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# COMMISSION STAFF WORKING DOCUMENT

Guidelines for the prudent use of antimicrobials in veterinary medicine. Practical examples.

Accompanying the document

# **COMMISSION NOTICE**

Guidelines for the prudent use of antimicrobials in veterinary medicine

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# **Table of Contents**

1	INTRODUCTION				
2	SCOPE AND PURPOSE				
3	REG	REGULATORY FRAMEWORK			
4	PRINCIPLES ON PRUDENT USE OF ANTIMICROBIALS				
	4.1 Issues to be considered before using antimicrobials				
	4.2	Particular issues to be considered before using critically important antimicrobials			
	4.3	Oral administration of antimicrobials to groups of animals via feed and drinking water			
	4.4	Responsibilities		11	
		4.4.1	Prescriber	11	
		4.4.2	Administrator of the antimicrobial	14	
		4.4.3	Pharmaceutical industry, pharmacists, retailers and wholesalers	17	
		4.4.4	Feed business operators	17	
		4.4.5	Food business operators	18	
		4.4.6	Veterinary faculties and agriculture schools	19	
		4.4.7	Veterinary professional associations	20	
		4.4.8	Industry stakeholder associations	21	
		4.4.9	Farmers' associations	22	
		4.4.10	Competent Authorities	22	
		4.4.11	Laboratories	23	
5	AWA	ARENESS	S-RAISING	23	
6	ENF	NEORCEMENT AND SANCTIONS			
7	DICI		DEVENTION AND DEDUCING THE MEED TO LIGE		
/	ANTIMICROBIALS				
	7.1	General		28	
	7.2	Pigs		30	
	7.3	Poultry .		31	
	7.4	Bovines and small ruminants			
	7.5	Aquaculture			
	7.6	Rabbits			
	7.7 Other species (pets, animals kept for fur and other non-food-producing species)			33	

8	SURVEILLANCE AND MONITORING	33
9	NATIONAL STRATEGIES	34
AN	NEX I: GENERAL GUIDELINES OR NATIONAL CONTROL PROGRAMMES	40
AN	NEX 2: EMA/CVMP RECOMMENDATIONS ON RESPONSIBLE USE	42
ANN	NEX 3: EUROPEAN STAKEHOLDER ASSOCIATIONS	51
ANN	NEX 4: INTERNATIONAL ORGANISATIONS	53

#### **1 INTRODUCTION**

#### 2 SCOPE AND PURPOSE

#### **3 REGULATORY FRAMEWORK**

#### 4 **PRINCIPLES ON PRUDENT USE OF ANTIMICROBIALS**

Pathogens susceptible to penicillin ought not to be treated with other beta-lactams or broad-spectrum antimicrobials unless the patient is allergic to penicillin.

- In salmonellosis, antimicrobial substances are used only in accordance with EU law e.g. in the case of a life-threatening systemic infection;
- In viral infections, antimicrobials ought not to be used as prophylaxis against secondary bacterial infections.

#### 4.1 Issues to be considered before using antimicrobials

## **AUSTRIA**

Guidelines for prudent use of antibiotics have been developed for veterinarians and have been published by the Federal Ministry for Health:

https://www.verbrauchergesundheit.gv.at/tiere/tiergesundheit/arzneimittel/tierarzne imittelanwendungund rueckstandskontrolle/leitlinie antibakterielle tierarzneimittel.html

## **BELGIUM**

A Centre for Pharmacotherapeutic Information (BCFI) was founded in 1970 under the impetus of the University Faculties of Pharmacology for which the Federal Agency for Medicines and Health Products (FAMHP) provides logistical support. The purpose of the Centre is also to ensure continuous pharmacotherapy training for veterinarians. Summaries and reviews on several topics about antibiotic use and resistance have been published in their *Folia Veterinaria*.

The Belgian Antibiotic Policy Coordination Committee (BAPCOC) created in 1999 is a federal agency promoting responsible use of antibiotics, mainly through dissemination of scientific information. This Commission relies strongly on 'One Health' principles and consists of several working groups: Ambulatory Practice, Veterinary Medicine, Awareness-raising, Hospital Medicine and Hospital hygiene.

From 1 March 2015, a new version of the Deontological Code of Veterinarians came into force with particular emphasis on the prudent use of 'antimicrobials and critically important antimicrobials' (Disciplinary Law).

General guidelines on herd health and prudent use of antibiotics for farmers and veterinarians are published by the Center of expertise on Antimicrobial Consumption and Resistance in Animals (AMCRA) for poultry, bovines and pigs.

#### **DENMARK**

Guidelines developed by the Danish Veterinary and Food Administration in collaboration with the industry, universities and other stakeholders have been in force since 2005 for treating pigs. From 2008 treatment guidelines for cattle veterinary practitioners were also developed and in 2010 evidence-based novel treatment guidelines for pig veterinary practitioners came into force. These include pharmacokinetics and –dynamics.

http://www.foedevarestyrelsen.dk/english/Animal/AnimalHealth/Veterinary\_medic ine/Pages/Evidence\_based\_prudent\_use\_guidelines\_for\_antimicrobial\_treatment\_o f\_pigs.aspx

The Danish pig industry has guidelines on good antibiotic practice for pig producers.

http://vsp.lf.dk/~/media/Files/PDF%20-%20Viden/PDF%20-%20Til%20staldgangen%20-%20God%20antibiotika%20-%20DK-UK-RUS/Marts%202013%20-%20UK/Samlet manual-UK.ashx

General guidance and optimisation of herd health, thereby reducing antimicrobial usage, has been in force for many years voluntarily in the form of herd health contracts. However, from 2010 non-voluntary herd health agreements are in force for swine and cattle. These emphasise health prevention strategies and animal welfare in order to reduce antibiotic usage and resistance.

#### **FINLAND**

The first recommendations on the use of antimicrobials against the most common infectious diseases in animals were given in 1996. Since then the recommendations have been updated twice. The recommendations cover ruminants, pigs, horses, cats, dogs, bees, poultry, fur animals and fish. They take account of the resistance of pathogenic bacteria in Finland and the antimicrobials available in Finland. The recommendations are available in Finnish and in Swedish.

Recommendations for the prevention and control of meticillin-resistant *Staphylococcus aureus* (MRSA) infection in animals were given in 2010. The recommendations give information on MRSA in animals and instructions on how to handle MRSA infection in animals.

#### FRANCE

ANSES, the French Agency for Food, Environmental and Occupational Health & Safety, has assessed the risks of antimicrobial resistance emerging due to patterns of antibiotic use in the field of animal health.

ANSES launched an internal request to conduct an assessment of the risks of emerging antimicrobial resistance phenomena due to patterns of antibiotic use in the veterinary sphere. Its goal was to specify the most appropriate animal health measures to implement in order to establish an effective antimicrobial resistance control policy. The report published provides recommendations for each sector and animal species. The recommendations include discontinuing preventive use of antibiotics, reserving latest-generation antibiotics for clearly identified and strictly regulated situations, and giving preference to narrow-spectrum antibiotics.

https://www.anses.fr/en/content/anses-publishes-its-assessment-risks-emergenceantimicrobial-resistance-related-patterns

https://www.anses.fr/sites/default/files/documents/SANT2011sa0071RaEN.pdf

Treatment guidelines have been developed by the French Veterinary Association. Specific guidance has been elaborated by species and disease.

# ITALY

The Ministry of Health has issued recommendations ('Manuale') for veterinarians and farmers on the prudent use of antimicrobials in pigs, poultry and rabbits. These recommendations include information on prudent and balanced use of antibiotics. The information covers susceptibility testing as a precondition, giving preference to narrow-spectrum antibiotics, preventing disease as a part of herd health programmes, animal welfare, etc.).

http://www.salute.gov.it/farmaciVeterinari/newsFarmaciVeterinari.jsp?id=1917&m enu=inevidenza&lingua=italiano

# <u>SPAIN</u>

Prescription Guidelines have been developed under the National Plan for Combating Antibiotic Resistance. They have been developed by species in collaboration with veterinary organisations, animal producer organisations, academia and other partners.

http://www.aemps.gob.es/publicaciones/publica/home.htm

# <u>SWEDEN</u>

Treatment guidelines have been developed by the Swedish Veterinary Association. In a second step, guidance for use of antimicrobials in pigs, cattle and sheep have been developed by the Medical Products Agency in cooperation with experts in the field. In this second step, dosing and treatment length were discussed. Alternative dosing was recommended for some old antimicrobials, such as penicillins, where information in the summary of product characteristics (SPC) was not in line with current science or the expert consensus.

http://amcra.be/en/adviezen/recommendations-prudent-use-antimicrobials

## UNITED KINGDOM

Guidance for Responsible Use of Medicines published by government (Veterinary Medicines Directorate (VMD), Department of Agriculture and Rural Development in Northern Ireland (DARDNI), Welsh government).

Guidance for vets on responsible prescribing of antibiotics under the cascade (VMD).

Livestock sector-based guidance on the responsible use of antibiotics (Responsible Use of Medicines in Agriculture Alliance, RUMA).

Guidance on prescribing and responsible use is published by professional veterinary associations: the British Veterinary Association (BVA), the British Small Animal Veterinary Association (BSAVA) and the British Equine Veterinary Association (BEVA).

# 4.2 Particular issues to be considered before using critically important antimicrobials

# **BELGIUM**

Formularies on the responsible use of antibiotics for pigs, poultry and bovines have been published by the Center of expertise on Antimicrobial Consumption and Resistance in Animals (AMCRA). They are used on a voluntary basis. First, second and third-choice antibiotic therapy is formulated for the most common diseases that need antibiotic treatment. A colour code is used to determine the conditions of use for each molecule, based on the importance of the molecule for animal and human health and classification of the molecules by the World Health Organisation (WHO) and the World Organisation for Animal Health (OIE). 'Yellow molecules' may be used with no additional conditions (laboratory testing is recommended). The use of 'orange molecules' requires at least a diagnosis based on laboratory testing. 'Red molecules' may be used only when the diagnosis is based on laboratory testing and the pathogen is resistant to first, second or third-choice antibiotics colour-coded yellow or orange. Quinolones and third and fourthgeneration cephalosporins are 'red molecules'. They may be kept on a farm only for a five-day treatment and do not belong in the stock of medicines a farmer is allowed to have by agreement with the veterinarian.

# CZECH REPUBLIC

A legal provision — Decree No 344/2008; §3 / 2 — stipulates the conditions for prescribing and handling the antimicrobials under the 'prudent use' regime, including possible fines when the law is not followed. The aim of this legal rule is to strengthen the practical application of the recommendations given in the summary of product characteristics (SPC) of certain veterinary medicinal products containing (fluoro)quinolones, third and fourth-generation cephalosporins, ansamycins (rifaximin) and aminoglycosides of higher generations (gentamicin, kanamycin). According to the Decree, these veterinary medicinal products can only be prescribed when non-susceptibility to first-line antimicrobials is proven and susceptibility to the antimicrobials of concern (e.g. fluoroquinolone) is confirmed.

## **DENMARK**

Denmark has enforced restrictions on fluoroquinolones since 2002. The restrictions require the veterinarian, before prescribing them, to carry out microbiological examination and susceptibility testing to ensure that no other type of antimicrobials would be effective.

## **FINLAND**

The off-label use of the following antimicrobials is banned in all animal species: avoparcin, vancomycin, teicoplanin, virginiamycin, third and fourth-generation cephalosporins, rifampicin (1), rifabutin, moxifloxacin (2), ofloxacin (2), levofloxacin (2), gatifloxacin (2), tigecyclin, mupirocin, telithromycin, daptomycin, linezolid, quinupristin-dalfopristin, carbapenems and monobactams. Any veterinary medicinal product containing these substances may be used only in accordance with the summary of product characteristics (no off-label use). This means it may be used (1) together with erythromycin, azithromycin or clarithromycin to treat neonatal foals with *Rhodococcus equi* infection and (2) in local treatment of eye infections in horses and companion animals.

In addition, fluoroquinolones, third and fourth-generation cephalosporins, new broad-spectrum macrolides and systemically administered colistines may be used in animals only if, on the basis of a reliable microbiological diagnosis and sensitivity testing, epidemiological knowledge or other veterinary medicinal justification, there is no efficient alternative treatment.

#### **FRANCE**

Law No 2014-1170 published in October 2014 provides for the publication of a list of critical antimicrobials by decree and specific measures for using these critically important antimicrobials.

The law includes a target to reduce the use of fluoroquinolones and third and fourth-generation cephalosporins by 25 % before December 2016.

## **ITALY**

In 2020 the Ministry of Health asked local competent authorities to step up controls on the use under cascade of 3rd and 4<sup>th</sup>-generation cephalosporins in poultry, especially broiler hatching eggs and one day-old chicks.

#### **NETHERLANDS**

National veterinary drugs legislation requires the veterinarian to carry out microbiological examination and susceptibility testing to ensure that no other type of antimicrobials would be effective before prescribing critically important antimicrobials (third and fourth-generation cephalosporins and fluoroquinolones).

