



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

DG(SANTE) 2016-8889 - MR

FINAL REPORT OF A FACT-FINDING MISSION  
CARRIED OUT IN  
THE NETHERLANDS  
FROM 13 SEPTEMBER 2016 TO 20 SEPTEMBER 2016  
IN ORDER TO  
GATHER INFORMATION ON THE PRUDENT USE OF ANTIMICROBIALS IN  
ANIMALS

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

## ***Executive Summary***

*This fact-finding mission on the prudent use of antimicrobials in animals took place in the Netherlands from 13 to 20 September 2016 and is part of DG Health and Food Safety's planned series of such missions to Member States. The objectives of this 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, there has been a very significant reduction in the use of antibiotics in animals in the Netherlands in recent years (a 58.4% decrease in sales from 2009 to 2015). Since prudent use policies have been enacted there has been a clear and associated decrease seen in levels of antimicrobial resistance in broilers, veal calves and pigs in the Netherlands. The policies were set up as a public-private partnership. Stakeholders in the major livestock production sectors - pigs, broilers, veal and cattle – together with the Royal Netherlands Veterinary Association took responsibility for effective measures, facilitated and supervised by the national government. This public-private cooperation resulted in the establishment of an independent body (the Netherlands Veterinary Medicines Authority) to analyse data on the use of antimicrobials at farm level and to set benchmarks.*

*Good practices applied in the Netherlands include transparency as regards recording and benchmarking of antibiotic use on farms, benchmarking of the prescribing patterns of veterinarians, strengthening the role of veterinarians, taking measures to improve animal health and promoting prudent use in line with official reduction targets. Promotion of the prudent use of antibiotics in animals has also been achieved by implementing policies based on expert scientific advice, monitoring antimicrobial resistance and promoting research and specific initiatives by producer organisations, with the support of government. These initiatives have been backed up with official supervision and controls in an overall One Health context. The findings highlight the progress that can be achieved in a relatively short time period to reduce the use of antibiotics in animals, and associated antimicrobial resistance, while safeguarding animal health and welfare, the economic viability of producers and avoiding an excessively legislative approach. In the near future, sector-specific reduction strategies will be developed and executed. Future strategies will focus more specifically on farms and veterinarians with persistent high use and high prescribing patterns of antibiotics respectively.*

*A number of aspects of the measures put in place in the Netherlands aimed at encouraging the prudent use of antimicrobials in animals could serve as an illustration of potential good practices to other Member States.*

## Table of Contents

1	INTRODUCTION.....	1
2	OBJECTIVES AND SCOPE OF THE MISSION.....	1
3	BACKGROUND TO THE MISSION SERIES.....	2
4	FINDINGS .....	3
<b>4.1</b>	<b>Background.....</b>	<b>3</b>
4.1.1	<i>Current national strategies and action plans influencing the use of antimicrobials in animals .....</i>	<i>3</i>
4.1.2	<i>Outcomes of current national strategies and action plans influencing the use of antimicrobials in animals.....</i>	<i>5</i>
4.1.3	<i>Monitoring of sales and use of antimicrobials.....</i>	<i>6</i>
4.1.4	<i>Monitoring of AMR and links to reduction in use of antimicrobials .....</i>	<i>6</i>
<b>4.2</b>	<b>Availability of antimicrobial veterinary medicinal products .....</b>	<b>7</b>
4.2.1	<i>Authorisation and distribution .....</i>	<i>7</i>
4.2.2	<i>Policies / practices encouraging reduction in use and prudent use of antimicrobials in animals and outcomes to date.....</i>	<i>12</i>
4.2.3	<i>Species-specific policy initiatives of industry organisations .....</i>	<i>15</i>
4.2.4	<i>Future initiatives from the competent authorities and other stakeholders .....</i>	<i>17</i>
<b>4.3</b>	<b>Control actions on the use of antimicrobials in animals.....</b>	<b>19</b>
5	OVERALL CONCLUSION .....	22
6	CLOSING MEETING .....	23
	ANNEX 1 – Legal References	

## ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ADD	Average daily dose
Amp-C	AmpC $\beta$ -lactamases are bacterial enzymes that hydrolyse 3 <sup>rd</sup> generation extended spectrum cephalosporins and cephamycins engendering resistance to these categories of antibiotic
AMR	Antimicrobial resistance
CBG-MEB	Medicines Evaluation Board <i>College ter Beoordeling van Geneesmiddelen</i>
CIAs	Critically important antimicrobials
DDDA <sub>F</sub>	Defined Daily Dose Animal at farm level
EMA	European Medicines Agency
ESAC-Net	European Surveillance of Antimicrobial Consumption-Network
ESBL	Extended-spectrum $\beta$ -lactamase producing organisms
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
KNMvD	Royal Veterinary Association of the Netherlands <i>Koninklijke Nederlandse Maatschappij voor Diergeneeskunde</i>
MARAN	Monitoring of antimicrobial resistance and antibiotic usage in animals in the Netherlands
NethMap	Consumption of antimicrobial agents and antimicrobial resistance among medically important bacteria in the Netherlands
NVWA	Netherlands Food and Consumer Product Safety Authority <i>Nederlandse Voedsel- en Warenautoriteit</i>
PCU	Population correction unit
SDa	The Netherlands Veterinary Medicines Authority <i>Autoriteit Diergeneesmiddelen</i>
SPC	Summary of product characteristics
VMPU	Veterinary Medicinal Product Unit

## **1 INTRODUCTION**

This fact-finding mission on the prudent use of antimicrobials in animals, carried out in agreement with the Dutch competent authorities, took place in the Netherlands from 13 to 20 September 2016 and is part of a planned series of such missions to Member States. The mission team, comprising two auditors from DG Health and Food Safety, a national expert from a European Union (EU) Member State and an observer from the European Medicines Agency (EMA), was accompanied throughout the mission by representatives of the competent authority, the Ministry of Economic Affairs. An opening meeting was held on 13 September 2016 with the Ministry of Economic Affairs, Ministry of Health, Welfare and Sport, Netherlands Food and Consumer Product Safety Authority (NVWA) and Medicines Evaluation Board (Veterinary Medicinal Products Unit - VMPU). At this meeting 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 the Netherlands (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 focussed on 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 – some findings have been made in this regard – and (ii) the monitoring of residues and contaminants in live animals and animal products. These two topics respectively were the subject of an audit in November 2016 DG(SANTE)2016-8919 and October 2011 (DG(SANCO)2011-8915).

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

Visits / Meetings		No	Comments
Competent authority	Central	2	Opening and closing meetings with the competent authorities
Monitoring and surveillance		3	Meeting with NVWA to discuss enforcement and controls carried out on the distribution and use of antimicrobials, meeting with Netherlands Veterinary Medicines Authority (SDa) to discuss the analysis of antibiotic usage data, benchmarking and promoting prudent use, meeting at Utrecht University to discuss data on risks of AMR related to use of antimicrobials in animals
Veterinary Associations		1	Meeting with Royal Veterinary Association of the Netherlands
Veterinary Practice		1	Treating both farm and companion animals
Farms		2	Pig farm and veal farm
Industry stakeholders		1	Meeting with sector organisations and industry stakeholders in the pig and veal sectors

### 3 BACKGROUND TO THE MISSION SERIES

This fact-finding mission forms part of one of a number of initiatives included in the European Commission's action plan <sup>1</sup> against the rising threats from AMR, and is specifically linked to actions 2 and 3 of the associated road map <sup>2</sup>: 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 <sup>3</sup>), the Commission received information highlighting a number of measures already taken by Member States on this topic. In order to gain a more comprehensive overview of the efforts being made within the EU to encourage the prudent use of antimicrobials in veterinary medicine, a questionnaire was sent by DG Health and Food Safety to all Member States in September 2015 and a number of Member States were selected to be 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.

