In response to information provided by the competent authority, any factual error noted in the draft report has been corrected.
Executive Summary

This fact-finding mission took place in Finland from 16 to 20 May 2016 as part of a planned series of missions to Member States by DG Health and Food Safety. The objectives of this fact-finding mission were to gather further information on the practical implementation of measures aimed at tackling the issues concerning antimicrobial resistance relating to the use of veterinary medicines and identify examples of good practice which could be helpful to other Member States in addressing this issue.

Overall, the report concludes the comprehensive and long-standing policies on the availability of antimicrobials, including critically important ones, together with initiatives to raise and maintain the awareness of antimicrobial resistance, have resulted in a relatively low and stable level of sales of antimicrobials and, at the same time, encouraged their prudent use. These factors have been reinforced with actions to enhance the animal health situation in Finland. Notwithstanding the fact that official controls are also contributing in this regard, the implementation of these policies and initiatives has been ensured thanks to their acceptance by, and active participation of, veterinarians and producers. Whilst it is not possible to distinguish the impact of each individual measure, the analysis of the available data and comparisons with the situation reported by other Member States has shown that the said policies and initiatives have helped to slow the development of antimicrobial resistance in Finland.

Various aspects of the measures put in place in Finland aimed at encouraging the prudent use of antimicrobials in animals and tackling the broader issue of antimicrobial resistance could serve as examples of potential good practice in other Member States.
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1 INTRODUCTION

This fact-finding mission took place in Finland from 16 to 20 May 2016 and was the fourth in a planned series of missions to nine Member States. The mission team, comprising two auditors from DG Health and Food Safety and a national expert from a European Union (EU) Member State, was accompanied throughout the mission by representatives of the central competent authority, the Finnish Food Safety Authority (EVIRA). An opening meeting was held with EVIRA on 16 May 2016 during which the objectives and scope and the itinerary for the fact-finding mission were confirmed.

2 OBJECTIVES AND SCOPE

The objectives of this fact-finding mission were to:

a) Gather further information on the practical implementation of measures aimed at tackling the issues concerning antimicrobial resistance (AMR) relating to the use of veterinary medicines.

b) Identify examples of good practice which could be helpful to other Member States in addressing this issue.

In terms of scope, the mission team examined the regulatory framework on veterinary medicines and on medicated feed currently in place in Finland (including for companion animals) and the implementation of existing recommendations and guidelines on the prudent use of antimicrobials in veterinary medicine – including those published by the Commission referred to in section 3. The following topics were not included in the scope of this mission: (i) the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria in certain food-producing animal populations and in food, and (ii) the control of residues and contaminants and the use of veterinary medicinal products in food-producing animals. The latter topic was the subject of an audit in May 2013 (report DG(SANCO)/2013-6764).

In pursuit of these objectives, the following meetings and visits took place:

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3 MISSION RATIONALE

This fact-finding mission forms part of one of a number of initiatives included in the European Commission's action plan against the rising threats from AMR, and is specifically
linked to actions 2 and 3 of the associated road map\(^1\), namely to strengthen the regulatory framework on veterinary medicines and on medicated feed and to introduce recommendations for prudent use in veterinary medicine, including follow-up reports. Separate actions are foreseen under the road map concerning the prudent use of antimicrobials in human medicine.

In preparing its guidelines for the prudent use of antimicrobials in veterinary medicines (Commission Notice: 2015/C299/04 of 11 September 2015\(^2\)), the Commission received information highlighting a number of measures already taken by Member States on this topic. In order to gain a more comprehensive overview of the efforts being made within the EU to encourage the prudent use of antimicrobials in veterinary medicine, a questionnaire was sent by DG Health and Food Safety to all Member States in September 2015 and a number of Member States were selected to be involved in this series of fact-finding missions. The main points from these fact-finding missions and the questionnaire responses will be presented in an overview report intended to highlight good practices and particular challenges identified in applying the prudent use of antimicrobials in veterinary medicine.

4 **FINDINGS AND CONCLUSIONS**

4.1 **BACKGROUND**

4.1.1 **Sales of antimicrobial veterinary medicinal products**

1. According to the most recent European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report for 2013\(^3\), sales of antimicrobials, including the critically important antimicrobials (CIAs), for use in food-producing animals (including horses) in Finland have remained stable between 2010 and 2013 (25–24 mg per population correction unit – PCU) and are relatively low compared with the range of 3.7 to 425.8 mg/PCU reported by the 26 countries contributing data in 2013. Sales of tablets, which are almost solely used in companion animals, accounted for 13.3% of all pharmaceutical forms of antimicrobials sold in Finland during 2013. Information on the proportion of antimicrobials used in the fur animal sector is not available, though it is included in the ESVAC sales data.