Veterinary practitioners will need a licence to dispense veterinary drugs. Licences will be granted by right but can be made subject to conditions.

Pork production quality systems have refrained voluntarily from using third and fourth-generation cephalosporins and fluoroquinolones.

The dairy production quality system has refrained voluntarily from using third and fourth-generation cephalosporins in dry cow treatment.

The Dutch guidelines for antibiotic medication limit the use of critically important and broad-spectrum antimicrobials.

http://www.gezondheidsraad.nl/en/publications/antibiotics-food-animalproduction-and-resistant-bacteria-humans

# <u>SPAIN</u>

A specific list of critically important antimicrobials has been drawn up. It is recommended that these be used only after susceptibility testing.

## **SWEDEN**

Since 1 January 2013 a regulation restricts the use of third and fourth-generation cephalosporins and fluoroquinolones in animals. The restriction means that, before prescribing these substances, the veterinarian should carry out microbiological examination and susceptibility testing to ensure that no other type of antimicrobials would be effective. Sweden has also restricted the possibility for veterinarians to prescribe certain antibiotic classes which are considered key for treating certain infections in humans and in which there are currently no authorised substances for use in animals, e.g. vancomycin, carbapenems.

## UNITED KINGDOM

In January 2012 the British Poultry Council introduced a voluntary ban on the use of fluoroquinolones and third and fourth-generation cephalosporins in chick production.

In 2014 the 'Red Tractor' farm assurance scheme updated its standards. For broilers, poussin and free range birds, the new standards require the following: no routine use of fluoroquinolones in broiler chicks, no use of third and fourth-generation cephalosporins in broiler chicks, and no routine use of any antibiotics in day-old chicks. For breeder layers and breeder replacements the updated standards require the following: no routine use of antibiotics in day-old placements and no use of third and fourth-generation cephalosporins at any stage of life.

# 4.3 Oral administration of antimicrobials to groups of animals via feed and drinking water

## **BELGIUM**

There is an agreement between the Federal Agency for the Safety of the Food Chain and the manufacturers of medicated feed concerning cross-contamination of medicines from medicated feed to blank feed.

http://www.favv-

afsca.fgov.be/productionanimale/alimentation/medicaments/ documents/2014-01-08\_update\_convention\_aliments\_medicamenteux\_FR.pdf

## CZECH REPUBLIC

A national legal provision stipulates that medicated feeds may be mixed in licensed feed mills only on the basis of a veterinary prescription. This must specify the animal species/category and treatment course, and provide exact information on the proper mixing and proper use of the medicated feed. Rules for self- and official checking of the quality of mixing, and rules/limits on cross-contamination, are also set. Off-label use of premixes is banned under the provision.

## **DENMARK**

Since 2014 Denmark has rules on herd medication to reduce antibiotic consumption. A farmer medicating a herd of pigs must conduct an annual confirmatory laboratory test of the diagnosis that justified medicating the herd. If the antibiotic threshold values are exceeded, giving rise to a 'yellow card', the number of checks on the herd's health will be increased in order to lower antimicrobial consumption. To this end, reducing medication in water is most important.

## FRANCE

Specific regulations have been adopted. Feed manufacturers' mills must implement Good Manufacturing Practices focused on homogeneity and cross-contamination. They must prove in an annual test that they have cross-contamination under control.

## **GERMANY**

A regulation is about to be published giving farmers responsibility for ensuring that only diseased animals are treated with oral medication. Technical dosing devices have to be as close to the animals being treated as possible. After the course of treatment all technical installations involved have to be cleaned.

## **IRELAND**

An official licence issued by the Department of Agriculture, Food and Marine is required before a farmer can incorporate antimicrobials into feed to produce medicated feed for their own use. Conditions are stipulated in the licence schedule for demonstrating the efficacy of the mixing procedure to ensure homogeneity and no cross-contamination. The licence to manufacture medicated feed is valid for three years and Department officials carry out inspections to check compliance with licence conditions. The rate at which the antimicrobial is incorporated is predetermined by the veterinarian prescribing it. Manufacture of medicated feed must be done in compliance with the Veterinary Written Direction issued by the veterinarian treating the herd/flock/fish farm.

Regarding oral medication via drinking water, antimicrobials can only be incorporated following veterinary instruction, with dosage rates and duration outlined in a veterinary prescription. Department officials also meet with and inspect veterinarians involved in intensive-rearing production systems, in particular the pig and poultry sector, with prudent prescription practices and usage of antimicrobials discussed and reviewed in the context of antimicrobial resistance (AMR).

# ITALY

Since 2012 the manufacture and use of medicated feedstuffs prepared with more than one premixes has to be prescribed under cascade, under the veterinarian's responsibility and in compliance with the withdrawal period required by Directive 2004/28/EC.

## **SWEDEN**

Approval by the Swedish Board of Agriculture is required if a feed operator wishes to mix medicines in the manufacture of feed or store medicated feed.

#### 4.4 **Responsibilities**

#### 4.4.1 Prescriber

## **BELGIUM**

Formularies on the responsible use of antibiotics for pigs, poultry and bovines have been published by AMCRA. First, second and third-choice antibiotic therapy is formulated for the most common diseases that need antibiotic treatment. A colour code is used to determine the conditions of use for each molecule. The formularies are available only to veterinarians.

Veterinarians are allowed to prescribe antibiotics only after clinical inspection and diagnosis. The maximum treatment period is five days. When there is a written agreement between the farmer and the veterinarian, the veterinarian can prescribe medicines for a period of two months. Only veterinarians and pharmacists can dispense antibiotics. If the medicines are dispensed by the veterinarian, an administration and delivery document must accompany the medicines.

## DENMARK

Denmark has a database of all veterinary prescribers called VetReg. <u>http://www.foedevarestyrelsen.dk/Leksikon/Sider/Dyrl%C3%A6geregistret----VetReg.aspx</u>

This database is linked to the Central Husbandry Register (CHR). All herds in Denmark have to be registered in the CHR.

http://www.foedevarestyrelsen.dk/english/Animal/AnimalHealth/Central\_Husband ry\_Register/Pages/default.aspx

The CHR is linked to the medicine database VetStat.

http://www.foedevarestyrelsen.dk/Leksikon/Sider/VetStat.aspx

Dispensing of medicines by veterinarians for treatment of animals under their care is limited to non-profit sales.

Antimicrobials are available only on prescription and prudent use is required by law. The animals must have been under the care of the veterinarian and he/she must have sufficient knowledge of them and/or have signed a herd health contract with the farmer in order to prescribe in a responsible manner.

Both the farmer and the veterinarian are required to keep records of any treatment of production animals for five years.

http://www.foedevarestyrelsen.dk/english/Animal/AnimalHealth/Veterinary\_medic ine/Pages/default.aspx The Danish pig industry has guidelines on good antibiotic practice for pig producers.

http://vsp.lf.dk/~/media/Files/PDF%20-%20Viden/PDF%20-%20Til%20staldgangen%20-%20God%20antibiotika%20-%20DK-UK-RUS/Marts%202013%20-%20UK/Samlet\_manual-UK.ashx

## **FINLAND**

Veterinarians have a limited right to prescribe and dispense medicines to treat animals under their care. The right is limited to the need in question. The prescription of antimicrobial veterinary medicinal products must be based on diagnosis. When there is need for repeated use or for group medication, the veterinarian should, whenever possible, have information on the sensitivity of the causative agent. In addition, the veterinarian can dispense such products to farms which belong to the national animal healthcare system, are under the veterinarian's control and where he or she has listed the usual needs for medication.

Since 1949 veterinarians are not allowed to make profits from selling medicines.

## **FRANCE**

The new law No 2014-1170 prohibits any discount or rebates on veterinary antimicrobials sold to veterinarians. Antimicrobials should be prescribed in line with official good practices.

All antimicrobial veterinary medicinal products are available only on prescription by a veterinarian, who in turn is permitted to prescribe only to animals in their care. Veterinarians involved in animal production are also obliged to follow regular training in which antimicrobial resistance is a specific item.

## **GERMANY**

All antimicrobial veterinary medicinal products are available only on prescription by a veterinarian, who in turn is permitted to prescribe only to animals in their care.

In addition to legal provisions, guidelines for the prudent use of veterinary antimicrobial drugs were established in 2000 and revised in 2010: <a href="http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/An">http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/An</a> <a href="http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/An">http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/An</a> <a href="http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/An">http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/An</a> <a href="http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/An">http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/An</a> <a href="http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/An">http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/An</a> <a href="http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/An">http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/An</a>

## **IRELAND**

Only a veterinarian registered with the Veterinary Council of Ireland may prescribe antimicrobials. The Veterinary Council of Ireland is a statutory body whose principal function is to regulate and manage the practice of veterinary medicine in the State in the public interest. The Veterinary Council has a Code of Professional Conduct and can take disciplinary action over fitness to practice if the code is breached.

Under national legislation, antimicrobials can be prescribed only when the animals have been under the care of the veterinarian and he/she has sufficient knowledge to prescribe in a responsible manner. National legislation requires the veterinarian to keep records to show that their responsibility for the animals is real rather than just nominal, as part of ensuring that the prescriber is in a position to prescribe appropriately.

# **ITALY**

The Ministry of Health is funding a project to rationalise inspection activities at pig slaughterhouses through an integrated approach to risk categorisation of pig breeding plants. The project aims to categorise each farm by introducing a score system based on specific check lists covering animal welfare, bio-safety, animal feeding and antimicrobial consumption.

The Ministry is also continuing work to digitalise veterinary prescriptions. A voluntary experimental stage of this task, involving wholesalers, started in 2013.

## **NETHERLANDS**

The 'administration by veterinarians only' regulation entered into force by March 2014. Under this regulation, in principle only veterinarians are allowed to prescribe and administer antibiotics to livestock.

However, under certain conditions livestock keepers are permitted to administer antibiotics themselves. To be granted permission, livestock keepers must comply with at least the following general conditions:

- they must have a centrally registered contract with a veterinarian;
- herd health and herd treatment plans must be up-to-date and contain measures to reduce the need for antibiotics;
- evidence of a regular herd inspection by the veterinarian has to be forwarded.

The legal establishment of these conditions strength the initial plans of the livestock industry.

Specific administration conditions are:

- antibiotics are to be prescribed and delivered only after clinical inspection of the animals and diagnosis by the vet and only for one course of treatment; the livestock keeper is allowed to finish a course of treatment initiated by the vet;
- for certain specific disorders, as documented in the herd treatment plan, a livestock keeper is allowed to start an antibiotic treatment of individual animals himself; however, this is with a few exceptions allowed only when first-choice antibiotics are indicated; only a limited number of doses, related to the number of animals in question, may be kept on the farm for this purpose.

## **NORWAY**

Veterinarians are allowed to dispense medicines only in acute situations. The dispensing of medicines by veterinarians to treat animals in their care is limited to non-profit sales.

# **SPAIN**

All antimicrobial medicinal products are available only under prescription by a veterinarian. In addition, Spain already has national legislation restricting veterinarians' right to sell antimicrobials so that they do not benefit economically from prescribing antimicrobials.

A common mandatory national system of electronic prescriptions and a computerised control system of treatments and consumption at farm level is under development.

## **SWEDEN**

When prescribing, veterinarians must consider the risk of emerging resistance to antibiotics and anti-parasitic substances emerging. A regulation also states that drugs should be used prudently and only when there is a need for it.

http://www.jordbruksverket.se/download/18.53b6e8e714255ed1fcc4fd9/13857137 79984/2013-042.pdf

The dispensing of medicines by veterinarians for treatment of animals in their care is limited to non-profit sales. They can dispense medicines only when the animal owner cannot get access to pharmacies or in acute situations.

## UNITED KINGDOM

All antimicrobial veterinary medicinal products are available only on prescription by a veterinarian, who in turn is permitted to prescribe only to animals in their care. The Royal College of Veterinary Surgeons' Code of Professional Conduct requires veterinarians to prescribe antimicrobials responsibly in order to minimise resistance.

In August 2014 the Veterinary Medicines Directorate (VMD) published guidance for vets on responsible prescribing of antibiotics under the cascade:

https://www.gov.uk/responsible-antibiotic-use-under-the-prescribing-cascade

To ensure prescribers have access to the most up-to-date information on veterinary medicines authorised in the United Kingdom, the VMD maintains an online Product Information Database. This gives online access to the current summary of product characteristics for every UK authorised veterinary antibiotic, and to public assessment reports where these are available:

http://www.vmd.defra.gov.uk/ProductInformationDatabase/

#### 4.4.2 Administrator of the antimicrobial

## **BELGIUM**

Administration of antimicrobials by the veterinarian is documented in the administration and delivery document. Administration by the farmer is recorded in the medicines register. If there is a contract for veterinary guidance, the herd veterinarian must check the medicine register every two months and make a global herd report every four months.

