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DG Health and
Food Safety

OVERVIEW REPORT

Measures to Tackle Antimicrobial Resistance Through the Prudent Use of Antimicrobials in Animals

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**OVERVIEW REPORT ON MEASURES TO TACKLE ANTIMICROBIAL RESISTANCE
(AMR) THROUGH THE PRUDENT USE OF ANTIMICROBIALS IN ANIMALS**

Executive Summary

This report summarises certain work carried out by the Directorate-General for Health and Food Safety regarding antimicrobial resistance (AMR) in veterinary medicine and, in particular, the efforts to encourage the prudent use of antimicrobials in animals, as advocated in the European Union (EU) guidelines for the prudent use of antimicrobials in veterinary medicine, published in September 2015. This work is part of the initiatives being undertaken by the European Commission to help tackle the rising threats to public and animal health posed by the development of AMR.

This report provides an overview of the situation in the Member States and Norway, Iceland and Switzerland in the above regard, and highlights examples of potential good practice which may be useful in developing approaches to tackling AMR in general, and to the use of antimicrobials in animals in particular. Some challenges in implementing policies for the prudent use of antimicrobials are also described.

Overall, the information gathered in the responses to a questionnaire sent to authorities and relevant organisations in the above countries and during the series of fact-finding missions on this topic carried out during 2016, shows that nearly all countries have either put in place, or are developing, strategies and a range of policies for the prudent use of antimicrobials. These include a variety of initiatives by competent authorities, stakeholders, or both; for instance, targets for the reduction of antimicrobial use and bans on the use of critically important antimicrobials in certain animal species. Veterinarians play a key role in encouraging producers to adopt preventive measures that avoid the need for antimicrobials, while also making informed decisions about the most appropriate antimicrobials to prescribe, and this is reflected in the policies put in place by countries reporting recent significant reductions in the use of antimicrobials, or their consistently low use.

The combined effect of the policies implemented at all levels can result in substantial reductions in antimicrobial use of more than 50 %, even where the national strategies are at an early stage and the associated policies are of voluntary nature, with the resulting limited ability to control and enforce compliance with them. The multiple factors influencing the development of AMR make it difficult to elucidate the impact of specific measures, although the analysis of monitoring of AMR and of antimicrobial usage shows an association between reductions in antimicrobial use and reduced levels of AMR. This series of fact-finding missions continued during 2017 and further visits are planned in 2018.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AMR	Antimicrobial resistance
CIAs	Critically important antimicrobials
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ESBL	Extended-spectrum β -lactamase producing organisms
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
FVE	Federation of Veterinarians of Europe
JACRA	Joint Interagency Antimicrobial Consumption and Resistance Analysis report
PCU	Population correction unit
RONAFA	EMA and EFSA Joint Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety
SPC	Summary of product characteristics
WHO	World Health Organization

1 INTRODUCTION

The rising threats to human and animal health posed by the development of antimicrobial resistance (AMR) are increasingly recognised globally along with the need for concerted action to limit its development and maintain an arsenal of effective antimicrobials to treat infections ¹.

The European Commission has been actively involved in matters relating to AMR for more than 15 years during which time it has set out a range of initiatives and actions aimed at tackling these issues ². Its first Action Plan against the rising threats from AMR ³ and associated road map ⁴ covered the period 2011 to 2016. Following an evaluation of the outcome of this plan, the Commission published its second AMR action plan in June 2017 ⁵. This new plan is based on a One Health approach (as described on page 4 of this AMR action plan), a globally recognised term ⁶, which acknowledges the links between the use of antimicrobials in human and veterinary medicine and the common threats posed to both by the development of AMR.

This report summarises work being carried out by DG Health and Food Safety as part of a number of initiatives included in the first AMR action plan (mainly actions 2 and 3 of the road map) and is directly relevant to the first objective of the new action plan – namely to make the European Union (EU) a ‘best practice’ region in the fight against AMR. In particular, this report aims to provide an overview of the efforts being made in the EU and beyond to encourage the prudent use of antimicrobials and to tackle AMR in animals, and to highlight potential examples of good practice which may be of use in developing policies and initiatives on these topics. The report will be updated regularly to incorporate relevant information gathered during additional fact-finding missions carried out from 2017 onwards. Comprehensive details of specific initiatives put in place in each country are not provided as these can be found in the published reports of the fact-finding missions carried out during 2016 (see Annex IV). These topics are also explored in depth in the European Medicines Agency (EMA) and European Food Safety Authority (EFSA) Joint Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety (RONAFA) ⁷.

¹ https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf

² https://ec.europa.eu/health/amr/action_eu_en

³ https://ec.europa.eu/health/amr/sites/amr/files/communication_amr_2011_748_en.pdf

⁴ https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/roadmap_amr_en.pdf

⁵ https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf

⁶ <http://www.euro.who.int/en/health-topics/disease-prevention/antimicrobial-resistance/about-amr/one-health>

⁷ <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4666/epdf>

Approaches taken to gathering information

The information used to prepare this report was gathered firstly through means of a questionnaire sent by DG Health and Food Safety in September 2015 (see Annex II), followed by fact-finding missions to nine Member States in 2016. The questionnaire was addressed to the competent authorities in all EU Member States, Norway, Iceland and Switzerland⁸, as well as to the members of the Advisory Group on Food Chain and Animal and Plant Health, and to the national organisations member of the Federation of Veterinarians of Europe (FVE) in the afore-mentioned countries. Providing a response to the questionnaire was entirely voluntary and the Commission acknowledges the effort involved by all those replying (see Annex III). The questionnaire sought to gather information on the distribution and use of antimicrobial veterinary medicinal products, including medicated premixes for animal feed, and evidence of how the guidelines on the prudent use of antimicrobials in animals have been put into practice. Nevertheless, some caution is urged in the analysis of the responses to the questionnaire, since there was some variation in the quality and completeness of some of the responses.

Following an analysis of the responses and other relevant information (such as the reports of the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project⁹), a number of countries were chosen to be involved in a series of fact-finding missions, which were carried out in 2016 in cooperation with the national competent authorities. The Member States visited (see Annex IV) included those reporting among the highest and lowest sales of antimicrobials to the ESVAC project and several which have reported significant downward trends in recent years. The fact-finding missions took account of the regulatory framework on veterinary medicines and on medicated feed (including for companion animals) currently in place in the countries visited, and the implementation of existing recommendations and guidelines on the prudent use of antimicrobials in veterinary medicine, including those published by the Commission (see below). After each fact-finding mission, the main observations and any good practices identified were presented in a report, which was published on the DG Health and Food Safety website, upon agreement of the competent authorities concerned. Links to these reports are provided in Annex IV. Recommendations for further improving the prudent use of antimicrobials were discussed during the course of the missions but were not formalised in the reports, as these were fact-finding missions.

The implementation of requirements for the monitoring of AMR in certain food and animals (stemming from Commission Implementing Decision 2013/652/EU¹⁰) were not included in the scope of the missions, as these are the subject of other audits carried out by DG Health and Food Safety. An interim report based on this audit series has been already published¹¹.

⁸ Currently 30 EU and European Economic Area Member States report data on the use of antimicrobials agents in animals to the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project (see section 3.1.).

⁹ http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jsp

¹⁰ References to all EU legal texts cited in this report are provided in Annex 1 and they refer, where applicable, to the last amended version.

¹¹ http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=110

What is prudent use?

In September 2015, the European Commission published guidelines for the prudent use of antimicrobials in animals¹², which set out many potential factors to be considered in establishing policies and actions which reflect the multi-faceted, complex issues involved in tackling AMR. They define the prudent use of antimicrobials as leading to more rational and targeted use of antimicrobials, thereby maximising their therapeutic effect and minimising the development of AMR. Taking into account cross- and co-resistance, which mean that any exposure to antimicrobials increases the occurrence of AMR, the final outcome of prudent use should be an overall reduction in the use of antimicrobials, predominantly by limiting their use only to situations where they are necessary. In such situations, antimicrobials should be used as targeted treatment based on clinical diagnosis and, whenever possible, on the results of microbiological susceptibility tests, and using an antimicrobial agent of as narrow-spectrum as possible. This approach is encapsulated in the motto 'as little as possible, as much as necessary'.

The ultimate objective is to reduce the need for antimicrobials by preventing disease (i.e. 'prevention is better than cure'). Animal diseases and infections should primarily be prevented by ensuring biosecurity, following good production and good management practices, and implementing integrated disease control programmes to minimise the occurrence of diseases and eradicate endemic disease.

What is meant by good practice in this report?

The many inter-linked factors which can influence the development of AMR and contribute to the prudent use of antimicrobials in animals make it problematic to assess the impact of specific actions in addressing these issues. Accordingly, the potential examples of good practices described in the report are mostly based on approaches taken to common issues which have supported or contributed significantly to the effective implementation of prudent use policies. Where examples of actions taken by particular countries are given, this is only to illustrate the range of approaches taken and should not be understood as an endorsement by the Commission. Challenges to the development and implementation of policies for prudent use of antimicrobials are also described.

Antimicrobials and antibiotics

Throughout this report, the term 'antimicrobial' is used to encompass antibiotics and antibacterial agents but excludes antivirals, antiparasitics and biocides (including disinfectants). This definition is consistent with that given in the EU prudent use guidelines referred to above.

¹² Guidelines for the prudent use of antimicrobials in veterinary medicine. OJ C 299, 11.9.2015, p. 7.
http://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/2015_prudent_use_guidelines_en.pdf

Critically important antimicrobials

Antimicrobials of particular importance in human medicine are considered critically important antimicrobials (CIAs)¹³, and there is broad consensus that these should be used with particular care in veterinary medicine. It should be noted that there is some divergence in the list of CIAs in accordance to different organisations, and that this report refers to the CIAs stemming from the scientific advice produced by EMA in this regard¹⁴.

