



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 November 2016
EMA/453536/2016
Veterinary Medicines Division

Overview of the comments received on 'Draft ESVAC Vision and Strategy 2016-2012' (EMA/326299/2015)

Stakeholder no.	Name of organisation or individual
1	SAFOSO AG
2	Bavarian State Ministry of the Environment and Consumer (STMUV)
3	British Veterinary Association (BVA)
4	Federation of Veterinarians of Europe (FVE)
5	Pig Health and Welfare Council (PHWC)
6	European Public Health Alliance (EPHA)

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1. General comments

Stakeholder no.	General comments	Outcome
1	<p>In general, the “ESVAC Vision and Strategy 2016-2020”, is a well written document, that highlights the importance of some very critical ideas/changes like:</p> <ul style="list-style-type: none"> i. The need to move from a voluntary reporting on the use of antimicrobials by the different countries (current situation) to a mandatory format (as planned in the new regulation governing veterinary medicinal products); ii. Collecting just sales data is insufficient or imperfect, and it is of much more usefulness to collect sales AND use data iii. The urgent need to have DDDvet and DCDVet defined <p>On the other hand, it does not cover issues related with the licensing of the different antimicrobial drugs. At the moment, the same commercial product is legally sold, in one country to multiple species. It is impossible to split the sales data, into the different animal species. Having this clarified is essential, if we are to qualify the importance of the different AMR transmission pathways.</p> <p>EFSA and ECDC now produce an annual joint report on antimicrobial resistance in zoonotic and indicator bacteria from humans, animals and food. Additionally, several EU countries have now moved to jointly reporting antimicrobial consumption in human and animals. We would welcome a move towards joint/harmonized reporting of antimicrobial consumption data in human and animals at European level.</p>	<p>Thank you. Noted.</p> <p>As described in the strategy one of the ESVAC objectives is to foster the collection of harmonised and standardised data in the EU/EEA countries on the use of antimicrobials by species.</p> <p>Please see the first Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA I) report where sales of human and animal medicines are already compared.</p>
2	<p>Sehr geehrte Damen und Herren,</p> <p>seitens des Bayerischen Staatsministeriums für Umwelt und Verbraucherschutz übermitteln wir Ihnen unseren Beitrag zur oben genannten Konsultation:</p> <p>Ein Vergleich der Verkaufsdaten antimikrobieller Stoffe für Tiere der europäischen Länder untereinander wird begrüßt. Dieser kann wertvolle Informationen zu den Tierhaltungssystemen in den EU-Mitgliedstaaten liefern und aufzeigen, ob und wie erfolgreich Maßnahmen zur Reduzierung des Antibiotikaverbrauchs in den EU-Mitgliedstaaten durchgeführt werden.</p>	<p>Noted.</p>

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	<p>Berücksichtigung finden müssen hierbei bereits bestehende Systeme. Die Gesamtmenge der an Tierärzten abgegebenen Stoffe mit antimikrobieller Wirkung wird in Deutschland seit dem Jahr 2011 jährlich nach bewährtem System durch das Deutsche Institut für Medizinische Dokumentation und Information (DIMDI) erfasst und der EMA übermittelt.</p> <p>Die Festlegung einheitlicher Maßeinheiten zur besseren Vergleichbarkeit der Daten zwischen den EU-Ländern sowie von Daten aus veterinärmedizinischen und humanmedizinischen Bereichen wird begrüßt. Dies steht im Sinne des One-Health-Ansatzes zur Reduzierung von Antibiotikaresistenzen.</p> <p>Die EMA hat die Tierarten Rind, Schwein und Geflügel als die wichtigsten Lebensmittel-liefernden Tierarten identifiziert. Eine Ausweitung der Erfassung von Antibiotika-Verbrauchsdaten auf andere (Lebensmittel-liefernde) Tierarten ist vor diesem Hintergrund zu prüfen. Das Verhältnis von Nutzen bzw. Erkenntnisgewinn und Aufwand der Datenerfassung muss sorgfältig abgewogen werden.</p> <p>Zudem hat Deutschland mit der 16. AMG-Novelle bereits ein Monitoring zur Erfassung von Einsatzhäufigkeiten von Antibiotika für zum Zweck der Mast bestimmte Rinder, Schweine, Hühner und Puten geschaffen. Erfahrungswerte zeigen, dass hier eine Unterscheidung nach Nutzungsarten innerhalb einzelner Tierarten sinnvoll ist, um Vergleiche im Hinblick auf den Antibiotikaeinsatz anzustellen. Wir regen daher an, zu prüfen, ob analog für die Sammlung von Verbrauchsdaten die Unterscheidung nach Produktionsrichtungen innerhalb einer Tierart sinnvoll wäre. Dies wird anhand der Zulassung ohnehin häufig unterschieden z.B. für Kälber oder Kühe mit jeweils unterschiedlichen Dosierungsschemata.</p>	
3	<p>BVA is grateful for the opportunity to respond to this consultation, which we have formulated via our Medicines working group.</p>	<p>Thank you.</p>
4	<p>FVE welcomes the enlarged approach presented in the new ESVAC vision and strategy for 2016-2020. We believe it is ambitious but in a realistic and pragmatic way.</p> <p>We are satisfied to see that project move to the collection of use data in different animal species from all EU and EFTA countries.</p> <p>We welcome the use of standardised units for the measurement (DDDvet and DCDvet).</p>	<p>Thank you. The ESVAC activity takes a pragmatic approach, taking into consideration data collection by animal species. We believe that more detailed data analyses will be carried out by</p>