<sup>1</sup> [http://ec.europa.eu/dgs/health\\_food-safety/docs/communication\\_amr\\_2011\\_748\\_en.pdf](http://ec.europa.eu/dgs/health_food-safety/docs/communication_amr_2011_748_en.pdf)

<sup>2</sup> [http://ec.europa.eu/health/antimicrobial\\_resistance/docs/roadmap\\_amr\\_en.pdf](http://ec.europa.eu/health/antimicrobial_resistance/docs/roadmap_amr_en.pdf)

<sup>3</sup> [http://ec.europa.eu/health/antimicrobial\\_resistance/docs/2015\\_prudent\\_use\\_guidelines\\_en.pdf](http://ec.europa.eu/health/antimicrobial_resistance/docs/2015_prudent_use_guidelines_en.pdf) OJ 11.9.2015 C 299/7 – C 299/26

## 4 FINDINGS

### 4.1 BACKGROUND

#### 4.1.1 *Current national strategies and action plans influencing the use of antimicrobials in animals*

1. Responsibilities for AMR policies are currently shared between the Ministry of Economic Affairs (for aspects related to animals) and the Ministry of Health, Welfare and Sport (for human health).
2. Reduction of both antimicrobial use and the incidence of AMR in livestock is considered a societal issue in the Netherlands, due in part to the density of animal production and close contact with the human population. The development of national policies to reduce the use of antibiotics in livestock have been motivated by the need to protect public health, maintain the current low level of AMR (and antibiotic use) in humans, limit the risk of AMR transmission from livestock to humans and growing concerns regarding the possible implications for human health of livestock production in the Netherlands.
3. In 2008, memoranda of understanding were signed by the animal production sectors and the Royal Veterinary Association of the Netherlands (KNMvD) based on a request from the Dutch Minister of Agriculture. Mandatory reductions in overall antibiotic use of 20% by 2011 and 50% by 2013 (based on sales data from 2009) were agreed with the production sectors (dairy cows, beef cattle, veal calves, pigs and broilers) on 16 April 2010 while the government set an additional target on 26 June 2012 of achieving a 70% reduction by 2015 based on the reduction already achieved in 2011. The aim was to have all antibiotic use on farms transparently recorded by the end of 2011. It should be noted that, in particular, the agreement on the need for transparency of use led to the establishment of the Netherlands Veterinary Medicine Authority (SDa) in 2010. The Veterinary Medicine Authority has an expert panel that is responsible for monitoring, setting benchmark values and reporting of annual usage data. In addition, the SDa is an advisory body for government and private parties.
4. A One Health National Action Plan on AMR (due to run for 5 years) has been in place in the Netherlands since 2015. Protection of human health lies at the centre of the Dutch One Health approach, with the establishment of clear goals and specific actions on aspects related to food, the environment, animals, healthcare and international aspects.
5. Concerning human health, the One Health Action Plan aims to reduce avoidable healthcare-associated infections by 50% and reduce incorrectly prescribed antibiotics across the entire healthcare chain by at least 50%. A reduction in the emergence and spread of multi-resistant bacteria in healthcare is now becoming apparent. Interventions in hospitals to reduce antibiotic use and address AMR have been shown by the competent authorities to have had an overall positive economic impact. Research is currently underway on the transmission of resistant bacteria via food and campaigns

have been organised to communicate to the general public the importance of food hygiene. Actions surrounding the next antibiotic awareness day in November 2016 will focus on the role of healthcare professionals, especially the leadership within and management of hospitals.

6. KNMvD considers that in recent years there has been a better appreciation and understanding among human health organisations in the Netherlands of the progress made and challenges still faced in the veterinary sector to reduce the use of antibiotics in animals. KNMvD has also asked some human health colleagues to take part in the preparation of veterinary prudent use guidelines in the framework of both fields learning from each other in a One Health context.
7. Prior to the adoption of the national AMR strategy, European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) sales data showed that the Netherlands was amongst the countries with the highest use of antibiotics in livestock, while ESAC-Net (European Surveillance of Antimicrobial Consumption-Network) data showed that antibiotic use in humans in the Netherlands was amongst the lowest internationally. This fed a perception that insufficient actions were being taken to promote reduced and prudent use of antibiotics in animals and led to actions being taken to reduce use from 2008 onwards.
8. An advisory report in 2011 from the Netherlands Health Council (an independent scientific advisory body whose legal task it is to advise Ministers and the Dutch Parliament in the field of public health and health/healthcare research <sup>4</sup>) on the use of antibiotics in food animal production and resistant bacteria in humans contained advice on risks to public health associated with the use of antibiotics in livestock farming. It concluded that it was very likely that transfer of Extended-spectrum  $\beta$ -lactamase producing organisms (ESBL) from food animal production to humans was taking place and it recommended various prohibitions in, and changes to, the use of specific antibiotics in the livestock industry. This report formed the basis for changes to the national legal framework for veterinary medicinal products which was renewed in 2013 via the Animals' Act, Decree on veterinary medicinal products and Regulation on veterinary medicinal products and the adoption of several policy measures to promote the prudent use of antimicrobials in animals.
9. On environmental aspects, the One Health Action Plan currently focuses on the spread of residues of antibiotics and AMR organisms, via wastewater from hospitals, farms etc. Once the scope of the issue has been defined, evidence-based measures to address these environmental aspects are intended to be proposed by the end of 2016.

---

<sup>4</sup> <https://www.gezondheidsraad.nl/en/task-and-procedure>

#### 4.1.2 Outcomes of current national strategies and action plans influencing the use of antimicrobials in animals

10. A number of examples of good practice in the prudent use of antimicrobials in farmed animals have been collated and published by the Dutch authorities <sup>5</sup>.
11. According to the most recent ESVAC report available when this fact finding mission was conducted, the sales of antimicrobials in 2013, including critically important antimicrobials (CIAs), for use in animals in the Netherlands were 69.9 mg per population correction unit (PCU), within a range of 3.7 to 425.8 mg/PCU among the 26 countries contributing data. This figure for the Netherlands represented a decline of 52% in the sales of veterinary antimicrobial agents from 2010 to 2013. The sales of 3<sup>rd</sup> and 4<sup>th</sup> generation cephalosporins decreased by 94% and sales of fluoroquinolones by 45% from 2011 to 2012, and in 2013 these represented 0.01% and 0.2% of total sales respectively.
12. The rate of decline in antibiotic use in animals is now levelling off, with an overall 0.65% reduction in 2015. However there were notable differences in antimicrobial use by sector with a 5% reduction in the use in pigs but a 17% increase in turkeys. As a result, consideration is being given to strengthening policies to further reduce antimicrobial use in animals.
13. A critical factor for the success of the Dutch policy on reducing veterinary antimicrobial use was considered by the competent authorities to have been the rapid response of the livestock production industry and KNMvD to the sense of urgency felt in human healthcare, research and subsequently at the political level. This facilitated a public-private approach with broad-based support and the use of the already operational production chain quality systems was the main vehicle to achieve this.
14. Farming and veterinary organisations had expressed concerns that policies to reduce the use of antibiotics may pose a risk to animal health and welfare and reduce farm productivity and profits. The authorities have concluded that there is not yet enough evidence to support this hypothesis. According to economic data collected by the Farm Accountancy Data Network <sup>6</sup> the overall rate of return for farms in the period 2009 to 2014 did not differ between farms with high and low use of antimicrobials <sup>7</sup>. The Council for Animal Affairs (*Raad voor Dierenaangelegenheden*) examined the effects of the policies on reduced use of antibiotics on animal health and welfare and was not able to discern a direct adverse effect of such policies, though in veal calves, in the initial years, some increased mortalities were seen.

