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

This fact-finding mission on the prudent use of antimicrobials in animals took place in Cyprus from 10 to 14 October 2016 and is part of DG Health and Food Safety’s planned series of such missions to Member States. 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 that very little has been done in Cyprus to date in the veterinary field to reduce the use of antimicrobials and encourage their prudent use. Whilst some initiatives have started, such as the Ministry of Health action plan – which has a veterinary component – and the dissemination of information to stakeholders on the use of antimicrobials in the veterinary field, most actions in this area are prospective and are contingent upon Ministry of Agriculture's approval of the draft action plan, which is still being elaborated by the Veterinary Services.

A fundamental issue which will need to be addressed is the current business model for the veterinary profession, whereby veterinary drug wholesalers directly employ a substantial proportion of the veterinarians providing services to the food-producing animal sector, leading to an over-reliance on veterinary drug sales as an income generator for the profession. The current business model is at odds with the objective to reduce the use of antimicrobial veterinary medicinal products, and may explain the relatively frequent use of antimicrobial prophylaxis via medicated feedingstuffs.

Nevertheless, it is encouraging that the competent authority recognises the above-mentioned issues and is committed to implement its (draft) action plan in due course.
# Table of Contents

1. Introduction
2. Objectives and scope of the mission
3. Background to the mission series
4. Findings
   4.1 Background
      4.1.1 Sales of antimicrobial veterinary medicinal products
      4.1.2 Organisations (governmental and non-governmental) involved in the development and implementation of policies pertaining to the use of veterinary medicinal products
   4.2 Availability of antimicrobial veterinary medicinal products
      4.2.1 Authorisation and distribution
      4.2.2 Special conditions applicable to the use of critically important antimicrobials
      4.2.3 Monitoring and surveillance on the use of antimicrobials in animals
   4.3 Prudent use of antimicrobials in animals
      4.3.1 Policies and practices
      4.3.2 Control activities by the competent authority
5. Overall Conclusion
6. Closing Meeting

Annex 1 – Legal References
### Abbreviations and Definitions Used in This Report

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMR</td>
<td>Antimicrobial resistance</td>
</tr>
<tr>
<td>CIAs</td>
<td>Critically important antimicrobials</td>
</tr>
<tr>
<td>DVOs</td>
<td>District Veterinary Offices</td>
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<td>ESVAC</td>
<td>European Surveillance of Veterinary Antimicrobial Consumption</td>
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<td>EU</td>
<td>European Union</td>
</tr>
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<td>PCU</td>
<td>Population Correction Unit</td>
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<td>VMPS</td>
<td>Veterinary Medicinal Products Section</td>
</tr>
</tbody>
</table>
1 INTRODUCTION

This fact-finding mission on the prudent use of antimicrobials in animals, carried out in agreement with the Cypriot competent authorities, took place in Cyprus from 10 to 14 October 2016 and is part of a planned series of such missions to Member States. The mission team, comprising two auditors, one National Expert and one observer from the New Zealand Ministry for Primary Industries, was accompanied throughout the mission by representatives of the central competent authority, the Ministry of Agriculture. An opening meeting was held on 10 October 2016 with the competent authority during which the objectives and scope of, and itinerary for, the fact-finding mission were confirmed.

2 OBJECTIVES AND SCOPE OF THE MISSION

The objectives of this fact-finding mission were to (a) gather information on the practical implementation of measures aimed at tackling the issues concerning antimicrobial resistance (AMR) related to the use of veterinary medicines and (b) identify examples of good practice which could be helpful to other Member States in addressing this issue.

The mission team examined the regulatory framework on veterinary medicines and on medicated feed currently in place in Cyprus (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 services referred to in section 3. The following topics were not included in the scope of this mission: (i) the monitoring and reporting of AMR 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 February 2014 (report DG(SANTE)/2014-7028).

