

Final report

**EFTA Surveillance Authority's and European Commission joint
fact-finding Mission to**

Norway from 27 February 2017 to 8 March 2017

in order to gather information

on the prudent use of antimicrobials in animals

Please note that comments from the Norwegian competent authority to factual errors in the draft have been included in the body of the report. Comments and information provided by the Norwegian competent authority are included in Annex 2.

Executive Summary

This joint fact-finding mission carried out by the EFTA Surveillance Authority (ESA) and the European Commission, took place in Norway from 27 February to 8 March 2017. The objectives of the mission were to gather further information on the practical implementation of measures aimed at tackling issues concerning antimicrobial resistance (AMR) relating to the use of veterinary medicines and to identify examples of good practice which could be helpful to countries in addressing this issue.

Norway has consistently reported some of the lowest sales of veterinary antimicrobials of the countries providing data to the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project. Likewise, the levels of AMR detected in bacteria isolated from human and animal populations have been relatively low compared to other European countries. This favourable situation can mainly be attributed to the longstanding and comprehensive initiatives taken under successive national AMR strategies, the latest of which covers the period 2015 to 2020 and is based on a One Health approach, with initiatives linked to the human, animal and environmental aspects.

Overall, the report concludes that the high level of cooperation and coordination between the authorities and stakeholders, underpinned by strong political support, has enabled a broad range of comprehensive actions to maintain and enhance animal health and avoid or eliminate issues linked to the development of AMR. Key factors contributing to this situation include promotion of nationwide and farm-level biosecurity and vaccination programmes, the de-coupling of the prescribing and sales of veterinary medicinal products, backed up by treatment guidelines which advocate individual rather than metaphylactic or prophylactic treatments, and a policy of culling animals with recurring, chronic conditions. The proposed developments to the prescription database VetReg will provide greater insights to the prescribing behaviour of veterinarians, enable knowledge sharing and benchmarking, and provide for actions aimed at the higher users, in order to achieve the targets for reduced antimicrobial use set out in the national AMR strategy.

Certain aspects of the Norwegian approach could serve as potential examples of good practice for other countries in tackling AMR and encouraging the prudent use of antimicrobials in animals.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AMR	Antimicrobial resistance
CIAs	Critically important antimicrobials
EFTA	European Free Trade Association
ESA	EFTA Surveillance Authority
ESBL	Extended-spectrum β -lactamase producing organisms
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
KSL	<i>Kvalitetssystemet i landbruket</i> (quality system for agriculture)
LA MRSA	Livestock-acquired Methicillin-resistant <i>Staphylococcus aureus</i>
NFSA	Norwegian Food Safety Authority
PCU	Population correction unit
VetReg	Data base where animal health professionals, pharmacists, and feed mills (producing medicated feed) register prescription data

1 INTRODUCTION

This joint fact-finding mission took place from the 27 February to 8 March 2017 and was carried out by the EFTA Surveillance Authority (ESA) and the European Commission's DG Health and Food Safety, in agreement with the Norwegian competent authorities. The mission team, comprising of two auditors from ESA and two auditors from DG Health and Food Safety, was accompanied throughout the mission by representatives of the competent authority, the Norwegian Food safety Authority (NFSA). On 27 February 2017, an opening meeting was held with representatives from several competent authorities (including NFSA head and regional offices, the Norwegian Medicine Agency, the Norwegian Veterinary Institute –NVI–, the Ministry of Health and Care Services, the Ministry of Trade Industry and Fisheries, and the Ministry of Agriculture and Food), where the objectives, scope and itinerary for the joint 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 and (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 Norway (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. The first topic has been the subject of several ESA audits, the last of which was carried out February 2014¹

The meetings with the competent authorities and the visits to establishments and associations during the mission are listed the table below.

	Number	Comments
Competent authorities	3	Initial meeting and final meeting with the Norwegian competent authorities, and meeting with representatives of NVI
Stakeholders	5	Meetings with representatives of the Norwegian Veterinary Association, the Norwegian meat and poultry research centre (Animalia), a Norwegian dairy product cooperative (TINE), the Norwegian Fur farm Association, and the Norwegian Agricultural Quality System (KSL Matmerk)
Veterinary Practitioners and fish health services	3	Meetings with veterinary practitioners treating both farm and companion animals and a fish health service
Farms	6	Meetings with two aquaculture farms, a hatchery, a fur farm, a dairy and a pig farm

3 MISSION RATIONALE

This fact-finding mission forms part of one of the 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 map²: 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

¹ <http://www.eftasurv.int/media/public-documents/707336.pdf>

² http://ec.europa.eu/health/antimicrobial_resistance/docs/roadmap_amr_en.pdf

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 ³), the Commission received information highlighting a number of measures already taken by EU Member States on this topic. In order to gain a more comprehensive overview of the efforts being made to encourage the prudent use of antimicrobials in veterinary medicine by EU Member States, Norway, Iceland and Switzerland, a questionnaire was sent by DG Health and Food Safety to these countries in September 2015, alongside a series of fact-finding mission whose organisation started in 2016 and of which the present joint fact-finding mission belongs. The main points from these fact-finding missions and the questionnaire responses will be presented in interim and overview reports which are intended to highlight good practices and particular challenges identified in applying the prudent use of antimicrobials in veterinary medicine.