---

<sup>5</sup> <https://english.eu2016.nl/documents/publications/2016/02/10/dutch-veterinary-good-practices>

<sup>6</sup> <http://www.wur.nl/nl/project/EU-Farm-Accountancy-Data-Network.htm>

<sup>7</sup> <https://english.eu2016.nl/documents/publications/2016/02/10/dutch-veterinary-good-practices>

### **4.1.3 Monitoring of sales and use of antimicrobials**

15. The key livestock sectors (pigs, dairy, broilers and veal calves) have established databases for recording the use of antimicrobials on farms and since September 2011, all antibiotic delivery records data on farms are provided to the SDa, an independent organisation funded by the government (50%), with four industry associations and KNMvD each contributing 10% of the total funding. Farm and veterinarian identification numbers are not anonymised, but recoded so that farms and veterinarians cannot be contacted by the SDa. Based on these data, SDa has defined a daily dose per animal at farm level (DDDA<sub>F</sub>). This provides the basis for SDa's benchmarking system for antibiotic use on farms and for their prescribing by individual veterinarians. The quality of data processing from veterinarians entering delivery records to sector quality systems compiling data and calculating Defined Daily Dosages per farm has been reviewed several times by an external auditing consultancy on the request of the Netherlands Veterinary Medicine Authority. Long-term trends per species are monitored by the use of the DDDA<sub>NAT</sub>. In this way trends can be followed for a period of more than 10 years for some sectors. Procedures for calculating the DDDA<sub>F</sub> are established by the SDa. The DDDA<sub>F</sub> is in principle used for benchmarking farms and the way it is being calculated can as a result change over time. Several sectors are in discussion with the SDa regarding refinement of the calculations (age categories of animals, use of growth curves etc.). Monitoring of prescription patterns of veterinarians, expressed as the Veterinary Benchmark Indicator (VBI) has been established since 2014.
16. Mandatory central registration of the use of antimicrobials has been in place for turkeys since 2012 and for farmed rabbits since 1 January 2016. Monitoring for farmed mink will be set up in 2017. Regular surveys are carried out concerning antibiotic use in sheep, dairy goats, horses and pet animals. SDa plans to issue advice at the end of 2016 concerning the monitoring of antibiotic use in these smaller sectors.
17. Monitoring of the use of antibiotics in companion animals (pets) focusses mainly on attempts to reduce the use of the CIAs fluoroquinolones and 3<sup>rd</sup> and 4<sup>th</sup> generation cephalosporins (13.5 kilograms of 3<sup>rd</sup> and 4<sup>th</sup> generation cephalosporins were used in 2013). Results of a recent SDa survey found that the use of these CIAs in pets had fallen by 75% from 2012 to 2014.

### **4.1.4 Monitoring of AMR and links to reduction in use of antimicrobials**

18. Since 2002, annual MARAN reports <sup>8</sup> have been published on the monitoring of AMR and antibiotic usage in animals in the Netherlands. On the human side the consumption of antimicrobial agents and AMR among medically important bacteria in the Netherlands are collated in the NethMap reports. The results highlight a clear link between declines in antimicrobial use and a reduction in levels of AMR.

---

<sup>8</sup> <http://www.wur.nl/nl/Expertises-Dienstverlening/Onderzoeksinstituten/Biovetinary-Research/Publicaties/MARAN-Rapporten.html>

19. Links have also been established between antibiotic use in animals and the incidence of AMR in humans as regards MRSA (methicillin-resistant *Staphylococcus aureus*) and ESBLs (even if AMR levels in human healthcare still remain low in the Netherlands). Whilst the relationship is complex and indirect, the competent authorities consider that this does not absolve veterinarians from taking appropriate actions regarding their prescribing of antibiotics.
20. A working group on harmonising monitoring has established national priorities for monitoring AMR in animals such as in *Salmonella* isolates from all species of food-producing animals, *Escherichia coli* from all species, screening of ESBL's and carbapenemase-producing *E. coli* and *Salmonella* from all animal species and screening of colistin resistance in *Campylobacter jejuni* isolates from broilers.
21. KNMvD considers that there is not, as yet, a complete overview of national and regional resistance of veterinary bacterial pathogens in the Netherlands and it is coordinating a two year research project (VETMAP) which is due to commence in 2017 to address this. The project will cover food-producing animals, companion animals and horses, looking at available data from passive surveillance and active monitoring in veterinary practices. It will focus on the two most important veterinary pathogens in each sector and will include monitoring of ESBLs, carbapenemases and colistin resistance in veterinary pathogens.

## **4.2 AVAILABILITY OF ANTIMICROBIAL VETERINARY MEDICINAL PRODUCTS**

### **4.2.1 Authorisation and distribution**

#### **4.2.1.1 Competent authorities involved**

22. The Ministry of Economic Affairs is responsible for the authorisation and supervision of the manufacturing, import and distribution of veterinary medicinal products and this task has been delegated to the national competent authority, the VMPU of the Agency Medicines Evaluation Board (CBG-MEB) residing under the Ministry of Health, Welfare and Sport. The Health Inspectorate (IGZ) is responsible for the inspection of the marketing authorisation holders of veterinary medicinal products, pharmacovigilance and Good Manufacturing Practice. The NVWA is responsible for the inspection of the importers, traders, distribution and the prescription and use of veterinary medicinal products. In addition SDA has established the framework for the legally obligatory registration of veterinary prescriptions to create transparency regarding the use of antibiotics and develop benchmark indicators for farmers and veterinarians.

#### **4.2.1.2 Special conditions for authorisation of antimicrobials**

23. The Ministry of Economic Affairs advised that in line with the EU summary of product characteristics (SPC) guidance, a selection from the available and agreed risk mitigation measures regarding, *inter alia*, prudent use is made for each authorised antimicrobial veterinary medicinal product. In addition, the product information has been 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.

24. Colistin is used principally in the pig and veal calf sectors. As it is classified by KNMvD as a 2<sup>nd</sup> choice antibiotic for the treatment of porcine weaning diarrhoea, susceptibility testing is not required prior to its use. The Health Council of the Netherlands advisory report of 2011 recommended phasing out colistin use in animals and a 68% reduction in use was achieved between 2011 and 2015. Colistin is no longer regarded as a preferred 2<sup>nd</sup> choice antimicrobial and can now only be prescribed when other antibiotics are proven to be ineffective.
25. Owing to the potential risks of transferable resistance and carbapenemases to human health, the use in food-producing animals of all new antibiotics such as carbapenems, tigecycline, daptomycin, oxazolidones, mupirocin etc. is not allowed. Fluoroquinolones and 3<sup>rd</sup> and 4<sup>th</sup> generation cephalosporins are not allowed to be used in animals unless it has been demonstrated that there are no alternative treatment options available. Colistin, all beta-lactams and all aminoglycosides are classified as 2<sup>nd</sup> choice antimicrobials which can only be used based on appropriate diagnosis by the veterinarian.