2. According to the Finnish Medicines Agency (Fimea) sales of veterinary antimicrobials (in kg) increased by 2% during 2014\(^4\). This was mainly accounted for by increases in the sales of tetracyclines for oral administration (total sales 2 576 kg in 2014 up from 2 389 kg in 2013) and of injectable penicillin. During the same period, there was a decrease in the sale of oral sulfa-trimethoprim. A total of 13 709 kg of antimicrobials were sold in 2014\(^5\), with betalactams (penicillins) accounting for approximately half of this (6 452 kg) followed by tetracyclines and sulphonamides and trimetoprim (2 893 kg). Sales of CIAs account for 4.7% of antimicrobial sales (8 kg of 3\(^{rd}\) and 4\(^{th}\) generation

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cephalosporins, 113 kg of fluoroquinolones and 521 kg of macrolides). According to information provided to the mission team, in the period 2010-2014, sales of macrolides decreased by approximately 10% whereas fluoroquinolones sales increased by 16-21%. In the latter case, this was a result of an additional 4 kg of active ingredient for oral administration to small companion animals.

3. According to data provided by EVIRA, in 2015 antimicrobials were used in approximately 4 300 tonnes out of 6 300 tonnes of medicated feed commercially produced for fur animals (the remainder mostly contained anthelmintics). In the same year, only a relatively low level of antimicrobials was used in medicated feed for pigs (approximately 20 kg out of a total of 7 140 kg of active ingredients used) and none was used for poultry.

4.1.2 Organisations for policy development and implementation

4. A comprehensive description of the competent authorities with responsibilities within the scope of this fact finding mission is provided in the DG Health and Food Safety country profile for Finland. A summary is given below.

5. EVIRA is broadly responsible for promoting safety, quality and reliability within the food chain. The animal health and welfare and feed and fertiliser units within the control department are responsible for controls on the use of veterinary medicinal products by practitioners and farmers and for the control of feed mills (including those producing for fur animal farms) and intermediaries for medicated feed. Municipalities are responsible for controlling the manufacture of medicated feed on fur farms. In the areas within the scope of this mission, EVIRA cooperates with other competent authorities, industry and professional bodies to provide training and to develop guidelines and strategic priorities for the future.

6. Fimea is a central administrative agency operating under the Ministry of Social Affairs and Health and is the national competent authority for regulating medicinal and veterinary medicinal products. Fimea issues licences and other permits to (veterinary) medicinal product producers, wholesalers and pharmacies and conducts inspections to verify compliance with the relevant requirements. Fimea is responsible for monitoring the sales of antimicrobials. In addition, it is responsible for the renewal of marketing authorisations.

7. Animal Health ETT (ETT) was established by producers and companies in the food industry when Finland joined the EU and is maintained by the dairies, slaughterhouses and egg packers. The association aims to promote the health and welfare of food producing animals by coordinating national animal health care for cattle, pigs and poultry and steering the import of production animals, their embryos, semen and feed to control the risk of disease. Of particular relevance to the scope of this mission are the guides published by ETT regarding animal health and the responsible use of veterinary medicinal products and the two databases which it administers as part of the herd health schemes for these sectors (see points 31 and 45). These are the national health and

6 http://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=FI
welfare register for swine farms (SIKAVA 7), and the national health and welfare register for cattle herds (NASEVA 8).

8. The Central Union of Agricultural Producers and Forest Owners (MTK) is a trade organisation and interest group representing farmers, forest owners and rural entrepreneurs. It has over 400 000 members and has an interest in promoting sustainable and environmentally sound production. In cooperation with similar organisations in neighbouring countries, it has formulated a number of documents setting out a common position on relevant topics, including AMR.

9. A task force 'Use of antimicrobials in animals' was established by the Ministry of Agriculture and Forestry in 1996, when sales of antimicrobials as feed additives (14 800 kg) were slightly higher than sales for therapeutic purposes (14 500 Kg). The task force concluded that the AMR situation in bacteria of animal origin was relatively satisfactory (compared with several other countries) and proposed some actions to maintain the situation. These included systematically reducing the use of antimicrobials as feed additives, to avoid the unnecessary use of antimicrobials, to undertake information and education initiatives, and to continuously monitor both the level of AMR and the use (sales) of veterinary antimicrobials.

10. The need to take joint action to maintain the efficacy of veterinary antimicrobials was acknowledged in a declaration prepared in 2010 9 following a meeting of experts from professional bodies with EVIRA. Six key messages were identified which were aimed mostly at: maintaining the relatively favourable animal health situation in Finland (see points 38, 51 and 52); ensuring antimicrobials are used responsibly (including basing their use on a reliable diagnosis, identification of the pathogen and susceptibility testing) and the development of programmes to monitor the use of and resistance to antimicrobials.

11. According to EVIRA, organisations involved in human and animal health met in the first formal consensus meeting on resistance – safeguarding the efficacy of medicines in 1997. Subsequently, a joint policy against AMR in the human and veterinary sectors was published in 1999 followed a year later by the establishment of a national human-veterinary zoonosis task force. In 2004, the first multiannual zoonosis strategy was published and the Finnish Zoonosis Centre was set up in 2007. More recently, the joint human and veterinary AMR task force was set up in 2012 and in 2013 the second Finnish zoonosis strategy with a special emphasis on AMR for the period 2013 to 2017 was published. The national expert group against AMR was formed for the period 2015 to 2017 to agree on the contents and co-ordinate the work on the national action plan for AMR. The plan is due to be completed by May 2017 in accordance with the World Health Organization global action plan against AMR 10.

