In response to information provided by the competent authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.
Executive Summary

This fact-finding mission took place in Romania from 21 to 25 November 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 (AMR) 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.

In 2014 the use of veterinary antimicrobials in Romania was below the average reported by the countries providing data to the European Surveillance of Veterinary Antimicrobial Consumption project and a slight decrease in use was seen in 2015. This situation is explained in part by their historically limited availability and their relatively high cost.

A national strategy for tackling AMR and an associated internal action plan for the period 2016-2018 have been drawn up by the National Sanitary Veterinary and Food Safety Authority together with the national reference institutes and in consultation with the Romanian College of Veterinary Surgeons, One Health New Medical Concept Romania Association, the Romanian Poultry Breeders’ Association and the National Association of Veterinary Medicinal Products Distributors in Romania. A similar national strategy is being prepared covering human health aspects. The veterinary national strategy is aimed at improving animal health, ensuring correct use of antimicrobials and raising awareness of the issues. Although this strategy is considered to be based on the One Health approach, its scope is largely limited to areas which fall directly within the remit of the competent authorities and as such, its main focus is on the 'correct use' of antimicrobials through compliance with legal requirements and national rules to restrict use.

Overall, the report concludes that the above measures are supported by regular official controls throughout the distribution and use of veterinary antimicrobial products. These controls will help encourage the prudent use of veterinary antimicrobials. Likewise, the wide range of training and other awareness raising activities carried out have helped familiarise farmers and veterinarians with AMR and general principles for the reduced and prudent use of antimicrobials. However, these have so far had little effect on the prescribing behaviour of veterinarians which is influenced by other factors including price and withdrawal period, especially regarding critically important antimicrobials. The report acknowledges that once the national AMR strategy is fully implemented there is potential for reduced and more prudent use of antimicrobials in animals, especially if certain constraints (notably the cost of diagnostic and susceptibility tests and of medicines) were also addressed.
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Annex 1 Legal References
# Abbreviations and Definitions Used in This Report

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<tr>
<td>AMR</td>
<td>Antimicrobial resistance</td>
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<td>CIAs</td>
<td>Critically important antimicrobials</td>
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<td>CMVRO</td>
<td>Romanian College of Veterinary Surgeons &lt;br&gt; <em>Colegiul Medicilor Veterinari din România</em></td>
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<td>CSVFSD</td>
<td>County Sanitary Veterinary and Food Safety Directorates</td>
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<td>EMA</td>
<td>European Medicines Agency</td>
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<td>ESVAC</td>
<td>European Surveillance of Veterinary Antimicrobial Consumption</td>
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<tr>
<td>EU</td>
<td>European Union</td>
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<tr>
<td>FVE</td>
<td>Federation of Veterinarians of Europe</td>
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<tr>
<td>ICBMV</td>
<td>Institute for Control of Biological Products and Veterinary Medicines &lt;br&gt; <em>Institutul pentru Controlul Produselor Biologice și Medicamentelor de Uz Veterinar</em></td>
</tr>
<tr>
<td>NSVFSA</td>
<td>National Sanitary Veterinary and Food Safety Authority &lt;br&gt; <em>Autoritatea Națională Sanitară Veterinară Și Pentru Siguranța Alimentelor</em></td>
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<tr>
<td>PCU</td>
<td>Population correction unit</td>
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<tr>
<td>SPC</td>
<td>Summary of product characteristics</td>
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<td>SVMP</td>
<td>Service of Medicinal Products Control, Nutrition and Laboratories</td>
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1 INTRODUCTION

This fact-finding mission, carried out in agreement with the Romanian competent authorities, took place from 21 to 25 November 2016 and was the ninth in a planned series of missions to Member States during 2016. The mission team, comprising of 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 Directorate for veterinary medicinal products and animal nutrition of the National Sanitary Veterinary and Food Safety Authority (NSVFSA). The objectives, scope and itinerary for this fact-finding mission were confirmed during the opening meeting which took place on 21 November 2016.

