be a number of years before systems are in place to collect comparable consumption data by species on a routine basis from most EU/EEA countries. For this reason, an interim approach is required if ESVAC is to achieve progress against this objective in the next five year period. Therefore

[1] See http://www.ema.europa.eu/docs/en_GB/document_library/Report/2015/01/WC500181485.pdf

sales data as a proxy for consumption will continue to be collected for the foreseeable future as the core ESVAC activity, even whilst work is carried out to develop systems to collect data on actual consumption of antimicrobials per species.

Over the next period ESVAC will, together with the MSs, explore if it is feasible to estimate the consumption per species based on an approximate allocation of the proportion of total sales that are used in each species for which an antimicrobial is indicated (stratification of sales data). This approach would be based on direct attribution of sales for use in one animal species for those products authorised for only one animal species and on attribution of proportions of sales to each major animal species for which the VMP is authorised in those cases where it is authorised for multiple species. Attribution of proportions is possible based on estimates for example from the Marketing Authorisation Holders or on the basis of field surveys. This approach might be applicable for those countries that in the short-medium term would not be able to invest the required resources to set up systems to collect harmonised and standardised antimicrobial consumption data, but are in need of an estimation of consumption per species. The approach might also be relevant for countries aiming to set up systems to collect only limited sets of data, such as from only some animal species, or to supplement the collection of data from a representative number of farms. As it is envisaged that the review of the new veterinary medicines regulation will require EU/EEA countries to collect antimicrobial consumption data by species, the stratification of sales data should be viewed as an interim approach until systems to collect data on consumption by species are in place.

Stratification of sales data could provide reasonable estimates of consumption with an acceptable coverage in terms of countries involved. ESVAC would collect or create the necessary data on the allocated proportion of sales of each antimicrobial to each species for all VMPs from participating EU/EEA countries and use these to stratify the sales data which will then be analysed and reported on a per-species basis. ESVAC can then enhance the analysis and reporting of the stratified sales data by use of the established Defined Daily Doses for animals (DDDvet) and Defined Course Doses for animals (DCDvet) and an appropriate denominator, to more accurately reflect the actual risk in terms of exposure of the different species to antimicrobials. A modified version of this approach could be used to obtain species data for the analysis of the relationship between sales of antimicrobials by animal species and resistance in the EU.

4.3. Units of measurement

To date, ESVAC has collected data on sales and used these to estimate the weight of active substance consumed by animals. ESVAC has recognised from the outset that this does not take into account the different doses of the different antimicrobials used to treat animals. In human medicine reporting of antimicrobial consumption is standardised by establishing Defined Daily Doses (DDD) which would allow for a more accurate estimate of the exposure to antimicrobials by animal species. ESVAC has collated data on dosing from Summaries of Product Characteristics provided by 9 MSs and defined the methodology necessary to assign Defined Daily Doses for animals (DDDvet) and Defined Course Doses for animals (DCDvet). The principles for the assignment have been published after public consultation on the Agency's website in 2015.

The objective of this work stream is to assign DDDvet and DCDvet for antimicrobials used in cattle, pigs, and broilers (poultry) and to maintain the system. The lists with DDDvet and DCDvet values will be published on the Agency's website in 2016. They will be used within the project for improved analysis of data on antimicrobial consumption per species.

The creation of this resource has the potential to be of global value. Antimicrobial resistance is a global challenge and policy makers require standardised data by which to compare different regions and

224 countries in terms of their use of antimicrobials and therefore, partly, their potential for generating
225 antimicrobial resistance. Over the next period, discussions will take place between the Agency, the
226 European Commission and international partners (e.g. WHO Collaborating Centre for Drug Statistic
227 Methodology) on how best to make use of this valuable asset at a global level, including how to ensure
228 that it is maintained into the future.

229 5. Related documents

230 ESVAC web
231 page: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_li
232 sting_000302.jsp&mid=WC0b01ac0580153a00.

233 European Commission proposal for a regulation of the European Parliament and of the Council on
234 veterinary medicinal products: http://ec.europa.eu/health/veterinary-use/rev_frame_index_en.htm.

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