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7 www.sikava.fi  
8 www.naseva.fi  
10 http://www.who.int/drugresistance/global_action_plan/en/
4.2 Policies regarding the availability of antimicrobial veterinary medicinal products

12. All antimicrobial veterinary medicinal products are prescription-only medicines. The only exceptions are for products (including antimicrobials) intended solely for aquarium fish, cage birds, homing pigeons, terrarium animals, small rodents and ferrets and rabbits kept exclusively as pets which can be sold without prescription in accordance with Article 4 of Directive 2001/82/EEC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products.

13. According to information provided by EVIRA, 17 antimicrobial veterinary medicinal products can be used under special licence. Fimea may grant a special permit for a medicinal product for the treatment of an individual animal or group of animals if an authorised medicinal product is not found by applying the cascade rules. In special circumstances, FIMEA may also, without separate application, issue a fixed-term special authorisation for a medicinal product, on the basis of which the product may be released for consumption even if it does not have a marketing authorisation in Finland. These products are listed under temporary special permits for veterinary medicinal products.

14. Fimea highlighted the importance of measures to ensure the availability of sufficient antimicrobials on the (relatively small) Finnish market and the potential that their prudent use could be compromised if supply were not maintained. According to the ESVAC report for 2013, there were 86 product presentations on the market compared to an average of 323 for the 26 countries supplying data. National measures include special permits for compassionate use, and exemption permits for foreign language packages and licences for lowering mandatory reserve requirements. Under national legislation, importers are obliged to maintain stock equivalent to at least 3 months’ sales (based on the previous year’s sales) for medicinal products which have been identified to have a critical medical significance. In certain circumstances, Fimea may modify these requirements as appropriate, to address temporary supply issues.

15. EVIRA and Fimea described the measures taken under national rules to minimise the impact of a temporary disruption to the supply of a key veterinary medicinal product. In March 2015, EVIRA became aware of an issue linked to the production of benzylpenicillin procaine which could potentially affect supplies to Finland. During the following 2 months, Fimea, EVIRA and representatives of the marketing authorisation holder and the wholesaler negotiated measures needed to ensure that the 3 months’ mandatory reserves could be extended by limiting the use to last for at least 6 to 9 months. Binding indications for the use of benzylpenicillin procaine were published as an annex to a decision of the Ministry of Social Affairs and Health. Since then, further measures were taken to obtain additional quantities of this veterinary medicinal products and the situation is yet to be fully resolved. Several veterinarians met were supportive of the measures taken as the timely intervention had enabled alternative medications to

be identified and ensured that supplies of benzylpenicillin procaine were generally available to treat those conditions where no alternatives were available.

16. There is a comprehensive body of national legislation and guidelines governing the availability, distribution and use of veterinary medicinal products, including antimicrobials. This was revised and further elaborated in 2014. Key aspects of these national measures are described below.

17. Since 1949, national legislation has prevented veterinarians from making a profit on veterinary medicinal products which they dispense. In accordance with the Act on Medication of Animals 387/2014, veterinarians should, as a general rule, only prescribe veterinary medicinal products for animals they have seen and they may only leave with the farmer sufficient medicines to complete the prescribed course of treatment. In case the veterinarian has not seen the affected animals, veterinary medicinal products can only be prescribed if the veterinarian has visited the farm recently and knows the health status of the farm and of the animals concerned and also has the results of microbiological tests. EVIRA acknowledged that the requirements relating to microbiological testing are not currently being enforced although control campaigns which will include this issue are planned (see section 4.3.2.).

18. Veterinarians may, at their discretion and subject to certain conditions being fulfilled, leave certain veterinary medicinal products (including antimicrobials) to treat a limited, defined range of conditions, on pig and cattle farms which participate in the national health care programmes (see point 47).

19. The use of 15 substances or groups of substances of antimicrobials for the treatment of animals is prohibited or restricted by a Government Decree (1054/2014). The list of antimicrobials concerned has been revised several times and currently includes certain CIAs, including 3rd and 4th generation cephalosporins and certain fluoroquinolones. As a general rule, antimicrobials that are used for the treatment of serious infections in humans are not allowed to be used in animals. However, if there is an authorised veterinary medicinal product on the market in Finland which contains such substances, they can only be used in accordance with the summary of product characteristics (SPC), which means that the cascade (as provided for in Articles 10 and 11 of Directive 2001/82/EC) does not apply to them.

20. The use of antimicrobials to treat, prevent or eradicate *Salmonella* in pigs, cattle, poultry and turkey is prohibited by Ministerial Decrees 1030/2013 and 1037/2013, respectively. If a flock or herd has been treated with antimicrobials for other reasons, it must be sampled after the withdrawal period has expired to check for the presence of this microorganism.

21. Conditions under which private import of veterinary medicinal products can take place are set down in Government Decree 1088/2002. Pet owners are only permitted to import veterinary medicinal products for animals which are actually travelling with them.