The Federal Agency for the Safety of the Food Chain has published a manual for farmers on the use of medicinal products on farms:

http://www.favv-afsca.fgov.be/publicationsthematiques/medicaments-exploitationagricole.asp

## FRANCE

There are several training programmes for farmers:

http://www.ifip.asso.fr/ouverturepdf.php?file=antbio.pdf

http://zoopole.com/ispaia/formation-professionnelle/notre-offre/recherche/

# **GERMANY**

A booklet on drug law for farmers has been published: <u>http://shop.aid.de/1575/Arzneimittelrecht-fuer-Nutztierhalter</u>

In 2014, a revision of the manual on the oral administration of veterinary medicines in the livestock sector through feed or drinking water was published <u>http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/Lei</u> <u>tfaden-Orale-Medikation.pdf? blob=publicationFile</u>

## **IRELAND**

To be supplied with and possess medicine, the owner of food-producing animals is required to have a prescription issued by the registered veterinarian who has responsibility for the care of the animals. The prescription will give the farmer instructions on how to administer the medicine.

The farmer is also required to keep detailed incoming and outgoing records of purchases and administration of veterinary medicines. These records are inspected by officials for compliance with the legislation. The inspections carried out at farm level on compliance with the legislative requirements on veterinary medicines place an emphasis on prudent use of antimicrobials and records of same.

# ITALY

Based on Regulation (EC) No 852/2004, the Ministry of Health has approved and published species-specific manuals of good husbandry practices. These set out the basic principles for managing veterinary medicines on farms.

http://www.salute.gov.it/imgs/C\_17\_pagineAree\_1187\_listaFile\_itemName\_15\_fil e.pdf

http://www.salute.gov.it/imgs/C\_17\_pagineAree\_1187\_listaFile\_itemName\_16\_fil e.pdf

http://www.salute.gov.it/imgs/C\_17\_pagineAree\_1187\_listaFile\_itemName\_14\_fil e.pdf

http://www.salute.gov.it/imgs/C\_17\_pagineAree\_1187\_listaFile\_itemName\_17\_fil e.pdf http://www.salute.gov.it/imgs/C\_17\_pagineAree\_1187\_listaFile\_itemName\_18\_fil e.pdf

http://www.salute.gov.it/imgs/C\_17\_pagineAree\_1187\_listaFile\_itemName\_21\_fil e.pdf

# **SPAIN**

All antimicrobial medicinal products are available only on prescription by a veterinarian. The administrator of antimicrobials to food-producing animals is thus required to possess a prescription. The prescription will detail all instructions for administering the medicine. The veterinarian has the responsibility for checking that the administration of the antimicrobial is correct. It is also mandatory for the farmer to keep detailed incoming and outgoing records of all medicinal products administered on the farm. Feed mills that manufacture medicated feed require a specific licence from the Ministry of Agriculture.

## **SWEDEN**

Some antimicrobials may be administered by pig farmers and beef cattle owners who have attended the training course approved by the competent authorities on conditional use of medicines. In such cases it is mandatory for the prescriber (the herd veterinarian) to visit the farm every fifth week to check and report on the use of antimicrobials to the competent authority.

http://www.jordbruksverket.se/download/18.32b12c7f12940112a7c80002228/1277 726332247/GLH-djur%C3%A4gare.pdf

## UNITED KINGDOM

Government action: the Veterinary Medicines Directorate (VMD) publishes a Code of Practice for responsible use of medicines on farms, most recently updated in December 2014. The Department of Agriculture and Rural Development in Northern Ireland (DARDNI) publishes a leaflet highlighting key responsible actions; and the Wales and Animal Health and Welfare Framework Group (Welsh Government) recently published information online on responsible use.

Non-governmental action: the Responsible Use of Medicines in Agriculture Alliance (RUMA) has formulated comprehensive guidelines for the responsible use of antimicrobials in the various livestock production sectors. These give advice on all aspects of medicines, from the responsibilities of the farmer and veterinary surgeon regarding administration, to strategies for reduced usage.

https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/424 685/Responsible\_use\_COP\_April\_2015.pdf

http://www.dardni.gov.uk/responsible-use-of-antimicrobials-in-livestockleaflet.15.108\_responsible\_use\_of\_antimicrobials\_in\_livestock\_leaflet\_final\_2.pdf

http://gwlad.gov.wales/health/use-antibiotics-responsibly/?lang=en

http://www.ruma.org.uk/antimicrobials.htm

## 4.4.3 Pharmaceutical industry, pharmacists, retailers and wholesalers

## **BELGIUM**

Advertising by marketing authorisation holders can be distributed only to veterinarians for products that are 'prescription-only', a regime under which all antimicrobials fall in Belgium.

## FRANCE

The French association for animal health industry (Syndicat de l'Industrie du medicament et réactif Vétérinaires, SIMV) has put in place an advertisement observatory in order to self-regulate laboratories' advertisements.

http://lemedicamentveterinaire.simv.org/

ANSES, the French Agency for Food, Environmental and Occupational Health & Safety has published a code of conduct for advertising in which specific items concern antimicrobials (Point 3.1). Each advertisement for an antimicrobial product shall mention that 'this VMP is an antimicrobial and all use has an impact on development of antimicrobial resistance.'

SIMV and the French agency are jointly considering the issue of VMP package sizes.

## ITALY

Advertising to the public of veterinary medicines is allowed only under authorisation by the competent authority (Decree of 14 June 2002 'Pubblicità dei medicinali veterinari presso il pubblico').

#### 4.4.4 *Feed business operators*

## **BELGIUM**

There is an agreement between the Federal Agency for the Safety of the Food Chain and the manufacturers of medicated feed concerning cross-contamination of medicines from medicated feed to blank feed.

http://www.favv-

afsca.fgov.be/productionanimale/alimentation/medicaments/ documents/2014-01-08 update convention aliments medicamenteux FR.pdf

An agreement also exists between the competent authority and the manufacturers of medicated feed concerning the use of zinc oxide in pig production. Low concentrations (e.g. 110 mg/kg instead of 150 mg/kg) are supplemented as additives in the fattening period. This compensates — because of the environmental risk — for the use of products containing zinc oxide in therapeutic concentrations in the immediate post-weaning period to treat piglet diarrhoea. The simultaneous use of colistin in treating piglet diarrhoea is forbidden.

For all veterinary antibiotics on the Belgian market, the Federal Agency of Medicines and Health Products (FAHMP) imposes a fee per package on behalf of the registration holders. In this way, for antibiotics both for farm and companion animals, a tax is charged according to the amount of active ingredient in the package. A higher fee is imposed on critically important antibiotics such as third or fourth-generation cephalosporins, quinolones or macrolides.

#### **DENMARK**

All feed business operators have to be licensed and inspected regularly.

## CZECH REPUBLIC

A system of licensed feed mills, which are regularly inspected, operates. *Off-label* use of the premixes is banned under the national legal provisions.

## **IRELAND**

Feed mills that manufacture medicated feed are licensed by the Department of Agriculture, Food and Marine. The licences have a three-year duration and specify certain conditions in relation to homogeneity testing to demonstrate the efficacy of the mixing and flushing procedures and the levels of active substance in the finished feed. All antimicrobial premixes can be incorporated into feed only in accordance with a Veterinary Written Direction written by the veterinarian with responsibility for the care of the animals. Inspections are carried out to ensure compliance with the licence conditions.

## **SPAIN**

Feed mills that manufacture medicated feed require a specific licence by the Ministry of Agriculture.

#### 4.4.5 Food business operators

## **BELGIUM**

In 2014 Belpork, the Belgian quality scheme for pig production, started mandatory centralised registration of all antibiotics delivered or prescribed at farm level. These data are used to benchmark the use of antibiotics at farm level.

AMCRA's 2020 vision statement, an initiative of the different stakeholders, defines the guidelines for the sector's policy on the use of antibiotics and antibiotic resistance among animals in Belgium. Three targets are set: a 50% reduction in antibiotic use by 2020, a 75% reduction in use of the most critical antibiotics by 2020, and and a 50% reduction in use of feed medicated with antibiotics by 2017. Seven objectives are set to reach these targets.

#### http://amcra.be/en/about-amcra

#### **DENMARK**

The Danish cattle and broiler industries voluntarily stopped the non-therapeutic use of all antibiotics for growth promotion in February 1998.

The Danish pig industry stopped all non-therapeutic use of antibiotics in pigs above 35 kg by April 1998, and for all age groups by January 2000. It voluntarily

restricted the use of third and fourth-generation cephalosporins in 2010. The cattle industry followed suit in 2014.

In 2015 the pig industry set the target of reducing tetracyclines by 50 % by 2018.

# **FRANCE**

The pig sector took the initiative to limit the use of third and fourth-generation cephalosporins at the end of 2010 (<u>http://www.leporc.com/faq.html#Q4</u>). The use of these antimicrobials fell by 65.6 % between 2010 and 2013.

In 2011 the rabbit sector signed an interprofessional charter to reduce antimicrobial usage.

http://www.cplb.fr/media/lapinfos dec 2011 029174100 1039 25042012.pdf

## **GERMANY**

The pig and poultry sectors have implemented systems for monitoring antibiotic use.

http://www.q-s.de/monitoringprogramme\_antibiotikamonitoring.html

# **ITALY**

A voluntary plan to reduce veterinary antimicrobial consumption was adopted in rabbit production in 2013. It will be adopted also for poultry production in 2015.

## **NETHERLANDS**

Pork production quality systems refrain voluntarily from using third and fourthgeneration cephalosporins and fluoroquinolones. The dairy production quality system has banned third and fourth-generation cephalosporins in dry cow treatment.

## UNITED KINGDOM

In 2012 the British Poultry Council introduced a voluntary ban on using certain critically important antibiotics — fluoroquinolones and third and fourth-generation cephalosporins — in parts of the production system.

In 2014 the 'Red Tractor' farm assurance scheme introduced new requirements for members on antibiotic use in chickens. These include restricting/prohibiting use of certain critically important antibiotics in specified life stages.

http://assurance.redtractor.org.uk/rtassurance/schemes/Standardshome/Standards20 14/changes%202014.eb

#### 4.4.6 Veterinary faculties and agriculture schools

## **ESTONIA**

Since 2005 the Institute of Veterinary Medicine and Animal Sciences of the Estonian University of Life Sciences has carried out a monitoring programme on

the antibiotic resistance of microbes from production animals and pets. It also undertakes high-level modern teaching and R&D activities in the field of animal nutrition, animal production, including aquaculture, animal genetics and breeding, reproductive biology, biotechnology, normal and pathological morphology, animal health, infectious and invasive diseases, therapy, food hygiene, food technology, and other subject areas related to animal science and veterinary medicine.

#### http://vl.emu.ee/en/

## FRANCE

A working group, chaired by the French Agency for Food, Environmental and Occupational Health & Safety has been created to consider harmonising and updating the syllabus on antimicrobial resistance in the four French veterinary schools.

## UNITED KINGDOM

The Veterinary Medicines Directorate provides lectures to vet students at UK vet schools on antimicrobial resistance policy and responsible prescribing of veterinary medicines.

## 4.4.7 Veterinary professional associations

## **BELGIUM**

The Belgian Order of Veterinarians stresses the importance of the prudent use of antibiotics in its latest version of the Deontological Code of Veterinarians. It emphases the prudent use of antimicrobials and critically important antimicrobials in particular (Disciplinary Law).

## **DENMARK**

The Danish Veterinary Association has developed species-specific guidance for dogs and cats.

## **IRELAND**

Veterinary Ireland launched its policy document on antimicrobial resistance in 2014.

http://www.veterinaryireland.ie

# ITALY

Under national legislation (Decree 193/2006) organisations and associations of veterinarians and breeders are required to promote annual educational initiatives for farmers and veterinarians to encourage mindful use of antibiotics, prevent antibiotic resistance and limit mass treatments. They have to report annually to the Ministry of Health (national competent authority) on the training activities carried out.

# **SPAIN**

Veterinary professional associations have increased collaborative efforts to strengthen educational programmes focusing on preventing the spread of antibiotic resistant bacteria that pose a serious threat to public health. Several guidelines on how to use antimicrobial products are in place.

## <u>SWEDEN</u>

The Swedish Veterinary Association has developed general guidance on prudent use and species-specific guidance for dogs and cats, horses, and cattle and pigs. The association has also developed a guideline for control of infections at veterinary healthcare services. This guidance has different programmes on adequate hygiene practices designed to prevent healthcare-associated infections, such as wound infections after surgery, urinary tract infections, pneumonia and gastro-enteritis.

http://www.svf.se/sv/Forbundet/Policydokument/

## UNITED KINGDOM

The British Veterinary Association (BVA), the British Small Animal Veterinary Association (BSAVA), and the British Equine Veterinary Association (BEVA) have all published information to guide the prescription and use of antimicrobials in veterinary practice.

http://www.bva.co.uk/activity\_and\_advice/antimicrobials.aspx

http://beva.org.uk/useful-info/Vets/Guidance/AMR

 $\frac{https://www.bsava.com/Portals/4/knowledgevault/resources/files/Protect_Poster.pd}{f}$ 

4.4.8 Industry stakeholder associations

## **IRELAND**

Animal Health Ireland is an industry-led, government-supported, not-for-profit public-private partnership between farmers, processors, animal health advisers and government. It has been raising farmers' awareness of the importance of healthy animals through its disease-prevention programmes, with emphasis on improved biosecurity and husbandry measures to reduce disease incidence.

http://animalhealthireland.ie

## **SWEDEN**

The producers' organisations are supported to update various biosecurity measures used in a biosecurity programme for cattle and pigs. Such biosecurity programmes have been in place for many years in the poultry sector.