2 DIRECTION AND PRIORITIES – NATIONAL STRATEGIES AND ACTION PLANS

A call to EU Member States to develop and implement national strategies or action plans for countering AMR which include specific elements (such as development of treatment guidelines, the use of diagnostic and susceptibility tests and enforcement of relevant national rules) was contained in the 2012 Council conclusions on the impact of antimicrobial resistance in the human health sector and in the veterinary sector – a One Health perspective¹⁵.

The commitment of the EU and its Member States to develop AMR action plans based on a One Health approach, was re-iterated in the conclusions and findings as presented during the EU Ministerial One Health Conference on AMR held in Amsterdam in February 2016¹⁶. The need for coordinated actions to tackle AMR in a One Health context was elaborated further in the Council Conclusions on the next steps under a One Health approach to combat antimicrobial resistance 17 June 2016¹⁷.

The issue has become more globally prominent with the World Health Assembly of the World Health Organization (WHO) urging all its Member States to have in place by 2017 national action plans on AMR that are aligned with the objectives of the WHO global action plan on AMR¹⁸, adopted in May 2015 by the 68th World Health Assembly of the WHO¹⁹.

Specific information on the development of national AMR strategies and action plans was not requested in the questionnaire (as it pre-dated the most recent calls outlined above), although this was sometimes included in the responses. The topic was discussed during the fact-finding missions carried out in 2016. Five of the nine Member States visited had AMR strategies in place which included at least some of the key sections set out in the 2012 Council conclusions and the principles set out in the Commission guidelines for prudent use of antimicrobials in animals. Three of these Member States were preparing their national AMR strategies, mostly based on already established policies and practices.

¹³ <http://www.fairfarms.com/portfolio-item/what-constitutes-critically-important-antimicrobials/>

¹⁴ http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/07/WC500170253.pdf

¹⁵ http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/131126.pdf

¹⁶ <https://english.eu2016.nl/documents/publications/2016/03/10/conclusions-and-findings-as-presented-during-the-eu-ministerial-one-health-conference-on-amr-on-the-10th-of-february-2016-amsterdam-copy>

¹⁷ <http://eu-un.europa.eu/eu-council-conclusions-on-the-next-steps-under-a-one-health-approach-to-combat-antimicrobial-resistance/>

¹⁸ http://apps.who.int/iris/bitstream/10665/193736/1/9789241509763_eng.pdf?ua=1

¹⁹ <http://www.who.int/antimicrobial-resistance/national-action-plans/en/>

Only one Member State had not begun drafting a national strategy and action plan. A list of national AMR action plans is available at the webpage of ECDC ²⁰.

The measures, scope and priorities of the national AMR strategies seen varied in the Member States visited, with several restricted largely to topics covered by existing EU or national legislation (e.g. mandatory vaccination programmes and checks on compliance with requirements for the distribution and use of veterinary medicinal products). The lack of legal bases relating to the prudent use of antimicrobials was cited as a limiting factor by two Member States. In some other Member States visited though, a combination of national legal requirements and professional obligations supported more extensive AMR strategies.

Targets for reductions in the use of antimicrobials were set out in several of the strategies seen, often in conjunction with a clear political commitment to address issues relating to AMR in certain key food producing species. However, the setting of targets was not seen as desirable or feasible by other Member States visited. Reasons for this included, typically, limitations in the data available to appropriately set targets for antimicrobial use, and to monitor progress made in fulfilling them, and the lack of a legal basis for enforcing these targets. In other cases, the main focus of the strategies was to maintain already relatively low levels of antimicrobial use or to achieve reductions or changes in antimicrobial use through behavioural change. Some competent authorities expressed the view that targets should be set on the basis of technical rather than political criteria, in order to avoid pushing them to levels at which animal welfare and the freedom of veterinarians to act is compromised.

In most cases, the national strategies had been developed with the involvement of professional and industry stakeholders, including those representing veterinarians and breeders Non-Governmental Organisations, as well as some representing consumers and, to a lesser extent, retailers. The key role that these can have in providing an impetus for reducing antimicrobial use was seen in several Member States visited, where a range of voluntary initiatives had contributed significantly to the adoption of prudent use measures. Examples include voluntary bans or restrictions on the use of certain CIAs in the poultry and pig sectors and avoiding routine treatments of mastitis in dairy cows. In addition, the involvement of veterinarians in the development of treatment guidelines not only helped to ensure that they were appropriate but also that they are taken up and accepted by other stakeholders.

3 MONITORING ANTIMICROBIAL CONSUMPTION AND LEVELS OF AMR

The ability to monitor the consumption of antimicrobials and the levels of AMR changes over time, and provides a useful tool for prioritising actions and measuring their impact.

3.1 MONITORING SALES OF ANTIMICROBIALS

Data on the sales of antimicrobials for use in animals provides a key measure of overall trends and, more specifically, of the impact of measures to encourage their reduced and more prudent use. All countries responding to the questionnaire indicated that sales data are routinely gathered, and all except Malta provide annual data to the ESVAC project.

²⁰ http://ecdc.europa.eu/en/healthtopics/Healthcare-associated_infections/guidance-infection-prevention-control/Pages/antimicrobial-resistance-strategies-action-plans.aspx

The seventh edition of the ESVAC report ²¹ highlights the considerable variation across the 30 countries contributing data in terms of the total sales of antimicrobials (with a range from 2.9 to 434.2 mg/Population Correction Unit – PCU). Similarly, the change in sales reported by 25 countries from 2011 to 2015 varied, with 15 countries reporting a decline in sales of more than 5 % whereas 8 countries reported an increase of more than 5%. For the 25 countries reporting sales data to ESVAC for the years 2011-2015, an overall decline in sales (mg/PCU) of 13.4 % was observed. Within these figures, notable variations were observed between countries in the proportion of 3rd and 4th generation cephalosporins, fluoroquinolones and polymyxins sold in 2015. Similarly, the proportion of pharmaceutical forms for group treatment varied between 7 % and 97 % of the total sales of antimicrobials within countries, highlighting the importance of oral administration of antimicrobials compared to injectable and intramammary preparations, which together account for 8.8 % of total sales. The report cautions about making more detailed comparisons between countries or for concluding about short term sales trends as many variable factors influence the overall sales data provided and the assumptions on which the standardised mg/PCU figures are based.

3.2 DATA ON THE USE OF ANTIMICROBIALS BY FARM / SPECIES

The collection of data for the use of antimicrobials by species has been the subject of guidance and consultation by EMA ²² ²³ and the Commission ²⁴, since this could support the development of more detailed measurements, such as defined daily doses, which could reflect dosing differences between substances and species, and give a more sophisticated measure of exposure of animals to antimicrobials. Furthermore, usage data collected by species at farm level could allow certain off-label (i.e. not in accordance with the Summary of Product Characteristics – SPC ²⁵) use of veterinary antimicrobials to be elucidated, which is currently not possible based on overall sales data. Importantly, the ability to monitor the use of veterinary antimicrobials in different species provides a valuable tool for prioritising actions (e.g. to target relatively high use sectors) and identifying their impact and supports the development of benchmarking schemes.

Eleven countries indicated in their response to the questionnaire that they collect usage data for certain species of food producing animals, and other countries were in the process of developing electronic prescription systems to capture such data. Certain features of the systems put in place by some of the Member States visited are highlighted below:

- The use of on-line databases, providing comprehensive data, is compulsory in Denmark in order to record details of the prescription, and the use of antimicrobials in

²¹ http://www.ema.europa.eu/docs/en_GB/document_library/Report/2017/10/WC500236750.pdf

²² http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/10/WC500152313.pdf
http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500224492&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc

²³ http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/10/WC500152313.pdf
http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500224492&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc

²⁴ https://ec.europa.eu/health/amr/events/ev_20170426_en

²⁵ https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-6/c/spcpharmaceuticals_10-07-2006_en.pdf

key species (e.g. pigs, dairy, broilers, veal calves) in the Netherlands, Finland, Germany, and Denmark.

- In Denmark, the use of automated systems reduces resource and time requirements in pharmacies, compared with manual input systems.
- In the Netherlands and Finland, the use of industry owned and operated databases reduces costs for the competent authorities, but may affect the availability of data.
- Data are accessed in an anonymised and/or aggregated form by the competent authorities of Denmark, the Netherlands, and Germany. This approach helps overcome potential data protection issues and concerns about how the information will be used.
- The analysis of data provides the basis for determining compliance with thresholds (the yellow card schemes) in the pig and dairy sectors in Denmark, for benchmarking the relative performance of veterinarians and farms in the Netherlands and Germany, and the operation of the 'antibiotic minimisation concept' in Germany. More generally, the data serve to inform policy development, monitor trends and target policy and control actions.

In the absence of species/farm specific recording schemes, it was still possible for the use of antimicrobials to be estimated in some cases. Although they can be of questionable accuracy and reliability, estimates of use can be obtained where they are based on a limited range of known factors, such as the use of antimicrobials by veterinary practices which specialise in one species of animal on a limited number of farms. This approach was also a useful means to gather information on the use of antimicrobials in pets.

Although there was a broad consensus among Member States visited regarding the potential benefits of collecting more detailed data on antimicrobial consumption (reflecting the outcome of EMA consultations referred to above), several highlighted the potential challenges of putting in place the systems needed to collect and validate the detailed data to accurately monitor the use of antimicrobials by species, and therefore questioned the likely cost-benefits of such an approach. The benefits of countries cooperating with each other to develop these systems, notably in terms of costs, resources and expertise, were discussed.

The availability of real-time data on the use of antimicrobials at farm / species level has under-pinned the development of various benchmarking or threshold schemes in some of the Member States visited.