4 FINDINGS

4.1 NATIONAL STRATEGIES AND ACTION PLANS INFLUENCING THE USE OF ANTIMICROBIALS IN ANIMALS

1. Multiannual national AMR strategies have been implemented in Norway since the late 1990's. The current 5 year strategy, which was adopted in June 2015 ⁴, is based on a One Health approach (as advocated in the World Health Organisation's Global AMR Action Plan ⁵) taking into account the strong connections between human, animal (including fish) health and the environment. Four Ministries (Ministry of Health and Care, the Ministry of Agriculture and Food, the Ministry of Trade Industry and Fisheries and the Ministry of Climate and Environment) and numerous stakeholders were involved in the development of this strategy. The national strategy took into account the report of a cross-sectorial expert working group which had assessed the outcomes of previous national AMR strategies and identified gaps in current knowledge which it would be beneficial to address ⁶.
2. The national AMR strategy aims to maintain and enhance the already relatively positive situation in Norway regarding animal health, AMR (in humans and animals) and low use of antimicrobials (including Critically Important Antimicrobials (CIA)) compared with other countries in Europe. It includes overall goals to further reduce the use of antibiotics in humans and animals, to encourage their prudent use and improve the knowledge about the development and spread of AMR in the environment. Specific targets for reducing the use of antimicrobials in animals set in previous strategies had been achieved (e.g. a 40% reduction in antimicrobial use (against a target of 25%) was achieved in 5 years up to 2000). Despite reporting the lowest levels of antimicrobial use in animals (see point 7) ambitious targets to reduce consumption further have been included in the current national AMR strategy – to reduce the use of antimicrobials in terrestrial animals and companion animals by 10% and 30%, respectively, of the amounts used in 2013. In human medicine, the objective is for Norway to become one of the three countries using the lowest levels of antimicrobials in Europe through a 30% reduction in their use in the general population and reducing the number of prescriptions (from 450 to 250) per 1 000 inhabitants per year.

³ http://ec.europa.eu/health/antimicrobial_resistance/docs/2015_prudent_use_guidelines_en.pdf.

⁴ <https://www.regjeringen.no/contentassets/5eaf66ac392143b3b2054aed90b85210/antibiotic-resistance-engelsk-lavopploslig-versjon-for-nett-10-09-15.pdf>.

⁵ <http://www.who.int/antimicrobial-resistance/global-action-plan/en/>

⁶ To start filling the identified knowledge gaps, research was done on the risks of AMR associated to food, animals and the environment. The reports of these assessments can be found here:

<http://www.english.vkm.no/dav/966281693f.pdf>

<http://www.english.vkm.no/dav/a9425ab9d0.pdf>

<http://www.english.vkm.no/dav/73b79b01c3.pdf>

<http://www.english.vkm.no/dav/3f634fa813.pdf>

3. Additional sector-specific goals have been included in the national AMR strategy for food-producing and companion animals, public health and the environment. The measures planned include a) mapping reservoirs of resistant bacteria in animals important to food safety, b) preventing livestock-acquired methicillin resistant *Staphylococcus aureus* (LA-MRSA) from becoming established in the Norwegian pig population, c) significantly reducing the presence of Extended-spectrum β -lactamase producing organisms (ESBL) in the poultry population, and d) phasing-out narasin and possibly other coccidiostats with antibacterial properties ⁷. Environmental measures include mapping resistant bacteria in representative environments and exploring the effects in nature of other potential resistance drivers such as disinfectants, biocides and heavy metals.
4. The Ministries involved in drafting the national AMR strategy are in the process of developing action plans setting out how the relevant goals will be achieved. Those of the Ministry of Health and Care Services ⁸ and the Ministry of Agriculture and Food ⁹ are complete. The action plan for the latter Ministry sets out proposals for: a) investigating reservoirs of AMR, b) enhancing infection controls and c) improving diagnostics, prescriptions and the prudent use of antimicrobials and describes a combination of initiatives for each. These include: 1) updating clinical guidelines for prescription, 2) supervising prescribing patterns, 3) making fuller use of the prescription database (see point 8), 4) facilitating the use of vaccines, 5) adopting an approach of 'wait and see' before prescribing antimicrobials for companion animals and, 6) imposing restrictions on the use of CIAs.
5. The Norwegian Meat and Poultry Research Centre (Animalia) ¹⁰ is co-ordinating a group of industry associations which is drafting an action plan aimed at preventing problems with AMR in Norwegian livestock through preventative veterinary medicine, organised disease eradication campaigns and prudent (correct) treatment of animals, as well as better documentation of treatment in the Animal Health Recording System (*Dyrehelseportalen*). It comprises actions to maintain a high level of biosecurity nationally, reduce disease prevalence and encourage the prudent use of antimicrobials. Additional activities aim at organising surveillance against selected resistant bacteria, researching AMR mechanisms and disease-prevention measures and fostering communication and interaction with other stakeholders at national and international level. It is proposed to define strict criteria for the use of certain CIAs and to ban the use of 3rd and 4th generation cephalosporins and colistin.¹¹