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 Romania (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 AMR in zoonotic and commensal bacteria in certain food-producing animal populations and in food and (ii) the monitoring of residues and contaminants in live animals and animal products. These two topics were the subject of audits in December 2016 (DG(SANTE)/2016-8677) and in February 2013 (DG(SANCO)/2013-6843), respectively.

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

<table>
<thead>
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<th>Visits / Meetings</th>
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<td>Veterinary Practice</td>
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<td>Farms</td>
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<td>Feed mill</td>
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<tr>
<td>Industry stakeholders</td>
<td>2</td>
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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 nine Member States were selected to be involved in this series of fact-finding missions during 2016. The main points from these fact-finding missions and the questionnaire responses will be presented in an interim and 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 NATIONAL STRATEGIES AND ACTION PLANS INFLUENCING THE USE OF ANTIMICROBIALS IN ANIMALS

1. A three-year national AMR strategy for the period 2016 to 2018 and an associated guide to the use of antimicrobials in animals has been developed by a working group made up of the technical directorates of the NSVFSA and the relevant national technical institutes (Institute for Hygiene and Veterinary Public Health, the Institute for Diagnosis and Animal Health and the Institute for Control of Biological Products and Veterinary Medicines (ICBMV)) with limited contributions from industry organisations and professional bodies (Romanian One Health Association and the Romanian College of Veterinary Surgeons (CMVRO)). The strategy was published following its approval in July 2016 \(^3\) along with guide referred to above \(^4\). During the opening meeting, the representative of the Health Ministry stated that a similar national AMR strategy for human health is being developed in a co-ordinated One Health approach to tackle AMR in Romania. As no further information was provided regarding the AMR strategy for human health, the observations below are restricted to the national AMR strategy for the veterinary sector.

\(^1\) http://ec.europa.eu/health/antimicrobial_resistance/docs/roadmap_amr_en.pdf
\(^3\) http://www.ansvsa.ro/download/antimicrobieni/Tabel-Strategie-pt-site-2.pdf
2. The AMR strategy is based on three general objectives, each with associated specific objectives and follow-up actions, which can be broadly summarised as (a) improving animal health, ensuring the correct use of antimicrobials in animals and raising awareness of AMR related issues through communication and training activities. The objectives, the actions to be taken and the follow-up actions of the NSVFSA AMR strategy are published on the NSVFSA website. The responsibilities, time limits and implementing stage of actions are internal documents of the Working group for monitoring the actions from the AMR strategy.

3. Although this strategy is considered to be based on a One Health approach, its scope is largely limited to areas which fall directly within the remit of NSVFSA, which is the regulatory control authority in the sanitary veterinary field, the 42 County Sanitary Veterinary and Food Safety Directorates (CSVFSD) at local level, and ICBMV. Their broad ranging responsibilities are described in detail in the country profile \(^5\) but, those of NSVFSA relating to veterinary medicinal products can be summarised as (a) issuing authorisations for their manufacture and distribution, (b) the prioritisation, planning and implementation of official controls to verify compliance with EU and national rules for the manufacture, distribution and use of veterinary medicinal products and (c) the monitoring and surveillance of residues and of AMR. ICBMV is among others responsible for issuing marketing authorisations for veterinary medicinal products and for their testing. Representatives of industry associations for the pig and poultry sectors met stated they had little involvement in or influence on the national AMR strategy.

4. As a result, there is an emphasis in the national AMR strategy on the 'correct use' of antimicrobials through compliance with legal requirements concerning the use of veterinary medicinal products (e.g. prescriptions, treatment records and withdrawal periods and the monitoring and surveillance of AMR), and reducing the need for their use through the implementation of mandatory animal health programmes. The promotion of prudent use of antimicrobials is mainly covered by training and other awareness raising activities (e.g. publication of guidance, publications in journals).

5. The national AMR strategy is largely qualitative in nature and aims to achieve reductions in the use of antimicrobials and their more prudent use by changing attitudes rather than through setting targets for reductions in particular production sectors.

6. Issues relevant to AMR and the prudent use of antimicrobials in animals were the topic of a recent veterinary seminar in Romania involving the Dutch authorities, organised at the instigation of the Dutch embassy in Bucharest.