3.3 MAKING THE CONNECTION BETWEEN ANTIBIOTIC USE AND AMR

The results of monitoring activities, including the harmonised EU programmes under Decision 2013/652/EU provide important indications of trends in the development of AMR at both European and national levels²⁶. Making fuller use of these data and other relevant ones

²⁶ http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001863.jsp&mid=WC0b01ac0580c0fa1d

(e.g. consumption of antimicrobials) provide an opportunity to gain a clearer understanding of the potential links between the use of antimicrobials and AMR and the impact of measures taken. Given the value of such information in guiding policy development, it can be considered good practice to perform such detailed analyses on an on-going basis.

Many of the Member States visited (and several other countries, according to their responses to the questionnaire) have established programmes for the detailed analysis and interpretation of the results both from their AMR surveillance in humans and animals (and products derived therefrom) and from the data on the consumption of antimicrobials. Examples highlighted in the responses to the questionnaire or discussed during the fact-finding missions include DANMAP²⁷ in Denmark, FINRES²⁸ in Finland, GERMAP²⁹ in Germany, MARAN³⁰ and NethMap³¹ in the Netherlands, NORMVET³² in Norway, and Swedres-Svarm³³ in Sweden. In addition, France has established the network *Résapath*³⁴, which brings together the results of AMR monitoring for bacteria responsible for infections in many species of animals (see section 7.3.3).

Notwithstanding the specialist expertise and other resources required, these programmes provide a deeper understanding of the various factors influencing the development of AMR at national level, including the use of antibiotics, and the impact of measures taken to prevent AMR. Taken as a whole, they also help provide a view of trends throughout Europe and complement the more comprehensive analysis described in the Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) reports^{35 36}, prepared by ECDC, EFSA and EMA. These reports highlight the links between antimicrobial consumption and AMR, and that the use of antimicrobials in the veterinary sector has implications for the development of AMR in humans (e.g. resistance to quinolones, used to treat salmonellosis and campylobacteriosis in humans, is associated with use of antibiotics in animals). Encouragingly, the results of the analyses carried out in certain countries indicate that reductions in antimicrobial use can lead to a decline in levels of AMR, although the data do not support the establishment of 'acceptable levels' or threshold for use below which AMR will not develop³⁷. These reports broadly support the case that using antimicrobials prudently is likely to limit or even contribute to reversing the development of AMR.

²⁷ <http://www.danmap.org/>

²⁸ <https://www.evira.fi/elaimet/elainten-terveys-ja-elaintaudit/laakitseminen/antibiottiresistenssin-seuranta/finres-vet-raportit/>

²⁹ <http://www.p-e-g.org/econtext/germap>

³⁰ <http://www.wur.nl/en/Research-Results/Projects-and-programmes/MARAN-Antibiotic-usage.htm>

³¹ <http://www.rivm.nl/dsresource?objectid=f9799644-beb0-405b-b35f-c3db66dc153b&type=pdf&disposition=inline>

³² <http://www.eng.vetinst.no/eng/Publications/NORM-NORM-VET-Report.html>

³³ <http://www.sva.se/en/antibiotika/svarm-reports>

³⁴ <https://www.anses.fr/fr/content/le-r%C3%A9seau-r%C3%A9sapath>

³⁵ http://www.ema.europa.eu/docs/en_GB/document_library/Report/2015/01/WC500181485.pdf

³⁶ http://www.ema.europa.eu/docs/en_GB/document_library/Report/2017/07/WC500232336.pdf

³⁷ <http://www.autoriteitdiergeniesmiddelen.nl/Userfiles/rapport%20ab%20en%20resistentie/def-engels-rapport-abgebruik-en-resistentie-0516.pdf>

Monitoring antimicrobial consumption and levels of AMR

Good practices:

- Collection and analysis of data on antimicrobial use by species / farm (even in anonymised form) enables more precise prioritisation of actions for the prudent use of antimicrobials and provides the basis for developing benchmarking / threshold schemes and can allow actions to be targeted at the highest users;
- Jointly analysing data on antimicrobial use and AMR enables links between the two to be identified and provides indications of the potential impact of measures to tackle AMR;
- Publication of the results of such analyses contributes to a deeper understanding of the situation in Europe.

Challenge:

- Potential resource and cost implications may hamper the development of the systems needed to gather and analyse data by species / farm – collaboration between countries may reduce the burden.

4 DISTRIBUTION OF ANTIMICROBIALS

4.1 VETERINARIANS AS GATEKEEPERS FOR THE DISTRIBUTION AND USE OF ANTIMICROBIALS

All countries responding to the questionnaire indicated that veterinary antimicrobial products are only available on prescription issued mostly by a veterinarian, or in a few cases fish biologists for aquaculture. Exceptions to this are limited to certain species kept as pets (e.g. aquarium fish, cage birds, homing pigeons, terrarium animals and certain rodents, ferrets and rabbits) in several countries.

This assigns a key role to the veterinarians in the distribution and use of veterinary antimicrobial products and as such, they have a major influence on the effective implementation of prudent use policies.

4.2 FOSTERING COMMITTED LINKS BETWEEN VETERINARIANS AND FARMERS

Most countries responding to the questionnaire noted that prescriptions for veterinary antimicrobial products should only be issued on the basis of a diagnosis and/or on the prescribing veterinarian having knowledge of the animals to be treated. Measures aimed at enabling veterinarians to be familiar with the health status of the animals were considered good practice in the majority of Member States visited: In four of these Member States, these either included requirements for farmers to have a contract with a veterinarian for the provision of animal health care (Finland and Denmark) or provided benefits to farmers who adopted them on a voluntary basis (Netherlands, Slovenia) In some cases, the minimum requirements for routine farm visits by the veterinarians are set down in national rules taking account of the species and number of animals present. The regular visits to farms, as opposed to only being called when a problem arises, were generally perceived as an opportunity for

veterinarians to provide advice to farmers regarding medium to long term initiatives aimed at improving animal health and reducing the need for antimicrobials (e.g. improvements in buildings, enhancing biosecurity, breeding programmes, etc.). Veterinarians in several of the Member States visited noted that these contractual arrangements help compensate for potential financial implications of prudent use policies (see section 7.3.2).

Several of the Member States visited where farmers need to have contracts with veterinarians for regular farm visits, also require health plans for the farm to be drawn up and reviewed regularly (at least annually). This could be considered as good practice as the health plans provide a means to objectively assess factors affecting animal health and welfare, their impact on productivity and to agree actions to enhance these aspects over time. Through this, the plans tend to promote preventive actions but they also often identified common conditions which could be expected to arise between veterinary visits and appropriate quantities of veterinary medicinal products (including certain antimicrobials) to treat them could, at the veterinarian's discretion, be prescribed or left on the farm. This approach avoids the need for farmers to call veterinarians to treat common conditions, saving both time and money, especially in remote regions (e.g. in Finland).

It should be noted that in two Member States visited (Romania and Slovenia), cultural and practical factors linked to the organisation of veterinary health care often resulted in stable associations between veterinarians and farmers without the need for a formal contract.

Distribution of antimicrobials

Good practices:

- Measures to foster closer links between veterinarians and farmers emphasise the advisory and professional health care role of the veterinarian and enables them to be familiar with the animals and conditions to be treated (in a targeted manner) and facilitates longer term planning including investments in preventive measures;
- An increased focus on preventive measures and resulting improvements in animal health reduces the need for treatments with antimicrobials.

5 COMMUNICATION AND AWARENESS RAISING ACTIVITIES

The need to raise awareness and increase information about the prudent use of antimicrobials features prominently in various international and national action plans and strategies for tackling AMR including those in the Member States visited. Based on the responses to the questionnaire and the results of the fact-finding missions, it is evident that significant efforts have been made by virtually all countries to increase awareness on AMR, with an emphasis on campaigns, publications, including guidance, and the provision of training on issues relevant to the prudent use of antimicrobials.

5.1 GUIDANCE AND OTHER INFORMATION

A substantial quantity of guidance documents relating to the prudent use of antimicrobials has been published by numerous public, professional and industry bodies. In their responses to

the questionnaire, 26 countries referred to specific and joint initiatives to raise awareness undertaken by the national competent authorities and industry or other professional stakeholders. Many of the guidance and information documents are publicly available and links to particular examples are available in the reports of each of the published fact-finding mission reports listed in Annex IV. The content and target audience of the guidance available varies from summaries of the general principles of the prudent use of antimicrobials, to more detailed descriptions of good agricultural and hygiene practice, or even species-specific guides to the implementation of vaccination programmes or strategies for managing specific conditions. In some cases, the guidance and other relevant information has been brought together under common national or international platforms which present it in an organised and easily accessible way, for instance AMCRA ³⁸ in Belgium and RUMA ³⁹ in the United Kingdom. In many cases, the Commission's guidelines for prudent use of antimicrobials (see section 1) have been published in their original form, or incorporated into other documents. In their responses to the questionnaire, 26 countries indicated that they have guidance on the correct storage, use and disposal of antimicrobials, including medicated feed in 12 cases. Certain guides aimed at veterinarians provide recommendations on the antimicrobials to be used for the treatment of common conditions in food-producing and some companion animals (see section 7.3.3). The value of providing information to pet owners to help address their concerns and lessen demands for antimicrobials were noted during the fact-finding missions and in several responses to the questionnaire, and examples of leaflets and other posters for this purpose were provided by Finland and France.

The value of guidance in raising awareness and encouraging the prudent use of antimicrobials was apparent during the fact-finding missions as was the potential for making wider use of the work already done throughout Europe, therefore avoiding the duplication of efforts. This is already the case for certain long-standing, proven guidance such as the Nordic Guidelines for Mastitis Control ⁴⁰ and the guidance published by the Federation of European Companion Animal Veterinary Associations for the treatment of small animals ⁴¹, both of which were referred to in many of the Member States visited. In one of these Member States, the competent authorities offered a cautionary note about the potential drawbacks of publishing too many documents giving similar but different messages and so causing confusion; these authorities are now in the process of collating the multitude of documents in a more coherent way.