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	<p>This will allow the data to more accurately reflect the actual risk on antibiotic resistance in terms of exposure of the different animal species to antimicrobials.</p> <p>We also welcome that in the latest report countries have been asked to analyse and comment on the trends seen in their country. This is important to put the figures into perspective, as factors such as livestock, climate, disease status and availability of alternatives (e.g. zinc oxide) can make big impact.</p> <p>In respect to moving to use date, we agree the most pragmatic approach is first to collect data for the main animal species and only later move to animal categories (e.g., piglets, pigs for fattening, sows for reproduction) or other species. In the long term, we should however try to move more in detail. Especially in respect to companion animals and wild and exotic animals, where from the volume of use perspective they are insignificant, from a risk-based approach due to the direct animal contact they have with their owners, we would urge them to be considered sooner rather than later.</p> <p>From a political level, requests are also coming to collect additional data such as the sales/use of other veterinary medicines, to include the clinical indications and dose regime why the antibiotic was prescribed or to include the livestock production systems. We suggest in a reflection paper to analyse and reflect on how feasible and useful the collection of these additional data are.</p> <p>We have very much welcomed the first “Joint Interagency Antimicrobial Consumption and Resistance Analysis Report (JIACRA)”, which is essential to take a true “One Health Approach”. We would suggest that this report is followed up yearly or at least bi-annually. We encourage to putting this as an integral part of the ESVAC strategy for 2016-2020.</p> <p>In respect to the global approach, we welcome the draft vision and strategy mentioning this, however this is done only in very vague terms. We recommend a more clear commitment to this global approach with clearly defined actions and milestones to reach.</p> <p>Last but not least, it is important to consider how to convince animal owner or keeper and</p>	<p>member states in the future; however, many EU member states will not be ready to invest vast resources into very detailed collection of data on use of antimicrobials. We might consider analysing the advantages and the costs of more sophisticated systems of data collection in the future.</p> <p>Please be informed that the second Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA II) report will be published by mid-2017.</p> <p>ESVAC is fully committed to the global approach on collecting data on antimicrobial consumption (e.g. involvement in OIE activities).</p> <p>Noted.</p>