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and in quantities not exceeding 1 month’s treatment. Conditions applicable to private imports by veterinarians are included in sections 7 and 8 of the above decree. It is further stipulated that veterinary medicinal products shall not be bought or received by mail from outside Finland, although it was acknowledged by the competent authorities that it would be problematic to enforce these requirements.

22. The Finnish industry producing animals for food voluntarily ceased using antimicrobial growth promoters during the 1990s. The use of virginiamycin was already stopped in 1990, the use of bacitracin in 1992 and flavomycin and avoparcin stopped in 1996. The only antimicrobial feed additives currently used are the coccidiostats narasin and monensin which are used prophylactically.

23. Farmers are only allowed to store antimicrobials (in secure, clean and appropriate conditions) within the prescription period, unless that prescription has been renewed.

24. The disposal of antimicrobials for food-producing animals, including the disposal of any unused medicated feed, is classified as risk waste, as are other medicines. Pharmacies are obliged to accept residues of medicines (such as antimicrobials) from consumers whereas the municipalities or veterinarians will advise about the disposal from farmers. According to provincial veterinarians from a Regional State Administrative Agency (RSAA), farmers with expired veterinary medicinal products are normally instructed to take them to a pharmacy or veterinarian. Under waste legislation, municipalities must collect waste medicines, including from pharmacies.

4.2.1 Special conditions applicable to critically important antimicrobials

25. Fimea confirmed that the product information for all veterinary medicinal products containing quinolones and/or fluoroquinolones and cefquinome and ceftiofur as active substances has been updated in line with the referral outcomes specified in Commission Decision C(2010)4684 of 1 July 2010 and Commission Implementing Decision C(2012)182 of 13 January 2012.

26. The 2012 report of the Finnish Veterinary Antimicrobial Resistance Monitoring and Consumption of Antimicrobials Agents (FINRES-Vet – see section 4.1.5.) highlights the relatively low use of CIAs, with sales of 3rd generation cephalosporins, macrolides and fluoroquinolones accounting for 0.03-0.09%, 3-3.6% and 0.6-0.7%, respectively of total sales of veterinary antimicrobials in the period 2010 - 2012. It should be noted that 3rd generation cephalosporins were only introduced to the market in 2010 and only in injectable forms. The majority of macrolides are sold in oral forms and their sales were stable during the period 2010 – 2012. Sales of fluoroquinolones have grown gradually since 2004, although the largest increase in sales (44% between 2009 and 2012) was for tablets for use in small companion animals. According to EVIRA and the veterinarians met, 3rd generation cephalosporins are preferred in some cases due to the relatively simple treatment regime (i.e. single dose), short withdrawal period and price.

27. The use of 3rd and 4th generation cephalosporins and certain fluoroquinolones is prohibited or restricted according to Government Decree 1054/2014 (see point 19). In accordance with a Decree of the Ministry of Agriculture, if no other efficacious medicine is available, fluoroquinolones, 3rd and 4th generation cephalosporins, new broad spectrum or long-acting macrolides and systemically administered colistins (which are not currently authorised for use in animals in Finland) can be used in animals subject to a reliable microbiological diagnosis and sensitivity testing, epidemiological knowledge or other justifiable grounds. Several control actions have been taken or are planned by EVIRA to verify that these requirements are fulfilled (see section 4.3.2.). One campaign aims to target the veterinarians purchasing the highest quantities of CIAs and in particular, in some small animal (cats) clinics where the convenience of long-lasting injections of CIAs may be preferred to repeated daily doses of alternative antimicrobials.

28. The veterinarians and farmers visited had not found it necessary to use CIAs as other antimicrobials were generally effective. The veterinarian visited who was treating both food-producing and companion animals reported one instance where a farmer had requested a CIA (ceftiofur) be used as it had no withdrawal period for milk, but the view of the veterinarian was that penicillins had proved to be more effective in this case and prescribed the latter. The dairy farmer visited had performed susceptibility tests for mastitis.

4.2.2 Monitoring and surveillance on the use of antimicrobials in animals

29. FINRES–Vet is coordinated by EVIRA and has three main objectives:

- to monitor the consumption of antimicrobials used to treat animals;
- to monitor AMR in major food-producing animals and pets;
- to analyse trends in resistance prevalence and to monitor the emergence of resistant clones and the appearance of new resistance phenotypes.

The results of the programme are published regularly 17.

4.2.2.1 Monitoring of sales

30. Fimea has monitored the sales of antimicrobial veterinary medicinal products in Finland since 1995 based on statistics obtained from pharmaceutical wholesalers. In 2010, the sales data collected were harmonised with the requirements of the ESVAC project (see point 1). Sales data for the period 2010 to 2014 are published on the Fimea website 18.

31. According to EVIRA, information on antimicrobial use by species is not currently available to the authorities and a meeting is planned to consider this issue with the industry. Although data contained in the SIKAVA and NASEVA databases could provide a ready source of information concerning the use of antimicrobials in these species, terms for access have still to be negotiated with ETT and the farmers. ETT has been collecting data on the use of antimicrobials in poultry for meat since 2007.

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Although data for laying hens are not collected, information provided by ETT shows little or no use of antimicrobials in this sector in recent years (see point 50).