5.2 TRAINING

Training on AMR and prudent use of antimicrobials was offered in various forms to veterinarians (including officials) and farmers in the Member States visited and it was also mentioned in the responses of other countries to the questionnaire.

Most veterinarians met during the fact-finding missions were familiar with issues relating to AMR and the prudent use of antimicrobials, although a small number had a limited

³⁸ <http://www.amcra.be/en>

³⁹ <http://www.ruma.org.uk/>

⁴⁰ <http://www.sva.se/globalassets/redesign2011/pdf/antibiotika/antibiotikaresistens/nordic-guidelines-for-mastitis-therapy.pdf>

⁴¹ [http://www.fecava.org/sites/default/files/files/DSAVA_AntibioticGuidelines%20-%20v1-1_3\(1\).pdf](http://www.fecava.org/sites/default/files/files/DSAVA_AntibioticGuidelines%20-%20v1-1_3(1).pdf)

understanding of more specific issues for example concerning CIAs. AMR and the prudent use of antimicrobials were reported to be covered briefly as part of their university courses, which neither provided them with state of the art knowledge of the topic nor adequately informed them of the different approaches taken by those countries in which they are employed. This particularly affected certain north European countries and those without veterinary colleges. Additional training provided as part of the veterinarians' on-going professional development helped in addressing this issue. However, although on-going professional development is compulsory in most countries, the courses followed are usually optional, and the preferred subjects are those directly linked to their main areas of work. As a result, participation in courses dealing only with AMR and the prudent use of antimicrobials was sometimes limited, and suggestions for remedying this situation included incorporating these subjects into the other courses and providing additional on-line training.

Farmers were often seen to be responsible for administering antimicrobials prescribed by the veterinarians, at least for certain conditions in the Member States visited. Training to help ensure that farmers could administer the antimicrobials properly and in accordance with the prescription was provided in several countries, and veterinarians could refuse to leave antimicrobials on farms if they doubted the farmers' ability in this respect. In most of the Member States visited, there has recently been a notable shift away from medicated feed to using powders or drinking water for the oral administration of antimicrobials. Although farmers sometimes referred to guidance on their proper use, they noted there is potential to increase understanding of this topic, including cleaning and avoidance of environmental contamination.

Communication and awareness raising activities

Good practices:

- Considerable efforts have been made by officials, professional and industry organisations to raise awareness of AMR through guidance and training which resulted in better understanding/improved practices by veterinarians and animal owners/keepers;
- Much of the guidance is readily accessible and there is potential to utilise this more widely and, in doing so, avoid duplication of effort.

Challenges:

- The curricula of under-graduate veterinary education do not always put enough emphasis on AMR and prudent use of veterinary antimicrobials;
- Ensuring veterinarians trained in one country are sufficiently aware of the requirements and practices relating to the use of antimicrobials in another where they work can be problematic;
- Issues relevant to AMR and prudent use are often included in on-going professional development for veterinarians but they may choose alternative modules more pertinent to their area of work.

6 'PREVENTION IS BETTER THAN CURE' – AVOIDING THE NEED FOR ANTIMICROBIALS

The concept that 'prevention is better than cure' involves many inter-linked elements, which together minimise disease through a holistic and integrated approach affecting the health of animals throughout their lifetime. While the disease pressure and situations varies, with some countries enjoying certain geographical, climatic and economic advantages, there were many common actions taken in key sectors associated with relatively high use of antimicrobials, in conjunction with stakeholders and authorities to avoid the need for antimicrobial treatments. These actions include national policies aimed at meeting specific objectives for particular sectors and/or species (e.g. rules requiring imported animals to be free from certain conditions), and also those introduced by farmers and veterinarians on their own initiative. Some examples of these actions, gathered from the replies to the questionnaire and during the fact-finding missions, are as follows:

- National rules are applied in a limited number of countries (e.g. Finland and Norway) to maintain the current high health status of their national herds through checks to prevent the introduction of certain conditions in animals entering the countries.
- The role of robust biosecurity measures in preventing the introduction of disease to the farms was highlighted in most countries (especially for pigs), with checks being carried out to verify that adequate measures are applied.
- At farm level, examples were seen of pig (all Member States visited), dairy (Spain) and rabbit (Spain) farms which breed their own replacement stock and so avoid the need to introduce animals from outside. In other cases (e.g. veal and pig in the Netherlands) farms were required to buy stock from a limited number of ideally known sources (e.g. three farms). In the veal sector, this has also enabled arrangements to be made concerning the health of calves on dairy farms – including administering vaccines – prior to their delivery to the veal producers. In poultry, agreements with the suppliers of parent stock have stopped the previously routine use *in ovum* of antimicrobials, including CIAs and reduced the levels of AMR seen in subsequent stages of the production process.
- Efforts to enhance the environment in animal houses (e.g. improved ventilation and building design) and promote good hygiene practice had reduced issues with common conditions in poultry, pigs and rabbits.
- Vaccinations have helped to virtually eliminate, or substantially reduce, the need for antimicrobials in many sectors. However, their use was sometimes constrained by their relatively high cost, availability and practicality issues – especially in short lived species.
- A programme to enhance the health of the national herd has been implemented in one Member State, where pig herds with relatively poor health status are culled and the site repopulated with healthy animals following thorough cleaning and disinfection.

- Other initiatives seen include improved feed quality (e.g. reduced mycotoxins in poultry feed, development of dry feed for fur animals), use of pre- and probiotics trialling of novel feed additives intended to improve gut health and digestibility of feed and enhanced resistance through breeding programmes.

The combination of measures such as those outlined above has enabled the use of antimicrobials to be almost phased out in certain sectors (e.g. poultry and aquaculture), and reduced significantly in others (e.g. avoiding the use of ‘starter packs’ in veal). In other sectors often associated with relatively high use of antimicrobials, farmers visited during the fact-finding missions had reduced their use by 50 % sometimes on their own initiative, without affecting productivity.

The major challenges highlighted in the fact-finding missions included the need for expert and financial support for farmers to adapt their management of the production process, limitations on the use of vaccinations (cost, availability and use in certain species) and the potential costs of modifying buildings, etc. In particular, some pig producers noted that it could be challenging to avoid increasing antimicrobial use to overcome the effects of potential restrictions on the use of zinc oxide in light of the EMA review of the safety and effectiveness of veterinary medicinal products containing this substance to be administered orally to food-producing species ⁴². (On 26 June 2017, the Commission adopted a Decision ⁴³ according to which Member States should withdraw (within 5 years) marketing authorisations for veterinary medicines containing zinc oxide administered orally to food producing species). Some success in this respect was reported by farmers with the limited number of vaccines authorised within the EU for the prevention of diarrhoea in piglets.

A comprehensive description of the range of measures taken by Member States to prevent infection is given in the RONAFAs report (see section 1).

'Prevention Is Better Than Cure'- Avoiding the need for antimicrobials

Good practice:

- Integrating a broad range of mandatory and voluntary measures to enhance animal health can substantially reduce the need for, or eliminate the use of, antimicrobials in certain species / production sectors;
- Despite some limiting factors, vaccination programmes can virtually eliminate, or substantially reduce, the need for antimicrobials in many sectors.

Challenges:

- Providing the necessary support in order for farmers to be confident in adopting new production methods and management techniques and in upgrading facilities as necessary;
- Availability, cost and other practical issues affect the uptake of vaccinations which could otherwise significantly reduce the need for antimicrobial treatments;

⁴² http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/referrals/Zinc_oxide/vet_referral_000122.jsp&mid=WC0b01ac05805c5170

⁴³ <http://ec.europa.eu/health/documents/community-register/html/vo26166.htm>

- Reducing the current levels of zinc oxide use without increasing the use of antimicrobials.

7 'AS LITTLE AS POSSIBLE, AS MUCH AS NECESSARY' – PRUDENT USE OF ANTIMICROBIALS

7.1 FACTORS AFFECTING THE RANGE OF ANTIMICROBIALS AVAILABLE

Two countries highlighted in their response to the questionnaire the importance of measures to ensure the availability of sufficient antimicrobials, especially for relatively small national markets, since their prudent use could be compromised if supply were not maintained. Examples of the steps taken in order to address this issue include special permits for welfare reasons, exemption permits for foreign language packages and mandatory reserve requirements for importers of certain antimicrobials.

The majority of countries responding to the questionnaire also have mechanisms in place to allow special licences to be issued for the use of antimicrobials in animals (e.g. for products from other Member States or imported from other countries and intended for off-label use), with typically less than 10, rising to a maximum of more than 40, such licences having been issued. In general, the majority of these special licences are not for CIAs. Ten countries stated that they have not issued any special licences for antimicrobials.

Subject to certain restrictions, cross-border sales of veterinary antimicrobials are allowed by six countries responding to the questionnaire, whereas these are currently not allowed in two Member States. The other Member States did not provide such information in their responses. There is a variable approach to internet sales with 12 countries specifically stating these are not possible, and 3 allow these sales on prescription and subject to certain controls.

7.2 RESTRICTIONS APPLICABLE TO THE USE OF VETERINARY ANTIMICROBIALS

A range of restrictions applicable to veterinary antimicrobials have been put in place from those addressing specific issues in a limited number of countries (e.g. a prohibition on using veterinary antimicrobial products to treat *Salmonella* infections) to more generalised, common practices which have implications for the prudent use of veterinary antimicrobial products. The main ones are outlined below.

Off-label use

Approximately two thirds of the countries noted in their response to the questionnaire that they either have, or are preparing, special measures (including training or guidance) or legislation to restrict the off-label use of veterinary antimicrobial products.