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	<p>prescribing veterinarians of animal treated to accept this extra administrative task of collecting these data without seeing it as yet another administrative burden that comes on top of the many they already have to do. In other words, it must be ensured from the start that farmer or keeper and veterinary associations in the different countries are involved, take ownership/keepership and see it developed in such a way that they recognise that collecting these data can benefit them. If it is seen as useful, better feedback and compliance will be achieved.</p>	
6	<p>The fact that ESVAC appears to have played an important role in terms of increasing awareness on the challenges from AMR is a positive development. It emphasises what EPHA already assumed: harmonised data collection on sales and use can (in)directly create pressure among Member States to do better and be more competitive.</p> <p>However, it should be emphasised what data must go to which organisation: who collects them, and for what reason? What is the ultimate goal of data collection (e.g. mere presentation / visualisation of objective data vs. drawing comparisons in order to stimulate policy and behavioural changes)? How is it connected to the European Commission's Action Plan on AMR, and the work undertaken by ECDC and EFSA?</p> <p>Moreover, what is the scope of data on 'antimicrobials': does it also include other kinds of resistance promoters, such as pesticides or heavy metals?</p>	<p>Noted.</p> <p>The purpose of data collection by ESVAC is primarily to monitor and interpret patterns and trends regarding antimicrobial use over time, in order to set risk assessment priorities. Various conferences convened by the EU and FAO/OIE/WHO have recommended that data on sales of veterinary antibacterial medicines should be collected to express national usage. The ESVAC mandate, the ESVAC reports and other available documents provide details concerning the points raised by the stakeholder, which are not considered within the scope of the ESVAC strategy.</p> <p>Pesticides or heavy metals are outside the scope of the ESVAC activities. The scope is precisely defined in the technical notes of the ESVAC sales reports (link).</p>

2. Specific comments

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31-33	4	<p>Comment: '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.'</p> <p>We totally agree with this sentence but would suggest for the 2016-2020 strategy to add one specific work stream to cover the one health aspect and the global aspect.</p> <p>Proposed Change: Add to the 2016-2020 a specific work stream to cover the One health and global aspect.</p>	<p>One health is embedded into the ESVAC project and would not be justified as an independent work stream for organizational reasons.</p> <p>As an example, experts from EFSA and the ECDC are regularly involved in the ESVAC work.</p>
45-48, 105-107	3	<p>Comment: In lines 46-48 the ESVAC mission references data collection and reporting in the major groups of species (poultry, pigs, veal, other ruminants, pets and fish). However, in lines 105-107 when discussing collection of consumption data by species the scope is limited to the three major food producing animal species; cattle, pigs and poultry. BVA suggests that the collection of consumption data in fish would be useful as an increasingly important source of protein for human consumption. We support the initial focus on food-producing animals and suggest that the Small Animal Veterinary Surveillance Network (SAVSNET) would be well placed to provide data on the consumption of antimicrobials by pet animals.</p>	<p>Noted.</p> <p>We acknowledge the importance of collecting fish data as well as companion animals data in the long term, but cannot commit further resources to such activity at the current moment.</p> <p>ESVAC is willing to collaborate with third parties that collect data on the consumption of antimicrobials. ESVAC activities are based on data provided by the official sources of the involved countries.</p>
46-48	1	<p>Comment: The "mission statement" seems to be getting outdated, as in "...based on national sales figures combined with estimations of usages in at least major groups of species..." Reading this "vision and strategy document", it seems that the focus is</p>	<p>The focus of the document of the ESVAC strategy is on usage data because this is the area for</p>

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		<p>increasingly more on having “use data” and not “sales figures” or “estimates of usages”. “Major groups of species” also can be misleading.</p> <p>Proposed change (if any): The ESVAC mission is “to develop a harmonised approach for the collection and reporting of usage data, divided in the (major) animal species”</p>	<p>which more development is required. Sales data are a key part of the ESVAC project and will continue to be in the future. No change required.</p>
61-65	6	<p>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.</p> <p>Comment: In what way has it played an important role?</p> <p>Proposed change (if any): Provide evidence of ESVAC’s utility, e.g. examples of campaigns and management activities.</p>	<p>The statement is cautious. Member states representatives have suggested that the collection of antimicrobial consumption data in general, including the data collected by ESVAC has played an important role as described in the text. Examples are provided in the ‘Reduction of the need to use antimicrobials in food-producing animals (RONAFA)’ report (link).</p>
66-68	6	<p>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.</p> <p>Comment: Which countries?</p> <p>Proposed change (if any): Provide examples of countries that have reduced the prevalence of resistance to antimicrobials in zoonotic bacteria.</p>	<p>Details are provided in the RONAFA report (link). The text in the strategy has been adapted to the conclusions of the report.</p>
68	5	<p>Comment: The effect on animal welfare is not included in the strategic importance of ESVAC. The ESVAC mission is to provide data. It is reasonable to comment on the consequences of data reporting but it would be preferable to if there were a broader set of comments.</p>	<p>Animal welfare is outside the scope of ESVAC. Animal welfare and use of antibiotics in animals is addressed in the RONAFA report (link).</p>