#### ***4.2.1.3 Classification system for antimicrobials used in veterinary medicine in the Netherlands***

26. Since the 1990's KNMvD's working party on veterinary antimicrobial policies has set up a classification system for antimicrobials used in veterinary medicines. Since 2012 the KNMvD's working party has classified antibiotics in the following way to reduce the selection pressure for AMR:
  - **1<sup>st</sup> choice** antimicrobials are ESBL-indifferent antimicrobial agents and can be prescribed for empirical therapy after diagnosis (amphenicols, tetracyclines, trimethoprim/sulphonamides, some macrolides/lincosamides, some penicillins)
  - **2<sup>nd</sup> choice** antimicrobials are antimicrobial agents not meeting the criteria for 1<sup>st</sup> or 3<sup>rd</sup> choice. They are not to be used unless the need for prescription and use is substantiated by a clinical examination and history, diagnostic and susceptibility testing (polymyxins such as colistin, all beta-lactams and aminoglycosides, quinolones, 1<sup>st</sup> and 2<sup>nd</sup> generation cephalosporins, some macrolides/lincosamides)
  - **3<sup>rd</sup> choice** antimicrobials are antimicrobials regarded as of critical importance for human medicine and are only to be prescribed and used in individual animals after performing diagnostic and susceptibility testing to show that there are no alternatives. This is a legal obligation (3<sup>rd</sup> and 4<sup>th</sup> generation cephalosporins and fluoroquinolones).

#### ***4.2.1.4 Distribution model for veterinary antimicrobials in the Netherlands***

27. Prescription-only veterinary medicinal products (including all antimicrobials) are available exclusively from veterinarians. Some veterinary medicinal products are prescription-only but may be purchased and supplied from a pharmacist or a licensed trader who are responsible for running their own veterinary pharmacy operations for their retail sale. These veterinary medicinal products can be antiparasitics, fungicides, some tranquilisers and non-steroidal anti-inflammatory drugs.
28. Since 2014 antimicrobials can only be administered by a veterinarian (previously, they could be administered by farmers). As an exception, antibiotics can be prescribed by the veterinarian and administered by the farmer after a clinical examination has been performed by the veterinarian and a diagnosis established in line with good veterinary practice (applicable medication and treatment guidelines) and subject to certain strict requirements being fulfilled, namely:
  - there must be a one-to-one agreement between the farmer and veterinarian;
  - the veterinarian must perform regular farm visits (for each production cycle of broilers, to pig farms at least once per month, to veal calf and dairy farms at least once every 3 months) and prepare a report on the animal health status of the farm and farmed animals with an evaluation on the use of antibiotics on the farm;
  - there must be a herd health plan and herd treatment plan which include a target for reducing the use of antibiotics on the farm during the year. The target(s) should be revised each year.
29. Based on independent research from 2011 KNMvD estimates that the operating profit from the sale of veterinary medicinal products in large animal practices accounts for between 8 and 25% of the total profits of the practice. The figure for small animal and horse practices is smaller (4%). Thus most of the veterinarians' profits come from providing advice and applying their specialist knowledge. KNMvD considers that this combined with the 58.4% reduction in antibiotic use between 2010 and 2015 shows that it is not necessary to decouple sales of antibiotics from prescription by veterinarians and that such a change would weaken the position of the veterinarian and pose a potential animal welfare risk if it led to delays and additional costs obtaining veterinary antibiotics from pharmacies.
30. Marketing incentives offered by pharmaceutical companies are governed by self-regulation and a code of advertising relevant to veterinary medicinal products is applied. The mission team was informed by KNMvD that pharmaceutical companies have organised information evenings for farmers to discuss the reduced and prudent use of antibiotics and some model and study farms also exist to promote best practices to farmers.

#### 4.2.1.5 *Conditions for use of veterinary antimicrobials and restrictions on preventive and off-label use*

31. Since January 2013 it has been mandatory for veterinarians to carry out susceptibility testing before the use in any animal of 3<sup>rd</sup> and 4<sup>th</sup> generation cephalosporins, fluoroquinolones and human antimicrobials which do not have a veterinary authorisation. In exceptional cases, treatment can be initiated with a 3<sup>rd</sup> choice antimicrobial if a susceptibility test is also performed, and then the treatment is adjusted subsequently to a non-3<sup>rd</sup> choice antimicrobial based on the susceptibility test result. This policy has led to an approximate 99% reduction in the use of 3<sup>rd</sup> and 4<sup>th</sup> generation cephalosporins and a more than 90% reduction in the use of fluoroquinolones. The costs of performing the susceptibility test have also discouraged the use of 3<sup>rd</sup> choice antimicrobials. According to the competent authorities, the National Reference Laboratory has established standards and a protocol for antimicrobial susceptibility tests and the laboratories (approximately 40 including private veterinary practices) carrying out such tests are required to participate in tests to show that they are performed competently and consistently.
32. Farmers are permitted to store on farm sufficient 1<sup>st</sup> choice antimicrobials to treat 15% of the animals on the farm which could be susceptible to a defined disease. For dairy farms, a store can be kept of 2<sup>nd</sup> choice antimicrobials to treat mastitis in up to 15% of the dairy cows present on the farm. Additionally, it is permitted to keep 2<sup>nd</sup> choice antimicrobials on farms to treat *E. coli* and meningo-encephalitis caused by *Streptococcus suis* in piglets, to treat respiratory diseases, enteritis and arthritis for a maximum 5% of the herd for veal calves and to treat diarrhoea in young dairy calves. These exceptions are only allowed when the veterinarian has visited the farm during the 14 days preceding treatment and only when providing an instruction identifying the animals which might need to be treated in this way.
33. Preventive use of antibiotics in animals was prohibited in 2011 by a change in the SPC and product labelling by CBG-MEB. The word "preventive" was deleted and replaced by "treatment" or if necessary by "herd treatment". The words "treatment and prevention" have been adapted in the Netherlands as "herd treatment when the disease has been diagnosed in the herd". Orally administered antimicrobials for metaphylactic use in food producing animals (herd treatment) can only be prescribed after a clinical inspection by the responsible veterinarian and farmers are not allowed to keep oral medication for herd treatments in stock.
34. Off-label use is interpreted in the Netherlands as the veterinarian deviating from the SPC/labelling by applying a different dose or different duration of treatment. This is prohibited in the Netherlands on several grounds. Firstly, it may lead to risks for public health (unsubstantiated use of antibiotics can increase the risk of resistance). Secondly, the specified withdrawal period is no longer appropriate as the product has not been tested by the marketing authorisation holder for this off-label use or misuse for which no formal benefit-risk assessment has been performed. Thirdly, adverse events if they

occur, cannot be properly assessed and the marketing authorisation holder is no longer accountable if adverse events do occur. It should be noted that off-label use is allowed under 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. Other Member States take a differing view of the relevant provisions of the Directive and rely on the professional responsibility of individual veterinarians to decide on such off-label use.

35. KVMvD stated that the Dutch policy of prohibiting off-label use could inadvertently cause problems with some old antibiotics, as experience in the veterinary community indicates that the dosages and treatment durations given in the SPC are no longer in line with the latest scientific knowledge. As a short term solution, the competent authority has reached agreements with the veterinary profession to formulate special conditions to allow veterinarians to deviate from the SPC for certain antibiotics as regards the dosage and duration of treatment if the deviation is based on scientific grounds. This is only permitted for specific antibiotics, specific indications and the exceptions are incorporated in the professional medication guidelines for veterinary use (formulary). The intention is that all veterinarians would thus deviate from the SPC in a consistent way for these products. Over the long term, manufacturers are expected to update and modify the SPCs in accordance with the latest scientific data and veterinarians in the Netherlands are required to report any need for a different (higher) dosage or treatment duration as an adverse effect (lack of efficacy).
36. KNMvD noted that the current prohibition on off-label use (especially for older products where the SPC does not reflect current veterinary knowledge) and requirements for the use of potentially ineffective 1<sup>st</sup> choice antimicrobials in preference to 2<sup>nd</sup> choice ones could potentially increase AMR issues. In addition, differences are reported by veterinarians between the *in vivo* and *in vitro* efficacy of antibiotics and limited other options for the import of suitable antibiotics from other EU Member States under the cascade are available. Finding suitable treatments for minor species such as goats and horses is also a challenge. KNMvD expressed support for the statement by the Dutch Council on Animal Affairs that "the wish to achieve a major reduction in antibiotic use should never lead to the attitude that higher disease incidence and mortality are acceptable".
37. As regards cascade use, in exceptional cases, veterinarians may deviate from the terms of the marketing authorisation by prescribing a veterinary medicinal product to animals for a disorder for which no veterinary medicinal product is marketed in the Netherlands, primarily to spare the animal unacceptable suffering. A written explanation is required from the veterinarian justifying why the cascade has been used and the NVWA monitors compliance with these requirements.
38. Concerning medicated feed, a risk assessment was performed in 2010 on the carry-over of medicines into non-medicated feed and stricter rules on this issue have been implemented since then leading some feed companies and farmer groups to voluntarily