## 4.4.9 Farmers' associations

# **DENMARK**

Food animal owners must have an education in administering veterinary medicine prescribed by their veterinarian, or else must pass a course given by the Danish Veterinary and Food Administration. See:

http://www.foedevarestyrelsen.dk/Leksikon/Sider/Dyreejeres-anvendelse-afmedicin.aspx

# **ITALY**

Under national legislation (Decree 193/2006) organisations and associations of veterinarians and breeders are required to promote annual educational initiatives for farmers and veterinarians to encourage mindful use of antibiotics, prevent antibiotic resistance and limit mass treatments. They have to report annually to the Ministry of Health (national competent authority) on the training activities carried out.

## **SPAIN**

It is mandatory for farmers to keep detailed incoming and outgoing records on all medicinal products administered on the farm. Prescriptions will be linked to a registered veterinarian who has responsibility for the care of the animals. The rational use of drugs on livestock farms is inspected every year under the National Plan of Food Chain Control.

## 4.4.10 Competent Authorities

## **BELGIUM**

The Federal Agency for the Safety of the Food Chain has a monitoring programme to follow antimicrobial resistance in commensal organisms and zoonotic bacteria of animals and food. Awareness-raising campaigns on antibiotic use and resistance are also heavily based on the annual national monitoring programme 'BelVet-Sac'. The Federal Agency for Medicines and Health Products collaborates with the Faculty of Veterinary Medicine of Ghent University to collect and analyse the data.

http://www.belvetsac.ugent.be/pages/home/

## **DENMARK**

The Danish Antimicrobial Resistance Monitoring and Research Programme (www.DANMAP.org) was established in 1995. The programme monitors and carries out research on antimicrobial usage and resistance in humans, animals and food. It involves scientists, risk analysts and risk managers working in both human and animal health.

#### http://www.danmap.org/

Since 2010 a joint Antimicrobial and Resistance action plan between the Ministry of Health and the Ministry of Food, Agriculture and Fisheries has been developed. A National Antimicrobial Board for Reduction of Antimicrobial use and Resistance

has been established, with representatives from the Danish Veterinary and Food Administration, the Danish National Board of Health and scientists from both veterinary and human health.

## FRANCE

The French Agency for Food, Environmental and Occupational Health & Safety is in charge of antimicrobial surveillance and publishes annual reports. This allows the impact and effectiveness of measures taken to be monitored.

https://www.anses.fr/en/content/antimicrobial-resistance

# **SPAIN**

The government fosters collaboration between public-private partnerships, pharmaceutical laboratories, practitioners associations and all stakeholders to help identify and implement measures to reduce the spread of antibiotic resistance.

In this context, national industry has developed guidelines for responsible use.

http://www.vetresponsable.es/vet-responsable/espanol/inicio 55\_1\_ap.html

## UNITED KINGDOM

Government activity on antimicrobial resistance is grounded in the national fiveyear antimicrobial resistance strategy which takes a 'One Health' approach. Information and supporting documents are on the government website:

https://www.gov.uk/government/collections/antimicrobial-resistance-amrinformation-and-resources

## 4.4.11 Laboratories

#### 5 AWARENESS-RAISING

#### EU LEVEL

European Antibiotic Awareness Day (EAAD) is an annual European health initiative coordinated by the European Centre for Disease Prevention and Control (ECDC) which provides a platform and support for national campaigns on the prudent use of antibiotics. EAAD is marked by national campaigns on the prudent use of antibiotics across Europe during the week of 18 November.

http://ecdc.europa.eu/en/eaad/Pages/Home.aspx

## **BELGIUM**

AMCRA collects and disseminates information on antimicrobial resistance to farmers and veterinarians through road shows, workshops, conferences, website publications, etc. It is financed mainly by the Federal Agency for the Safety of the Food Chain and the Federal Agency for Medicines and Health Products.

## **DENMARK**

An evidence-based guideline on prudent use for pig veterinarians has been published.

http://www.foedevarestyrelsen.dk/english/Animal/AnimalHealth/Veterinary\_medic ine/Pages/Evidence\_based\_prudent\_use\_guidelines\_for\_antimicrobial\_treatment\_o f\_pigs.aspx

The Danish pig industry has guidelines on good antibiotic practice for pig producers.

http://vsp.lf.dk/~/media/Files/PDF%20-%20Viden/PDF%20-%20Til%20staldgangen%20-%20God%20antibiotika%20-%20DK-UK-RUS/Marts%202013%20-%20UK/Samlet manual-UK.ashx

The National Antibiotic Council holds an Awareness Seminar every year on European Antibiotic Awareness Day.

## **ESTONIA**

The Estonian University of Life Sciences developed recommendations for the use of antibiotics in 2012. The recommendations are available on the website of the competent authority, the Veterinary and Food Board: 'Recommendations for prudent use of antibiotics in the treatment of different animal species' addressed to farmers and veterinarians:

http://www.vet.agri.ee/static/files/1289.antibiootikumide%20kasutamine%20eri%2 0loomliikide%20puhul.pdf

'Recommendations on the use of antibiotics in cattle diseases' addressed to veterinarians:

http://www.vet.agri.ee/static/files/1290.ab%20kasutamine%20veised.pdf

'Recommendations on the use of antibiotics in swine diseases' addressed to veterinarians:

http://www.vet.agri.ee/static/files/1291.AB%20kasutamine%20sead.pdf

## **FINLAND**

Guidelines on the prevention and control of MRSA infections in animals and various animal settings were published in 2010 by the Finnish Food Safety Authority. Finland has also published recommendations for the use of antimicrobial agents in the treatment of the most significant infectious diseases in animals.

http://wwwb.mmm.fi/julkaisut/tyoryhmamuistiot/2003/tr2003\_9a.pdf

The Finnish Food Safety Authority organises an annual training day for veterinarians on VMPs. The programme focuses on the prudent use of antimicrobials.

The Finnish Pig Producers Association has organised two series of training days for pig producers and farm workers. The training covered prudent use of antimicrobials, prevention of diseases in order to reduce the need for medication, etc. The Finnish Food Safety Authority and the Finnish Health Care Association also participated.

# FRANCE

A guideline on antimicrobial prescription good practices for veterinarians was published in 2009.

http://www.sngtv.org/4DACTION/Telechargement Action/Fichier3056.pdf

Detailed treatment guidelines have been prepared by the veterinary associations.

## **GERMANY**

Guidelines on prudent use of veterinary antimicrobial drugs were established in 2000 and revised in 2010:

http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/An tibiotikaleitlinien.pdf? blob=publicationFile

Farmers are targeted by a booklet which deals with drug law for farmers:

http://shop.aid.de/1575/Arzneimittelrecht-fuer-Nutztierhalter

They are also the target of a manual for the oral administration of veterinary medicines in the livestock sector through feed or drinking water, which was revised in 2014:

http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/Lei tfaden-Orale-Medikation.pdf?\_\_blob=publicationFile

The new strategy to minimise antibiotic use in animal husbandry is a topic addressed in many advanced training events and national congresses.

## **IRELAND**

The Department of Agriculture, Food and Marine organised a conference to coincide with European Antibiotic Awareness Day 2014 to increase the focus on AMR and map out how the agricultural sector can play its part in developing strategies to address the issue in a collaborative and sustainable way. It is envisaged that this conference will be an annual event, with a joint conference with the health sector to be held possibly in 2017.

## ITALY

The Italian authorities have developed recommendations for farmers and veterinarians called 'Manual for prudent use of antimicrobials in poultry, pig and rabbit production'.

http://www.salute.gov.it/farmaciVeterinari/newsFarmaciVeterinari.jsp?id=1917&m enu=inevidenza&lingua=italiano

# NORWAY

The Norwegian Husbandry Organisations published prudent use guidelines in 1996 which were implemented through comprehensive training of veterinarians in all regions of Norway during the late 1990s. The Norwegian Medicines Authority published prudent use guidelines in 1999 which were revised in 2012.

http://www.legemiddelverket.no/Veterinaermedisin/terapianbefalinger/Documents/ Terapianbefaling\_bruk%20av%20antibakteriellt%20midler%20til%20produks.pdf

## **SPAIN**

Each year on European Antibiotic Awareness Day Spain holds a dedicated event to promote the prudent use of antibiotics. Specific tools for primary and secondary schools are being developed to raise awareness of the importance of antibiotics as early as possible. Training of different groups, such as universities, professionals, farmers, etc., are carried out regularly.

http://www.magrama.gob.es/es/ganaderia/legislacion/

http://www.vetresponsable.es/vet-responsable/espanol/inicio\_55\_1\_ap.html

## <u>SWEDEN</u>

The Swedish Veterinary Association has developed general guidance on prudent use and species-specific guidance for dogs and cats, horses, and cattle, pigs and sheep. See an example at <u>http://www.svf.se/sv/Forbundet/Policydokument/</u>

There is also a national coordination function against antimicrobial resistance and healthcare-associated infections. The task is to support regular and cross-sectoral collaboration between all actors involved in efforts to combat antimicrobial resistance and healthcare-associated infection. The work includes human and veterinary medicine, public health, animal husbandry, food and environment.

The coordinating group includes a large number of agencies and works according to jointly developed instructions. The function has developed a comprehensive communication strategy and arranges a national antibiotics forum for broad dialogue and collaboration to take stock of needs and exchange information with relevant stakeholders in the field. The work includes human and veterinary medicine, public health, animal husbandry, food and environment. A joint action plan was adopted in March 2015.

http://www.socialstyrelsen.se/smittskydd/vardhygienochantibiotikaresistens

## UNITED KINGDOM

The Veterinary Medicines Directorate (VMD) runs a continuing programme of sector-specific engagement fora which first convened representatives from academia, animal keepers (farmers, pet owners etc.), vets and retailers in November 2013. Intelligence from these groups and sector trade bodies has informed the VMD's work on strengthening surveillance of antibiotic use and resistance, and is helping target work on promoting responsible use.

The VMD, along with many others in the animal health sector, contributes to European Antibiotic Awareness Day to promote key messages on antibiotic resistance and responsible use of antibiotics to vets, farmers, pet owners and the general public.

#### 6 ENFORCEMENT AND SANCTIONS

## CZECH REPUBLIC

Some veterinary antimicrobials containing VMPs are under the 'prudent regimen' according to Decree No 344/2008; §3 / 2 which stipulates the conditions for prescribing and handling the antimicrobials under the 'prudent use' regimen, including possible fines when law is not followed. Targeted inspections of veterinarians with the highest rate of prescription have therefore been performed, based on analysis of consumption patterns. Priority has been given to targeting fluoroquinolones and the highest use of third and fourth-generation cephalosporins. The inspections have also involved checks of the laboratory protocols, based on which the VMPs containing these antimicrobials were prescribed. Inspections are subject to plans based on the trends in prescription and use of these VMPs under the 'Prudent use' regimen.

## **DENMARK**

All antimicrobial consumption in production animals must be reported to the medicine database VetStat at herd, animal species and age-group level. All prescriptions and administration of antimicrobials in herds are checked on a risk basis which covers 5% of all herds a year. The number of mandatory herd health visits by a veterinarian and the number of laboratory tests to perform when treating pigs with flock medication is determined by the level of antimicrobial use at herd level,

A yellow card system has been introduced to spot heavy users and target action where it can have the greatest potential impact on reducing AMR.

http://www.foedevarestyrelsen.dk/english/Animal/AnimalHealth/Pages/The-Yellow-Card-Initiative-on-Antibiotics.aspx

Since 2011 surveillance of resistance to critically important antibiotics in pigs has been mandatory.

## **FINLAND**

One of the risk bases for checking on veterinarians is the amount of antimicrobials they purchase from wholesalers. Veterinarians who purchase more third-generation cephalosporins than average are also checked.

## **GERMANY**

With the 16<sup>th</sup> revision of the drug law the competent authority has been given a range of actions it can take if necessary to reduce the application of antibiotics. As a last resort, animal husbandry can be suspended for a defined period.

http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/Me dicinalProductsAct-AMG.pdf?\_\_blob=publicationFile

## **IRELAND**

Inspections are carried out at all links in the supply chain of antimicrobials, and sanctions are provided for in relation to breaches of legislation. For online sales, the licence issued to sell veterinary medicines via the internet does not permit sales of prescription-only medicines. Illegal importation of antimicrobials is monitored and the State has imposed penalties, including successful court prosecutions.

