Objective 4: Optimize the use of antimicrobial medicines in human and animal health

Global

Codex Alimentarius Commission

The Codex Alimentarius Commission (CAC) was established by FAO and WHO in 1963 to develop international food standards, guidelines and codes of practice that contribute to the safety, quality and fairness of the international food trade.

- The Codex Code of Practice to Minimize and Contain Antimicrobial Resistance provides additional guidance for the responsible and prudent use of antimicrobials in food-producing animals. Its objectives are to minimize the potential adverse impact on public health resulting from the use of antimicrobial agents in food-producing animals, in particular the development of antimicrobial resistance. The document defines the respective responsibilities of authorities and groups involved in the authorization, production, control, distribution and use of veterinary antimicrobials such as the national regulatory authorities, the veterinary pharmaceutical industry, veterinarians, distributors and producers of food-producing animals.

  Code of practice to minimize and contain antimicrobial resistance (CAC/RCP 61-2005)

- The Codex Committee on Residues of Veterinary Drugs in Foods was formed (a) to determine priorities for the consideration of residues of veterinary drugs in foods; (b) to recommend maximum levels of such substances; (c) to develop codes of practice as may be required; and, (d) to consider methods of sampling and analysis for the determination of veterinary drug residues in foods.

  http://www.codexalimentarius.org/committees-and-task-forces/en/?provide=committeeDetail&idList=6

Essential Medicines lists

Lists of essential and critical medicines are published for both human and veterinary medicine:

- WHO Model List of Essential Medicines 2013
  http://www.who.int/medicines/services/essmedicines_def/en/

- WHO List of Critically Important Antimicrobials for Human Medicine
  http://www.who.int/foodborne_disease/resistance/cia/en/

- OIE List of antimicrobial agents of veterinary importance
  http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/OIE_list_antimicrobials.pdf

GeneXpert

GeneXpert® is a state-of-the-art test machines for tuberculosis (TB) that shorten the time to diagnose drug-resistant strains of TB from weeks to only a few hours. By allowing health workers to quickly diagnose drug resistant TB and put patients immediately on treatment, GeneXpert® devices can help halt the spread of this deadly form of the airborne disease. GeneXpert® machines detect resistance to rifampicin, one of the most commonly used first-line antibiotics for the treatment of TB and can also detect TB in patients that are co-infected with HIV.


Global Respiratory Infection

GRIP has produced a range of downloadable materials for prescribers, patients and pharmacies and is committed to:
### Partnership (GRIP)
- Consistent, sustainable evidence-based advocacy and intervention for rational antibiotic use and antimicrobial stewardship
- Formulating a framework for non-antibiotic treatment options for respiratory tract infections, such as sore throat, common colds, influenza and cough
- Facilitating multi-stakeholder commitment to antibiotic stewardship and rational antibiotic use.


### Green Light Committee (GLC) Initiative
The WHO and the Stop TB Partnership currently support countries to manage multidrug-resistant TB (MDR-TB) through the Green Light Committee (GLC) Initiative. Established in 2000, the GLC Initiative is the mechanism that enables access to affordable, high-quality, second-line anti-TB drugs for the treatment of multi-drug resistant TB. The GLC Initiative is comprised of the GLC Committee, the WHO/GLC Secretariat, the Global Drug Facility, and partners who provide financial and technical assistance.


### International Pharmaceutical Federation (FIP)
FIP is the global federation of national associations of pharmacists and pharmaceutical scientists. Through its 132 Member Organisations, FIP represents and serves more than 3 million practitioners and scientists around the world. In its 2008 *Statement of Policy on Control of Antimicrobial Medicines Resistance*, FIP urges pharmacists to:
- Give proper counselling advice and provide appropriate written information when dispensing antimicrobials.
- Encourage patients to take the full prescribed regimen and, if not possible, to appropriately dispose of any unused antimicrobial medicines.
- Work with prescribers to order sufficient doses to complete or continue a course of therapy.
- Recommend therapies other than antimicrobials for minor ailments.
- Provide updated medicine information on antimicrobials to prescribers as well as health-care professionals who administer or otherwise influence the use of medicines.
- Effectively monitor the supply and use of antimicrobials by their patients.

[www.fip.org](http://www.fip.org)

### Ministers Summit on ‘The benefits of responsible use of medicines - Setting policies for better and cost-effective healthcare’
The Netherlands hosted a Ministers Summit in 2012 on the theme of ‘The Benefits of the Responsible Use of Medicines - setting policies for better, cost-effective healthcare’ with the aim:
- To explore and identify solutions to improve outcomes for patients in the use of medicines
- To support sustainable and cost-effective healthcare around the world.