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76-79	6	<p>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.</p> <p>Comment: Which countries are still not participating and what are the reasons? And which countries have not seen a decrease in overall sales?</p> <p>Proposed change (if any): State whether any MS is/are still not participating and why. Also state where sales have not decreased and the plausible reasons for that.</p>	<p>Countries provide national data on voluntary basis. At this stage only one country is not yet included in the ESVAC report. As this situation might change in the future we prefer not to specify it. Details on the increase or decrease of sales in member states are published annually in the ESVAC reports. (link)</p>
93	5	<p>Comment: It could be made clearer what the change of activity is; the ESVAC reports are currently annual so what will the change be?</p>	<p>The phrase refers to the beginning of the project. The ESVAC report will continue to be produced annually.</p>
83-84	6	<p>In the period 2016-2020, ESVAC intends to continue collecting and publishing overall sales data from as many EU/EEA countries as possible</p> <p>Proposed change (if any): Add that data reporting should be mandatory for all EU-28 Member States.</p>	<p>Data reporting might be mandatory once the review of veterinary medicines legislation is implemented.</p>
83-84, 93-94	3	<p>Comment: BVA supports the ongoing collection of overall sales data from as many EU/EEA countries as possible, which has been a cornerstone of work on antimicrobial resistance thus far.</p>	<p>Noted. Thank you.</p>
85	1	<p>Comment: "covered approximately 95% of the food-producing animal population". The EFFORT project identified gaps on knowledge on different animal species populations in Europe. EMA/ESVAC could contribute to the clarification and harmonization of simple definitions (e.g. cattle or swine different age/production groups) as this would contribute to have a harmonized reporting of the usage quantities.</p> <p>Proposed change (if any): To add "Promote a harmonized definition of the different age/production groups of the main food-producing animal species" to the 2016-2020</p>	<p>Promoting a harmonized definition of different age and production groups of the main food-producing animal species is outside of the scope of the ESVAC project, however, the guidance on collecting data by</p>

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		objectives of the "Collection of consumption data by species" work stream.	animal species to be published shortly for consultation should help to define some of those parameters for the collection of use data by species at EU/EEA level.
87	1	Comment: Sales data from Switzerland have been so far presented in Annex of the ESVAC annual report, although the data is collected using the same approach than the EU countries. Proposed change (if any): Include Switzerland in the core document in future ESVAC reports.	Switzerland has been included in the latest (2014) report since data are now provided at package level.
94-96	6	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. Comment: While automisation of data collection is good, quality control is clearly essential. How is the validity / accuracy of the data safeguarded? Proposed change (if any): Add a paragraph on quality control measures.	Further considerations are ongoing on how to continue improving the quality of the ESVAC sales data, no specific details can be provided at this stage.
99-103	4	Comment: FVE agree that ESVAC database, should be part of the EMA SPOR data repository. FVE position has been that the product database is directly linked to the pharmacovigilance database.	Noted. This option is currently being discussed.
105-113	5	Comment: Very supportive of this activity	Thank you. Noted.
107	1	Comment: Listed species are not consistent with those presented in the ESVAC mission line 48. It seems consumption data will be collected only in a subset of species listed line 48. Proposed change (if any): Ensure the list of species for which consumption data will be collected is consistent with the one presented in the ESVAC mission line 48	We acknowledge the divergence, we aim to collect data from all animal species; the guidance to be published shortly on collecting data by species should be adaptable to collect data from other species than those