4.2 MONITORING OF SALES OF ANTIMICROBIALS AND LEVELS OF AMR

4.2.1 Monitoring of sales of antimicrobials

6. Norway has been monitoring the sales of antimicrobials for animals and humans since the late 1990's using data provided by wholesalers (reporting is compulsory since 2002) and the Norwegian Institute of Public Health (for human prescriptions). Almost 90% of antimicrobials are used in human medicine while only 10% is for veterinary use.
7. In 2014, Norway reported the lowest sales of antimicrobials for use in animals of the 29 countries contributing data to the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC report ¹²). Sales amounted to 3.1 mg/population correction unit (PCU) compared to a maximum of 418.8 mg/PCU. NFSA noted that,

⁷ According to NFSA, narasin had already been phased-out when the mission team was in Norway.

⁸ <https://www.regjeringen.no/contentassets/915655269bc04a47928fce917e4b25f5/handlingsplan-antibiotikaresistens.pdf>

⁹ <https://www.regjeringen.no/contentassets/1c8a01d8b6fb4d7ca0908fa006e85160/handlingsplan-mot-antibiotikaresistens-lmd-150316.pdf>

¹⁰ Animalia is an organisation funded by the Norwegian farmers, owned by the meat and poultry industry and operating under the supervision of the Norwegian Agricultural Authority. Farmers pay contributions to finance its activities.

¹¹ At the present time no colistin VMPs are marketed in Norway

¹² http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/10/WC500214217.pdf

sales were similar in 2015 apart from a decline in their use in aquaculture fish. The ESVAC report shows that narrow-spectrum penicillins are the most frequently used class of antimicrobials for food producing animals and that the vast majority of antimicrobials marketed were for treatment of individual animals. Sales of CIAs accounted for only 0.01 % (3rd generation cephalosporins) and 0.2% (fluoroquinolones) of the total amount of antimicrobials sold in 2014. According to the NFSA, 3rd generation cephalosporins are only used in companion animals and neither 4th generation cephalosporins nor colistin are marketed in Norway for use in animals.

8. Since 2011 (for aquaculture species) and 2012 (for terrestrial animals) fish health biologists and veterinarians are obliged to register their prescriptions, the antimicrobials they administer themselves to food-producing animals and those which are left for the owner to administer, on-line through a number of portals. The information is ultimately compiled in the VetReg, a database where animal health professionals register prescription data which is managed by NFSA. Pharmacies and feed mills producing medicated feed must also register in VetReg the antimicrobials they dispense based on the prescriptions they receive. VetReg has limited information on the use of antimicrobials in companion animals and there is no obligation for prescriptions for fur animals to be recorded in VetReg.
9. Resources have been allocated to develop VetReg to enable the extensive information it contains to be analysed to identify e.g. trends and patterns in prescribing behaviour using different criteria (e.g. for individual farms, veterinarians, species and production phases etc.) and to make the information available for professionals. According to NFSA, studies of fish prescriptions have already been carried out ¹³.

4.2.2 Monitoring of AMR

10. Surveillance programmes for AMR in humans, animals, food and feed have been carried out since at least 2000 and the results (along with data on the use of antimicrobials) are published in the form of NORM and NORM Vet reports (Usage of Antimicrobial Agents and Occurrence of AMR in Norway) for humans and animals, respectively. Analyses of the data enable the significance of trends in the development of AMR and their potential links to be evaluated. This information is used to identify areas to be audited, as the basis for risk assessments and to evaluate the effectiveness of measures taken against AMR. The 2015 reports ¹⁴ notes that in Norway, the proportion of bacteria sensitive to most antimicrobials is among the highest in Europe, which is thought to be as a result of the longstanding and comprehensive range of measures implemented on this topic.
11. Under the national AMR strategy, the competent authority has carried out AMR monitoring in food and animals (based on EEA requirements) and in clinical isolates and the presence of certain bacteria in the environment (wild fauna (mammals and birds) sewage and organic fertilisers). Future monitoring and surveillance activities will include, amongst others, more targeted surveillance on clinical isolates and resistance to CIAs.
12. The 2015 NORM Vet report highlights three main areas of concern for which actions are being taken under the national AMR strategy: the presence of LA-MRSA in pig herds, the presence of ESBL in broiler flocks and meat, and quinolone-resistant *Escherichia coli* in turkey flocks and meat (and to a lesser extent also in broiler flocks and meat). The origin of this quinolone resistance is currently unknown as these are not used in the poultry industry, although, DNA analysis of these *E. coli* isolates

¹³ In a study carried out in 2014 in aquaculture fish, the amount of antimicrobial used (measured by the dispensed amounts based on recorded prescriptions in VetReg) was successfully validated against antimicrobial sales data provided by wholesalers. Details of this study can be found here: <https://seafood.no/contentassets/c5a14b9acf3b4f1b9753263586513a68/use-of-antibiotics-in-norwegian-aquaculture.pdf>

¹⁴ <http://www.vetinst.no/overvaking/antibiotikaresistens-norm-vet>

indicates that there are cases where the same type of resistance to quinolones in animals is implicated in resistance to fluoroquinolones found in humans.