An example of these was seen in two Member States visited, where off-label use of antimicrobials is prohibited by national rules except in exceptional and justified cases. In the Netherlands in particular, veterinarians using products off-label are required to justify their actions to a professional board in order to avoid sanctions. The Dutch competent authorities noted that the information gathered from these cases will contribute to a harmonised national

understanding of situations where such off-label use is justified. In the Member States visited which applied restrictions on the off-label use of antimicrobials, the veterinarians met stated that they were mostly able to manage, but they acknowledged that this restriction could limit the treatment options available and potentially lead to less desirable antimicrobials (from an AMR perspective) including CIAs being used. In contrast, several countries noted in their responses to the questionnaire or during the missions, that increasing the dose/duration of treatments above that specified in the SPC allows certain older antimicrobials such as penicillins, to be used effectively to treat conditions which would otherwise require the use of other less desirable (from an AMR perspective) antimicrobials. One country visited (Finland) recommended such off-label use in its official recommendations for prudent use of antimicrobials, while also recognising that care should be taken in determining appropriate withdrawal periods.

Other specific restrictions have been applied to the use of the 'cascade'⁴⁴, in particular where it involves CIAs. Eight countries indicated in their response to the questionnaire, that use under the cascade must be supported by diagnostic and susceptibility tests (see section 7.3.3), although this often proved to be impractical (owing to the availability or costs of suitable tests and/or the time to receive results) or was not enforced in the Member States visited. In one of these Member States, the competent authorities noted that the SPC is legally binding and, as such, veterinarians may only deviate from it in medical emergencies.

Prophylactic and metaphylactic use

There is limited information available about the preventive⁴⁵ and metaphylactic⁴⁶ use of antimicrobials (discussions on AMR-related definitions are ongoing at EU and global level), as the majority of countries responding to the questionnaire do not systematically collect such detailed data. Two Member States visited had carried out studies to assess the extent of these practices. In one case, the study was based on a comparison over time of trends in the use of herd treatments against those for individual animals to assess likely changes in metaphylactic and prophylactic treatments. In the other case, the study was based on information collected on farms during a specific campaign; herd treatments where no diagnosis was indicated in the treatment records were considered to be prophylactic.

Five countries noted, in their responses to the questionnaire, that prophylactic use is either not permitted in general or it is restricted, including through legally prohibiting the preventive use of medicated feed or through voluntary bans in the poultry and rabbit sectors. However, it is not known if this approach has simply led to an increase in the administration of

⁴⁴ The 'cascade' (provided for by Articles 10 and 11 of Directive 2001/82/EC) enables veterinarians to safeguard animal health and welfare, when no suitable authorised veterinary medicines are available, by prescribing other medicines, on an exceptional basis and subject to special conditions.

⁴⁵ Prevention (or prophylaxis) is defined as administration of a veterinary medicinal product to healthy animals to prevent infection if the risk for infection is very high and the consequences severe.

⁴⁶ Metaphylaxis is defined as the treatment of all clinically healthy (but presumably infected) animals kept in the same group as animals with clinical signs of a contagious disease. Metaphylaxis is always combined with the treatment of the diseased individuals
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/03/WC500183773.pdf

antimicrobials via drinking water which, as one country noted, in the absence of disease in all or the majority of animals, would indeed constitute prophylactic or metaphylactic use.

In the Member States visited, efforts had been made to raise awareness of the potential risks of AMR developing when antimicrobials were used in these ways and downward trends in the use of medicated feed (which is often used for group treatments) in many countries supports an assumption that the messages are having an impact. Nevertheless, in the two Member States visited which report the highest sales of antimicrobials, prophylactic use via medicated feed was widespread. Some farmers visited in one of these countries had substantially reduced their reliance on medicated feed through investments in technology and management practices, but others met considered it problematic to make the necessary changes.

Critically important antimicrobials

Ten countries indicated in their responses to the questionnaire that they have legal restrictions or other conditions on the use of CIAs, ranging from an obligation to obtain a diagnosis and/or susceptibility tests prior to use to limiting their use to situations where there is no alternative. Other measures include specific restrictions, limitations on the duration of treatments, planned bans on their prophylactic or metaphylactic use, and restrictions on their use under the cascade (see above). Eleven countries stated that they have not introduced any specific national restrictions or prohibitions on the use of CIAs.

In some cases, it was noted that CIAs continued to be used for certain conditions despite these restrictions, as they are sometimes cheaper than other effective alternatives and have fewer implications for the farmers (notably zero withdrawal period for milk and less need for repeat doses in a treatment).

Colistin

In light of the updated advice from EMA on the use of products containing colistin in animals⁴⁷ information was gathered on the approach being taken by the Member States visited (where use varied from 0 to 36 mg/PCU) to limit the potential development of resistance to this antibiotic. Based on this advice, and taking account of the Commission Decision of 14 July 2016⁴⁸ (on withdrawal of marketing authorisations for all veterinary medicinal products containing colistin in combination with other antimicrobial substances for oral use) the Member States visited had withdrawn the marketing authorisations for products containing colistin in combination with other antimicrobials.

Early indications from a voluntary initiative, which involved 35 % of the pig sector in one Member State reporting relatively high use of colistin (36 mg/PCU), shows that it should be possible to substantially reduce its use. Pig farmers participating in this scheme had halved the quantities of colistin used but noted only a slight impact on profitability and productivity following an initial slight increase in mortality. Interestingly, this change was thought to have

⁴⁷ http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2016/05/WC500207233.pdf

⁴⁸ <http://ec.europa.eu/health/documents/community-register/html/vo25976.htm>

improved the palatability of feed which in turn resulted in some increased productivity compared to that seen previously.

7.3 FACTORS INFLUENCING THE PRESCRIPTION OF ANTIMICROBIALS

There are many potential factors which can influence the decision to prescribe antimicrobials and the ones chosen to treat conditions in food producing and companion animals. The main ones influencing the prescribing behaviour of veterinarians are highlighted in the results of a survey carried out by the Heads of Medicines Agencies and the FVE⁴⁹. Several measures taken which have exerted a positive influence on these issues were noted in the responses to the questionnaire and in certain Member States visited.

7.3.1 *Benchmarking and threshold schemes*

The availability of real time data on the prescribing and use of antimicrobials in certain countries has provided the basis for establishing benchmarking schemes for a range of species and thresholds for the maximum use of antimicrobials in pigs and cattle (see section 3.3). The benchmarking schemes provide a ready means for veterinarians (and farmers) to compare the quantities of antimicrobials prescribed and used with others in the same farming sectors and for those which deviate significantly from the average to be monitored closely or targeted for control activities. For example, the Dutch scheme is based on 'traffic light' colours, providing a simple and transparent indicator of the relative prescription and use of veterinary antimicrobials; as a result, it encourages veterinarians and farmers to take actions to be placed in a better category (with a below average use). This provides a motivation for veterinarians and farmers to consider carefully their use of antimicrobials.

The 'yellow card' schemes implemented in the Danish pig and dairy sectors take a more direct approach to influencing the prescription and use of antimicrobials through establishing thresholds for their maximum use at each stage of the production process. Respecting these thresholds is encouraged through a range of measures taken when they are exceeded without adequate justification. Although this approach is credited with helping to significantly reduce antimicrobial use in the sectors concerned, some of the farmers and veterinarians met expressed a note of caution in that the thresholds should be set at an appropriate level, so that there is sufficient flexibility in the scheme to avoid potential welfare issues due to lack of treatment options or their delay.

Both the benchmarking and threshold schemes enable the possibility to apply a range of weighting factors to different classes of antimicrobials as an additional means to influence the choice of antimicrobials used. For example, the weighting factor applied to tetracyclines for use in pigs has been increased to deter their use. Such an approach raises the possibility of reducing the factors applied to preferred antimicrobials, in conjunction with those recommended as first choice in treatment guidelines (see section 7.3.3).

7.3.2 *Financial considerations*

Several financial factors which potentially impact on the prescribing of antimicrobials were often noted by veterinarians in the Member States visited. These included the direct impact

⁴⁹ <http://veterinaryrecord.bmj.com/content/vetrec/173/19/475.full.pdf>

on their salaries, where their income is at least partly dependent on the sale of antimicrobials, and the potential loss of clients who may be tempted to change their veterinarian if their demands for antimicrobials to be prescribed are not met. The relative importance of these factors among all of those influencing the prescription of antimicrobials is difficult to quantify but they present a potential conflict of interest between balancing the need to earn an income while, at the same time, ensuring that antimicrobials are used prudently.

The requirements for contracts to be established between farmers and veterinarians for regular herd health visits (see section 4.2) were generally supported by veterinarians met in the Member States visited. In particular, they help emphasise the value of veterinarians as advisors rather than prescribers of veterinary medicines, provide some financial certainty through regular farm visits and preparation of the health plans while also discouraging farmers from shopping around to obtain veterinary medicinal products, including antimicrobials, from other sources.

In addition to motivating veterinarians and farmers to consider their prescribing and use of antimicrobials, the benchmarking and threshold schemes described above, provide a means to monitor the types and quantities of antimicrobials being used and to target actions against those whose prescribing or use is considered potentially unacceptable. In both the Dutch and German systems, those farmers and veterinarians with consistently high antimicrobial use are required to take actions to reassess and reduce antimicrobial use. While this approach relies on the availability and transparency of comparative data concerning sales and use of antimicrobials (unlike a ban on sales by veterinarians), it enables veterinarians to be responsible for the sale, distribution and use of antimicrobials on the farms they serve.

Several North European countries visited considered that they have avoided the potential for conflicts of interest by long-standing national rules decoupling the sale and prescribing, or prohibiting veterinarians from profiting from the sale of veterinary medicinal products, including antimicrobials. Under these rules, veterinarians can supply only sufficient quantities of antimicrobials (without profit) to initiate treatments and most veterinary antimicrobial products are dispensed by veterinary pharmacies. However, the experience in other Member State with similar rules shows they do not necessarily lead to relatively low sales of antimicrobials. The lack of a clear correlation between decoupling of sales and prescribing of veterinary antimicrobials and their levels of use is also noted in the RONAF report (see section 1). This may in part be explained by the results of the FVE survey referred to above, in which veterinarians ranked profit margin and marketing factors as the least important of the factors investigated which influence prescribing behaviour.