phase out the production and use of premixes and medicated feed. In any case, such use in the Netherlands is relatively low with the tendency to administer antimicrobials via drinking water or in powders for top-dressing of feed. KNMvD has developed guidelines on group treatment of animals with antibiotics via these routes.

39. KNMvD also has guidelines for good pharmacy management including the storage and disposal of veterinary waste. Regarding the disposal of unused or expired antibiotics from farms, it is currently under discussion whether farmers should return these products to the veterinarian for disposal or whether this could cause certain biosecurity risks. Alternative systems for disposal are also being considered. Farmers are responsible for removing residual antibiotics and expired medicines from the farm although there is no specific legislation for the disposal of veterinary medicines, including antimicrobials, other than the general regulations for commercial (chemical) waste.

#### **4.2.2 Policies / practices encouraging reduction in use and prudent use of antimicrobials in animals and outcomes to date**

40. To date, initiatives to encourage the prudent use of antimicrobials have mainly focussed on the 4 production sectors (dairy, pigs, broilers, veal calves) which account for approximately 87% of antibiotic use in animals in the Netherlands, while in 2016 the rabbits for meat production sector voluntarily asked to participate in the existing prudent use initiatives. From 1 January 2016, these rabbit farms have been subject to the requirements for the one-to-one farmer veterinarian contract, regular farm visits and development of a herd health plan). In 2017 SDa will set benchmarks for antibiotic use in farmed rabbits and the objective of the sector is to reduce antibiotic use by 70% between 2011 to 2018 (a reduction of 55% having already taken place between 2011 to 2015). The use of 3<sup>rd</sup> choice antimicrobials (3<sup>rd</sup> and 4<sup>th</sup> generation cephalosporins and fluoroquinolones) in this sector is low, accounting for 1% of total antibiotic use.
41. An evaluation of the impact of measures taken to promote prudent use showed there had been a significant reduction in the use of 2<sup>nd</sup> choice antimicrobials for specific diseases (70% in dairy calves, 38% in veal calves and 9% in piglets). Concerns were expressed by the veal farmer visited regarding restrictions on the availability on-farm of effective 2<sup>nd</sup> choice antimicrobials for farmers to administer directly when they identify a severely sick animal (e.g. gentamicin). These may be alleviated by proposed relaxations to these rules in January 2017 which are:
  - instead of the veterinarian having visited the farm in the preceding 14 days (this is only being maintained for the high risk period of piglets up to 8 weeks of age and veal calves until 10 weeks of age), it will be sufficient for the farmer to contact the veterinarian, for example by phone, to justify the use of the 2<sup>nd</sup> choice antibiotic;
  - instead of being used for a list of prescribed diseases, a maximum of 3 farm-specific diseases will need to be specified for which use of the 2<sup>nd</sup> choice antimicrobial is considered necessary;

- the maximum on-farm store of 2<sup>nd</sup> choice antibiotic to treat 5% of the veal calves is being adjusted to 5% of the veal calves present, 10% of young dairy calves and 10% of each house of piglets.
42. Based on the detailed data on the use of antimicrobials on farms (DDDA<sub>F</sub>) and being prescribed by veterinarians, SDA has established a three tier benchmarking system for dairy farms and those with pigs, broilers and veal calves. The benchmarking follows a pragmatic approach which is based on benchmarking values derived from the median use (green to orange) or 75<sup>th</sup> percentile of the distribution. For the green target zone, use should be below the original 2009 thresholds of median use. For the orange signalling zone, the actual use lies between the median and the 75<sup>th</sup> percentile of higher usage. For the red action zone the actual use is above the 75<sup>th</sup> percentile of higher use farms. In 2015 SDA evaluated the relationship between reduction in use and changes in resistance levels. These associations are not specific enough to propose benchmarking on the basis of resistance levels. In some sectors, the number of farms in the red zone is still relatively high (veal and poultry) compared to the other sectors. Therefore, more emphasis is given to reduction of antibiotic use in farms which are in the red zone over longer periods of more than one year. Farms in the red zone have to produce a farm health plan in which they describe how they will improve the usage pattern.
  43. According to farmers met by the mission team, the ability to readily assess their use of antimicrobials and compare themselves to other farms has provided a motivation and some competition to make changes in order to be placed at the lower end of use in the green zone. Both farmers and veterinarians appreciated the fact that there are no consequences if farms temporarily move into the orange or red categories following an increase in the use of antimicrobials. However, details of farms which are in the red action zone for three successive reporting periods are passed to the competent authorities for possible investigation by NVWA.
  44. The representatives of the pig and veal industry schemes met, noted that it is intended to focus in future on assisting those farmers who are consistently categorised in the red zone to make changes in order to reduce their antimicrobial use.
  45. As regards veterinarians, these are classified by SDA using a Veterinary Benchmark Indicator based on the proportion of their farm clients (with whom they have a one-to-one contract) who fall into the green, orange and red zones of antibiotic use (see finding 42). Veterinarians in the green target zone have less than 10% of their clients in the red action zone of high antibiotic use. Those in the orange signalling zone have between 10 and 30% of their clients in the red action zone of high antibiotic use and those in the red action zone have more than 30% of their clients falling into the red action zone of high antibiotic use. It is noted that differences in prescription patterns can be relatively high between veterinarians (up to a factor of 5-10). This is remarkable considering that the prescription patterns always involve multiple farms. SDA stimulates discussions among veterinarians about what should be considered 'normal differences' in prescription patterns as part of the benchmarking process.