4.3 DISTRIBUTION MODEL FOR VETERINARY ANTIMICROBIALS IN NORWAY

13. Antimicrobials can be dispensed only by authorised pharmacies or, in the case of medicated feed, by a feed mill, on prescription issued by a veterinarian or, in the case of aquaculture, *also* by a fish health biologist. Veterinarians may dispense sufficient medicines for farmers (if they are considered to be sufficiently competent) to finish the course of treatment. The long-standing national rules to de-couple the prescribing and sales of veterinary medicinal products are considered by NFSA to be a key contributing factor in maintaining the relatively low use of antimicrobials in Norway. Furthermore, the code of good veterinary *praxis* in production animals considers that sales of veterinary medicinal products represent an unprofessional way for veterinarians to earn money. In addition, it is not permitted to sell veterinary antimicrobial products via the internet. Collaboration with customs departments is in place to detect such consignments from abroad.
14. Special exemptions enabling the use of veterinary antimicrobials without a Norwegian marketing authorisation may be granted following the cascade principles.
15. Pop-up warnings have been included in the web-based summary of products characteristics database to alert users that CIAs are considered as last resort treatments.
16. It is not currently required for farmers to have a contract with specified veterinarians to carry out routine herd health visits, although consideration is being given to establishing some requirements for a minimum frequency of visits notably for farmers wanting to keep veterinary medicinal products to administer to their animals. In practice, the farms visited during this mission were visited regularly by veterinarians and industry associations.

4.4 POLICIES / PRACTICES ENCOURAGING REDUCTION IN USE AND PRUDENT USE OF ANTIMICROBIALS IN ANIMALS AND OUTCOMES TO DATE

4.4.1 Reducing the use of antimicrobials

17. Successive national AMR strategies have prioritised actions to maintain and enhance the relatively high health status of Norwegian livestock with the support of authorities, and professional and industry stakeholders.
18. Requirements for the import of live animals have been established by the animal health authorities¹⁴ with additional, complimentary requirements developed by the Norwegian Livestock Industry Biosecurity Unit (*KOORIMP*). These complimentary requirements¹⁵ by the industry aim at avoiding the introduction and spread of several diseases and conditions (e.g. paratuberculosis, foot rot, Porcine Reproductive and Respiratory Syndrome, ESBL and LA-MRSA), both through imports of live animals or via farm workers. They comprise preventative measures to be taken at the export facilities which include aspects such as quarantine, blood testing, compulsory foot bath treatments, etc. Imported parent chicks of poultry are tested after arrival to Norway, and efficient extra hygiene measures are implemented in case of positive ESBL-tests. LA-MRSA-positive animals would not be imported as the authorities monitor its presence in a national program and affected animals are slaughtered regardless of the origin. Farmers importing animals without proof of compliance with requirements by the industry risk increased insurance premiums and that slaughterhouses will refuse to sell and distribute meat from the imported animals.

¹⁵http://www.animalia.no/upload/Filer%20til%20nedlasting/KOORIMP/KOORIMP_KIF_%C3%A5rsmelding2015.pdf

19. Within Norway, coordinated efforts have been made by the industry organisations, farmers and the competent authorities to eradicate certain conditions and cases of AMR in food producing animals. Eradication is compulsory for certain diseases and is voluntary for others. The involvement of NFSA in the eradication activities helps to ensure important measures such as restrictions on the movement of livestock and payment of compensation for culled animals. Programmes carried out to-date have resulted in the eradication of several conditions where antibiotics would be used in their treatment (e.g. bovine viral diarrhoea in 2006 and enzootic pneumonia in pigs in 2010) while others are on-going. Some examples of these include the following:
- In pigs, LA-MRSA, dysentery (almost eradicated), toxin-producing *Pasteurella multocida* and pneumonia caused by *Actinobacillus pleuropneumonie*. A research program has been launched
 - In small ruminants, foot rot, paratuberculosis, and CAE is almost eradicated and in cattle control programs are established for contagious mastitis (Str. Agalactia), BRSV and BCoV..
 - In poultry, ESBL and necrotic enteritis. The poultry industry has required companies providing the breeding stock (located outside Norway) not to use antimicrobials prophylactically and to ensure stock sent to Norway is free of ESBL.
20. Animalia and other industry organisations have developed voluntary species-specific health programmes for pigs, poultry, dairy cattle and sheep¹⁶ with the involvement of the veterinary authorities and associations. These highlight the main challenges for maintaining the high health status of livestock farms (amongst others, the presence of diseases in the breeding herds, the trade of live animals between farms, inadequate biosecurity measures or the hiring of foreign personnel) and potential mitigation measures. Some of these are market incentives (e.g. a higher price paid in the slaughterhouse for animals from farms which participate in these programmes) which encourage participation in these initiatives. A dairy farmer visited showed the mission team an article on MRSA in cattle in a Norwegian farmer's magazine which provided instructions to prevent its spread. In addition, the farmer had received advice on issues from the quality of the milk to feeding and animal welfare from the dairy cooperative, Animalia, private veterinarians and other industry stakeholders.
21. Widespread practices that help in reducing the use of antimicrobials include breeding for increased resistance to disease, ensuring good quality and health of the early stages of the animals' lifecycle, operating routines to avoid stress, and in the case of land-based farmed fish, stricter standards for water circulation and improved hygiene at hatchery level.
22. To protect the health status of aquaculture, commercial movements of farmed fish within Norway are subject to national restrictions agreed between the fish health authorities and the fish industry which effectively prevents risks associated with movements from relatively low health status areas to those with a higher health status. Norway also has additional guarantees related to freedom of certain fish diseases.
23. The planned developments to the VetReg database (see point 9) will provide an important means to target the higher users of antimicrobials which is key to achieving the targets for reducing antimicrobial use set out in the national AMR strategy (see point 2). The veterinarians met noted that it would be challenging to achieve the 30% target for reducing antimicrobial use in companion animals with the largest savings potentially being achieved through discouraging the routine pre- and post-operative use. Greater reductions raise ethical questions about the desirability of using relatively