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

<table>
<thead>
<tr>
<th>Visits / Meetings</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competent authority</td>
<td></td>
</tr>
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</tr>
<tr>
<td>Veterinary Practice</td>
<td>1</td>
</tr>
<tr>
<td>Farms</td>
<td>2</td>
</tr>
<tr>
<td>Feed mill</td>
<td>1</td>
</tr>
</tbody>
</table>
3 BACKGROUND TO THE MISSION SERIES

This fact-finding mission series addressed one of a number of initiatives included in the European Commission's 2011 action plan against the rising threats from AMR, and is specifically linked to actions 2 and 3 of the associated road map: 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), 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 European Union (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 visited by the Commission in order to see the practical implementation of prudent use principles on-the-spot.

A summary of the outcomes of both the questionnaire responses from the Member States and the fact-finding missions will be presented in an interim and final overview report intended to highlight current good practices and challenges identified in implementing policies underpinning the prudent use of antimicrobials in veterinary medicine.

4 FINDINGS

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, sales of veterinary antimicrobials in Cyprus (expressed in milligrams (mg) per population correction unit (PCU)) decreased by 4% from 2011 to 2014 (from 425.8 mg to 392.5 mg), within a range of 3.1 to 418.8 mg/PCU among the 26 countries contributing data to ESVAC. The majority of antimicrobials sold (around 95%) were for oral medication, most of which were medicated premixes mainly intended for use in pigs. The sales of critically important antimicrobials (CIAs) accounted for 4.9% of total antimicrobial sales, with macrolides being the most commonly sold CIAs accounting for 4.5% of the total sales in 2014 (see point 11).

2. According to the competent authority, a detailed breakdown of the use of antimicrobials by species or production ages is not currently available. However, the officials met declared that this could be ascertained by checking the lists of the 21 veterinary

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wholesaler's customers (veterinary practices), as the competent authority knows the types of farms serviced by the veterinary practices. Further information on the reasons why the different types of antimicrobials were most frequently used (for instance, the therapeutic indication or the frequency of use) was not currently available but was considered by the competent authority to be useful in order to design effective strategies to reduce the use of antimicrobials. The planned establishment of a system of electronic prescription was expected to contribute to this end.

4.1.2 Organisations (governmental and non-governmental) involved in the development and implementation of policies pertaining to the use of veterinary medicinal products

3. A description of the organisation of the competent authorities responsible for controls on veterinary medicinal products is given in the country profile for Cyprus ⁵. In summary, the Veterinary Services (within the Ministry of Agriculture) through the Veterinary Medicinal Products Section (VMPS) and the Council of Veterinary Medicinal Products are responsible for authorising establishments and for conducting controls on the distribution and use of veterinary medicinal products, including medicated feed. Controls on the use of antimicrobials at farm level are carried out by technicians from the District Veterinary Offices (DVOs).

4. A National Strategic Plan to combat AMR was published in December 2012 by the Ministry of Health under the “One Health” approach ⁶. This plan is managed by the National Committee on Antibiotics which includes representatives from both the human and veterinary medicine fields. The plan is mainly focused on the human health side and although it includes some actions in the veterinary field (for instance, improving diagnosis and use of antibiotics in animals) there are, as yet, no concrete measures to encourage the prudent use of antimicrobials in the veterinary field.

5. Notwithstanding the National Strategic Plan, officials from the Veterinary Services stated that a specific (separate) action plan was considered to be the right tool to address the high level of veterinary antimicrobials sold in Cyprus over the last few years. To that end, a five year Action Plan to combat AMR is currently being drafted by the Veterinary Services and, subject to political agreement, the plan is expected to be adopted by mid-2017. The draft plan contains several types of measures, including awareness-raising campaigns, strengthening the prevention of infections in food-producing animals, controls on the use of CIAs and recommendations on the prudent use of antimicrobials – which are in line with the Commission's published guidance.

6. The Pancyprian Veterinary Association is a representative body of veterinarians comprising mostly companion animal practitioners. In terms of the activities carried out in relation to AMR, representatives from the association stated that it has distributed to

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⁵ http://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=CY
⁶ http://www.moh.gov.cy/moh/moh.nsf/0/6b4121829d8502a5c2257e210026e74c/$FILE/ATTLV98V%CE%95%CE%98%CE%9D%CE%99%CE%9A%CE%97%20%CE%A3%CE%A4%CE%A1%CE%91%CE%94%CE%97%CE%93%CE%99%CE%9A%CE%97%20%CE%99%CE%91%20%CE%A4%CE%95%CE%9B%CE%99%CE%9A%CE%9F.pdf
its members, guidelines on prudent use of antimicrobials 7 issued by the Federation of European Companion Animal Veterinary Associations.