During the Summit the importance for every country to better manage the use of antibiotics was stressed. Examples of strategies and interventions to engage and educate various stakeholders were provided in the final report: *The benefits of responsible use of medicines - Setting policies for better and cost-effective healthcare*. Low-, middle- and high-income countries from all six World Health Organization (WHO) regions participated in the Summit.

<table>
<thead>
<tr>
<th>Organization</th>
<th>Description</th>
</tr>
</thead>
</table>
| VICH Guidelines | VICH is a trilateral (EU-Japan-USA) programme aimed at harmonising the technical requirements for data necessary for the marketing authorisation (also called ‘registration’) of a veterinary medicinal product. There are two guidelines in the area of antimicrobial safety:  
- Guidance on Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-producing Animals with Respect to Antimicrobial Resistance  
- Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food.  
http://www.vichsec.org/what-is-the-role-of-vich.html  
| World Health Organization (WHO) | The World Medicines Situation 2011 brings together in one place new data on key topics relating to the pharmaceutical sector, including Pharmaceutical Consumption, Rational Use of Medicines, and Good Governance for the Pharmaceutical Sector.  
http://www.who.int/medicines/areas/policy/world_medicines_situation/en/ |
| World Organisation for Animal Health (OIE) | The responsible and prudent use of antimicrobial medicines in animal health has been covered in a number of OIE documents, events and activities:  
- The OIE Global Conference on the Responsible and Prudent Use of Antimicrobial Agents for Animals, International Solidarity to fight against Antimicrobial Resistance, in 2013, was supported by the WHO and FAO and attracted more than 300 participants from over 100 countries. Conference recommendations are at: (http://www.oie.int/eng/A_AMR2013/Recommendations.htm).  
- The OIE has developed a tool to evaluate and strengthen Veterinary Services and their capacity to implement International Standards: the OIE Performance of Veterinary Services PVS Pathway http://www.oie.int/support-to-oie-members/pvs-pathway/  
- Regional Seminars for OIE National Focal Points for Veterinary Products are held regularly and cover the quality of antimicrobial agents, prudent use and antimicrobial resistance.  
- The OIE has established Twinning Programmes for Veterinary Education and Veterinary Statutory Bodies. http://www.oie.int/Veterinary_Education_Twinning_Guide.pdf  
WVA has worked with WHO, FAO and OIE on AMR and the use of antimicrobials:  
- World Veterinary Summit in Cape Town 2011 on ‘Lessons Learned and Future Approaches on the Use of Antimicrobials’. |
Regional

Africa

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>GARP (Kenya)</td>
<td>GARP-Kenya leadership, through the Infection Prevention and Control Network-Kenya (IPNET-Kenya) organized the first meeting on antibiotic stewardship in Kenya and the region in November 2013.</td>
</tr>
</tbody>
</table>

Asia

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asia-Pacific Economic Co-operation (APEC)</td>
<td>The APEC project <em>Capacity Building in HIV and Clinical Infectious Diseases for APEC Economies</em> includes training in Antimicrobial Stewardship Program (ASP), Infection Control and Outpatient Parenteral Antibiotic Therapy (OPAT).</td>
</tr>
</tbody>
</table>

Europe

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to Medicines Index</td>
<td>The Access to Medicine Index independently ranks pharmaceutical companies’ efforts to improve access to medicine in developing countries. The Index has been published every two years since 2008.</td>
</tr>
</tbody>
</table>

Antibiotic Prescribing and Resistance in European Children (ARPEC) | The general objective of the project (2010-2013) was to produce data that could help improve the quality of antibiotic prescribing for children in Europe and reduce the prevalence of antimicrobial resistance in bacterial infections in children. The *ARPEC Educational Tool* is one of the specific deliverables of the ARPEC project whose overall aim is the development of a web-based educational training programme for paediatricians on the principles of prudent antibiotic prescribing containing country-specific prescribing and resistance data. Module 1 is on ‘The basics of rational and prudent antibiotic use for common childhood infections in ambulatory care’. | 

Antimicrobial Advice ad hoc Expert Group (AMEG) | AMEG was set up to answer four questions posed by the European Commission in April 2013 when it requested scientific advice from the EMA on the impact of the use of antibiotics in animals on public health and animal health and measures to manage the possible risk to humans. The request was structured in the form of four questions: |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• The use in animals of ‘old’ antibiotics or new antibiotics belonging to ‘old’ classes of antibiotics that have been re-introduced or newly used to treat multidrug-resistant infections</td>
</tr>
<tr>
<td></td>
<td>• The merits or otherwise of classifying antimicrobials considered critically important for humans into different categories with respect to</td>
</tr>
</tbody>
</table>
their recommended use in animals;