# **ITALY**

Italy has developed the Ministerial 'Guideline for official controls on distribution and use of veterinary medicines' for local official veterinary services. This gives great importance to controls on prudent use of antimicrobials in breeding plants for food-producing animals. Under the national legislation (Decree 193/2006), offlabel use of veterinary medicines outside the cascade is punished with fines.

## THE NETHERLANDS

The Netherlands has developed and implemented a strategy for lower and more prudent use of antibiotic in livestock production based on herd data:

http://www.autoriteitdiergeneesmiddelen.nl/Userfiles/pdf/SDa-rapporten/sdareport-usage-of-antibiotics-in-agricultureal-livestock-in-the-netherlands-in-2013-september-2014.pdf

## UNITED KINGDOM

The Veterinary Medicines Directorate launched its voluntary Accredited Internet Retailer Scheme in 2012 to help online customers buy veterinary medicines safely. Accreditation requires compliance with specified criteria covering supply procedures, information for customers and advertising of veterinary medicines. The Directorate targets illegal sales of antibiotics through intelligence-led enforcement activity.

In parallel to revisions made to the Royal College of Veterinary Surgeons (RCVS) Practice Standards Scheme (a voluntary accreditation scheme), 'responsible use' has been included within the VMD's inspections assessment for veterinary practice premises to evaluate how practices implement responsible prescribing principles.

## 7 DISEASE PREVENTION AND REDUCING THE NEED TO USE ANTIMICROBIALS

## 7.1 General

## **BELGIUM**

Ghent University has developed a web application which determines the biosecurity status of a farm.

Bio-check: http://www.biocheck.ugent.be/v4/home/

It has also developed an application which calculates the farm's use of antibiotics through a scientifically based method and compares the score with other farmers.

AB-check: http://www.abcheck.ugent.be/v2/home/

Both can be consulted free of charge by farmers and veterinarians.

# **DENMARK**

*Salmonella* control programmes have been established in poultry, pig and cattle production. The first programme in broiler production was launched 25 years ago and subsequent programmes were developed as a consequence of increasing numbers of human cases. The programmes aim to eliminate (poultry and cattle) or reduce (pig) *Salmonella* in animals and food.

To limit the spread of MRSA to the human population, Denmark is in the process of instituting tighter hygiene requirements. These involve developing a biosecurity plan for each farm, personal hygiene (shower and hand disinfection), and clothing hygiene (laundry wash at the farm) requirements, and mandatory hygiene courses for people handling pigs.

Denmark levies differentiated taxes on antimicrobials (which are higher for CIAs) and no taxes on vaccines in order to promote the use of vaccines instead of antimicrobials.

Research into alternatives to antimicrobials, reduction in herd sizes and relations with animal welfare is being carried out funded.

## **GERMANY**

The strategy to minimise the use of antibiotics in animal husbandry implemented with the 16. revision of the German Drug Law aims at improving animal husbandry and thus, by improving animal health, at reducing the need for antibiotic treatment.

# <u>SPAIN</u>

Spain has adopted a national five-year plan to combat antimicrobial resistance with the final goal of reducing the consumption of antimicrobials in animal husbandry. Six strategies are included in this plan covering both animal and human resistance. They aim to promote appropriate use, ensure effective surveillance systems, promote control and prevention of resistance, research and innovation, and develop a communication & education plan.

## http://www.aemps.gob.es/home.htm

The national plan has already led to several products. For instance, biosecurity guidelines and good farming practices have been developed by species.

http://www.magrama.gob.es/es/ganaderia/legislacion/

http://www.vetresponsable.es/vet-responsable/espanol/inicio\_55\_1\_ap.html

# SWEDEN, NORWAY

Sweden and Norway operate a voluntary hygiene programme, driven by industry and approved by the authority, to reduce the introduction of *Salmonella* in herds or flocks. In the future, the programme will form part of an overall biosecurity programme. The biosecurity programme for poultry is in place since 2007 and requires infection control and prevention, including easy clean and the sanitising of sheds and furnishings. See also examples under Chapter 7.7.

#### UNITED KINGDOM

Through 'Rural Development Programme for England' schemes, the UK Department for the Environment, Food and Rural Affairs (Defra) encourages farmers to take action to control endemic disease. These measures include farm health planning and preventative actions to build herd/flock resilience to disease, thereby reducing need for treatments and supporting productivity.

Defra provides guidance for on-farm biosecurity across livestock sectors, including preventing the introduction of diseases onto farms. Defra is also funding or cofunding a number of research projects to identify and test new approaches aimed at preventing or minimising endemic diseases, and to understand the factors which influence farmers' behaviour regarding preventative healthcare. Current projects include a research fellowship focusing on the costs and cumulative benefits of specific biosecurity measures for farmers.

The Red Tractor Assurance scheme now includes a separate section on biosecurity and disease control in its Farm Standards.

https://www.gov.uk/disease-prevention-for-livestock-farmers

http://assurance.redtractor.org.uk/rtassurance/schemes/Standardshome/Standards20 14.eb

#### 7.2 **Pigs**

## **BELGIUM**

Zinc oxide as medicated feed may be used in pigs during the immediate postweaning period instead of colistin for the treatment of post-weaning diarrhoea. To compensate for the surplus use of zinc oxide and minimise the environmental risk, it was agreed with the sector through a covenant to lower the concentrations of zinc oxide administered during the fattening period as additives to 110 mg/kg instead of 150 mg/kg as legally allowed.

## CZECH REPUBLIC

The excessive need for medication in industrial pig farming during the 1970s and 1980s has been tackled. In the following period, improved management and technology, together with introduced vaccination against major pathogens (EP, PCV2, APP) led to a significant drop in mass medication in the pig industry. Other measures such as repopulation of the herds also improved their health and reduced the need for antimicrobials significantly.

## **DENMARK**

In Denmark 2500 ppm zinc oxide in feed is used for pigs in the first 14 days after weaning, reducing the need for antibiotics.

#### **FINLAND**

Finland has banned the use of antimicrobials to prevent, eradicate or treat salmonellosis in pigs.

#### **SWEDEN**

A voluntary system for controlling swine dysentery has markedly reduced the need for treatment. It involves identifying the disease, herd investigation and advice on how to clear the infection from the farm. Farmers with certain types of insurance receive support from their insurance companies provided they follow the advice. The sales of products mainly intended to treat swine dysentery have decreased by 85% over 10 years.

#### 7.3 Poultry

#### **BELGIUM**

Antimicrobials may not be used for the treatment of any serotype of *Salmonella* in poultry. AMCRA has published an opinion on the self-regulation of the poultry sector.

http://amcra.be/fr/avis-autoregulation

#### **FINLAND**

Finland has banned the use of antimicrobials in preventing, eradicating or treating salmonellosis in poultry.

#### **SWEDEN**

Sweden's animal welfare programme is effective and includes biosecurity. It targets *Salmonella* but is also effective for a number of other pathogens.

#### 7.4 Bovines and small ruminants

#### **BELGIUM**

Belgium has a mandatory bovine viral diarrhoea (BVD) control programme. All newborns are tested. Persistent infected immunotolerant calves are no longer allowed to be introduced into veal calf fattening units.

AMCRA has published an opinion on the self-regulation of the three bovine sectors (meat calves, milk production and meat production).

http://amcra.be/fr/avis-autoregulation

#### CZECH REPUBLIC

Thanks to a voluntary initiative by certain farmers and consulting companies to carry out in-house culture testing of pathogens causing mastitis in dairy cattle, mastitis treatment has become more effective. Consequently, the use of antimicrobials to control mastitis in lactating cows has decreased.

#### DENMARK

Only simple penicillins are allowed for the treatment of mastitis unless a laboratory test shows this will not be effective.

#### FINLAND

Finland has banned the use of antimicrobials to prevent, eradicate or treat salmonellosis in bovines.

#### **GERMANY**

Manual on the control of bovine mastitis published by the German Association for Veterinary Medicine (Deutsche Veterinärmedizinische Gesellschaft DVG):

http://www.dvg.net/index.php?id=1286

#### **NETHERLANDS**

The Dutch Royal Veterinary Association has published a guideline for drying off dairy cows. The guideline provides advice and tools for prescribing and using antibiotics for drying off dairy cows. The guidelines are aimed at reducing prophylactic use of antibiotics as much as possible.

https://www.knmvd.nl/dossiers/12108456/Antibiotica/actueel/item/10833979/KN MvD-publiceert-eerste-richtlijnen-voor-dierenartsen-over-verantwoordantibioticumgebruik

#### 7.5 Aquaculture

## **NORWAY**

Efficient vaccines against cold water vibriosis in farmed fish were introduced in 1987 and against furuncolosis in 1993. This reduced annual sales (in kilogram of active substance) of antimicrobial medicinal products for therapeutic use from a peak of 48 tonnes in 1987 to 3 tonnes in 1993 and 1.5 tonnes in 2012. Over the same period fish production increased from 3 000 to 1 200 000 tonnes.

#### UNITED KINGDOM

A similar trend is seen in the UK, where sales of total antibiotics for fish only (tonnes active ingredient) have fallen from 7 tonnes in 1994 to 1 tonne in 2013. The live weight of fish slaughtered for food use rose from 70 000 to over 175 000 tonnes (1994-2012 data).

#### 7.6 Rabbits

#### <u>SPAIN</u>

A specific national strategy has been developed to facilitate the availability of medicinal products for rabbits, in order to avoid the use under cascade and provide alternatives to antimicrobial use.

# 7.7 Other species (pets, animals kept for fur and other non-food-producing species)

#### **SWEDEN**

All findings of MRSA, meticillin-resistant *Staphylococcus pseudintermedius* (MRSP) and *Enterobactericeae* producing carbapenemases in all animals are notifiable since 2008.

http://www.jordbruksverket.se/download/18.5bc6627d140113bd5471adc/1375434 763330/2013-023.pdf

In September 2013 a regulation 'on preventive and specific hygiene measures to prevent the spread of zoonoses and other infectious agents' was amended to include basic biosecurity rules. Furthermore, all veterinary practices must have and implement a hygiene plan. These measures include restrictions for horse and companion animals when clinical infection of MRSA/MRSP is suspected/detected.

http://www.jordbruksverket.se/download/18.2ae27f0513e7888ce22800010291/136 9377313559/2013-014.pdf

#### 8 SURVEILLANCE AND MONITORING

#### **DENMARK**

In Denmark age group-dependent benchmark values are set from VetStat data.

#### **FRANCE**

The new law No 2014-1170 obliges all stakeholders selling, distributing or delivering veterinary antimicrobials to declare their sales to the French competent authority. A decree is in progress to implement this.

#### **NETHERLANDS**

The Netherlands gather data in the herds and use these to set age group-dependent benchmarking values and benchmarks for veterinarians.

http://www.autoriteitdiergeneesmiddelen.nl/en/benchmark.nl/en/benchmark

#### UNITED KINGDOM

The United Kingdom conducts the following surveillance in addition to antibiotic sensitivity testing of zoonotic bacteria from animals conducted in accordance with EU requirements:

- antibiotic sensitivity testing of veterinary pathogens from clinical sample submitted to government laboratories (1998-present);
- monitoring of veterinary antibiotic sales data from 1993-present (legal requirement since 2005).

These surveillance results are reported yearly in the UK Veterinary Antibiotic Resistance and Sales Surveillance report:

https://www.gov.uk/government/publications/veterinary-antimicrobial-resistanceand-sales-surveillance-2013

The Veterinary Medicines Directorate is working with livestock and companion animal sectors to establish systems for surveillance of antibiotic consumption in animals in the UK.

#### 9 NATIONAL STRATEGIES

#### For examples of national strategies see also Annex I

## **AUSTRIA**

In 2013 the Federal Ministry of Health published the intersectoral national action plan to fight against antimicrobial resistance (NAP-AMR) that defines concrete responsibilities and actions of the human, veterinary and food sector. <u>http://www.bmg.gv.at/home/Schwerpunkte/Krankheiten/Antibiotikaresistenz/NAP</u> <u>AMR\_Der\_oesterreichische\_Nationale\_Aktionsplan\_zur\_Antibiotikaresistenz</u>

## **BELGIUM**

The national action plan to minimise the development of resistance is based on several recommendations from AMCRA.

AMCRA brings together various stakeholders: farmers, feed manufacturers, pharmaceutical industry, veterinarians and veterinary faculties. The recommendations are validated by the competent authorities. General guidelines on prudent use of antibiotics for farmers and veterinarians, specific formularies on responsible use of antibiotics for veterinarians, self-regulation recommendations for food-producing animals, recommendations on the use of zinc oxide and recommendations for a data collection system have been published.