¹⁶ More detailed information (in Norwegian) on these programmes can be found here:
<http://www.animalia.no/Dyrevelferd-og-dyrehelse/Helsetjenesten-for-svin/>
<http://www.animalia.no/Dyrevelferd-og-dyrehelse/Helsetjenesten-for-sau/>
<http://www.animalia.no/Dyrevelferd-og-dyrehelse/Helsetjenesten-for-fjorfe/>
<http://storfehelse.tine.no/jurhelse>

high amounts of antimicrobials to treat recurring or chronic conditions in individual pet animals (for instance, chronic dermatitis in dogs that do not respond well to antimicrobials) versus euthanizing them.

24. Most terrestrial livestock farmers in Norway are members of an agricultural quality scheme applicable to terrestrial farmed animals called *Kvalitetssystemet i landbruket* (KSL)¹⁷. This scheme is designed to allow farmers to show compliance with the relevant rules and regulations including those related to the prevention of infections and the obligations of farmers and veterinarians concerning veterinary antimicrobials. The scheme comprises a set of standards, external and internal (self) audits against these standards. NFSA has access to the database where non-compliance is recorded and can use this information to identify recurring issues in order to target its official controls (see point 33). In the dairy farm visited, the farmer described a visit from the KSL and pointed out that their consultancy is beneficial, in particular for newcomers in the sector.
25. Vaccination is generally encouraged as a means to reduce antimicrobial use. Significant examples include vaccination against post-weaning diarrhoea in pigs caused by *E. coli* and the long-standing vaccination programmes in aquaculture salmonids. According to the figures provided by NFSA, the vaccination programme for salmonids has enabled a 99% reduction in the use of antimicrobials use in these species between 1987 and 1996. This was confirmed by the representatives of the aquaculture industry met who added that the rapid uptake of vaccines initially produced in other countries was a key factor in the early success of this initiative.
26. Livestock farmers receive advice on disease prevention and good husbandry practices during visits from a range of different industry stakeholders (see point 20). In the case of fur animals, a veterinarian from the fur association met explained, most farmers participate in a voluntary certification scheme which includes a health control part under which there are three compulsory veterinary visits during the most critical periods of the production cycle (mating, post-weaning and pelting). Further initiatives in this area include moving from wet to dry feed to reduce the risk of infections and encouraging farmers and veterinarians to send samples of clinical cases for diagnosis.
27. High standards in animal welfare for all food-producing animals (as required by national legislation) have resulted in improved rearing conditions, which in turn contribute to a lower use of antimicrobials. Examples of this comprise the "Welfur" initiative¹⁸ for fur animals that incorporates the use of improved cages, ample water availability (to avoid that mothers are sucked in excess) and the presence of toys (to reduce fights and stress). Other measures on welfare include compulsory restricted stock densities for intensively reared species such as poultry, pigs and aquaculture fish.

4.4.2 Actions to encourage the prudent use of antimicrobials

28. Given Norway's relatively favourable position regarding the use of antimicrobials and the levels of AMR, the main focus of efforts to promote the prudent use of antimicrobials is by raising awareness of the issues among veterinarians and farmers, providing guidance on the most appropriate antimicrobials to use and, in the future, developing the means to share knowledge.
29. Awareness-raising activities are carried out under the NFSA communication strategy (for instance, publication on AMR-related articles in specialised magazines), seminars on AMR organised under the Nordic co-operation scheme¹⁹ and attempts to involve

¹⁷ <http://www.matmerk.no/no/ksl>

¹⁸ Welfur is a science-based animal welfare assessment programme voluntarily initiated by the European fur sector in 2009. More information can be obtained at <http://www.fureurope.eu/fur-policies/welfur/>.