32. Each year, EVIRA requests wholesalers to provide information regarding the amounts of antimicrobials purchased by veterinarians and some crude indicators of use by species can be obtained for those practices which specialise in treating a limited range of animal species. Information obtained from such analyses is used for targeting control actions (see section 4.2.2).

33. In accordance with national requirements, veterinarians prescribing medicated feed should send one of the four copies of the prescription to the RSAA. This provides some information on the use of medicated feed, although according to EVIRA, it may not be complete as veterinarians do not always remember to send copies of the prescription as required. From time to time, EVIRA requests copies of prescriptions from the feed mills for control purposes.

4.2.2.2 Resistance monitoring

34. The FINRES-Vet programme started in 2002 using a range of indicator bacteria taken on alternate years from poultry, cattle and pigs. The programme included zoonotic bacteria (*Salmonella* and *Campylobacter*) and selected animal pathogens. The programme includes specific monitoring of resistant bacteria and incorporates the requirements of mandatory EU and national (e.g. for *C. jejuni*) programmes. The selected animal pathogens include *Escherichia coli* (from porcine enteritis), *S. pseudintermedius* (from canines and felines) and mastitis pathogens from cattle and, since 2011 data from companion animals as well as horses has originated from analyses of samples sent to the Faculty of Veterinary Medicine in Helsinki.

35. Specific monitoring of resistant bacteria has been carried out on methicillin-resistant *S. aureus* (MRSA) in pigs in 2008 as part of an EU baseline survey. Also, in 2009-2010 and 2011-2012, specific MRSA surveys were conducted, and in 2015 these were extended to include MRSA in pork meat. Studies of extended-spectrum ß-lactamases / Ampicillin C ß-lactamases (ESBL/AmpC) started in 2011 and have examined samples from broilers, pigs and cattle. Samples have also been taken from imported poultry.

36. The studies indicate that AMR has developed to moderate or high levels in only a limited number of isolates and, overall, levels remain relatively low and stable compared with the situation in other Member States. The studies conclude that this situation can be at least partly attributed to the overall effect of the policies taken to reduce the need for antimicrobials and to encourage their prudent use. According to EVIRA, it is not possible to distinguish the impact of each individual measure.
Conclusions on policies on the availability of antimicrobial veterinary medicinal products

37. The comprehensive and long-standing policies on the availability of antimicrobials for animals, including CIAs, have resulted in a relatively low and stable level of sales, thus providing a sound foundation for the implementation of targeted initiatives that have encouraged the prudent use of antimicrobials. The analysis of the available data and comparisons with the situation reported by other Member States has shown that these policies have helped to slow the development of AMR in Finland. Whilst it is not possible to distinguish the impact of each individual measure, this situation can be at least partly attributed to the overall effect of the policies taken to reduce the need for antimicrobials and to encourage their prudent use.

4.3 POLICIES AND CONTROL ACTIONS ON THE PRUDENT USE OF ANTIMICROBIALS IN ANIMALS

4.3.1 Policies on the use of antimicrobials in animals

38. The officials, veterinarians, farmers and industry associations met highlighted a number of factors in Finland which have facilitated efforts to reduce the need to use antimicrobials and to ensure that they are used prudently. In particular, a combination of Finland’s location and climate coupled with policies (supported by stakeholders) to avoid the introduction and spread of diseases with imported animals and to eradicate certain conditions has resulted in a relatively favourable animal health situation. According to EVIRA, there is a trend to strengthen on-farm biosecurity measures which should further enhance the animal health situation. Representatives of EVIRA also highlighted the strong and successful efforts made by other Nordic / Scandinavian countries in this area.

39. As part of its work to enhance the health of production animals in Finland, ETT has prepared a number of instructions and guides for imports (animals and feed) and for managing diseases and use of preventive measures and veterinary medicinal products on farms 19. These guides highlight good hygiene practices, the importance of biosecurity measures, background information on important conditions of pigs and handling and storage of veterinary medicines and contain sections on antimicrobials and AMR. In particular, the document ‘Poultry medication guide – controlled use of medication in poultry’ highlights similar issues but pays particular attention to the use of vaccines.

40. According to EVIRA and the veterinarians met, there has been a long standing emphasis on the need to use antimicrobials prudently and this concept is an integral part of veterinarians’ university studies and on-going training in Finland, which promotes a generally consistent approach to prescribing among veterinarians. In addition to regular training and publicity related to this topic, veterinarians may also exchange knowledge via specialist, closed groups on social media. These efforts have helped to raise and

maintain awareness of the issues surrounding AMR and the prudent use of antimicrobials and ensure that these concepts are broadly accepted and understood within the sector. These factors, combined with the long-standing national rules preventing veterinarians from making a profit on sales of veterinary medicinal products (see point 18) have affected the prescribing culture of Finnish veterinarians. On some occasions, controls on farms have identified cases where veterinarians who have qualified in other Member States have followed different, unacceptable approaches to the use of veterinary medicinal products as they are not aware of the Finnish rules (see point 59).