7.3.3 *Decision support tools*

In addition to general awareness raising and training about AMR issues (see sections 5.1 and 5.2), many of the responses to the questionnaire included examples of activities aimed at providing veterinarians with the means to make informed decisions about the most appropriate antimicrobials to prescribe for given conditions, taking into account risks of AMR, the welfare of the animals and the cost effectiveness of the treatments. These activities, which can be considered as good practices, generally fall into the three categories below.

Treatment guidelines

In addition to the general guidance and training on the principles of prudent use (see section 5.1), approximately half of the Member States visited have drawn up detailed guidelines or recommendations setting out the preferred choices of antimicrobials for treating common conditions in food producing and companion animals. These recommendations have been prepared and updated regularly in consultation with relevant experts taking account of the AMR situation within the country. Despite some initial resistance to their introduction, these are now generally accepted and followed in practice by veterinarians (even where this is not mandatory) who also noted that among others, the recommendations provide a useful means to resist pressure from farmers for alternatives to be prescribed.

Although the specific details vary, the broad approach in each case is similar with the first, second and third choice of antimicrobials listed for each condition in ascending order of importance, from an AMR perspective. Criteria for prescribing each category of antimicrobials are often specified with a diagnosis always required but with additional testing requirements and restrictions applying to second and third choice antimicrobials. For example, third choice antimicrobials are reserved for treatment of individual animals only after performing diagnostic and susceptibility tests which show there are no alternatives. The most demanding requirements are reserved for the use of CIAs.

Diagnostic and susceptibility tests

The use of diagnostic and susceptibility tests to inform decisions about the choice of antimicrobials is advocated in the EU prudent use guidelines (see section 1) and it is either encouraged or required in many countries responding to the questionnaire. This applies particularly to CIAs, where it is mandatory in 10 countries to carry out susceptibility tests to demonstrate that there are no suitable alternatives prior to using them. The enacting of such requirements was reported to have contributed to a substantial reduction in the use of CIAs in several Member States visited. For example in one country, this led to an approximate 99 % reduction in the use of 3rd and 4th generation cephalosporins and a more than 90 % reduction in the use of fluoroquinolones. Substantial but non-quantified decreases in the use of CIAs were also reported by other Member States.

In the dairy sector, the routine use of antimicrobials for the treatment of mastitis and for drying-off has been reduced in many Member States visited through the increased availability of diagnostic and screening tests, and a greater understanding of the epidemiology of this condition. In one Member State, farmers and veterinarians were encouraged by the dairies and officials to use domestically produced test kits to culture samples to check for the presence of viable bacteria, in order to identify those animals requiring treatment with antimicrobials. Despite these initiatives, it was noted that CIAs were often used to treat symptoms of mastitis, even where other antimicrobials would be effective, due to their short withdrawal period, relatively low price and relatively straightforward treatment regime.

While operators and veterinarians met in the Member States visited acknowledged the role of such tests in supporting the choice of antimicrobials to be used, several drawbacks which challenge their usefulness were highlighted. These include i) the time taken to obtain results,

ii) the (sometimes prohibitive) cost of these tests, iii) the lack of availability of suitable tests, and iv) the concern that there could be significant differences between the *in-vitro* and *in-vivo* activity of the antimicrobials tested.

Measures to address some of the concerns regarding the suitability, performance and reliability of susceptibility tests have been adopted in several Member States. These include requirements that laboratories performing susceptibility tests should satisfy performance and accreditation criteria overseen by national reference laboratories. The scope of substances included in the tests should be sufficiently comprehensive to allow clear conclusions about the likely effectiveness of the available antimicrobials.

In most Member States visited, the potential to utilise the results of susceptibility and diagnostic tests to build an overview of the national and regional AMR of veterinary bacterial pathogens has not really been explored, despite the potential benefits this could provide. A notable exception is France, which has created the network *Résapath* (see section 3.3), with the objectives of monitoring AMR in pathogenic bacteria of animal origin, characterising the genetic background for specific resistance profiles and providing technical support to the network of 74 laboratories currently involved. In 2015, *Résapath* compiled data from 41 298 antibiograms for veterinary pathogenic bacteria (estimated as approximately half of the veterinary antibiograms performed in France). These showed a reduction in resistance to 3rd and 4th generation cephalosporins in several sectors such as calves, hens, horses, cats and dogs, as well as reduction in resistance to fluoroquinolones for several years, to levels that have now stabilised. The results provide a useful source of information for veterinarians and farmers regarding potential issues with AMR in their areas.

Enhancing access to SPC and product information

All countries responding to the questionnaire confirmed that the product information for all veterinary medicinal products containing quinolones and/or fluoroquinolones (including cefquinome and ceftiofur as active substances) has been updated in line with the Commission's decision following the referral procedure of 1 July 2010 on quinolones for food producing animals, Commission Decision C(2012)182 of 13 January 2012 and the Commission's decision following the referral procedure of 28 February 2014⁵⁰.

In practice, the results of the analysis of the survey on the prescribing behaviour of veterinarians carried out by the Heads of Medicines Agencies and the FVE, indicate that the SPC is rarely consulted, partly owing to difficulties in accessing the relevant information. In this respect, one Member State visited in 2016 (Spain) has avoided the need to produce and update bulky printed compendiums through the development of several apps (CIMA VET⁵¹, CIMA VET APP and NOMENCLATOR VETERINARIO) to provide an on-line source of up-to-date information regarding veterinary medicinal products, which can also be accessed

⁵⁰ Commission Decision C(2010) 4684 of 1 July 2010, and Commission Implementing decision C(2014) 1484 of 28 February 2014 following the referral procedures by the European Medicines Agency's Committee for Medicinal Products for Veterinary Use.

http://ec.europa.eu/health/documents/community-register/2010/2010070177969/dec_77969_en.pdf
<http://ec.europa.eu/health/documents/community-register/html/vo25077.htm>

⁵¹ <https://cimavet.aemps.es/cimavet/medicamentos.do>

via mobile devices, including smartphones. Several other countries visited were either considering or actively developing other online systems.

'As Little As Possible, As Much As Necessary' – prudent use of antimicrobials

Good practices:

- Restrictions on the use of certain antimicrobials can be a useful tool to encourage prudent use – providing they do not unduly limit treatment options or affect animal welfare;
- Adopting a range of measures to mitigate the effect of factors which could increase the likelihood of antimicrobials being prescribed inappropriately;
- Use of tools such as treatment guidelines, susceptibility tests and access to SPC helps to inform decisions regarding use and choice of antimicrobials.

Challenges:

- Ensuring an adequate range of antimicrobials is available especially in relatively small countries;
- Avoiding the use in certain cases of CIAs (for reasons of price, short withdrawal periods and simple treatment regime) where other less critical alternatives are available;
- Ensuring the suitability, reliability and performance of diagnostic and susceptibility tests used to inform decisions regarding the use of antimicrobials.

8 CONTROLS ON THE PRUDENT USE OF ANTIMICROBIALS

The majority of the Member States visited carried out controls to check compliance with the EU (and national) requirements applicable to the distribution and use of veterinary medicinal products (e.g. prescriptions, traceability, treatment records, etc.) and animal welfare (normally as part of cross-compliance checks). However, few checks were performed on the prudent use of antimicrobials owing to the lack of legal requirements covering this topic. In several Member States, officials carrying out controls used these as an opportunity to discuss relevant issues with the farmers. According to the officials met, this was a useful means to raise awareness of prudent use issues.

Official controls were also performed on the EU requirements for the production and distribution of medicated feed (Council Directive 90/167/EEC). The controls seen in the Member States visited included verification that operators had carried out checks on homogeneity and had measures in place to avoid the carry-over of medicines into non-medicated feed. The levels of carry-over deemed acceptable in different Member States varied from the limit of detection up to 3 % (the latter based on the limits applicable to the technically unavoidable carry-over of coccidiostats used as feed additives). In the former case, this had resulted in a significant decline in the production of medicated feed, which was sourced from neighbouring Member States when needed. In contrast, few checks were carried out to ensure that the oral administration of antimicrobials via powders and drinking water was done properly, despite the increase in these practices (see section 5.2).

In several Member States visited, national rules and other measures (such as official treatment guidelines) provided the basis for controls on aspects of prudent use of antimicrobials and the imposition of sanctions when non-conformities were detected. In Denmark, exceeding the thresholds applicable to the use of antimicrobials under the ‘yellow card’ schemes for pigs and cattle, led to automatic penalties unless adequate justification could be provided. Similarly, unjustified off-label use of antimicrobials contrary to national rules was punishable with a range of sanctions in another Member State (Netherlands). Such a robust approach was not always needed to change behaviours and encourage compliance with requirements. For example, in one Member State veterinary practices with relatively high use of CIAs were asked to provide officials with the results of the susceptibility and diagnostic tests required by national rules, to justify their use. This served the purpose of making veterinarians aware that their use of antimicrobials was noticeable and that certain obligations and costs were associated with the use of CIAs. This action led to significant reductions in the use of CIAs.

Throughout the fact-finding missions, veterinarians and officials noted that care should be taken to ensure that the approach for enforcing compliance with specific targets does not compromise animal welfare by deterring or preventing use of antimicrobials to treat sick animals. Several Member States visited also highlighted the risk that rigid enforcement of national rules and targets restricting the use of antimicrobials can lead to farmers and veterinarians being tempted to obtain antimicrobials illegally, resulting in the need to be vigilant on this issue.

Official controls on the prudent use of antimicrobials

Good practice:

- In the absence of a clear legal basis for compliance checks, official controls on farms still provide an opportunity to raise awareness among veterinarians and farmers of the need to use antimicrobials prudently (e.g. by discussing points relating to prudent use during official controls).