¹⁹ <http://www.norden.org/en/nordic-council-of-ministers/council-of-ministers/nordic-council-of-ministers-for-health-and-social-affairs-mr-s/declarations-and-statements/declaration-on-antimicrobial-resistance-through-a-one-health-perspective/>.

pet owners in taking samples from themselves and the environments where companion animals live to investigate the presence of AMR determinants in certain bacteria isolated from these samples. The Norwegian Veterinary Association provides on-going training and awareness raising activities including annual seminars for veterinary students during their final academic year where issues on prudent use of antimicrobials and AMR are discussed. Students studying in veterinary faculties in other countries are also targeted to ensure they are familiar with the Norwegian approach to antimicrobial use and AMR should they practice in Norway. The association has also agreed with NFSA on the implementation of a compulsory e-learning course on the prudent use of antimicrobials for veterinarians granted a preliminary licence to practice. This association also closely co-operates with various governmental agencies and industry organisations in working groups where matters related to the use of antimicrobials are discussed. In addition, they have published two guidelines (the ethical professional guidance for veterinarians and the good veterinary practice in production animals) where issues on AMR and prudent use are explicitly discussed.

30. The publication of prudent use guidelines for terrestrial farmed animals was first included in the national AMR strategy in 1998. In 2011 the Norwegian Medicines Agency was commissioned to update these guidelines. Representatives from the industry associations for cattle, pigs, sheep and goats, private practice veterinarians and representatives from the Veterinary Institute, NFSA and the Norwegian Medicines Agency participated in the updating of the guidelines, which were published in 2012. In 2014, guidelines for companion animals were prepared and those for horses are currently being drafted. These guidelines comprise a description of the most common bacterial diseases for the relevant species and the first and second line treatment with antimicrobials for each of them²⁰. Given the relatively low levels of AMR in Norway, the majority of first-choice treatments are based on narrow-spectrum penicillins. Second choice antimicrobials include amoxicillin. CIAs are not included in the recommendations. The veterinarians met were well aware of these guidelines and were following them when prescribing antimicrobials.
31. It is envisaged that once the planned developments to the VetReg database have been made (see point 9) that the diagnosis established and the corresponding antimicrobials chosen by individual veterinarians will become (anonymously) available to other veterinarians. This will facilitate knowledge sharing and the peer-reviewing of prescription patterns. According to the competent authorities, research shows that this will be an effective means to improve prescribing behaviour and to bring it more in-line with the published prudent use guidelines. Moreover, representatives of Animalia supported the use of this information to enable veterinarians and farmers to benchmark their use of antimicrobials against the average for similar types of farms and production systems.

4.5 CONTROL ACTIONS ON THE USE OF ANTIMICROBIALS IN ANIMALS

32. The Norwegian medicines agency is responsible for the official control of the manufacturing and distribution of veterinary medicinal products (including antimicrobials) and medicated feed along the chain. Checks on the use of antimicrobials in farms and veterinary practices are under the responsibility of NFSA. More detailed information on the system of official controls can be found in the last ESA report on the topic²¹.
33. In 2012 NFSA carried out a national campaign to check the use of veterinary medicinal products in terrestrial animals including the use of VetReg. The project focused in particular on pig production and included checks on the prescribing patterns and record-keeping of veterinarians attending pig farms. Some non-compliances were found regarding records, the use of VetReg and the prescribing choices. A similar

²⁰ <https://legemiddelverket.no/veterinermedisin/terapiabefalinger>

²¹ <http://www.eftasurv.int/media/public-documents/707336.pdf>

campaign was carried out in the autumn of 2016 to review how fish health biologists and veterinarians prescribe. This review included specific prescribing practices and diagnoses noted on the prescription, as well as whether the guidelines established by the authorities were being followed.

34. The guidelines for the prudent use of antimicrobials are not legally binding and, as a result, representatives from NFSA stated it is problematic to unambiguously determine if veterinarians have followed the principles and to apply any penalties for not doing so. To address this and other issues, the legislation on the use of veterinary medicinal products (including antimicrobials) is being revised. It is intended to make explicit the obligation for prescribers to comply with prudent use guidelines, which could support official controls in this area in the future.

5 OVERALL CONCLUSIONS

Norway has consistently reported some of the lowest sales of veterinary antimicrobials of the countries providing data to the ESVAC project. Likewise, the levels of AMR detected in bacteria isolated from human and animal populations have been relatively low compared to other European countries. This favourable situation can mainly be attributed to the longstanding and comprehensive initiatives taken under successive national AMR strategies, the latest of which covers the period 2015 to 2020 and is based on a One Health approach, with initiatives linked to the human, animal and environmental aspects.

The report concludes that the high level of cooperation and coordination between the authorities and stakeholders, underpinned by strong political support, has enabled a broad range of comprehensive actions to maintain and enhance animal health and avoid or eliminate issues linked to the development of AMR. Key factors contributing to this situation include promotion of nationwide and farm-level biosecurity and vaccination programmes, the de-coupling of the prescribing and sales of veterinary medicinal products, backed up by treatment guidelines which advocate individual rather than metaphylactic or prophylactic treatments, and a policy of culling animals with recurring, chronic conditions. The proposed developments to the prescription database VetReg will provide greater insights to the prescribing behaviour of veterinarians, enable knowledge sharing and benchmarking, and provide for actions aimed at the higher users, in order to achieve the targets for reduced antimicrobial use set out in the national AMR strategy.