7. The representatives of the farmers' associations met represented mainly sheep and goat stock farmers. All declared that their activities focus mainly on the support of farmers' financial interests and have not included to date any activities related to AMR and the prudent use of antimicrobials.

4.2 AVAILABILITY OF ANTIMICROBIAL VETERINARY MEDICINAL PRODUCTS

4.2.1 Authorisation and distribution

8. All antimicrobial veterinary medicinal products intended for use in both food-producing and companion animals are prescription-only medicines in Cyprus 8. There is no requirement for farmers to have a contract with a veterinarian to provide regular farm visits, but according to the relevant national legislation, veterinarians can only administer antimicrobials to animals for which they are directly responsible. Antimicrobials for veterinary use can be dispensed by veterinarians or by pharmacies based on a veterinary prescription. Veterinarians and pharmacies purchase antimicrobials from authorised wholesalers (there are 21 of these in Cyprus). As regards medicated feed, there are 11 commercial feed mills and 37 on-farm mixers (35 in pig farms and 2 in poultry farms) authorised to manufacture this type of feed in Cyprus.

9. A number of competent authority officials, farmers and veterinarians met stated that most veterinarians serving the food-producing animal sector derived their income from the sales of antimicrobials and do not charge farmers for professional advice. This is because of the structure of the veterinary profession in Cyprus whereby these veterinarians are directly employed by the wholesalers and there is a financial incentive to sell medicines to farmers. This was acknowledged by the competent authority to represent a clear conflict of interest and was deemed to be one of the main reasons explaining the relatively high use of antimicrobials in Cyprus compared to other Member States.

10. Officials from the Veterinary Services stated that there are currently no legal provisions or disciplinary actions which can be applied from the professional body regulating the veterinary profession, in respect of the business model currently in place in Cyprus (and the inherent conflict of interest). The mission team was informed that this had been brought to the attention of the Director-General of the Ministry of Agriculture in June 2015 and the draft action plan (see point 5) highlights the need to adopt measures to reduce the financial incentives to prescribe antimicrobials.

4.2.2 Special conditions applicable to the use of critically important antimicrobials

11. There are no specific mandatory requirements in place concerning the dispensing and use of CIAs in Cyprus. ESVAC data for 2014 (see point 1) showed that sales of fluoroquinolones and 3rd and 4th generation cephalosporins, accounted (each) for 0.2% (equivalent to 0.1 tonnes) of the total sales of antimicrobials within a range of 0.01% to 1.5% for the former and 0.01% to 11.9% for the latter among the countries contributing data to ESVAC. During the period 2011-2014, the consumption of fluoroquinolones in Cyprus increased from 0.51 to 0.94 mg/PCU and from 0.16 to 0.79 mg/PCU in the case of 3rd and 4th generation cephalosporins. Officials from the Veterinary Services were not aware of the reasons for this increase.

12. Regarding colistin, Cyprus' sales in the 2014 ESVAC data were 11mg/PCU (range of 0 to 36 mg/PCU among the 26 contributing countries). At the time the mission was carried out, the relevant webpage of the Veterinary Services showed 11 veterinary medicinal products containing colistin, 9 of which were intended for oral use either as medicated premix or as an oral solution. Of these 9, 4 also contained amoxicillin. The competent authority informed the mission team that the marketing authorisations for the combination products (colistin and amoxicillin) were withdrawn, following the Commission implementing Decision from July 2016 and the owner of the pig farm visited was aware of this withdrawal – he was using this treatment as a second option to treat post-weaning diarrhoea when the first option was not effective.

4.2.3 Monitoring and surveillance on the use of antimicrobials in animals

13. Since 2010, the Veterinary Services have been collecting data on the sale of veterinary medicinal products which are distributed from wholesalers to pharmacies and veterinarians. From 2011 to date these data have been included in the ESVAC project.