\(^5\) \url{http://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=RO}
4.2 Monitoring of Sales of Antimicrobials and Levels of AMR

4.2.1 Monitoring of sales of antimicrobials

7. Data for the sales of antimicrobials in animals are included for the first time in the European Surveillance of Veterinary Antimicrobials Consumption (ESVAC) report for 2014. These indicate that sales of antimicrobials, including the critically important antimicrobials (CIAs), for use in animals in Romania were 39 mg/population correction unit (PCU), which is below the average of the range of sales data (3.1 to 418.8 mg/PCU) reported by countries contributing data to the project. During the same period, sales of quinolones (including fluoroquinolones) amounted to 6% and cephalosporins to 0.1% of the total amounts of antimicrobials sold for use in animals. The reporting of sales of antimicrobials for use in animals became mandatory in 2015. According to NSVFSA, preliminary data for 2015 indicates a downward trend in sales. The relatively low sales of antimicrobials for use in animals were attributed in part to their limited availability and cost – veterinarians met estimated that advice accounted for 20% of their service charge while the remainder is for the costs of veterinary medicinal products (including antimicrobials).

8. Information on the use of antimicrobials by species is not currently available, although NSVFSA estimates the pig and poultry sectors are the most important.

9. According to NSVFSA, data concerning the trade in medicated feed from other Member States is compiled from notifications made to CSVFSD where the feed is brought in. Data provided to the mission team indicates that in 2015, there was a limited trade in medicated feed in three counties in Romania.

4.2.2 Monitoring of AMR

10. The national AMR strategy includes a specific objective to carry out the programme on the monitoring and reporting of AMR in zoonotic and commensal bacteria, in accordance with EU legislation, for the period 2014 to 2018. Further information on the implementation of these programmes can be found in the relevant DG(SANTE) audit report referred to in section 2 above.

11. According to NSVFSA, there is a network of 11 accredited regional and national laboratories which can carry out susceptibility tests on official (and private) samples, although operators are free to use private laboratories for this purpose. An overview of these tests and any issues identified regarding AMR was not available.

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7 In their comments on the draft report, the competent authorities provided updated data showing that in 2014 a total of 277.03 tonnes of antimicrobials were sold for use in animals - equivalent to 109.05mg/PCU.

8 In their comments on the draft report, the competent authorities provided data showing sales of antimicrobials for use in animals in 2015 totalled 259.59 tonnes (6.3% lower than the revised sales figures for 2014) – equivalent to 100.54 mg/PCU (7.81% lower than for 2014).
Although the potential risks to human and animal health posed by increasing levels of AMR are referred to in the national AMR strategy and other publications, there is little reference made to the results of the AMR monitoring and surveillance activities and in particular if any issues which merit attention have been identified.

4.3 DISTRIBUTION MODEL FOR VETERINARY ANTIMICROBIALS IN ROMANIA

4.3.1 Authorisation and distribution

In Romania, farmers and pet-owners may purchase veterinary antimicrobial products from authorised veterinary pharmacies only with a veterinary medicinal prescription, issued by a free-practice veterinarian, or those working within university or veterinary clinics. In accordance with national rules, veterinary antimicrobial products should only be prescribed following a clinical examination of the animal(s) by the veterinarian. The justification for the sale of veterinary medicines by veterinary pharmacies must be recorded in the prescription register.

Farmers may purchase larger quantities of veterinary medicinal products for specific treatments from authorised wholesalers using an order stamped and signed by the veterinarian. A veterinarian is required to issue a prescription for the subsequent use of these veterinary medicinal products. The majority of veterinary antimicrobial products are sold in this way. The sale of veterinary medicinal products via the internet is forbidden.

As a general rule, only veterinarians are permitted to use and administer veterinary medicinal products. Exceptions to this provide for animal owners to administer veterinary medicinal products (other than injectable products) which are prescribed and recommended by a free-practice veterinarian and for auxiliary veterinary staff in veterinary clinics to administer them under the supervision of a veterinarian. The veterinarian is obliged to prescribe the quantity of antimicrobials required for the complete treatment.