41. According to representatives of MTK, the producers are broadly supportive of initiatives such as prudent use of veterinary medicines, as these help reassure consumers and support their perception that Finnish food is produced to a high standard. This is seen as adding value and helping to differentiate Finnish food from that traded or imported from elsewhere.

42. In 1996, the Ministry of Agriculture and Forestry first compiled examples for the treatment of common conditions of production and companion animals in cooperation with veterinary organisations with expertise in different fields. These were updated and published as recommendations in 2003, 2009 and the latest edition was released in 2016. The treatment recommendations take into account the AMR situation in Finland and the range of antimicrobials available on the market. Veterinarians must justify not following these recommendations although there are no penalties for not doing so. Veterinarians met during the mission were generally supportive of the recommendations and followed them in practice.

43. In the latest version of the recommendations, there is an increased emphasis on avoiding the use of antimicrobials as much as possible, e.g. for simple skin infections in dogs it is now suggested to use certain shampoos rather than antimicrobials. None of the recommendations propose using CIAs as a first choice treatment. The recommendations suggest that to ensure the efficacy of treatments using certain older antimicrobials, a dosage higher than that specified in the SPC should be administered (e.g. for penicillins instead of 20 ml per cow specified in the SPC, 50 ml per cow should be administered), at the prescribing veterinarian's own risk. The need to consider any implications for the withdrawal period is highlighted in the instructions and veterinarians met by the mission team had adjusted the withdrawal periods accordingly.

44. There are a number of conditions set down in national legislation that veterinarians should respect when deciding to prescribe antimicrobials, including making a clinical or microbiological diagnosis before instituting treatment. In some cases, a microbiological diagnosis and relevant epidemiological data should be available to show that no other antimicrobials would be effective. Where an animal or group of animals need to be treated repeatedly for the same condition, the veterinarian is required to confirm the diagnosis and to carry out a susceptibility test at least annually.

45. National herd health programmes have been established for the pig and cattle sectors which provide a basis for setting central targets for the use of veterinary medicinal
products, including antimicrobials. Farmers participating in these schemes are required to have a contract in place for the provision of veterinary care, with a mandatory minimum frequency of visits. A health plan for each farm should be drawn up by the visiting veterinarian and be reviewed annually. The use of veterinary medicinal products in pigs must be recorded in the SIKAVA databases (see point 7) which enables the implementation of the health plans to be monitored by the veterinarians. The use of this database has been mandatory since 2014 for pig farms participating in the scheme. If the veterinarian leaves medicines on the farm for future use, legislation defines additional requirements e.g. the minimum frequency of visits is dependent on the number of animals on the farm and the use of medicines on these farms must be recorded in the SIKAVA or NASEVA databases.

46. At the discretion of the veterinarians, farmers participating in these herd health programmes and fulfilling the requirements above may be left certain veterinary medicinal products including antimicrobials (not CIAs) to treat a range of common conditions (defined in national legislation) which could arise between veterinary visits. This approach was originally intended to reduce the practical difficulties to provide prompt treatment of common conditions on farms which are often considerable distances away from veterinary practices. Farmers may participate in voluntary training on the use of veterinary medicinal products but the veterinarians are still free to decide whether to leave veterinary medicinal products for future use. One of the veterinarians met provided details of a case where it was decided not to allow the farmer to keep veterinary medicinal products for future use and so all treatments on this farm continue to be administered by veterinarians.

47. Herd health plans were available on the pig fattening farm visited and for the breeding farm from where the piglets were sourced. In both cases, there were contracts in place for veterinary visits at the frequency prescribed in national legislation. According to the veterinarians responsible for both farms, the treatment plans and their implementation were reviewed during each visit based on the records inserted in the SIKAVA database and indicators of animal health such as records of tail-biting, signs of joint infections or arthritis and mortality were assessed. Data from microbiological tests and slaughterhouses were also taken into account. The herd health plans were reviewed annually or if any significant changes in herd health were seen.

48. The operator of the pig farm visited had participated in training for the handling and administration of veterinary medicinal products and had been left some medicines for future use. The symptoms of the conditions and details of the treatments to be administered by the farmer were clearly explained in the herd health plan. The treatments had been recorded in the SIKAVA database as required.

49. A herd health plan was also in place at the dairy cattle farm visited which included an annex setting out the symptoms for conditions which could arise before the next visit by the veterinarian and the treatments to be administered. Under this plan, veterinary antimicrobials could be administered by the farmer for subclinical mastitis, fever and sore hooves. In cases where the veterinarian had initiated a course of treatment (e.g. a course of six daily treatments of which the farmer would administer the treatment for 5
days), the entire course of treatment was entered into NASEVA by the veterinarian. However, in this way it was not always evident that the farmer had actually administered the entire course of antimicrobials as prescribed by the veterinarian or whether the treatment had been stopped as soon as the animals appeared healthy.