#### http://www.amcra.be/fr/avis

AMCRA used its recommendations to introduce the 2020 vision statement. This is an initiative of the different stakeholders and defines the guidelines for the sector's policy on the use of antibiotics and antibiotic resistance among animals in Belgium. Three targets are set: a 50 % reduction in antibiotic use by 2020, a 75 % reduction in use of the most critical antibiotics by 2020, and a 50 % reduction in use of feed medicated with antibiotics by 2017. Seven objectives are set to reach these targets.

#### http://amcra.be/en/about-amcra

The development of a centralised national database on the use of antibiotics in poultry, veal calves and pigs is in the pipeline. The data will be input by veterinarians and farmers and used to benchmark at the level of the veterinarian and the farm. The development of the data collection system and the analyses of the data are financed by supplementary taxes on the sales of veterinary antibiotics.

Awareness-raising campaigns on antibiotic use and resistance are also heavily based on the annual national monitoring programme 'BelVet-Sac'. The Federal

Agency for Medicines and Health Products collaborates with the Faculty of Veterinary Medicine of Ghent University to collect and analyse the data.

## CZECH REPUBLIC

A joint human and veterinary national antibiotic programme (NAP) was established in 1995 and has been regularly updated. An NAP action plan was adopted for the period 2011-2013; its results were evaluated, and it was updated, in 2014. More information available (in the Czech language only) at: http://www.szu.cz/zakladni-informace

## **DENMARK**

Denmark has for many years operated risk management strategies to combat antimicrobial resistance and use.

http://www.foedevarestyrelsen.dk/english/SiteCollectionDocuments/25\_PDF\_word filer%20til%20download/05kontor/Risk\_management\_antimicrobia\_%20use\_and %20resistance\_Denmark\_E.pdf

The veterinary medicine database VetStat, established in 2000, records every antibiotic prescribed to production animals at the age-group, herd and veterinarian level: <u>http://www.foedevarestyrelsen.dk/Leksikon/Sider/VetStat.aspx</u>

In 2003 the Medicine Control Task Force, a special unit under the Danish Veterinary and Food Administration, was established. The special unit plans riskbased controls and assists the regional veterinary officers in difficult cases. It also assists the police and the public prosecutor.

In 2007 a task force was established between the Danish Medicines Agency, the Danish Veterinary and Food Administration and taxation authorities in order to ensure that there are no economic relationships between veterinary practitioners and the medical industry.

Denmark set the target of reducing antimicrobial use in pigs by 10% between 2009 and 2013. A further 15% reduction should be reached in 2018.

Since 2010 Denmark has a 'yellow card' programme based on population-based threshold values for antibiotic consumption. The programmes promotes prudent use in pig production through mandatory action plans to reduce antibiotic usage in herds above the threshold values. Since 2011 the yellow card initiative has been strengthened by the introduction of a 'red card' — an order to reduce herd density if the yellow card order has not proven successful

http://www.foedevarestyrelsen.dk/english/SiteCollectionDocuments/25\_PDF\_word \_filer%20til%20download/Yellow%20Card%20Initiative.pdf

http://www.foedevarestyrelsen.dk/english/Animal/AnimalHealth/Pages/The-Yellow-Card-Initiative-on-Antibiotics.aspx

Under a new political agreement, antibiotics will be subject to a tax system that will encourage prudent use, with higher taxes on CIAs than narrow-spectrum antibiotics and vaccines.

http://www.foedevarestyrelsen.dk/Dyr/Laegemidler\_til\_dyr/Sider/Initiativer-forantibiotika-og-antibiotikaresistens.aspx

# **FRANCE**

Within its 'Écoantibio 2017' programme, France has set a target to reduce the use of antimicrobials by 25 % over five years.

http://agriculture.gouv.fr/lutte-contre-l-antibioresistance

In addition, law No 2014-1170, published in October 2014, includes a target to reduce use of fluoroquinolones and third and fourth-generation cephalosporins by 25 % before December 2016.

## **GERMANY**

Germany has for many years had risk management strategies to promote prudent use of antibiotics and combat antimicrobial resistance and use.

See German Drug Law (medicinal products act) paragraph 56a:

http://www.bmg.bund.de/fileadmin/dateien/Downloads/Gesetze\_und\_Verordnunge n/GuV/A/AMG\_English\_Version\_130115.pdf

The new 16<sup>th</sup> revision of the German Drug Law contains a mandatory strategy aiming at minimising the use of antibiotics. It operates with an index for the frequency of treatment, which has to be determined in each farm twice a year. To allow benchmarking the index is also calculated for the whole of Germany. If the index of a farm is above a defined threshold, the farmer and/or the competent authority have to take measures to reduce the need for antibiotics. See §§ 58ff of the German medicinal products act http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/Me dicinalProductsAct-AMG.pdf?\_\_blob=publicationFile

The German Ministries for Health, Nutrition and Agriculture and for Education and Research developed the German Strategy against Antimicrobial Resistance (DART), which has been revised. There is also an English translation of the new DART 2020:

http://www.bmel.de/DE/Tier/Tiergesundheit/Tierarzneimittel/\_texte/Antibiotika-Dossier.html?nn=539690&notFirst=false&docId=6188468

<u>BMEL - Animal health - DART 2020: Fighting antibiotic resistance for the good of both humans and animals</u>

## **IRELAND**

The Department of Agriculture, Food and Marine (DAFM) has responsibility for controls on the supply and use of veterinary medicines including antimicrobials in Ireland. In 2013 DAFM convened a working group to look at potential actions under five headings; improved understanding on the actual use of antimicrobials; enhanced surveillance and monitoring of antimicrobial resistance development; prudent use of antimicrobials; review of the use of critically important antimicrobials. Work has started to collect data on antimicrobial use in the pig sector as well as on a number of initiatives to educate veterinarians and farmers. In 2014, a multistakeholder conference was held to coincide with European Antibiotic Awareness Day and an interdepartmental committee between the Department of Health and DAFM was established. The committee is jointly chaired by both departments. Its terms of reference include raising public and professional awareness in the health and agricultural sectors of the public and animal health threat of AMR, as well as providing guidance on a coordinated approach across the human, agricultural, food and environmental sectors.

## **ITALY**

A national action plan to promote responsible use of antimicrobials in veterinary medicine is going to be issued. The plan includes the following future actions:

- Establishing an AMR Task Force
- Developing training programmes for vets and pharmacists
- Improving the information exchange system between consumption data and control activities on VMP residues in food
- Research programmes to develop diagnostics for early diagnosis
- Consumption data analysis
- Developing a communication campaign to promote responsible use of antibiotics in companion animals.

Italy is also developing a system, at present on a voluntary basis, to collect data on the sale and consumption of antibiotics by digitalising veterinary prescriptions. The system would extend from the pharmaceutical industry, retailers and wholesalers, pharmacists, veterinary prescribers, feed business operators to farmers.

#### **NETHERLANDS**

The authorities have formulated targets for reducing the use of antimicrobials in animal husbandry from a 2009 baseline: -20% in 2011, -50% in 2012 and -70% in 2015.

<u>http://www.government.nl/issues/antibiotic-resistance/documents-and-publications/leaflets/2014/02/28/reduced-and-responsible-use-of-antibiotics-in-food-producing-animals-in-the-netherlands.html</u>

## **NORWAY**

The Norwegian Husbandry Organisations set a target to reduce consumption of antimicrobials in terrestrial food-producing animals by 25% from the 1995 level. The observed reduction from 1995-2000 was 40% and the level has been stable since then:

http://www.vetinst.no/Publikasjoner/Norm-Vetrapporten/Norm-Norm-Vetrapporten-2012 The government published its first action plan for the containment of antimicrobial resistance in the human and animal field in 2000.

http://www.regjeringen.no/nb/dep/hod/dok/rapporter\_planer/planer/2002/tiltakspla n-for-a-motvirke-antibiotikare.html?id=102037

In 2008 a second action plan was published:

http://www.regjeringen.no/upload/HOD/Dokumenter%20FHA/Nasjonal%20strateg i%20infeksjoner-antibiotikaresistens.pdf

# <u>SPAIN</u>

Spain has adopted a national five-year plan to combat antimicrobial resistance. Six strategies are included in this plan covering both animal and human resistance. They aim to promote appropriate use, ensure effective surveillance systems, promote research and innovation, and develop a communication & education plan.

http://www.aemps.gob.es/home.htm

## **SWEDEN**

Sweden has a national strategic programme against antimicrobial resistance (Govt. Bill 2005/06:50). The main aims of the strategies are surveillance of the use of antimicrobials and antimicrobial resistance, reducing the need for antimicrobials by preventing disease and controlling infection, and a correct and prudent use of antibiotics based on diagnosis. The strategy also covers use of non-medical products, such as food and plants, and other measures such as environmental arrangements.

http://data.riksdagen.se/fil/E7711022-5A78-4842-988D-10780E89E8D4

In March 2015, an updated action plan for all concerned national authorities was adopted. The plan includes human and veterinary medicine, public health, animal husbandry, food and environment.

http://www.socialstyrelsen.se/nyheter/2015mars/myndighetsgemensamhandlingspl anskaminskaantibiotikaresistensen

## UNITED KINGDOM

The United Kingdom published a joint human and veterinary five-year AMR strategy in September 2013. The strategy aims to minimise the development of resistance and focus on conserving existing antibiotics, stimulate the development of alternative treatments and improve knowledge and understanding of resistance. The strategy calls upon a wide range of health and government organisations to engage with and contribute to this work. It also highlights the importance of working with the farming, food, retail and pharmaceutical sectors, as well as the academic community and professional bodies.

In December 2014 a first year progress report was published, incorporating the implementation plan for the strategy.

https://www.gov.uk/government/collections/antimicrobial-resistance-amrinformation-and-resources

## ANNEX I: GENERAL GUIDELINES OR NATIONAL CONTROL PROGRAMMES

Links to national control programmes and strategies on AMR in the Member States

- Austria: <u>http://www.bmg.gv.at/home/Schwerpunkte/Krankheiten/Antibiotikaresistenz/NAP</u> <u>AMR Der oesterreichische Nationale Aktionsplan zur Antibiotikaresistenz</u>
- Belgium: http://amcra.be/en/about-amcra
- Czech Republiek: <u>http://www.szu.cz/tema/prevence/narodni-antibioticky-program?lred=1</u> <u>http://www.szu.cz/uploads/AP\_NAP\_2011\_2013.pdf</u>
- Denmark:

http://www.danmap.org/ http://www.foedevarestyrelsen.dk/english/ http://www.foedevarestyrelsen.dk/english/SiteCollectionDocuments/25\_PDF\_word\_ filer%20til%20download/Yellow%20Card%20Initiative.pdf http://www.foedevarestyrelsen.dk/english/Animal/AnimalHealth/Pages/The-Yellow-Card-Initiative-on-Antibiotics.aspx

- France: <u>http://agriculture.gouv.fr/le-plan-de-lutte-contre-l,17134</u>
- Germany:

http://www.bmel.de/DE/Tier/Tiergesundheit/Tierarzneimittel/\_texte/Antibiotika-Dossier.html?nn=539690&notFirst=false&docId=6188468 http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/Med icinalProductsAct-AMG.pdf?\_\_blob=publicationFile

• Ireland:

http://www.hpsc.ie/hpsc/A-Z/MicrobiologyAntimicrobialResistance/StrategyforthecontrolofAntimicrobialResist anceinIrelandSARI/

- Italy: <u>http://www.salute.gov.it/portale/temi/p2\_3\_animali.html</u>
- Netherlands: <u>www.autoriteitdiergeneesmiddelen.nl/english</u>
- Norway: <u>http://www.legemiddelverket.no/Veterinaermedisin/terapianbefalinger/</u> <u>Documents/Terapianbefaling\_bruk%20av%20antibakteriellt%20midler%20til%20pr</u> <u>oduks.pdf</u>
- Spain: http://www.aemps.gob.es/publicaciones/publica/home.htm

# • Sweden:

http://www.sva.se/sv/Antibiotika/Strama-VL/ http://www.socialstyrelsen.se/smittskydd/vardhygienochantibiotikaresistens/nationel lsamverkansfunktion http://www.socialstyrelsen.se/nyheter/2015mars/myndighetsgemensamhandlingsplan skaminskaantibiotikaresistensen

• United Kingdom:

https://www.gov.uk/government/collections/antimicrobial-resistance-amrinformation-and-resources

#### ANNEX 2: EMA/CVMP RECOMMENDATIONS ON RESPONSIBLE USE

The Committee for Medicinal Products for Veterinary Use (CVMP) of the European Medicines Agency has made recommendations on the use of antimicrobials, most of which belong to those classified as critically important antimicrobials, namely quinolones, third and fourth-generation cephalosporins, macrolides and colistin. Recommendations have also been produced on pleuromutilins and gentamicin. The CVMP has also produced recommendations to address the problems related to the use of veterinary medicines and MRSA (meticillin-resistant *Staphylococcus aureus*) and MRSP (meticillin-resistant *Staphylococcus pseudintermedius*) and the risk of antimicrobial resistance transfer from companion animals. All these recommendations are based on the considerations of the CVMP experts on antimicrobials (CVMP Antimicrobials Working Party (AWP), formerly Scientific Advisory Group on Antimicrobials (SAGAM)). In many cases these recommendations have resulted in referrals or in recommendations to be further implemented.