Veterinarians may only prescribe veterinary antimicrobial products for use on commercial holdings if they are employed by a veterinary practice which has a valid veterinary services contract in place (stipulating the frequency of visits to be carried out) with the farms concerned. The veterinary practices must be a separate legal entity to the commercial holdings they are responsible for. These measures help to avoid conflicts of interest and limit opportunities for animal owners to 'shop around' to obtain veterinary medicinal products from multiple sources. Information provided to the mission team on the farms visited indicated that commercial holdings had a veterinary services contract in place and that veterinarians visited the farms on a regular basis. In one case, veterinarians were present on the farm on a full time basis.

The multitude of so-called back-yard farms are not required to have a veterinary services contract in place with a veterinary practice but, according to the veterinarians met, they mostly rely on the services provided by the veterinary circumscriptions (practices which have been contracted by the State to carry out certain tasks such as tuberculosis
sampling, administration of rabies vaccines, sampling of bees). Farmers must pay for the veterinary services and, according to the veterinarians met the price of the service includes the cost of veterinary medicines and other products.

18. According to national law, the off-label use of veterinary medicinal products is prohibited. It is permissible in exceptional circumstances to use medicines in accordance with the cascade provided for in EU legislation. To help veterinarians in applying the cascade, a Romanian version of the guidance produced by the Federation of Veterinarians of Europe ⁹ (FVE) has been made available. Veterinarians met during the mission acknowledged that the inability to use antimicrobials off-label in cases where clinical experience indicates a higher dose or longer treatment duration than that specified in the summary of product characteristics (SPC) is needed, can prevent the use of otherwise effective antibiotics (such as older penicillins). However, they stated that it was rarely necessary to consider off-label / cascade use of veterinary antimicrobial products owing to the wide range of products available in Romania. According to NSVFSA, access to human medicines for use in animals is generally not possible as pharmacies dispensing such medicines will not recognise a veterinary prescription.

19. The metaphylactic and prophylactic use of veterinary antimicrobial products is not restricted and a specific exercise to assess the extent of these practices was carried out by NSVFSA and CSVFD in the last year. In an example discussed by the mission team, all commercial holdings had been visited and where treatment had started prior to diagnosis or if no diagnosis were recorded, this was considered to be prophylactic use. A sample of the data seen indicated prophylactic use of oral forms of antibiotics is regularly identified, including the use of fluoroquinolones (enrofloxacin) in drinking water, and that metaphylactic use occurs less frequently. Where these uses are identified, CSVFD inspector advises the farmer and / or veterinarian against continuing to follow these practices. NSVFSA is currently compiling the data gathered before deciding on its next steps.

20. According to information provided by NSVFSA, there were 16 authorised producers of medicated feed in Romania in 2016. Limited quantities of medicated feed may also be traded from other Member States. Producers are required to have in place procedures to ensure the homogeneity of their medicated feed and to avoid carry-over of medicines into non-medicated batches. Evidence that own checks to verify the effectiveness of these measures (i.e. that critical limits are not exceeded) have been carried out on a regular basis is checked during official controls (see section 4.3.).

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4.3.2 Special conditions for authorisation of antimicrobials

21. ICBMV advised that the SPC and the product information (leaflets and labels) have been checked and updated as required for all veterinary antimicrobial products concerned by the referral outcomes specified in Commission Decision C(2010)4684 of 1 July 2010 for veterinary medicinal products for food producing animals containing quinolones and / or fluoroquinolones as active substances and those in Commission Implementing Decision C(2012)182 of 13 January 2012 for veterinary medicinal products which contain the active substances cefquinome and ceftiofur. Lists of authorised veterinary antimicrobial medicines, including those containing CIAs, have been published on the ICBMV website and are updated regularly.

22. According to ICBMV, the marketing authorisations for the two veterinary medicinal products containing colistin in combination with other antibiotics have been withdrawn.

23. Restricting the use of CIAs in animals is a specific objective of the national AMR strategy. Actions envisaged include using CIAs only where this is justified by the results of susceptibility tests or laboratory diagnosis and by restricting their distribution to wholesalers supplying only veterinary practices. According to NSVFSA, a step-by-step approach is being taken by firstly identifying with ICBMV the veterinary medicinal products which contain CIAs. This will be followed by drafting legislation to restrict their use, in particular for group treatment of animals, and to limit use under the cascade.