50. According to EVIRA, the measures implemented by the Finnish poultry sector to improve the health of flocks could be considered as an example of good practice. The focus on preventive and biosecurity measures has made it possible to virtually eliminate the use of antimicrobials in this sector during the last few years. Measures based on ETT instructions stipulate strict controls on the import of chicks which include their quarantine and screening to ensure freedom from viral and bacterial diseases and resistance factors. These measures help avoid underlying infections which could lead to bacterial infections and an increased need for antimicrobial treatments. Good hygiene practice during the fattening stage is also emphasised with an ‘all in –all out’ approach and thorough cleaning and disinfection between batches. The implementation of these measures has been supported by various training and education sessions and the publication of a range of guidance and instructions.

51. In the pig sector, the emphasis has been on prevention rather than cure and according to EVIRA, the combination of relatively good husbandry conditions and freedom from certain diseases (e.g. porcine reproductive and respiratory syndrome and transmissible gastro-enteritis) has enabled the reduced use of antimicrobials in pigs as also the secondary bacterial infections are absent. This good practice has been supported by ETT’s import rules for animal health which have contributed to the eradication in Finland of a number of conditions in the last 10-15 years (e.g. enzootic pneumonia caused by *Mycoplasma hyopneumoniae* and also mange).

52. Provincial veterinarians from the RSAA met provided a number of examples where changes in the management of trout farms and fur animals had greatly reduced, or eliminated the need to use antimicrobials. In trout, up to 4.5 tonnes of tetracyclines were used annually in the 1980’s but the implementation of a vaccination programme against Vibriosis and Furunculosis resulted in a 90% drop in their use. A control campaign targeting the top users of 3rd generation cephalosporins in 2012 (see point 65) had identified that one veterinarian treating only fur animals had used illegally 3rd generation cephalosporins in fur animals on several fur animal farms. This usage accounted nearly 50% of the national annual sales of 3rd generation cephalosporins. Work carried out with the veterinarians showed the main use was linked to inflammation in the eyes of fur animals resulting from dehydration during certain periods of the year. The need for antimicrobial treatments was eliminated by using isotonic salts / sugar solutions to prevent dehydration in the fur animals.

53. The veterinarian visited who was treating production and companion animals, highlighted that many owners expect antimicrobials to be prescribed for their pets, even if they are not needed, and it is burdensome to explain to owners the reasons for not using them. A leaflet recently published by EVIRA should help reduce pressure on veterinarians to prescribe antimicrobials by providing pet owners with basic information
concerning antimicrobials, their use, limitations and some reasons why they are not always prescribed as well as highlighting the risks posed by AMR.

54. Future work planned by EVIRA is mostly aimed at maintaining the current relatively low levels of use of antimicrobials in food producing animals as to cut them further may risk affecting animal welfare. Consideration is being given to potentially reduce the use of veterinary antimicrobials in pet animals.

4.3.2 Control actions

55. Within the scope of its mission, EVIRA is responsible, amongst others, for preparing the multi-annual control programme, gathering data to establish the use of antimicrobials in different animal species, and providing training for veterinarians, pharmacies and animal owners. The RSAAs are, amongst others, responsible for controlling veterinary practitioners and producers of food-producing animals, or ordering municipal veterinarians to carry out controls. The municipal veterinarians are contracted to carry out certain tasks on behalf of the State. Those carrying out controls relating to the use of veterinary medicinal products on farms cannot also be directly or indirectly involved in providing veterinary care on the farms in question.

56. The multi-annual control programme in accordance with the Act on Medication of Animals 387/2014 was first developed in 2015 and will begin to be implemented in 2016. Three actions are particularly relevant to the use of antimicrobials: (a) education by EVIRA and provincial officers on the revised national legislation (see sections 4.2. and 4.3.), (b) ensuring that herd health veterinarians have up-dated the herd health care plans (see point 45) to take account of the revised national legislation, and (c) establishing control practices for the relevant records contained in the industry databases SIKAVA and NASEVA.

57. RSAAs’s controls on the use of veterinary antimicrobial products in food producing animals are based on follow-up of findings by dairies of antimicrobials in milk or on suspicion. Some additional random controls may also be carried out. The controls focus on checking if the instructions of the veterinarians are being followed, if veterinary medicinal products are stored and disposed of correctly and to confirm the veterinarian is acting in accordance with national legislation. The requirements for record keeping and identification of animals during treatment are checked.

58. According to EVIRA, approximately 100 inspections are performed each year, mainly on dairy farms and a few pig farms. Residues of antimicrobials are detected in approximately 15 – 20 samples each year. A goal of inspecting 80 farms a year (cattle and pigs) throughout the country has been established in the multi-annual control programme. Representatives of the RSAA met had not performed on farm controls until 2015 apart from following-up findings of antimicrobials in milk. Now they are planning to combine on-farm controls on veterinary medicinal products with those carried out for animal welfare issues and checks on EU cross-compliance 20.

20 http://ec.europa.eu/agriculture/direct-support/cross-compliance/index_en.htm
The controls on farm had identified a few cases where veterinary medicinal products had been brought into Finland by veterinarians from Baltic Member States, mainly as a result of them not being familiar with the national policies which are included in the syllabus of students in the Finnish veterinary faculty. In one case, officers from a RSAA carried out follow-up checks and found the practice had not stopped. The veterinarian concerned was informed about the relevant national requirements and restrictions on the import of veterinary medicinal products. According to EVIRA, there have been no findings in the last 10 years of farmers importing veterinary medicinal products.