Certain aspects of the Norwegian approach could serve as potential examples of good practice for other countries in tackling AMR and encouraging the prudent use of antimicrobials in animals.

6 CLOSING MEETING

A closing meeting was held on 8 March 2017 with representatives of the competent authorities. At this meeting, the main findings and preliminary conclusions of the fact-finding mission were presented by the joint mission team. The competent authorities did not indicate any disagreement with these.

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 726/2004	OJ L 136, 30.4.2004, p. 1-33	Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
Dir. 2000/60/EC	OJ L 327, 22.12.2000, p. 1-73	Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy
Dir. 2001/82/EC	OJ L 311, 28.11.2001, p. 1-66	Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products
Dir. 2002/32/EC	OJ L 140, 30.5.2002, p. 10-22	Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed - Council statement
Dir. 2008/105/EC	OJ L 348, 24.12.2008, p. 84-97	Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council
Dec. 2013/652/EU	OJ L 303, 14.11.2013, p. 26-39	2013/652/EU: Commission Implementing Decision of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria
Dec. 2013/652/EU	OJ L 303, 14.11.2013, p. 26-39	2013/652/EU: Commission Implementing Decision of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria



EFTA Surveillance Authority
35 Rue Belliard
BE 1040 Brussels
BELGIUM

Your ref	Our ref	Date
	16/996	30 June 2017

Subject: Joint fact-finding mission to Norway from 27 February to 8 March 2017 in order to gather information on the prudent use of antimicrobials in animals

Please find enclosed the the Norwegian Food Safety Authority's response to the draft report from the EFTA Surveillance Authority's and DG-SANTE of the European Commission's joint fact-finding mission to Norway from 27 February to 8 March 2017 in order to gather information on the prudent use of antimicrobials in animals.

Yours sincerely

Cathrine Steinland
Deputy Director General

Anne Felde Doser
Senior Adviser

This document is signed electronically and has therefore no handwritten signature

Enclosures: 1

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7

Att. Egil Steingrímsson

Statens tilsyn for planter, fisk, dyr og næringsmidler



Fact-finding mission to Norway on the prudent use of antimicrobials in animals.

With reference to the draft report of 27 april from EFTA Surveillance Authority, after fact-finding mission to Norway from 27 February to 8 March 2017. Norway will hereby present comments to the draft report.

Overall we are satisfied with the report which gives a good description of the situation. However, there are some misunderstandings and minor mistakes that we would like to clear.

Comments to the draft report

Page 6, 4.1, 1. line 6. Change to "Ministry of Trade Industry and Fisheries", not "Ministry of Fisheries"

Page 8 Number 5:

The Norwegian Meat and Poultry Research Centre (Animalia) 10 is coordinating a group of industry associations which is drafting an action plan aimed at preventing problems with AMR in Norwegian livestock. This is planned through preventative veterinary medicine, organized disease eradication campaigns and prudent (correct) treatment of animals, as well as better documentation of treatment in the Animal Health Recording System (Dyrehelseportalen). It comprises actions to maintain a high level of biosecurity nationally, reduce disease prevalence and encourage the prudent use of antimicrobials. Additional activities aim to organize surveillance of selected resistant bacteria, research of AMR mechanisms and disease-prevention measures and fostering communication and interaction with other stakeholders at national and international level. It is proposed to define strict criteria for the use of certain CIAs and to ban the use of 3rd and 4th generation cephalosporins and colistin. At the present time no colistin VMPs are marketed in Norway.

Page 9, 4.3 13. Antimicrobials can be dispensed only by authorised pharmacies or, in the case of medicated feed, by a feed mill, on prescription issued by a veterinarian and, in the case of aquaculture, also by a fish health biologist.

Page 10, Number 18:

Requirements for the import of live animals have been established by the animal health authorities 14 with additional, complimentary requirements developed by the Norwegian Livestock Industry Biosecurity Unit (KOORIMP). These complimentary requirements by the industry aim to avoid the introduction and spread of several diseases and conditions (e.g. paratuberculosis, footrot, PRRS as well as ESBL and LA-MRSA in pigs), both through import of live animals or via farm workers. They include preventative measures to be taken at the export facilities which include aspects such as quarantine, blood testing, compulsory foot bath treatments, etc. Imported parent chicks of poultry are tested after arrival to Norway, and efficient extra hygiene measures are implemented in case of positive ESBL-tests. LA-MRSA-positive animals would not be imported as the Authorities monitor the presence in a national program and affected animals are slaughtered regardless of origin. Farmers importing animals without proof of compliance with requirements by the industry, risk increased insurance premiums and that slaughterhouses will refuse to sell and distribute meat from the imported animals.

Page 10, Number 19. Within Norway, coordinated efforts have been made by the industry organizations, farmers and the competent authorities to eradicate certain conditions and cases of AMR in food producing animals. Eradication is compulsory for certain diseases and is voluntary for others. The involvement of NFSA in the eradication activities helps to ensure important measures such as restrictions on the movement of livestock and payment of compensation for culled animals. Programs carried out to-date have resulted in the eradication of several conditions where antibiotics would be used for their treatment (e.g. bovine viral diarrhea in 2006 and enzootic pneumonia in pigs in 2010) while others are ongoing. Some examples of these include the following:

In pigs, LA-MRSA, dysentery (almost eradicated), toxin-producing *Pasteurella multocida*. For pneumonia caused by *Actinobacillus pleuropneumoniae* a research program has been launched too.