The CVMP reports can be found here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\_content \_000384.jsp&mid=WC0b01ac058002dd37#Antimicrobials and here http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\_listing/docum ent\_listing\_000385.jsp&mid=WC0b01ac058080a585

#### Quinolones

The European Commission launched a referral under Article 35 of Directive 2001/82/EC, regarding all veterinary medicinal products containing quinolones including fluoroquinolones intended for use in food-producing species, on 28 April 2009. The referral aims to ensure that the products identified containing quinolones are indicated only for appropriate conditions, that dosage strategies are set to minimise the likelihood of antimicrobial resistance developing and that appropriate withdrawal periods are fixed to guarantee consumer protection. The Commission converted the final opinion into a Decision on 1 July 2010.

Amendments to be included in the package leaflet of the products concerned were as follows:

# For products containing fluoroquinolones (enrofloxacin, marbofloxacin, danofloxacin and difloxacin):

'Official and local antimicrobial policies should be taken into account when the product is used.'

'Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials.'

'Whenever possible, fluoroquinolones should only be used based on susceptibility testing.'

'Use of the product deviating from the instructions given in the summary of product characteristics (SPC) may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.'

# For products containing quinolones (flumequine, oxolinic acid):

'Official and local antimicrobial policies should be taken into account when the product is used.'

'Whenever possible, quinolones should only be used based on susceptibility testing.'

'Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the quinolones and may decrease the effectiveness of treatment with other (fluoro)quinolones due to the potential for cross resistance.'

Full details of these recommendations can be found in the following documents:

Public statement on the use of (fluoro)quinolones in food-producing animals in the European Union: development of resistance and impact on human and animal health (http://www.ema.europa.eu/docs/en\_GB/document\_library/Public\_statement/2009/10/W C500005152.pdf)

Reflection paper on the use of fluoroquinolones in food-producing animals — Precautions for use in the SPC regarding prudent use guidance (<u>http://www.ema.europa.eu/docs/en\_GB/document\_library/Other/2009/10/WC50000517</u> <u>3.pdf</u>)

## Third and fourth-generation cephalosporins

The European Commission launched a referral under Article 35 of Directive 2001/82/EC, regarding all veterinary medicinal products containing systemically administered (parenteral and oral) third and fourth-generation cephalosporins (ceftiofur and cefquinome) intended for use in food-producing species, on 17 March 2011. The CVMP was requested to give its opinion regarding the inclusion of prudent use advice for these antimicrobials in line with the revised reflection paper on the use of third and fourthgeneration cephalosporins in food-producing animals in the European Union: development resistance and impact on and animal health of human (EMEA/CVMP/SAGAM/81730/2006-Rev.1). It was also asked to address the risk associated with potential misuse in poultry and the need for specific measures, in particular the need for warning sentences in the product information. The Commission converted the final opinion into a Decision on 13 January 2012.

All the references to indications, target species and withdrawal periods for poultry were deleted from the marketing authorisation for those products as cephalosporins are not authorised for use in poultry in the EU. The following phrase is to be included in the SPC of those products: 'Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans.'

The other amendments to be included in the SPC of the products concerned are as follows:

'*Product name (to be completed nationally)'* selects for resistant strains such as bacteria carrying extended spectrum betalactamases (ESBL) and may constitute a risk to human health if these strains disseminate to humans e.g. via food. For this reason, '*product name (to be completed nationally)*' should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly (refers to very acute cases when treatment must be initiated without bacteriological diagnosis), to first-line treatment. Official, national and regional antimicrobial policies should be taken into account when the product is used. Increased use, including use of the product deviating from the instructions given in the SPC, may increase the prevalence of such resistance. Whenever possible, '*product name (to be completed nationally)*' should only be used based on susceptibility testing.'

*Product name (to be completed nationally)'* is intended for treatment of individual animals. Do not use for disease prevention or as a part of herd health programmes. Treatment of groups of animals should be strictly restricted to ongoing disease outbreaks according to the approved conditions of use.'

For products indicated for bovine metritis: 'Do not use as prophylaxis in case of retained placenta.'

The detailed recommendations can be found in the opinion following an Article 35 referral for all veterinary medicinal products containing systemically administered (parenteral and oral) third and fourth- generation cephalosporins intended for use in food-producing species (http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/referrals/Cep halosporins/vet\_referral\_000056.jsp&mid=WC0b01ac05805c5170).

The basis for the CVMP recommendations on the revised reflection paper on the use of third and fourth-generation cephalosporins in food-producing animals in the European Union is: development of resistance and impact on human and animal health (<u>http://www.ema.europa.eu/docs/en\_GB/document\_library/Scientific\_guideline/2009/10/WC500004307.pdf</u>)

#### Macrolides

The CVMP has produced recommendations on the use of macrolides (and lincosamides and streptogramins) as follows:

'Prudent use of antimicrobials should be strongly promoted. It is acknowledged that macrolides are first-line treatment against a number of animal diseases but still there is a need to avoid overuse, for e.g. general prophylaxis where no specific diagnose is evident or where the disease in question would self-cure without antimicrobials.'

'Duration of treatment should be limited to the minimum time required to cure diseases. There might be a need to review certain SPCs to reduce the approved treatment duration if it is found to be unnecessarily long in relation to the severity of the disease.'

'Doses should preferably be selected considering AMR-related risks. For old products where data on dose selection are sparse, doses should anyway be reviewed and if they are obviously too low (e.g. compared to other products containing the same active substance) this should be addressed. In particular, there are often several different doses approved for different indications and thus there is an option to increase doses where relevant without asking for new tolerance or safety data.'

'Indications for use should preferably be restricted to those for which efficacy has been proven and general indications without a solid clinical basis should be avoided. For old products where data are sparse, indications should be reviewed and revised where appropriate to be as accurate as possible. In particular, combination products are of concern as there seem to be products on the market for which the choice of included active components is questionable.'

'The use of combinations in situations where products with a single active substance would be enough unnecessarily increases selection pressure for antibiotic resistance.'

'In addition the document indicates that the CVMP is of the opinion that antimicrobial resistance should not be considered in isolation but a global approach to the problem is needed. Implementation of prudent use principles remains a cornerstone to contain resistance, together with biosecurity and other measures to promote animal health and thereby reduce the need for treatment.'

A referral procedure under Article 35 of Directive 2001/82/EC as amended for veterinary medicinal products containing tylosin to be administered orally via feed or drinking water to pigs was completed on 8 May 2014. The CVMP recommended variations to the terms of the marketing authorisations for the products concerned. As a result, the indication 'Swine dysentery caused by *Brachyspira hyodysenteriae*' was deleted from the SPC and the following special precaution for use added: 'A high rate of in vitro resistance has been demonstrated in European strains of *Brachyspira hyodysenteriae* implying that the product will not be sufficiently efficacious against swine dysentery.' The treatment duration was limited, where applicable, to a period of three weeks.

Full details of these recommendations can be found in the following documents:

Opinion following an Article 35 referral for veterinary medicinal products containing tylosin to be administered orally via feed or the drinking water to pigs (<u>http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/referrals/Veterinary\_medicinal\_products\_containing\_tylosin\_to\_be\_administered\_orally\_via\_feed\_or\_the\_drinking\_water\_to\_pigs/vet\_referral\_000098.jsp&mid=WC0b01ac05805c5170).</u>

Reflection paper on the use of macrolides, lincosamides and streptogramins (MLS) in food-producing animals in the European Union: development of resistance and impact on human and animal health (http://www.ema.europa.eu/docs/en\_GB/document\_library/Scientific\_guideline/2011/11/WC500118230.pdf).

## MRSA

In March 2009 the CVMP published a reflection paper on 'MRSA in food-producing and companion animals in the European Union: epidemiology and control options for human and animal health.' The paper focuses on the epidemiology, ecology and control of MRSA in living food-producing and companion animals, with particular emphasis on the impact of the use of antimicrobial agents in veterinary medicine. The document provides a series of recommendations that are summarised below:

'Adherence to the principles of prudent use remains a key measure to manage risks for spread of MRSA. Special consideration should be given to improving controls related to group and flock medication of food-producing animals and routine perioperative

treatment of companion animals and horses when implementing guidelines on responsible use.'

'Monitoring of the consumption of antimicrobials in the EU is needed to identify and target action towards sources of unnecessary use of antimicrobials. This will also allow for evaluation of the effectiveness of measures taken in this respect.'

'Development of non-antimicrobial control measures should be encouraged.'

'In case of antimicrobial treatment of MRSA infections, the risk of emergence of further resistance in the strain of MRSA infecting the animals should be considered. Use in animals of last-resort medicines for MRSA treatment in humans should be avoided. Any use of such molecules in companion animals and horses should take into account the public health risk involved and should therefore involve discussions with public health practitioners.'

<sup>c</sup>CVMP bases its opinions on authorisation of veterinary medicinal products on an assessment that the benefits of a product outweigh its risks. If the Committee receive applications for authorisation of products containing molecules used as last-resort medicines for MRSA treatment in humans, the CVMP will pay special attention in this assessment to the need to ensure the continued efficacy of such molecules in human medicine.<sup>2</sup>

The EMA/CVMP/SAGAM reflection paper on MRSA in food-producing and companion animals in the European Union: epidemiology and control options for human and animal health can be found here:

(http://www.ema.europa.eu/docs/en\_GB/document\_library/Scientific\_guideline/2009/10/ WC500004311.pdf)

## MRSP

In January 2011 the CVMP published a reflection paper on meticillin-resistant *Staphylococcus pseudintermedius* (MRSP). MRSP constitutes a major new risk to animal health. Although most infections could be controlled without antimicrobials, there are severe cases that might be life-threatening for which only few, if any, effective veterinarian- approved antimicrobials are available for treatment. MRSP itself is not a direct concern for human health, but it causes an indirect risk to humans as treatment of MRSP in MRSA-carrying animals may lead to additional resistances in MRSA, which has zoonotic potential.

The reflection paper recommendations are summarised as follows:

'It would be beneficial to reduced total antimicrobial usage.'

'Unnecessary use of antimicrobials should be avoided.'

'Whenever possible, use of antimicrobials should be substituted by other strategies. In addition to the use of antimicrobials there are other factors, in particular related to hygiene and travel that need to be considered to limit dissemination of MRSP. Appropriate wound management without antimicrobials will be sufficient for many MRSP infections.'

'Adherence to the principles of prudent use remains a key measure to manage risks for spread of MRSP in accordance with internationally agreed guidance. Special considerations should be given to routine perioperative use in companion animals when implementing these guidelines.'

'Development of non-antimicrobial MRSP treatments should be encouraged. Measures like promoting scientific advice should be considered.'

'In cases where no veterinary medicinal product for animals is authorised for the specific MRSP condition, animals might be treated with other medicinal products. These may contain antimicrobial agents that are regarded as critically important in human medicine for use against MRSA. Treatment of dogs and cats with such antimicrobial agents could result in development of additional resistances with subsequent spread to humans.'

'Use of antimicrobials for decolonisation seems to be of limited value and should be avoided.'

'If antimicrobial treatment of a severe infection is necessary, the risk of emergence of further resistance in the strain of MRSP infecting the animals should be managed to avoid subsequent spread of resistance to animals and humans.'

'Use of antimicrobials listed by the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR, 2009) as sole therapy or one of few alternatives to treat MRSA in humans (glycopeptides, streptogramins, glycylcyclines, lipopeptides and oxazolidinones) should be avoided to the extent possible. Treatment of MRSP with products containing any of these substances should be evidence-based and restricted to very specific, carefully selected cases where the disease is life threatening and alternative treatments (including non-antimicrobial) have failed. MRSA carriers and animals in contact with people with confirmed MRSA infection or people at high risk for MRSA infections should not be treated.'

'CVMP bases its opinions on authorisation of veterinary medicinal products on an assessment that the benefits of a product outweigh its risks. If the Committee receives applications for authorisation of products containing molecules used as last-resort medicines for MRSA treatment in humans, the CVMP will pay special attention in the assessment to the need to ensure the continued efficacy of such molecules in human medicine.'

'Surveillance of consumption of antimicrobial agents in dogs and cats (including use of products approved for use in humans) is required to evaluate the effect of different interventions and for further risk analysis.'

The EMA/CVMP/SAGAM reflection paper on MRSP can be found here: <u>http://www.ema.europa.eu/docs/en\_GB/document\_library/Scientific\_guideline/2011/02/</u><u>WC500102017.pdf</u>.