According to EVIRA, a limited number of controls (3 - 4 farms per year) are carried out each year on fur farms, mainly for welfare reasons. Operators of fur farms are not required to keep records of the use of veterinary medicinal products, including antimicrobials, on the basis of the Act on Medication of Animals, as fur animals are not food producing animals. However, in accordance to the Act on Animal Welfare, it is obligatory to keep records on treatments of fur animals.

In accordance with the multi-annual control programme, RSAAs plan to inspect 4-5% of veterinary practitioners, with those deemed to be the highest risk being checked every 3-4 years while the rest would be checked either at random or on suspicion. Targeting criteria include the purchase of relatively large amounts of veterinary antimicrobial products or those veterinarians that have several herd health agreements in place. Veterinarians who have purchased 3rd generation cephalosporins but only treat animal species for which these are not authorised (i.e. species other than pigs, cattle and dogs and cats) may also be targeted for controls. In the 10 years prior to developing the multi-annual control programme, only a relatively limited number of veterinarians (approximately 20) were inspected by RSAAs each year, mainly on the basis of complaints or suspicion and there was considerable variation in the number of controls performed by the different provinces.

The Provincial veterinarians from the RSAA met described controls carried out on municipal and private veterinarians which mainly consist of interviews and checks on the notes relating to different types of farms they visit. More important to the scope of this mission is the focus on ensuring that the requirements of the herd health programmes and the prescription of medicines for future use (see points 45 and 46) are respected. The justifications for using certain antimicrobials (e.g. susceptibility test results) are also checked.

In 2015, 16 inspections of veterinarians have been carried out nationally and the justifications for the use of veterinary antimicrobials required under national legal requirements were missing in two cases. According to EVIRA, issues such as improper storage or discrepancies in the records for the use of veterinary medicinal products were identified in 31 of the last 50 inspections carried out nationally.

In one case, investigations carried out following the detection of a residue of antimicrobials in milk, identified that the farmer had administered a dry cow treatment to the wrong animal owing to human error. The farmer was stopped from receiving veterinary medicinal products for future use.
65. EVIRA has established a number of control campaigns which target the top 10 users of certain types of veterinary medicinal products. These are announced in advance and are mainly based on correspondence and documentary checks rather than on-site inspections. The approach helps raise awareness of the requirements relating to the campaign and requires limited resources. As regards antimicrobials, a permanent project has been established in 2016 under which the 10 veterinarians purchasing the highest quantities of 3\textsuperscript{rd} generation cephalosporins will be asked to provide evidence that these have been used in accordance with the legal requirements (e.g. on the basis of susceptibility tests, and following the conditions in the SPC). A similar project is planned for 2017 on the use of long-acting macrolides. Similar campaigns are planned to check on the use of zinc oxide in piglets and antimicrobials in fish production.

66. As regards medicated feed, producers are required to include measures to reduce carry-over of medicines into non-medicated batches in their Hazard Analysis Critical Control Points programmes and to carry out regular checks on the homogeneity of the medicated feeds they produce. EVIRA requires that the variation between batches is no more than ±10\%. Inspection reports seen by the mission team showed that these issues had been checked during routine inspections by EVIRA and the results were satisfactory.

**Conclusions on policies and control actions on the use of antimicrobials in animals**

67. The longstanding initiatives to raise and maintain awareness of AMR and the prudent use of antimicrobials have helped ensure that the official rules and industry guidance on these topics are accepted and implemented by veterinarians and producers. These factors, combined with actions to enhance the animal health situation in Finland, have contributed to the relatively low use of antimicrobials in animals and the development of practices which could serve as examples of potential good practice in other Member States. The recent revision of the legislation to restrict the prescription and use of CIAs, in conjunction with the national multiannual official control programme, and initiatives targeting the highest users of these substances, have helped to further raise awareness of the prudent use of antimicrobials.

**5 Overall Conclusions**

The comprehensive and long-standing policies on the availability of antimicrobials, including CIAs, together with initiatives to raise and maintain the awareness of AMR, have resulted in a relatively low and stable level of sales of antimicrobials and, at the same time, encouraged their prudent use. These factors have been reinforced with actions to enhance the animal health situation in Finland. Notwithstanding the fact that official controls are also contributing in this regard, the implementation of these policies and initiatives has been ensured thanks to their acceptance by, and active participation of, veterinarians and producers. Whilst it is not possible to distinguish the impact of each individual measure, the analysis of the available data and comparisons with the situation reported by other Member States has shown that the said policies and initiatives have helped to slow the development of AMR in Finland.
Various aspects of the measures put in place in Finland aimed at encouraging the prudent use of antimicrobials in animals and tackling the broader issue of AMR could serve as examples of potential good practice in other Member States.

6 CLOSING MEETING

A closing meeting was held on 20 May 2016 with the representatives of the central competent authorities. At this meeting, main findings and preliminary conclusions of the mission were presented by the mission team. The central competent authorities did not indicate any disagreement with these.
## ANNEX 1 – LEGAL REFERENCES

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