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			included in the current strategy.
107	4	Comment: While we agree to start with pigs, poultry and cattle, we plea for including companion animals/wild and exotic animals rather sooner than later.	See comments above.
108	1	Comment: "These data should allow [...] for comparison per species between countries". Will a distinction be made between animal categories (e.g. veal and other ruminants as mentioned in line 48)? Proposed change (if any): If yes, add "These data should allow [...] for comparison per species and animal categories between countries".	Currently under discussion in the above mentioned guidance.
109-110	1	Comment: The sentence is not entirely clear: "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." Proposed change (if any): If the sentence refers to the form, rewrite the sentence to clarify this aspect. If it refers to the DDDvet and DCDvet (as it seems) please clarify.	Noted. The sentence has been rephrased. "Form" has been substituted by "manner".
122	4	Comment: It is a bit unclear what "animal population at risk of treatment" as this is only explained later. Proposed change (if any): Reword	Noted. Further clarified.
138-139	3	Comment: BVA is pleased to see that the EMA recognises that manual collection of data on consumption per species on a national level would not be a sustainable approach in the long term. Consequently, BVA supports the focus on automated or semi-automated data collection.	Noted.
141	5	Comment: Is there an indication of what will be regarded as an acceptable % representation? It would be preferable if this related to production rather than number of farms as most production tends to come from a small number of farms.	This will be addressed in the Guidance for the collection of data on antimicrobial use by species from national data collection systems.
166-170	6	Comment: Does the fact that data from local farms are not included mean that the EMA links prescribing behaviours to unnecessary uses of antimicrobials?	No, the strategy does not discriminate against local farms, nor links any prescribing

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			behaviour with unnecessary use of antimicrobials.
173-174	4	<p>Comment: Experience from the Netherlands shows that in case of collecting information related to an identifiable farm or veterinarian, the issue 'who is owner/keeper of the data' (data-confidentiality) is coming into play. For example if the vet has to put the data of the farmer/keeper into a database, he should be legally entitled to do so, especially when there is no compulsory (by animal/quality sector or law requirements) collecting of data</p> <p>Proposed Change: Add one sentence on data confidentiality.</p>	The document Principles for ensuring the confidentiality of data supplied to the ESVAC (link) addresses the confidentiality of the ESVAC data. Not required to add any reference to the ESVAC strategy.
175-177	6	<p>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.</p> <p>Comment: What were the reasons (resources and legal) cited by the countries that do so? What are the challenges?</p> <p>Proposed change (if any): Mention the reasons for this.</p>	The main reasons are mentioned at the beginning of the paragraph.
181 →	4	<p>Comment: Stratification will not be able to take into account off-label use.</p> <p>Proposed Change: Recognise in the text that the stratification will not be able to take into account "off-label use".</p>	Noted. The text has been modified accordingly.
182-184	1	<p>Comment: This sentence seems to contradict much of the general vision and strategy that the rest of the document suggests. The document emphasizes the need to collect use and sales data, so somehow it is disappointing to read that "...ESVAC will explore if it is feasible to estimate the consumption per species based on an approximate allocation of the proportion of total sales..."</p> <p>Proposed change (if any): "ESVAC will support (via training or electronic tools, for example) countries in the developing of methodologies that will allow the collection and stratification of sales and use data, separated per species.</p>	Not agreed. We consider that the proposal is carefully worded to avoid confusion and takes into account the limited resources of the ESVAC project.
196	5	<p>Comment: The end of this paragraph suggests that EMA/ESVAC anticipate the new legislation requiring collection of usage data from all farms, not just a proportion.</p>	The ESVAC does not anticipate any outcome of the new

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		Is this correct?	veterinary medicines legislation but has identified a willingness from MSs to collect data from farms, pharmacies or veterinary practices.
196-197	1	Comment: Stratification of sales data might also face some confidentiality issues in countries with limited number of market authorisation holders (MHA) (e.g. when only 1 or 2 MHA provide products of a given class for a given animal species).	See comments above on data confidentiality.
223	1	<p>Comment: We agree with the statement "policy makers require standardized data by which to compare different regions and countries". However, using standardized data (e.g. standardized DDDvet) also implies a harmonisation of actual usage. Currently, countries do have different treatment practices (e.g. daily doses or weights at treatment). Using national data can add to the information provided by standardized data.</p> <p>Proposed change (if any): A sentence should be added line 225: "In addition to the standardized approach developed as part of the ESVAC project, member states should be encouraged to develop national monitoring systems that fit their antimicrobial treatment practices and provide supplementary information, for example to relate antimicrobial usage to antimicrobial resistance"</p>	<p>This document reflects the ESVAC strategy for collection of data.</p> <p>Although we sympathize with the statement we consider it as outside the scope of the ESVAC strategy.</p>