Challenges:

- Many initiatives to encourage prudent use of antimicrobials are voluntary so limiting the actions available to ensure they are implemented;
- Understanding and controlling the potential risks from an AMR perspective, posed by the oral administration of antimicrobials (via drinking water or powders) and the presence of low levels of antimicrobials which can be carried-over into non-medicated feed.

9 IMPACTS TO DATE

Overall, the results of the fact-finding missions demonstrate the importance of taking steps to implement prudent use policies as a means to reduce consumption of antimicrobials in animals, or maintain relatively low levels of consumption. The potential impact of taking such steps is particularly noticeable in the Netherlands, which reported a relatively high use of antimicrobials in 2009 and had achieved a 58 % decrease in their use in key food

producing animal species by 2014. Such achievements do not necessarily require regulatory intervention as initiatives taken by veterinary and industry associations, or by individual farmers, have resulted in similar reductions in antimicrobial use at least in certain species in other countries. The further refinement of long-standing policies for prudent use has helped those countries with already relatively low consumption of antimicrobials to achieve further reductions in certain sectors, notably with support of benchmarking and threshold schemes, and focusing on certain priority areas. These include actions on veterinarians and farmers associated with relatively high use of antimicrobials and policies to discourage the use of certain classes of antimicrobials in farm and pet animals. In Denmark for example, the use of weighting factors for different classes of antimicrobials used to treat pigs and dairy cattle under the ‘yellow card’ schemes, is aimed at further reducing the use of certain antimicrobials (e.g. tetracyclines and CIAs in pigs).

Although some farmers met were concerned about the potential costs and impact on mortality and productivity which could be incurred by adopting prudent use measures, few negative impacts were reported by those which had taken such steps. The major challenges identified concerned changes in management practice, especially when changing from preventive use of antimicrobials to using them to treat individual animals once symptoms appear. One Member State visited (Spain) observed economic benefits in terms of productivity and savings on the costs of medicines following a significant reduction in the use of antimicrobials in medicated feed.

Similar results were also described following a report containing a detailed analysis of the economic impacts of implementing prudent use policies in the Netherlands⁵². The inclusion of case studies and inputs from farmers to identify good practices and potential pitfalls further reinforces the message that significant reductions in antimicrobial use can be achieved without adversely affecting technical and economic factors. Further research was recommended on the potential role of socioeconomic factors associated with antibiotic use on pig farms⁵³.

Additional opportunities to share good practice and encourage veterinarians and farmers with relatively high use of antimicrobials to adopt prudent use measures are being developed in several countries. In one Member State visited, this includes research to identify critical success factors in those farms with relatively low antimicrobial use.

The potential impact of the implementation of prudent use policies on the levels of AMR cannot be elucidated easily owing to the many different factors influencing AMR. Despite this, several countries have reported indications that AMR is declining as a result (see section 3.3) and these may become more apparent with time.

⁵² <https://www.government.nl/binaries/government/documents/reports/2016/01/27/good-practices-use-of-antibiotics/dutch-veterinary-good-practices.pdf>

⁵³ <http://www.wur.nl/nl/Publicatie-details.htm?publicationId=publication-way-343137323431>

Impacts to date

- Substantial reductions in antimicrobial use have been achieved following the adoption of a policy for their prudent use;
- Regulatory intervention is not always required as initiatives taken by veterinary and industry associations, individual farmers or retailers all contribute to the overall reduction in antimicrobial use;
- Case studies show that adopting an integrated approach incorporating preventive measures and using antimicrobials in accordance with prudent use principles does not adversely affect animal welfare, productivity or profitability in the long term;
- There is scope to better share experience and potential good practices to help others adopt prudent use measures and to identify common critical success factors;
- There is some evidence to suggest that using antimicrobials prudently may lead to reductions in levels of AMR.

10 ACTIONS PLANNED BY THE COMMISSION SERVICES

The Commission services have already evaluated the preliminary results presented in this report and have initiated the following actions, which are aimed at promoting the prudent use of antimicrobials in animals in Member States, as part of its wider strategy on AMR.

1. To further contribute to making the EU a 'best practice' region in the fight against AMR, the Commission has continued this series of fact-finding missions during 2017 and plans to carry out further visits in 2018.
2. In addition to publishing overview and individual reports from these fact-finding missions, the Commission plans to promote the dissemination of the information gathered through its Better Training for Safer Food initiative.
3. Where appropriate, the information gathered will be taken into account in the on-going inter-institutional discussions on the proposals for new Regulations on veterinary medicinal products and on the production of medicated feed⁵⁴, which will replace the current legislation in these areas⁵⁵.
4. The Commission plans to request ECDC, EFSA and EMA to continue joint analysis of data from the relevant surveillance systems on consumption of antimicrobials and AMR in humans, animals and food in the EU, and provide updated reports (JIACRA).
5. To support its aim of making the EU a best practice region concerning AMR, as set out in the Commission's One Health Action Plan on AMR, the Commission and ECDC will carry out Country Visits to assist Member States to development their strategies, action plans and policies to tackle AMR in a One Health context.

⁵⁴ These draft new Regulations envisage a comprehensive set of provisions addressing AMR including, amongst other, a ban on preventive use of antibiotics in groups of animals, the possibility to reserve certain antimicrobials for humans only and the compulsory collection of data on sales and use of antimicrobials.

⁵⁵ Directive 90/167/EC and Directive 2001/82/EC

6. The Commission will continue to support Member States in their efforts to address AMR issues in a One Health context as set out in its action plan on AMR, including through the EU-funded Joint Action on AMR.

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dir. 90/167/EEC	OJ L 92, 7.4.1990, p. 42-48	Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community
Dir. 2002/32/EC	OJ L 140, 30.5.2002, p. 10-22	Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed - Council statement
Dir. 2001/82/EC	OJ L 311, 28.11.2001, p. 1-66	Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products
Dec. 2013/652/EU	OJ L 303, 14.11.2013, p. 26-39	2013/652/EU: Commission Implementing Decision of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria
OJC 2010/295	OJ C 295, 29.10.2010, p. 1	Commission Decision of 01-07-2010 concerning, in the framework of Article 35 of Directive 2001/82/EC of the European Parliament and of the Council, the marketing authorisations for veterinary medicinal products for food producing species containing quinolones and/or fluoroquinolones as active substances
Dec. 2012/182/EU	OJ L 92, 30.3.2012, p. 28-30	2012/182/EU: Commission Implementing Decision of 28 March 2012 on a Union financial contribution to a programme for the control of organisms harmful to plants and plant products in the French overseas departments for 2012

ANNEX II QUESTIONNAIRE SENT TO MEMBER STATES, ICELAND, NORWAY, AND SWITZERLAND, NATIONAL VETERINARY ASSOCIATIONS, AND STAKEHOLDERS

1. Please describe the routes by which farmers and pet-owners in your country get access to antimicrobials to treat their animals ¹ (including fish) and the national rules/legislation in place governing such access to antimicrobials (e.g. prescription-based or over-the-counter sales, sourcing from veterinarians, pharmacies, other professionals, internet or cross-border sales etc.). (this question is addressed to both competent authorities and stakeholders)
2. If antimicrobials for use in animals (including fish) can be dispensed in your country without a veterinary prescription (including premixes for medicated feedstuffs) please give details on the specific antimicrobials (active substance, target species) which can be dispensed in this way without a prescription and if there are any special circumstances for their use, for example in different types of pet animals (cats, dogs, rabbits etc.) or horses, for small farms/backyard flocks or for farmers using animals only for their own consumption. (this question is addressed to competent authorities only)
3. Please provide a list of any veterinary medicinal products authorised for use in your country (for farmed, pet or companion animals including horses) containing the following critically important antimicrobials²:
 - 3rd and 4th generation cephalosporins such as cefovecin, ceftiofur, cefoperazone and cefquinome;
 - Fluoroquinolones such as enrofloxacin (ciprofloxacin), difloxacin, marbofloxacin, danofloxacin, orbifloxacin, pradofloxacin, ibafloxacin and sarafloxacin;
 - Macrolides (and related substances azilides and/ or ketolides) such as erythromycin, josamycin, tilmicosin, kitasamycin, spiramycin, tulathromycin, gamithromycin, tildipirosin, tylvalosin and tylosin.

This list should include the trade name of the veterinary medicinal product, the pharmacologically active substance(s) and the target species. (this question is addressed to competent authorities only)

4. For veterinary medicinal products for food producing animals containing quinolones and/ or fluoroquinolones as active substances, please indicate any measures which have been taken nationally to update the product information (summary of product characteristics/ SPC, package insert/ leaflet, labelling) in line with Commission Decision C(2010)4684 of 1 July 2010.³ Please give details on any products whose product information has not yet been updated in line with this Decision. (this question is addressed to competent authorities only)
5. For veterinary medicinal products which contain the active substances cefquinome and ceftiofur, please indicate any measures which have been taken nationally to update the product information (summary of product characteristics/ SPC, package insert/ leaflet,

¹ For the purposes of this questionnaire, the term 'animals' includes both food-producing animals and companion animals/ pets.

² Based on the WHO list of highest priority critically important antimicrobials published in 2012 <http://www.who.int/foodsafety/publications/antimicrobials-third/en/> .