14. The competent authority stated that with the exception of mastitis-producing bacteria and some skin-related conditions in dogs, it does not have in place any other surveillance and monitoring programmes additional to the mandatory monitoring and reporting of AMR in zoonotic and commensal bacteria in certain food-producing animal populations required by EU legislation. The competent authority considered that the available data for Cyprus on AMR of the different bacteria examined in these mandatory programmes, along with figures showing a relatively high level of consumption of antimicrobials should be presented to veterinarians and farmers to help raise awareness of the link between high consumption and AMR and that this should facilitate the collaboration of both groups to reduce the use of antimicrobials.

4.3 PRUDENT USE OF ANTIMICROBIALS IN ANIMALS

4.3.1 Policies and practices

15. According to the Veterinary Services there are currently no legal measures in place intended to enforce the prudent use of antimicrobials. To date the focus has been to raise awareness about issues concerning AMR through the publication and distribution of leaflets (provided to the mission team) regarding the legal obligations related to the use of antimicrobials, the link to the rising threat of AMR and how antimicrobials should be used in a prudent way. Such measures are also included in the draft action plan to fight AMR.

16. Representatives from the Pancyprian veterinary association stated that in their opinion, an effective way to reduce the use of antibiotics on farms would be to make it legally compulsory for farmers to have a contract with a veterinarian. They considered that decoupling the prescription and dispensing of antimicrobials by the same veterinarian would not necessarily have the intended effect (of reducing the volume of antimicrobials sold) as it may encourage a black market.

17. The representatives from the farmers' associations met considered that measures to reduce the use of antimicrobials (particularly in pig and poultry farms – which account for the majority of use of in-feed antimicrobials) such as enhancing biosecurity and improving the health status of animals (for instance by reducing the stock density) would likely face opposition from stock farmers as this would significantly increase their production costs and make livestock farming in Cyprus unprofitable.

18. The Veterinary Services considered that it would be important to offer incentives to farmers to take measures to improve the health and biosecurity status of their livestock as a means of reducing reliance on antimicrobial use. In this context the European Commission Rural Development Plan 2014-2020 \(^{11}\) was cited. This includes some financial aid for sheep and goat farms which comply with animal welfare standards, including the presence of specific biosecurity measures.

19. The pig-breeding farm visited had a number of measures in place to reduce the need for the use of antimicrobials. These included a range of biosecurity measures such as a semi-closed production system (repopulating females from their own stock) fencing of the premises, compulsory disinfection for incoming vehicles, environment-controlled houses and a vaccination programme against porcine circovirus, mycoplasma, Escherichia coli, Haemophilus parasuis, erysipelas and parvovirus. Nevertheless, the owner of the farm stated that it still had problems with mycoplasma and \(H.\) parasuis, whose presence had been confirmed in the past through blood tests. To tackle these endemic infections, the farm was routinely using antimicrobials through medicated feed (produced on-farm) mainly to prevent the onset of clinical symptoms. According to the owner of the farm, the attending veterinarian does not carry out diagnostic tests to confirm the presence of the suspected diseases or to rule out other diseases before

prescribing the antimicrobials. Preventive treatments to date have been effective. Alternatives to the prophylactic use of antimicrobials have not been considered.

20. The dairy farm visited used a computer-based herd management programme for the milking cows on the farm utilising transponder data from each animal which was used by the farm veterinarian to monitor individual animal's health status and determine appropriate therapeutical interventions. As regards the use of antimicrobials, first-line antimicrobials for mastitis were injectable penicillins, while third generation cephalosporins were the second-line option and fluoroquinolones the third one. Susceptibility tests were not done because there was normally no time for them (as the cows would quickly show clinical signs of mastitis) and the current treatment strategy was normally effective.

21. The veterinarian of the mixed animal practice visited provided services to a number of sheep and goat farms. The veterinarian stated that common conditions such as mastitis and respiratory infections were treated with penicillins and oxytetracycline (respectively) and only if these failed would the off-label use of a fourth generation cephalosporin (cefquinome) be resorted to. In common with the situation observed on both the pig and dairy farm the veterinarian did not perform susceptibility testing (either for production or companion animals).