4.4 Policies / Practices Encouraging Reduced and Prudent Use of Antimicrobials in Animals and Outcomes to Date

24. Encouraging the reduced and more prudent use of antimicrobials in animals is encompassed by the three general objectives of the national AMR strategy. The majority of actions envisaged under the first two objectives focus mainly on complying with EU and national legal requirements such as those for the housing and transport of pigs and poultry, respectively, the implementation of mandatory vaccinations (e.g. for Newcastle disease, rabies and anthrax) and ensuring the requirements for the distribution and use of veterinary medicinal products are met. Several actions are described which aim at restricting the use of CIAs (see section 4.1.2.) and limiting the use of antimicrobials under the cascade (see point 17), mainly through the adoption of new national rules.

25. The third general objective of the national AMR strategy focusses on communication and awareness raising activities by organising trainings for officials (who are expected to pass on their knowledge to operators and veterinarians), increased collaboration with relevant parties and through the publication of information on AMR.

26. In this respect, the mission team was provided with numerous examples of publications highlighting the risks for animal and human health posed by the development of AMR and more specific guidance documents setting out the principles of responsible and

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10 [www.icbmv.ro](http://www.icbmv.ro)
prudent use of antimicrobials in animals. These include the Commission guidelines referred to in section 2 and translations of those published by FVE and distributed alongside its own guidance by CMVRO 11, which also developed an internet-based e-learning module on this topic. Information and training sessions have also been provided to officials, operators and veterinarians.

27. It was noted by the mission team that much of the guidance and other documentation provide somewhat generic information rather than specific indications of what veterinarians should do, such as by suggesting the most appropriate first, second (and third) choices of antimicrobials to treat common conditions. This was reflected in the knowledge of veterinarians met who were mostly informed about the general aspects of AMR and the responsible use of antimicrobials in animals, but their awareness of more specific issues such as the prudent use of CIAs was limited.

28. A number of issues which could hamper the more prudent use of antimicrobials were identified by veterinarians met:

- The price and withdrawal period for antibiotics were often cited as the most important factors determining the choice of treatment. In some cases, this led to fluoroquinolones being used where alternatives could have been effective.

- The cost of susceptibility testing to identify suitable antibiotics is borne by the animal owners and was considered by the veterinarians met to be a key factor limiting their wider use. As an example, a susceptibility test for a sample taken from a pet cat costs in the region of €65 which many owners on low incomes cannot afford to pay. As a result, veterinarians prefer to start treatment without carrying out susceptibility tests.

29. In the commercial farms visited, susceptibility tests had been carried out regularly but the results were not always taken into account in determining the most appropriate treatment regime. In several cases, veterinarians explained they had used an antibiotic which the susceptibility indicated would be ineffective due to differences in its in-vivo and in-vitro activity.

30. Representatives of industry associations and farmers met, described a range of initiatives which have been taken in the poultry and pig sectors which have led to reductions in the use of antimicrobials. These include the implementation of strict biosecurity and hygiene regimes and increased use of vaccinations in the poultry sector which has resulted in no antibiotics being used by 20 – 25% of the poultry sector. In the pig sector, a similar focus on biosecurity, hygiene and improved herd health (including using autogenous vaccines) has been supplemented by the trialling of a broad range of feed additives to promote digestive health and, more recently, the use of zinc oxide for diarrhoea at the weaning stage.

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11 https://cmvro.ro/antibiorezistententa/
CONTROL ACTIONS ON THE USE OF ANTIMICROBIALS IN ANIMALS

31. In 2013, the Service of Medicinal Products Control, Nutrition and Laboratories (SVMP) was established with responsibility for controls in the area of veterinary medicinal products. Working with other relevant departments, it prepares technical / operational documentation to provide a uniform basis for official controls carried out by CFSVD. SVMP is responsible for monitoring the implementation of the official control programmes, based on quarterly reports provided by CFSVD.