³ http://ec.europa.eu/health/documents/community-register/2010/2010070177969/dec_77969_en.pdf

labelling) in line with Commission Implementing Decision C(2012)182 of 13 January 2012.⁴ Please give details on any products whose product information has not yet been updated in line with this Decision and whether the product information for products containing cefovecin has been similarly updated. (this question is addressed to competent authorities only)

6. Are there any special legal provisions or guidelines applied in your country concerning the authorisation, distribution and use of critically important antimicrobials in animals (3rd and 4th generation cephalosporins, fluoroquinolones and macrolides as per the WHO list of highest priority critically important antimicrobials published in 2012)? If yes, please give additional details. Please indicate if any of these critically important antimicrobials are specifically prohibited from use in animals in your country or if their use is restricted based on specific diagnostic requirements etc. If so please provide the legal basis for such a prohibition or restriction of use. (this question is addressed to competent authorities only)
7. Please provide information on any antimicrobials for use in animals where as part of the national marketing authorisation procedure the applicant has included (or been required to include) additional information on the product information (summary of product characteristics/ SPC, package insert/ leaflet, labelling) concerning the prudent use of the product, especially for any critically important antimicrobials. Please list the antimicrobials in question and the relevant prudent use advice included in the product information. (this question is addressed to competent authorities only)
8. Please provide a list of antimicrobial veterinary medicinal products (including the active substance and trade name) which are either authorised in your country or can be used off-label in poultry hatcheries and day-old chicks, and if there are any additional national rules or legislation governing the use of such antimicrobials in hatcheries and day-old chicks⁵. (this question is addressed to competent authorities only)
9. Are there any veterinary antimicrobials in your country which are used under special licence in animals (e.g. medicinal products intended for off-label use authorised for entry from another Member State or imported from a third country)? If so, please provide a list of these products, the active substances, target species and withdrawal periods. (this question is addressed to competent authorities only)
10. Do you have any measures or initiatives in place to control or restrict the off-label use of antimicrobials in animals, particularly 3rd and 4th generation cephalosporins, fluoroquinolones and macrolides? If so please describe the legal basis for these measures (if applicable) and indicate how compliance is monitored including any data collected on off-label use. (this question is addressed to both competent authorities and stakeholders)
11. Has any information been collected in your country concerning the preventive⁶ use of orally administered antimicrobials (including via medicated feed, in drinking water or by

⁴ <http://ec.europa.eu/health/documents/community-register/html/vo22101.htm>

⁵ As background to this question, in recent years concern has been expressed regarding the use of 3rd generation cephalosporins in chickens for example *in ovo* or as day-old chicks and possible links to antimicrobial resistance.

⁶ Prevention defined as administration of a veterinary medicinal product to healthy animals to prevent infection if the risk for infection is very high and the consequences severe.

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/03/WC500183773.pdf

- top-dressing of animal feed) in food-producing animals? If yes please give details, including for which species this information has been collected etc. (this question is addressed to both competent authorities and stakeholders)
12. Has any information been collected in your country concerning the metaphylactic⁷ use of orally administered antimicrobials in food-producing animals? If yes please give details. (this question is addressed to both competent authorities and stakeholders)
 13. Have any guides of good practice been developed in your country concerning the correct storage, use and disposal of antimicrobials used in food-producing animals, including the disposal of any unused medicated feed? (this question is addressed to both competent authorities and stakeholders)
 14. Please provide information on any national measures or guidance documents⁸ which have been put in place by the **competent authorities** in your country concerning the control and supervision of usage of antimicrobials in animals, including prudent use, in farmed, pet or companion animals and horses and also covering medicated feedingstuffs. Relevant details which should be provided include:
 - the name of the body which has developed the guidance documents;
 - the date when they became applicable and to which animal species they apply;
 - whether the application of each of these measures or guides is voluntary or compulsory;
 - if there are any consequences or penalties if these measures are not respected in practice;
 - if any assessment of the effectiveness of these prudent use measures has been undertaken, please provide a brief summary of the outcome. (this question is addressed to competent authorities only)
 15. Please provide information on any national measures or guidance documents⁹ which have been put in place by the **national professional bodies** (such as the veterinary or pharmacists' associations) in your country concerning the prudent use of antimicrobials in animals, including in farmed, pet or companion animals and horses and also covering medicated feedingstuffs. Relevant details which should be provided include:
 - the name of the body which has developed the guidance documents;
 - the date when they became applicable and to which animal species they apply;
 - whether the application of each of these measures or guides is voluntary or compulsory;
 - if there are any consequences or penalties if these measures are not respected in practice;
 - if any assessment of the effectiveness of these prudent use measures has been undertaken, please provide a brief summary of the outcome. (this question is addressed to stakeholders only)

⁷ Metaphylaxis defined as the treatment of all clinically healthy (but presumably infected) animals kept in the same group as animals with clinical signs of a contagious disease. Metaphylaxis is always combined with the treatment of the diseased individuals
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/03/WC500183773.pdf

⁸ If publicly available, please provide a link to the respective document or a copy of the document.

⁹ If publicly available, please provide a link to the respective document or a copy of the document.

16. If you have identified any other good/best practices in your country concerning the use of antimicrobials, including critically important antimicrobials (CIAs), in animals (whether farm, pet or companion animals including horses) please provide a summary of these best practices and how they have been disseminated to stakeholders and implemented. (this question is addressed to both competent authorities and stakeholders)

ANNEX III COMPETENT AUTHORITIES AND STAKEHOLDERS THAT RESPONDED TO THE DG SANTE QUESTIONNAIRE

Competent authorities

Austria – Bundesministerium für Gesundheit (BFG)
Belgium – Federaal Agentschap voor de Veiligheid van de Voedselketen-Agencje Fédérale pour la Sécurité de la Chaîne Alimentaire (FAVV-AFSCA)
Bulgaria – Bulgarian Food Safety Agency (BFSA)
Croatia – Ministarstvo Poljoprivrede (MPS)
Cyprus – Ministry of Agriculture, Rural Development and Environment (MOA)
Czech Republic – Ministerstvo Zemědělství (MZE)
Denmark – Miljø- og Fødevareministeriet – Fødevarestyrelsen (FVST)
Estonia – Maaeluministerium
Finland – Finnish Food Safety Agency (Evira) and Finnish Medicines Agency (Fimea)
France – relevant authorities via Représentation permanente de la France auprès de l'Union européenne
Germany – Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) with contribution from the following stakeholders: German Veterinary Association (BTK), Federal Association of Practising Veterinary Surgeons (BPT)
Greece – Hellenic Ministry of Rural Development and Food
Hungary – Földművelésügyi Miniszter (FM)
Ireland – Department of Agriculture, Food and the Marine
Italy – Ministero della Salute
Latvia – Pārtikas un Veterinārais Dienests (PVD)
Lithuania – State Food and Veterinary Service (SFVS)
Luxembourg – Organisme pour la Sécurité et la Qualité de la Chaîne Alimentaire (OSQCA)
Malta – Permanent Representation of Malta to the EU
Netherlands – Ministerie van Economische Zaken (MinEZ)
Poland – Główny Inspektorat Weterynarii (Wetgiw)
Portugal – Direção Geral de Alimentação e Veterinária (DGAV)
Romania – Autoritatea Națională Sanitar-Veterinară și pentru Siguranța Alimentelor (ANSVSA)
Slovakia – Štátna Veterinárna a Potravinová Správa (SVPS)
Slovenia – Ministrstvo za Kmetijstvo, Gozdarstvo in Prehrano (MKGP)
Spain – Ministerio de Agricultura, Alimentación y Medio Ambiente (MAgrAMA)
Sweden – Jordbruksverket
United Kingdom – Department for Environment, Food and Rural Affairs (DEFRA)
Iceland – Matvælastofnun (MAST)
Norway – Statens tilsyn for planter, fisk, dyr og næringsmidler (Mattilsynet)
Switzerland – Federal Food Safety and Veterinary Office (FSVO)

Members of the advisory group on Food Chain and Animal and Plant Health that have provided responses, position papers, and/or policy documents

Bureau Européen des Unions de Consommateurs (BEUC)
Centre de Liaison des Industries Transformatrices de Viandes de l'Union Européenne
COPA-COGECA – Comité des Organisations Professionnelles Agricoles de l'Union Européenne
Confédération Générale des Coopératives Agricoles de l'Union Européenne
EUROGROUP FOR ANIMALS – Eurogroup for Animal Welfare
Fédération Européenne des Fabricants d'Aliments Composés pour Animaux (FEFAC)
Federation of Veterinarians of Europe (FVE)

FVE member organisations

Finnish Association of Veterinary Practitioners
CNOV – Ordre National des Vétérinaires
FSFV – Fédération des Syndicats Vétérinaires de France

Veterinary Ireland

FNOVI – Federazione Nazionale degli Ordini Dei Veterinari Italiani

CRV – College Of Romanian Veterinarians

GST-SVS – Gesellschaft Schweizer Tierärztinnen und Tierärzte / Société des Vétérinaires

Other stakeholders

Centre of expertise on Antimicrobial Consumption and Resistance in Animals (AMCRA)

AVINED

Confederación Española de Fabricantes de Alimentos Compuestos Para Animales (CESFAC)

European Platform for the Responsible Use of Medicines in Animals (EPRUMA)

Finnish Association for Animal Disease Prevention (ETT)

Hungarian Poultry Product Board

Associação Portuguesa dos Industriais de Alimentos Compostos para Animais (IACA)

Finnish Central Union of Agricultural Producers and Forest Owners (MTK)

Unitalia

ANNEX IV FACT-FINDING MISSIONS CARRIED OUT IN 2016 AND CONSIDERED IN THIS REPORT

Country	Dates carried out	Reference No.
Denmark	1 to 5 February 2016	2016-8882
http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3642		
Slovenia	7 to 11 March 2016	2016-8883
http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3771		
Germany	19 to 26 April 2016	2016-8890
http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3676		
Finland	16 to 20 May 2016	2016-8886
http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3715		
Czech Republic	20 to 24 June 2016	2016-8885
Not published		
Netherlands	13 to 20 September 2016	2016-8889
http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3753		
Cyprus	10 to 14 October 2016	2016-8884
http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3759		
Spain	13 to 20 October 2016	2016-8887
http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3832		
Romania	21 to 25 November 2016	2016-8888
http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3812		

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