#### Pleuromutilins

In February 2014 the CVMP published a revised reflection paper on pleuromutilins (tiamulin and valnemulin). The recommendations indicate that pleuromutilins are an essential group of antimicrobial agents in veterinary medicine, especially as they are the sole treatment option for enteritis in pigs caused by isolates of *Brachyspira hyodysenteriae* (swine dysentery) resistant to lincosamides and macrolides. The negative

consequences if such a pathogen were to become pleuromutilin resistant would thus be considerable both from an economic and an animal welfare perspective. The following recommendations were made:

'To contain resistance, unnecessary use and also the preventive use of pleuromutilins without applying adequate control programmes should be avoided.'

'Pleuromutilins should only be used for treatment and metaphylaxis of disease. The exception would be use in well-defined eradication programmes for swine dysentery and epizootic rabbit enterocolitis that have been established by the veterinarian in conjunction with the farmer. Such eradication programmes should be restricted in time and include appropriate measures of effectiveness. This should be clearly stated in the SPCs for all products. Approved indications such as prevention of disease other than during eradication programmes should be withdrawn.'

Indications should be worded to clearly express the intended use. General indications (e.g. those that do not include named target pathogens) should be avoided. Enhancement of production (e.g. increase of feed efficiency or growth promotion) is not regarded as an acceptable indication and should be withdrawn.

Duration of treatment should be limited to the time needed to cure diseases. Summaries of Product Characteristics where the approved treatment duration is found to be unnecessarily long should be reviewed.

The EMA/CVMP/AWP recommendations on pleuromutilins can be found here: <a href="http://www.ema.europa.eu/docs/en\_GB/document\_library/Scientific\_guideline/2014/02/WC500161930.pdf">http://www.ema.europa.eu/docs/en\_GB/document\_library/Scientific\_guideline/2014/02/WC500161930.pdf</a>

#### Colistin

Following a request from the European Commission to the European Medicines Agency for advice on the impact on public and animal health of the use of antibiotics in animals, specific advice was produced on colistin. This advice was prepared by the EMA Antimicrobial Advice ad hoc Expert Group (AMEG), endorsed by the CVMP and CHMP (Committee for Medicinal Products for Human Use) and published in July 2013.

The following recommendations were made:

'Colistin should only be used for treatment (cure or metaphylaxis) of disease, and should not be used for prophylactic use.'

'The SPCs of veterinary products containing colistin should be revised to take fully into account responsible use considerations (indications, SPC warnings ...). In the case of products containing colistin in combination with another antimicrobial, a scientific justification for the authorisation of a fixed combination would be required.'

An Article 35 referral procedure under Directive 2001/82/EC as amended was completed in 2010 addressing the posology and withdrawal periods of products containing colistin sulfate at 2 000 000 IU per ml for administration in drinking water. The benefit-risk balance for the colistin products involved was considered positive for gastrointestinal infections caused by non-invasive *E. coli* susceptible to colistin. However, the balance was considered negative for treatment of gastrointestinal infections caused by *Salmonella* spp. in calves, lambs, pigs and poultry.

A further Article 35 referral was completed in 2015 regarding veterinary medicinal products containing colistin to be administered orally. This resulted in modification of the SPC of the products involved; horses were deleted from the target species. Any indication for prophylactic use or production enhancement was deleted. The presence of disease in the herd should be established before metaphylactic treatment. The indications were restricted to enteric infections caused by non-invasive E. coli susceptible to colistin. And the following recommendations were added: 'Do not use colistin as a substitute for good management practices. Colistin is a last-resort drug in human medicine for treatment of infections caused by certain multi-drug resistant bacteria. In order to minimise any potential risk associated with widespread use of colistin, its use should be limited to treatment or treatment and metaphylaxis of diseases, and should not be used for prophylaxis. Whenever possible, colistin should only be used based on susceptibility testing. Use of the product deviating from the instructions given in the SPC may lead to treatment failures and increase the prevalence of bacteria resistant to colistin.' In addition treatment duration was restricted to seven days. The detailed recommendations can be found in the opinion following an Article 35 referral for all veterinary medicinal products administered containing colistin be orally to (http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/referrals/Col istin oral/vet referral 000104.jsp&mid=WC0b01ac05805c5170).

Overall use of colistin in the Member States is currently monitored as part of the ESVAC project. The monitoring system should be improved to provide figures on use per species, production type and weight class.

The European Commission's harmonised monitoring of AMR, which requires all Member States to perform standardised and quality-controlled susceptibility testing of colistin on representative samples of zoonotic and indicator bacteria (*Salmonella* spp. and *E. coli*), is of importance. This monitoring system should be linked to a system where a random selection of all resistant isolates identified are screened for new resistance mechanisms, in particular for emergence of transferrable resistance genes.

Surveillance of target animal pathogens from clinical cases should be implemented to ensure early detection of any change in resistance patterns. There is currently no official surveillance of target animal pathogens; such a system should therefore be implemented.

be The EMA/CVMP/CHMP/AMEG reports colistin found on can here: http://www.ema.europa.eu/docs/en GB/document library/Other/2013/07/WC500146812 .pdf and here: http://www.ema.europa.eu/docs/en GB/document library/Report/2013/07/WC50014681 3.pdf. The information from the second CVMP referral on colistin can be found here: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/referrals/Coli stin oral/vet referral 000104.jsp&mid=WC0b01ac05805c5170

#### Gentamicin

A referral procedure under Article 35 of Directive 2001/82/EC, as amended, for veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to horses was completed on 6 November 2014. The CVMP recommended that the dosing regimen should be optimised to take into account pharmacodynamics and pharmacokinetic characteristics, target animal safety and clinical experience with gentamicin.

The CVMP also recommended variations to the terms of the marketing authorisations for the products concerned, including the following warnings: 'Whenever possible, use of the product should be based on susceptibility testing of the bacteria isolated from the animal.' and 'The dosing regimen must not be exceeded. Use of the product deviating from the instructions given in the SPC increases the risk of nephrotoxicity, and may increase the prevalence of bacteria resistant to gentamicin.'

Full details of those recommendations can be found in the following documents: Opinion (and annexes) following an Article 35 referral for veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to horses (<u>http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/referrals/Gentamicin/vet\_referral\_000103.jsp&mid=WC0b01ac05805c5170</u>)

#### Companion animals

On 15 January 2015 the CVMP published a revised EMA/CVMP/AWP reflection paper on the risk of antimicrobial resistance transfer from companion animals. The paper's recommendations include:

- the use in companion animals of substances regarded as critically important antimicrobials for human medicine should be carefully assessed considering the importance of those substances for public health, and
- possible limitations on the use of human last-resort (life-saving) antimicrobials for treatment of companion animals should be considered.

The reflection paper also proposes that risk assessment guidelines should be developed to address the risk to public health from antimicrobial resistance due to antimicrobial use in companion animals and that a comprehensive approach should be taken to limiting the need for use of antimicrobial agents in companion animals. This includes:

- training veterinary personnel in responsible use of antibiotics;
- improving communication with clients on rational use of antibiotics;
- strengthening infection prevention and control in veterinary hospitals and clinics and hygiene in the home; and
- developing alternative treatment and management strategies, especially for chronic infections.

Thepapercanbefoundhere:http://www.ema.europa.eu/docs/en\_GB/document\_library/Scientific\_guideline/2015/01/WC500181642.pdf

# ANNEX 3: EUROPEAN STAKEHOLDER ASSOCIATIONS

# The Federation of Veterinarians of Europe (FVE)

• The Federation of Veterinarians of Europe (FVE) recently published two leaflets on 'Responsible use of antimicrobials'.

http://www.fve.org/uploads/publications/docs/fve\_antimicrobials\_a3\_hr03.pdf and http://www.fve.org/uploads/publications/docs/fve\_antimicrobials\_a4\_hr02.pdf

- Responsible Use of Medicines in Agriculture Alliance (RUMA) guidelines
  - Pig guidelines: <u>http://www.ruma.org.uk/guidelines/antimicrobials/long/RUMA\_antimicrobials/long/RUMA\_antimicrobial\_long\_pigs\_revised\_final\_Nov\_2013.pdf</u>
  - o Poultry guidelines: http://www.ruma.org.uk/poultry.htm
  - o Cattle guidelines: http://www.ruma.org.uk/cattle.htm
  - Fish guidelines: <u>http://www.ruma.org.uk/fish.htm</u>
  - o Sheep guidelines: <u>http://www.ruma.org.uk/sheep.htm</u>
- Royal Dutch Veterinary Association
  - Prudent use Guideline for Horses (2011) http://wvab.knmvd.nl/wvab/formularia/formularia
  - Prudent use Guideline for Pigs (2012) <u>http://wvab.knmvd.nl/wvab/formularia/formularia</u>

# Federation of European Companion Animal Veterinary Associations (FECAVA):

- FECAVA key recommendations for infection control in veterinary practices <u>http://www.fecava.org/sites/default/files/files/FECAVA%20Key%20recommodat</u> ion%20for%20Hygiene%20and%20Infection%20Control.pdf
- FECAVA advice on responsible use of antimicrobials <u>http://www.fecava.org/sites/default/files/files/FECAVA%20Advice%20on%20Re</u> <u>sponsible%20use%20of%20Antimicrobials.pdf</u>
- FECAVA recommendations for appropriate antimicrobial therapy <u>http://www.fecava.org/sites/default/files/files/FECAVA%20Recommendations%</u> <u>20for%20Appropriate%20Antimicrobial%20Therapy.pdf</u>
- FECAVA advice to companion animal owners on responsible use of antibiotics and infection control <u>http://www.fecava.org/sites/default/files/files/FECAVA%20Advice%20to%20Co</u> <u>mpanion%20Animal%20Owners%20on%20responsible%20use%20of%20Antibi</u> <u>otics(2).pdf</u>

## **European Platform for Responsible Use of Medicines in Animals (EPRUMA):**

• The European Platform for Responsible Use of Medicines in Animals (EPRUMA) is a multi-stakeholder platform linking best practice with animal health and public health. It aims to promote the responsible use of medicines in animals in the EU. <u>http://www.epruma.eu/</u>

# ANNEX 4: INTERNATIONAL ORGANISATIONS

## WORLD HEALTH ORGANISATION (WHO):

- Antimicrobial resistance: http://www.who.int/drugresistance/en/
- Global Action Plan on Antimicrobial Resistance: <u>http://www.who.int/drugresistance/global\_action\_plan/en/</u>
- WHO Global Principles for the Containment of Antimicrobial Resistance in Animals Intended for Food: <u>http://whqlibdoc.who.int/hq/2000/who\_cds\_csr\_aph\_2000.4.pdf</u>
- The evolving threat of antimicrobial resistance Options for action: <u>http://www.who.int/patientsafety/implementation/amr/publication/en/</u>
- WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR): http://www.who.int/foodsafety/areas\_work/antimicrobial-resistance/agisar/en/
- WHO list of Critically Important Antimicrobials (CIA) for human medicine: http://www.who.int/foodsafety/areas\_work/antimicrobial-resistance/cia/en/

# **WORLD HEALTH ORGANISATION. REGIONAL OFFICE FOR EUROPE** (WHO):

• Antimicrobial resistance: <u>http://www.euro.who.int/en/health-topics/disease-prevention/antimicrobial-resistance</u>

# FOOD AND AGRICULTURAL ORGANISATION OF THE UNITED NATIONS (FAO):

- Antimicrobial resistance: http://www.fao.org/antimicrobial-resistance/en/
- Addressing antimicrobial resistance: <u>http://www.fao.org/3/a-as931e.pdf</u>
- Responsible use of antimicrobials in aquaculture: <u>ftp://ftp.fao.org/docrep/fao/009/a0282e/a0282e00.pdf</u>

# **CODEX ALIMENTARIUS:**

• Guidelines for Risk Analysis of Antimicrobial Resistance (CAC/GL 77-2011): http://www.codexalimentarius.org/standards/list-of-standards/  Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005): http://www.codexalimentarius.org/standards/list-of-standards/

# WORLD ORGANISATION FOR ANIMAL HEALTH (OIE):

- Antimicrobial resistance: <u>http://www.oie.int/for-the-media/amr/</u>
- Terrestrial Animal Health Code Section 6: Veterinary public health

Chapter 6.6: Introduction to the recommendations for controlling antimicrobial resistance: http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre antibio introduction.htm

Chapter 6.7: Harmonisation of national antimicrobial resistance surveillance and monitoring programmes: http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre antibio harmonisation.htm

Chapter 6.8: Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals: http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre antibio monitoring.htm

Chapter 6.9: Responsible and prudent use of antimicrobial agents in veterinary medicine: <u>http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre\_antibio\_use.htm</u>

Chapter 6.10:Risk analysis for antimicrobial resistance arising from the use of antimicrobials in animals: <u>http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre\_antibio\_risk\_ass.htm</u>

• Aquatic Animal Health Code Section 6. Recommendations for antimicrobial use in aquatic animals: <u>http://www.oie.int/index.php?id=171&L=0&htmfile=titre\_1.6.htm</u>

# WORLD VETERINARY ASSOCIATION (WVA):

Position on Responsible Use of Antimicrobials: http://www.worldvet.org/library.php?item=62&cat=1&view=item