- The potential impact of authorising new antimicrobials or classes of antimicrobials, for use in animals on the treatment of resistant bacteria in humans;
- Risk mitigation measures for antimicrobials that are already authorised for use in veterinary medicine and are considered as critically important for humans.


| Antimicrobial resistance and causes of non-prudent use of antibiotics in human medicine (ARNA) | The ARNA project aims to contribute to a more prudent use of antibiotics in human medicine in Europe, with a specific focus on the use of non-prescribed antibiotics. The overall aim is to assess the non-prudent use of antibiotics in the European Union (EU) and to encourage policies that lead to a more prudent use of antibiotics. More specifically, the project aims to:
- Identify key factors that drive the sales and non-prudent use of antibiotics in human medicine obtained without prescription
- Assess the level of enforcement of legal prescriptions of antimicrobial agents in the EU
- Document good practices aimed at strengthening a more prudent use of antibiotics
- Develop policy options for a more prudent use of antibiotics.
The project is a collaboration between NIVEL, University of Antwerp and TNS-NIPO, for two years from July 2014. [http://www.nivel.nl/en/arna](http://www.nivel.nl/en/arna) |
| Ban on antibiotics as animal growth promoters | An EU-wide ban on the use of antibiotics as growth promoters in animal feed came into effect on January 1, 2006. The last four antibiotics which had been permitted as feed additives to help fatten livestock were no longer allowed to be marketed or used from this date. The ban was the final step in the phasing out of antibiotics used for non-medicinal purposes. [http://europa.eu/rapid/press-release_IP-05-1687_en.htm](http://europa.eu/rapid/press-release_IP-05-1687_en.htm) |
| European Committee on Antimicrobial Susceptibility Testing (EUCAST) | EUCAST is a standing committee jointly organized by the European Society of Clinical Microbiology and Infectious Diseases (ESCMID), ECDC and European national breakpoint committees. EUCAST deals with breakpoints and technical aspects of phenotypic in vitro antimicrobial susceptibility testing. Breakpoints for new agents are set as part of the licensing process for new agents through EMA. EUCAST has also done a lot of work developing ECOFF (Epidemiological cut-off values) and promoting the concept. [http://www.eucast.org/](http://www.eucast.org/) |
| European Platform for the Responsible Use of Medicines in Animals (EPRUMA) | EPRUMA is a multi-stakeholder platform linking best practice with animal health and public health. It aims to ensure best practice through responsible use of medicines in the prevention and control of animal diseases. Established in 2005, it works to promote the responsible use of medicines in animals in the EU in order to maintain efficacy and both prevent and minimise adverse reactions. Members include veterinarians; farmers; manufacturers of animal medicines and diagnostics; feed manufacturers; professionals working in animal health and sanitary security; professionals working in sustainable agriculture; pharmacists. Its 2008 "Best practice framework for the use of antimicrobials in food-producing animals" is available in 12 languages. [http://www.epruma.eu/about/about-epruma.html](http://www.epruma.eu/about/about-epruma.html) [http://www.epruma.eu/publications/all-publications/section/1/section.html?filter_category=0&filter_order=a.created&start=10](http://www.epruma.eu/publications/all-publications/section/1/section.html?filter_category=0&filter_order=a.created&start=10) |
### Genomics to combat Resistance against Antibiotics in Community acquired low respiratory tract infections in Europe (GRACE)

The GRACE project focused on community-acquired lower respiratory tract infections (CA-LRTI). The overall objective of GRACE was to combat antimicrobial resistance through integrating centres of research excellence and exploiting genomics in the investigation of CA-LRTI. Microbial and human genomics were integrated with health sciences research consisting of clinical observational and intervention studies, health economics and health education to change practice in managing CA-LRTI. 

www.grace-lrti.org

### Guidance on perioperative antibiotic prophylaxis

In the area of appropriate use of antibiotics a systematic review and evidence-based guidance to improve the compliance of healthcare professionals with appropriate administration, timing, dosage and duration of perioperative antibiotic prophylaxis for the prevention of surgical site infections has been published. 