46. The proportion of veterinarians within the red action zone differs significantly between the production sectors in which they work due to differing levels of antibiotic use in the various sectors. In 2014 the figures were 23% for veterinarians dealing with veal calves, 16% for broilers, 13% for pigs and 3% for dairy cattle. Under the private industry schemes, veterinarians with 30% or more of their clients in the red action zone need to develop an improvement plan and explain why such a high proportion of their clients are in the red action zone.
47. Further to what is planned for the rabbit sector, it is expected that SDa will establish new benchmarks for antibiotic use in the different animal sectors during 2017 once the first results from studies examining critical success factors for low antibiotic use become available. These 'Critical Success Factor Studies' have been initiated at the end of 2016 and will report findings in 2017. These studies basically compare high-using farms and veterinarians with low-using farms and veterinarians based on farm characteristics (type of farm, management, hygiene measures etc.) and should give indications on which factors can be intervened upon in order to reduce antimicrobial usage. These same studies will also be used by SDa for revising the benchmarking values. A final benchmark for the dairy sector reflecting minimal and prudent use of antibiotics will be established during 2016 as this sector is considered to have already successfully achieved low levels of antibiotic use and a low incidence of AMR.
48. KNMvD has also been proactive in the development of a private quality assurance system for veterinarians (certified veterinarians: *geborgde dierenarts*<sup>9</sup>) working in the pig, dairy cattle, veal calf and poultry sectors (participation is voluntary). This quality system specifies certain mandatory training courses (for example on preparing herd health plans). Veterinarians who are not registered by the veterinarian private quality system are not able to work on farms which participate in the industry private quality schemes (pigs, dairy cows, veal calves and broilers), although one of the two private quality schemes in the pig sector has recently lifted this requirement.
49. In the Netherlands, the veterinary profession has drawn up private guidelines of its own with regard to the prudent use of antibiotics. These currently cover 10 species<sup>10</sup>. In response to the 2011 Health Council of the Netherlands advisory report, KNMvD's antimicrobial guidelines were revised to reduce the risk of ESBL and Amp-C selection. Currently these guidelines are under further revision taking into account recent advice from the Health Council to further reduce the use of colistin in animals.
50. In 2016, an evaluation of KNMvD guideline for dry cow management was performed which showed that this was used by 92% of dairy cattle practitioners surveyed when they were drafting their herd health plans for their clients. Of those surveyed, 66% considered the recommendations in this guideline to be useful and applicable in practice.
51. An evaluation of KNMvD guideline on *S. suis* in weaning piglets is also underway with the outcome expected in October 2016, while during 2016 and 2017 KNMvD plans to

---

<sup>9</sup> <http://www.geborgdedierenarts.nl/pluimveedierenarts/verordening-en-besluit>

<sup>10</sup> Available online at [www.wvab.nl/formularia](http://www.wvab.nl/formularia)

develop four new guidelines, including some on the use of antimicrobials in veal calves and broilers.

52. Other than a voluntary and general quality system based on postgraduate education, KNMvD has no system in place to enforce the adoption of these guidelines by veterinarians although they are taken into account by NVWA and the veterinary disciplinary board in assessing the actions of veterinarians. Veterinarians are legally obliged to prescribe antimicrobials according to the species-specific antimicrobial guidelines when preparing herd health plans for farms.
53. Whilst the prudent use guidelines published by the European Commission (see section 3) have also been reviewed by KNMvD, they are not considered to add much detail to measures which have already been applied in the Netherlands.

### **4.2.3 Species-specific policy initiatives of industry organisations**

#### **4.2.3.1 Veal calf industry**

54. The mission team met with representatives of the industry quality scheme for veal calves. Measures taken in the veal sector have included improving the arrival conditions for young calves (frequency of feeding and house temperature), minimum criteria for the age and health of arriving calves (e.g. any infections of navel or joints), limiting the number of farms from which farms source animals, reducing the mixing of calves from different origins upon arrival at the veal farm, trying to achieve a higher health and hygiene status (e.g. promoting vaccination against certain diseases on the dairy farms of origin) and additional requirements for farms using high levels of antibiotics.
55. To date a 44% reduction in the use of antibiotics in veal calves has been seen since 2010, with the vast majority of those used (86%) being 1<sup>st</sup> choice, 13.9% being 2<sup>nd</sup> choice and 0.1% 3<sup>rd</sup> choice. A 26% reduction in the incidence of AMR levels in veal calves has been reported.
56. For the period 2016-2020 the focus is on continuing to improve the quality of arriving veal calves through integrated research and in cooperation with the dairy industry, traders and collection centres, sharing knowledge and best practices for the rearing of young calves, national policies for the eradication of infectious bovine rhinotracheitis and bovine viral diarrhoea and exchanging data through the production chain from the dairy farm to the veal calf farm and vice versa. A revised average daily dose system is being implemented based more specifically on the type of animal (white or rosé veal). To improve the robustness of the current benchmarking system, action will be focussed on the higher use orange zone and red zone farms.

#### **4.2.3.2 Pig industry**

57. The mission team also met with representatives from one of the two industry quality schemes for the pig sector. In 2009 a working committee involving farmers, veterinarians, feed companies, slaughterhouses and the Animal Health Service (now a private sector organisation conducting, *inter alia*, research, providing advice and

laboratory services to the industry) developed a master plan to address the issue of use of antimicrobials in the sector. The plan was based on the principles of private quality systems for farmers and veterinarians and included aspects such as creating awareness, monitoring and benchmarking of farmers and veterinarians and setting goals instead of formal regulation (self-regulation). There is also a national regulation that pig farmers can source piglets from a maximum of only three other farms. A "positive list" of veterinary medicines to be used was also developed (excluding 3<sup>rd</sup> choice antimicrobials). The plan comprised 10 specific action points:

- measuring the use of antibiotics by ADD/year;
- performing a baseline assessment for AMR;
- promoting the more widespread use of existing knowledge and best practices;
- transferring veterinary information;
- receiving feedback from slaughterhouses on deviations detected at slaughter;
- extra surveillance for farmers who were not members of the quality system;
- no use of medicated feed;
- monitoring illegal use of antibiotics on farms and slaughterhouses;
- mandatory registration of veterinarians for the scheme and in the private quality system for veterinarians;
- developing a communication plan for stakeholders and society.

58. From 2009 to 2015 these measures contributed to a 56% reduction in the overall use of antibiotics on pig farms with no critically important antimicrobials for human treatment being used in pigs.

59. A new master plan for the pig sector has been developed for the period 2016-2020, seeking to further improve animal health by improving farm management, rewarding low antibiotic use (green) farms by market rewards and lighter regulation and providing extra assistance to high using (red) farms. Action points included in the new master plan comprise:

- a programme to improve animal health;
- a proposal to reward farms with low antimicrobial use;
- new tools to measure the effect of lower antibiotic use on AMR;
- the measurement of AMR in veterinary pathogens;
- introduction of a system to monitor for diseases on farms;
- analysis of critical success factors for low antibiotic use and their implementation;
- more systematic cleaning and disinfection of transport vehicles;
- research on feed adjustments which could reduce the need for antimicrobial use;

- more intensive assistance for farms using high amounts of antimicrobials;
  - an exploration of incentives to promote lower use of antimicrobials.
60. The pig quality scheme representative stated that successful measures taken in this sector had been achieved primarily by cooperation throughout the production chain and with the national government. Whilst the measures have been successful in the Netherlands, it was stated that cultural and societal differences in other countries may mean that similar measures would not have the same impact or be so easily implemented in all other countries.

#### **4.2.4 Future initiatives from the competent authorities and other stakeholders**

61. In order to develop policy for the period 2016 to 2020, the Health Council was asked to prepare a follow-up report on the risks to human health of the use of antimicrobials in animals, considering that ESBLs are still most risky for human health, carbapenemase-producing bacteria are an emerging risk and there are specific issues surrounding colistin use in animals making it difficult to totally phase out its use. This second Health Council report of December 2015 <sup>11</sup> concluded that the policy to reduce use of antibiotics in animals had been effective but cautioned that continued vigilance was required since the trend towards reduced use had largely ceased in 2015. The existing policy on colistin use in animals was highlighted as needing to be updated. The report considered that policy and research was needed to increasingly focus on farms in the zone of highest antibiotic use and veterinarians having a high proportion of such clients. It considered that more attention was needed on companion animals and, in addition to the carbapenemase problem, identified *mcr-1* (methylases) as an issue of concern.
62. Overall, the existing policy goals have largely been achieved as regards the quantity of antimicrobials used (reduction in sales, prescriptions issued by veterinarians and usage on farms) and the quality of their use (substantially reduced use of 3<sup>rd</sup> choice antimicrobials, fewer group treatments of calves and pigs, more selective dry cow treatments). The competent authorities noted that the measures taken had a surprisingly fast and substantial effect on the occurrence of AMR in food-producing animals. Critical success factors identified by the competent authorities included defining clear reduction targets, measures being initiated by private animal production sectors in conjunction with the national veterinary association aimed at prudent use and transparency regarding use of antibiotics (a bottom up approach), an independent control unit (SDa) to benchmark use of antibiotics by farms and veterinarians and a national AMR monitoring programme to facilitate the identification of relevant trends.
63. Policies for the period 2016 to 2020 are thus moving from a general policy of reduction of antibiotic use in animals to more sector-specific policies. Improving animal health is the central goal, with healthy animals considered as being the normal standard and sick animals being the exception. In line with the policies of self-regulation by the industry