In small ruminants, foot rot, paratuberculosis, and CAE is almost eradicated and in cattle control programs are established for contagious mastitis (*Str. Agalactia*), BRSV and BCoV.

In poultry, reduce the occurrence of ESBL and necrotic enteritis. The poultry industry has required companies providing the breeding stock (located outside Norway) not to use antimicrobials prophylactically with a goal of only importing stock to Norway which is free of ESBL.

Page 10, Number 20. Animalia and other industry organizations have developed voluntary species-specific health programs for pigs, poultry, dairy cattle and sheep 15 with the involvement of the veterinary authorities and associations. These highlight the main challenges for maintaining the high health status of livestock farms (amongst others, the presence of diseases in the breeding herds, the trade of live animals between farms, inadequate biosecurity measures or the hiring of foreign personnel) and potential mitigation measures. Some of these are market incentives (e.g. a higher price paid in the slaughterhouse for animals from farms which participate in these programs) which encourage participation in these initiatives. A dairy farmer visited showed the mission team an article on MRSA in cattle in a Norwegian farmer's magazine which provided instructions to prevent its spread. In addition, the farmer had received advice on issues from the quality of the milk to feeding and animal welfare from the dairy cooperative, Animalia, private veterinarians and other industry stakeholders.

Page 11, Number 22. To protect the health status of aquaculture, commercial movements of farmed fish within Norway are subject to national restrictions in accordance to EU legislation, which are agreed on between the fish health authorities and the fish industry. These restrictions effectively prevents risks associated with movements from areas with relatively low health status to areas with a higher health status. Norway also has additional guarantees related to freedom of certain fish diseases.

Page 13, Number 33. line 7: Should read: "fish health biologists and veterinarians".

Yours sincerely

Ole-Herman Tronerud

Acting Head of section animal Health
Animal Departement
The Norwegian Food Safety Authority, Head Office

EFTA Surveillance Authority and EU Commission services' response to the competent authority's comments on draft report DG (SANTE)/2017-6199–Norway– gather information on the prudent use of antimicrobials in animals

6 July 2017

Reference in draft report		(Short description) Competent authority's comments	ESA and Commission services' comments	Action in response to competent authority's comments		
Page	Section			Not accepted	Accepted	
					Text amended	Footnote (no.)
2	Point 1	Change to "Ministry of Trade Industry and Fisheries", not "Ministry of Fisheries"			√	
3	Point 5	(Add text in Italics)...This is planned through preventative veterinary medicine, organized disease eradication campaigns and prudent (correct) treatment of animals, <i>as well as better documentation of treatment in the Animal Health Recording System (Dyrehelseportalen)</i> . ..communication and interaction with other stakeholders <i>at national</i> and international level. It is proposed to define strict criteria for the use of certain CIAs and to ban the use of 3rd and 4th generation cephalosporins and colistin. At the present time <i>no colistin VMPs are marketed in Norway</i> .	Comment on colistin will be on a footnote		√	√
5	Point 13	(Add text in Italics)...Antimicrobials can be dispensed only by authorised pharmacies or, in the case of medicated feed, by a feed mill, on prescription issued by a veterinarian and, in the case of aquaculture, <i>also</i> by a fish health biologist.			√	

6	Point 18	<p>(Redraft the point as suggested): Requirements for the import of live animals have been established by the animal health authorities 14 with additional, complimentary requirements developed by the Norwegian Livestock Industry Biosecurity Unit (<i>KOORIMP</i>). These complimentary requirements by the industry aim to avoid the introduction and spread of several diseases and conditions (e.g. paratuberculosis, footrot, PRRS as well as ESBL and LA-MRSA in pigs), both through imports of live animals or via farm workers. They include preventative measures to be taken at the export facilities which include aspects such as quarantine, blood testing, compulsory foot bath treatments, etc. Imported parent chicks of poultry are tested after arrival to Norway, and efficient extra hygiene measures are implemented in case of positive ESBL-tests. LA-MRSA-positive animals would not be imported as the Authorities monitor the presence in a national program and affected animals are slaughtered regardless of origin. Farmers importing animals without proof of compliance with requirements by the industry, risk increased insurance premiums and that slaughterhouses will refuse to sell and distribute meat from the imported animals.</p>			√	
6	Point 19	<p>(Add underlined text) In pigs, LA-MRSA, dysentery (almost eradicated), toxin-producing <i>Pasteurella multocida</i>. For pneumonia caused by <i>Actinobacillus pleuropneumoniae</i>, <u>a research program has been launched too.</u> <input type="checkbox"/> In <u>small ruminants, foot rot, paratuberculosis, and CAE is almost eradicated and in cattle control programs are</u></p>	The diseases are referred to by their full name instead of the abbreviations		√	

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