32. Regular official controls to check compliance with the national and EU requirements at all stages of the distribution and use of veterinary medicinal products have been included in the Multi Annual Control Plan since 2015. In addition to these, thematic control campaigns were organised in each of the last three years to examine particular aspects relating to pharmacies, warehouses and veterinary practices.

33. According to NSVFA, the standard templates used by CFSVD for controls on veterinary medicinal products were updated in 2016 to include some aspects relevant to the prudent use of antimicrobials in animals. These include checks on: the clinical diagnosis recorded in the treatment register, evidence of a clinical examination of the animals and, records for the administration of antibiotics. Attention is also paid to any off-label or cascade use of veterinary medicinal products and, in the latter case, the sourcing of any human medicines used (as these should not be dispensed on a veterinary prescription). Where deficiencies are identified CFSVD provides information to help raise awareness of the operators and veterinarians regarding the principles of prudent use of antimicrobials.

34. Data provided by SVMP show non-compliances in the completeness and accuracy of the prescription registers in veterinary pharmacies were identified in approximately 17% of checks in 2015 and 13% of those carried out in 2016. These ranged from missing minor data to an absence of prescriptions. Sanctions ranging from administrative warnings to fines were imposed in approximately 33-48% of these cases. The level of non-compliances detected in warehouses was much lower (approximately 3% of checks carried out) with very few cases where order forms for veterinary medicinal products were missing.

35. Approximately 2 000 inspections were carried out in veterinary practices annually in 2015 and 2016 and nonconformities concerning documentation, record keeping and discrepancies between stock and order forms were identified in approximately 10% of the inspections. Sanctions were imposed in cases where the deficiencies were considered to be serious.

36. Controls carried out on producers of compound and medicated feed in 2015 and 2016 identified a range of nonconformities. In particular, a case where medicated feed was being produced without the necessary authorisation, that another producer had not carried out homogeneity tests as required and in two further cases, that veterinary medicines were being used without a prescription.
The medicated feed producer visited had established own-check procedures and appropriate critical limits to verify the batches were homogenous and to avoid carry-over of medicines into non-medicated batches. Evidence could be provided to show that the cleaning procedures (e.g. flushing before production of non-medicated feed) and sequencing of production to limit carry over were applied in practice.

5 **Overall Conclusions**

| In 2014 the use of veterinary antimicrobials in Romania was below the average reported by the countries providing data to the European Surveillance of Veterinary Antimicrobial Consumption project and a slight decrease in use was seen in 2015. This situation is explained in part by their historically limited availability and their relatively high cost. 
A national strategy for tackling AMR and an associated internal action plan for the period 2016-2018 have been drawn up by the NSVFSA together with the national reference institutes and in consultation with the CMVRO, One Health New Medical Concept Romania Association, the Romanian Poultry Breeders' Association and the National Association of Veterinary Medicinal Products Distributors in Romania. A similar national strategy is being prepared covering human health aspects. The veterinary national strategy is aimed at improving animal health, ensuring correct use of antimicrobials and raising awareness of the issues. Although this strategy is considered to be based on the One Health approach, its scope is largely limited to areas which fall directly within the remit of the competent authorities and as such, its main focus is on the 'correct use' of antimicrobials through compliance with legal requirements and national rules to restrict use.

The above measures are supported by regular official controls throughout the distribution and use of veterinary antimicrobial products. These controls will help encourage the prudent use of veterinary antimicrobials. Likewise, the wide range of training and other awareness raising activities carried out have helped familiarise farmers and veterinarians with AMR and general principles for the reduced and prudent use of antimicrobials. However, these have so far had little effect on the prescribing behaviour of veterinarians which is influenced by other factors including price and withdrawal period, especially regarding critically important antimicrobials. The report acknowledges that once the national AMR strategy is fully implemented there is potential for reduced and more prudent use of antimicrobials in animals, especially if certain constraints (notably the cost of diagnostic and susceptibility tests and of medicines) were also addressed.

6 **Closing Meeting**

A closing meeting was held on 25 November 2016 with the representatives of the competent authorities. At this meeting, main findings and preliminary conclusions of the mission were presented by the mission team. The competent authorities did not indicate any disagreement with these.
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