---

<sup>11</sup> Taking the form of an advisory letter  
[https://www.gezondheidsraad.nl/sites/default/files/201531e\\_advisory\\_letter\\_tightening\\_up\\_on\\_antibiotic\\_use\\_in\\_animals.pdf](https://www.gezondheidsraad.nl/sites/default/files/201531e_advisory_letter_tightening_up_on_antibiotic_use_in_animals.pdf)

and public-private cooperation, the four major sectors (pigs, broilers, dairy cows, veal calves) have been asked to develop their own proposals for antibiotic use reduction plans.

64. Initiatives being considered include for pig farms greater attention to hygiene, animal transport and benchmarking of animal health standards with antibiotic use on farms. The broiler sector is examining the possibility to use slower-growing birds and the veal sector is trying to develop greater cooperation with dairy farms supplying calves to their industry, to ensure that the animals are of an improved animal health standard, from herds vaccinated against certain diseases etc. Recent increases in dairy herd sizes upon the removal of milk quotas resulted in an increased number of calves born from heifers on dairy farms, which were of a lower bodyweight and more prone to disease when transported to veal calf farms.
65. Several on-going multi-disciplinary research projects aim to identify critical success factors contributing to the low use of antibiotics in animal husbandry (or the "failure" factors leading to high use) and to test the impact of the most effective measures for reducing antibiotic use in a field pilot study involving high-using farmers and their farm advisors. The outcome will help inform further prudent use initiatives in these sectors.
66. Taking broiler chickens as an example, the project for this production sector will also consider relevant aspects such as hatcheries and the farm supply chain. The influence of factors such as the location, size, layout of farm, type of chickens and husbandry system will be analysed as well as farm management aspects such as vaccination policy, climate control, feed, water, use of antibiotics, origin of chickens etc. Farmer social-behavioural factors will also be considered, such as the expected cost-benefit ratio of any measures taken, practical feasibility of any adjustments proposed, perceived relevance to the sector, social impact and the farmer's attitude to using antibiotics, any social pressure exerted, knowledge and skills and whether any incentives can be introduced to promote the reduced use of antibiotics on farms. The second phase of the project will involve testing effective approaches identified for antibiotic reduction (including through coaching) in a field pilot with high use farms and involving their veterinarians and other farm advisors.
67. KNMvD has identified future challenges to achieve further reductions in antibiotic use while maintaining animal health and welfare, retaining the support of the veterinary profession and creating a level playing field across the EU. For example, concerning colistin which is used in some Member States, KNMvD considers that its use (if at all) must be restricted to animals at risk (cohorting). KNMvD also emphasised the importance of further improving animal health and sustainability by innovating animal husbandry systems, preventing the illegal use and trade of antimicrobials and strengthening international cooperation to combat AMR.
68. KNMvD highlighted the significant financial contribution which it makes along with the private industry schemes to the operating costs of SDa and supporting the development of guidelines, which are available to all veterinarians even though only approximately 70% of them are paid members of KNMvD (the annual KNMvD membership fees range

from approximately €200 to €1 500 per year). KNMvD also stated that the number of its members and associated income are also falling partly owing to the proactive approach it has taken in supporting strict AMR initiatives. Given this, both KNMvD and representatives of the private quality schemes met during the mission considered that additional or alternative and more sustainable sources of funding will be needed to support AMR policies in the Netherlands over the long-term.

### 4.3 CONTROL ACTIONS ON THE USE OF ANTIMICROBIALS IN ANIMALS

69. NVWA is the surveillance authority performing, *inter alia*, control actions such as inspections of farmers and veterinarians. For veterinary medicinal products these cover the chain from wholesale and retail level (veterinarians) to the animal holder/owner. For antibiotics and other prescription-only medicines these controls focus on supply of the products by the veterinarians and their use by the veterinarian and animal holder. NVWA also cooperates with customs authorities regarding the import of veterinary medicinal products and border control checks performed to detect illegal imports. Of the 200 NVWA inspectors spread across 14 teams covering cattle, pigs, poultry, animal welfare etc., approximately 10 of the inspectors are veterinarians and these concentrate mostly on performing animal welfare inspections.
70. NVWA's control actions on antimicrobials are based on a fraud analysis, risk analysis and compliance analysis. A variety of control actions are performed. These include zero point controls, prioritised controls, veterinary inspection campaigns, frequency controls (such as under the national residue monitoring plan), basic cross-compliance controls and controls in response to notifications and complaints. Since 2011, the use of antibiotics on broiler farms, pig farms, veal calf farms and dairy cattle farms has been recorded in the central databases of the private sector industry organisations. From 2015, NVWA has been given access to these database records at a national level and can request data aggregated at a national level for a specific time period. Daily use of antibiotics on individual farms is not visible to NVWA but overall data on antibiotics prescribed as well as the name of the farmer and veterinarian can be viewed. Data on animal movements and mortalities may also be taken into account by NVWA in planning its veterinary inspection campaigns. Details of farms which appear three times or more in the red zone of higher antibiotic use are also passed to NVWA and these data can be used in planning risk-based inspections.
71. NVWA's controls on the prudent use of antimicrobials were based originally on the antibiotic use reduction targets established in 2009. NVWA performed a "gatekeeper" project in 2010 and 2011 focussing on non-prudent use of antimicrobials and off-label use. This found that veterinarians did not always prescribe antibiotics in compliance with the rules, especially as regards dosage and treatment guidance for pigs and broilers. For example, in the pig sector veterinarians often did not show due diligence as regards establishing a diagnosis when prescribing antibiotics, did not always have convincing justifications for the treatments applied and did not routinely evaluate the treatment

outcomes. Some veterinarians were found to have prescribed antibiotics preventively following pressure from their clients.