22. During the visit to the commercial feed mill the mission team checked a number of prescriptions issued for different farms for medicated feed destined for calves and lambs or kids. Medicated feed was systematically prescribed around calving or lambing as the diagnosis on the prescriptions always read "bacterial infections after calving or lambing" (as applicable). A combination of sulphonamides and trimethoprim plus oxytetracycline was systematically prescribed for all cases.

23. In this feed mill measures were in place to reduce carry-over including flushing the line and physically cleaning some of the equipment (like the mixer and the pelleting machine). Samples had been taken to verify the effectiveness of these measures and the results were satisfactory. As regards homogeneity, tests were carried out using different antimicrobials and the results seen were largely satisfactory.

24. The on-farm feed mill on the pig farm had two mixers, one dedicated to the production of medicated feed. Flushing with a small amount (in relation to the volume of the mixer) of calcium carbonate was carried out to minimise carry-over of different antimicrobials but the effectiveness of this measure had not been assessed. Concerning homogeneity, tests to measure it were regularly done and the results obtained were below the limit set by the operator (10% coefficient of variation).

4.3.2 Control activities by the competent authority

25. VMPS has the responsibility for monitoring the prescription and distribution of antimicrobials from wholesalers and retailers (pharmacies and veterinary clinics). Among other things, officials check the presence of correctly completed prescriptions and that the amount of antimicrobials in stock tallies with the difference between those
purchased and sold. The veterinary clinic (mixed-animal practice) visited had been regularly subject to such official controls and no shortcomings had been found to date.

26. The use of antimicrobials at farm level is checked by DVO officials. Each of the farms visited had been subject to such official controls at least once in the last 3 years with the focus being on verifying that veterinary medicinal products were used in accordance with label instructions, that the corresponding prescriptions were correctly completed and that farmers keep the statutory treatment records. To date such controls have not addressed the issue of prudent use (e.g. verifying that a correct diagnosis has been made by means of supporting evidence indicating the correct choice of antimicrobial therapy).

27. The production of medicated feed both in commercial feed mills and in home mixers is checked by officials from VMPS. VMPS strongly encourages feed business operators to use a dedicated line to produce medicated feed, to flush the line after medicated feed is manufactured and to reuse this flushing material in an appropriate manner. The competent authority provided the mission team with several examples of results of testing of finished feedingstuffs which according to the explanation given, were used to monitor the effectiveness of flushing. The commercial feed mill visited was also monitoring the effectiveness of their flushing procedures. As regards homogeneity of mixing, VMPS evaluates the results of the feed business operators’ own checks.

5 Overall Conclusion

Very little has been done in Cyprus to date in the veterinary field to reduce the use of antimicrobials and encourage their prudent use. Whilst some initiatives have started, such as the Ministry of Health action plan – which has a veterinary component – and the dissemination of information to stakeholders on the use of antimicrobials in the veterinary field, most actions in this area are prospective and are contingent upon Ministry of Agriculture's approval of the draft action plan, which is still being elaborated by the Veterinary Services.

A fundamental issue which will need to be addressed is the current business model for the veterinary profession, whereby veterinary drug wholesalers directly employ a substantial proportion of the veterinarians providing services to the food-producing animal sector, leading to an over-reliance on veterinary drug sales as an income generator for the profession. The current business model is at odds with the objective to reduce the use of antimicrobial veterinary medicinal products, and may explain the relatively frequent use of antimicrobial prophylaxis via medicated feedingstuffs.

Nevertheless, it is encouraging that the competent authority recognises the above-mentioned issues and is committed to implement its (draft) action plan in due course.
6 CLOSING MEETING

A closing meeting was held on 14 October 2016 with the competent authority. At this meeting, the main findings and preliminary conclusion were presented by the mission team and the competent authority did not disagree with these.
## ANNEX 1 – LEGAL REFERENCES

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<th>Legal Reference</th>
<th>Official Journal</th>
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