72. A follow-up programme of zero point controls performed by NVWA in the pig sector in 2012 found that the incidence of preventive use of antibiotics had decreased to 32% compared to 50% in the 2010 gatekeeper project. There was a 42% incidence of off-label use compared to 58% in 2010, a reduction to 20% of treatments not having any specific diagnosis (25% in 2010) and a halving of the proportion of farms visited having used 3<sup>rd</sup> choice antimicrobials (25% in 2012 compared to 51% in 2010). The controls on 83 farms and 67 veterinarians in 2012 (all selected at random) resulted in 12 notifications of veterinarians to the veterinary disciplinary board.
73. New national legislation on prudent use was enacted in 2013 and 2014, based, *inter alia*, on the Health Council report of 2011. This instituted the channelling regime where only veterinarians could prescribe antibiotics. Zero point controls were conducted between 2011 and 2014 focussing on a reduction in preventive and metaphylactic use of antibiotics and reduction in use of 3<sup>rd</sup> choice antimicrobials in animals. Between 2014 and 2016, zero point controls, prioritised controls and veterinary inspection campaigns took place, revealing deficiencies in the recording of veterinary treatments, limited knowledge among veterinarians and farmers of the new legislation and non-prudent use of antimicrobials, in particular 3<sup>rd</sup> choice antimicrobials.
74. Controls on broiler farms in 2010, 2012 and 2015 found that during this period flock treatments with antimicrobials upon arrival of the birds fell dramatically from 68%, to 58%, to 8% of the farms inspected respectively. Treatment with antimicrobials after vaccination fell from 41% to 15% to 4% of the farms inspected. Treatments with antimicrobials after thinning of the flock fell from 44% to 41% to 15% and flock treatments with 3<sup>rd</sup> choice antimicrobials fell from 62 of 68 farms in 2010 to 15 of 33 farms in 2012 and down to 0 of 24 farms inspected in 2015.
75. NVWA's controls on veal farms, associated veterinary practices and veterinarians found that the percentage of farms treating arriving calves with antimicrobials fell from 88%, to 81% to 18% in 2011, 2012 and 2014 respectively. The incidence of use of 3<sup>rd</sup> choice antimicrobials on inspected farms was 98%, 92% and 0% in each of the above years.
76. Controls performed in the meat rabbit sector (farms and veterinarians inspected between 2014 and 2015) found deficiencies in the recording of veterinary treatments by farmers and that all of the farms used herd treatment with antibiotics.
77. Between 2014 and 2016 NVWA has performed other inspection campaigns on veterinarians (including companion animal veterinarians) and on the use of mastitis treatments in dairy cattle. The results of these campaigns were unpublished at the time of this fact-finding mission.
78. When non-compliances are detected in official controls, possible sanctions can include an official warning, re-inspection, a case taken under administrative or criminal law or reporting of a veterinarian to the national veterinary disciplinary board. The veterinary disciplinary board deals with potential breaches of good veterinary practice and is

composed of judges and veterinarians. Where inspections find that professional and medication guidelines developed by the national veterinary organisations have potentially not been followed NVWA reports this to the Chief Veterinary Officer who decides if the case should be referred to the veterinary disciplinary board. Potentially the veterinarian's registration to practice could be suspended by the veterinary disciplinary board and fines of €2 500 have been applied in some cases. Verdicts of the disciplinary board are published in an anonymised form online <sup>12</sup>.

79. Controls on farmers and veterinarians have focussed on recent national legislation to ban the preventive use of antibiotics in animals, promotion of prudent use by veterinarians and farmers and requirements for susceptibility testing to be performed when 3<sup>rd</sup> choice antimicrobials are used. Guidelines issued by veterinary professional bodies in the Netherlands are taken into account when performing these controls and expert advice may be sought in some cases, for example when there appears to be a conflict between the legislative provisions and guides of good veterinary practice, for example the prescribing of 3<sup>rd</sup> choice antimicrobials in pets.
80. Recent intensified enforcement campaigns by NVWA on veterinary antibiotics have included the innovative use of residue analysis (performing on-site tests on the animals, for example screening saliva and hair from pigs for residues), involving a separate project team within NVWA focussing on the illegal use of antibiotics. An NVWA project on the intensified enforcement of veterinary antibiotics use/guidelines started in February 2015 aiming to develop innovative enforcement techniques, using knowledge of the farm production sectors and models of production. The project involves different departments across NVWA and there is intensive collaboration via a working group of enforcement officers established under the EU Heads of Medicines Agencies.
81. As part of this intensified enforcement project NVWA has been examining the one-to-one relationship between farmers and veterinarians, the possibility for farmers to source antibiotics from other veterinarians and the number of farms for which individual veterinarians are responsible.
82. A survey of antibiotic deliveries to 3 233 pig farms in the Netherlands in the first half of 2015 (data from the 2 Dutch quality schemes for the pig sector) found that 414 farms were receiving more than 95% of the antibiotics used on the farm from a veterinarian other than the one the farmer had a one-to-one contract with. The position of KNMvD is that less than 30% of the antibiotics used on a farm should be prescribed by a veterinarian other than the one with whom the farmer has concluded a one-to-one contract and this is only to cope with occasions when the contracted veterinarian is ill, on leave or otherwise not available to the farmer.
83. The sourcing of antibiotics by farmers via foreign veterinarians or traders, procurement of antibiotic active substances and internet purchases are also being investigated by NVWA. A case of illegal antibiotic use in the broiler sector from 2010-2012 involved products sourced from China. The detection of antibiotic residues on feathers has been

---

<sup>12</sup> <http://tuchtrecht.overheid.nl/zoeken-in-domein/diergeneeskundigen>

used in practice to identify if antibiotics have been administered during a broiler chicken's short life-span. The food chain information accompanying broiler chickens to slaughter requires the farmer to specify if any antibiotics or other medicines have been administered during the whole lifespan of the broilers.

84. Good practices considered by NVWA to have emerged from its work include the focussing of controls on the role of the veterinarian in prudent use and the use of innovative on-site testing to check for undeclared administration of antibiotics, as well as effective cooperation between the public and private sectors to share information, analyse available data from private data systems and food chain information etc. to underpin risk-based controls, communicate on risks and give feedback on the outcome of inspections to improve overall compliance.
85. Regarding controls and enforcement performed by NVWA and private quality systems, KNMvD has the impression that sometimes these controls are not uniformly applied and concentrate too much on the letter rather than the spirit of the law, with controls on off-label use sometimes causing tensions and some veterinarians feeling they are being punished for seeking the optimal treatments for animals. However the competent authorities confirmed that the optimal treatment for animals is allowed, provided that the reason for not following the specific regulations is recorded by the veterinarian.

## 5 OVERALL CONCLUSION

Overall, there has been a very significant reduction in the use of antibiotics in animals in the Netherlands in recent years (a 58.4% decrease in sales from 2009 to 2015). Since prudent use policies have been enacted there has been a clear and associated decrease seen in levels of antimicrobial resistance in broilers, veal calves and pigs in the Netherlands. The policies were set up as a public-private partnership. Stakeholders in the major livestock production sectors - pigs, broilers, veal and cattle – together with the Royal Netherlands Veterinary Association took responsibility for effective measures, facilitated and supervised by the national government. This public-private cooperation resulted in the establishment of an independent body (the Netherlands Veterinary Medicines Authority) to analyse data on the use of antimicrobials at farm level and to set benchmarks.

Good practices applied in the Netherlands include transparency as regards recording and benchmarking of antibiotic use on farms, benchmarking of the prescribing patterns of veterinarians, strengthening the role of veterinarians, taking measures to improve animal health and promoting prudent use in line with official reduction targets. Promotion of the prudent use of antibiotics in animals has also been achieved by implementing policies based on expert scientific advice, monitoring antimicrobial resistance and promoting research and specific initiatives by producer organisations, with the support of government. These initiatives have been backed up with official supervision and controls in an overall One Health context. The findings highlight the progress that can be achieved in a relatively short time period to reduce the use of antibiotics in animals, and associated antimicrobial resistance, while safeguarding animal health and welfare, the economic viability of producers and avoiding an excessively legislative approach. In the near future, sector-specific reduction

strategies will be developed and executed. Future strategies will focus more specifically on farms and veterinarians with persistent high use and high prescribing patterns of antibiotics respectively. A number of aspects of the measures put in place in the Netherlands aimed at encouraging the prudent use of antimicrobials in animals could serve as an illustration of potential good practices to other Member States.

## **6 CLOSING MEETING**

A closing meeting was held on 20 September 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.

## 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. 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. 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. 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
OJC 2010/295	OJ C 295, 29.10.2010, p. 1	Commission Decision of 01-07-2010 concerning, in the framework of Article 35 of Directive 2001/82/EC of the European Parliament and of the Council, the marketing authorisations for veterinary medicinal products for food producing species containing quinolones and/or fluoroquinolones as active substances