*Systematic review and evidence-based guidance on perioperative antibiotic prophylaxis.*


### Guidelines for prudent use of antimicrobial agents in animals

The EC will publish by the end of 2014 *Guidelines for prudent use of antimicrobials in veterinary medicine*; this document will include an annex with practical examples of national strategies in the EU Member States to combat antimicrobial resistance in the veterinary sector.

http://ec.europa.eu/health/files/committee/73meeting/pharm666_commission_s_reply_to_consultation.pdf

### Horizon 2020 Innovation Prizes

Horizon 2020 has introduced innovation prizes (‘inducement prizes’) as an instrument to deliver breakthrough solutions to problems of societal interest in Europe. The next contest for €1 million of prize money opens at the beginning of 2015 and the challenge is: Reducing the Mis-use of Antibiotics. Upper respiratory tract infections are a major reason for the prescription of antibiotics; this Prize will reward a rapid test that can identify at the point of care patients with upper respiratory tract infections that can be managed safely without antibiotics.


### Legislation and recommendation on veterinary medicines

To strengthen the regulatory framework on veterinary medicines and on medicated feed:


- To address Antimicrobial Resistance related to the use of veterinary medicinal products: Revision of the Veterinary Medicines Legislation. Commission proposal in 2014
- To address Antimicrobial Resistance related to the use of medicated feed: set harmonised limits for residues for veterinary medicines in non-target animal feed related to the production of medicated feed and possible other actions. Commission proposal in 2014.
- To verify on-the-spot that Member States meet all of their obligations in respect to the existing and revised regulatory framework on veterinary medicines and medicated feedstuffs: Audit by the Food and Veterinary Office Health Protection and Feed Hygiene teams.

To introduce recommendations for prudent use in veterinary medicine, including follow-up reports:


- *Use existing legal tools to the utmost to ensure prudent use of antimicrobials in the veterinary sector*  
- Scientific recommendations of the Committee for Medicinal Products for Veterinary Use (CVMP) on the need for further referrals of
critically important antimicrobials.  

| **Prudent use of antimicrobial agents in human medicine** | **Alliance to Save Our Antibiotics (ASOA)**  
ASOA is an alliance of health, medical, environmental and animal welfare groups working to stop the over-use of antibiotics in livestock farming. It was founded by the Soil Association, Compassion in World Farming, and Sustain in 2009. It has campaigned to reduce overall antibiotic use on EU farms by 50% by 2015  
http://www.soilassociation.org/animalwelfare/antibiotics/alliancetosaveourantibiotics |
| **Appropriateness of prescribing antibiotics in primary healthcare in Europe with respect to antibiotic resistance (APRES)** | **APRES investigated the appropriateness of prescribing antibiotics in primary health care. Based on the gained insights, it set out to develop guidelines for prescription behaviour of antibiotics throughout Europe. The multicountry collaboration started in October 2009 and ran for 4 years.**  
http://www.nivel.nl/en/apres  
| **Council of European Dentists (CED).** | **The CED’s Task Force on Antibiotics in Dentistry is responsible for preparing positions and planning activities related to the use of antibiotics in dentistry and specifically to antimicrobial resistance. In November 2014, the CED together with other European health professionals developed recommendations to raise awareness among dentists, doctors and veterinarians on the prudent and responsible use of antibiotics.**  
http://www.eudental.eu/about.html |
| **European Association of Hospital Pharmacists (EAHP)’s 7 ‘rights’** | **EAHP’s 34 member countries passed a policy statement on antimicrobial resistance at its 2014 General Assembly. This statement outlines the need for action to ensure: improved antimicrobial stewardship; an improved research environment for new antimicrobial agents; and improvement in the prudent use of antibiotics in other sectors, such as the veterinary sector. It calls for the hospital pharmacist to be embedded in the heart of national strategic responses to the AMR crisis. The policy statement mandates EAHP to raise awareness and conduct campaign and advocacy activity in line with the statement.**  
| **HAPPY AUDIT** | **HAPPY AUDIT was a project on respiratory tract infections in general practice supported by the European Union. The objective of the project** |
was to improve the quality of diagnostic procedures and treatment of respiratory tract infections in order to ensure that only the right patients received the necessary antibiotics. Its aim was to reduce the total antibiotic prescribing rate in order to avoid development of resistance. A total of 618 doctors from Denmark, Sweden, Lithuania, Russia, Spain and Argentina participated in the project.

http://www.happyaudit.org/

Nordic Health Research and Innovation Networks (NRI-Networks)  
NRI-Networks (or NRI) is an independent, non-profit organisation working to promote health research and innovation in the Nordic region. NRI is based on partnership where the partners are university hospitals, universities and other research organisations, the pharmaceutical industry, the medical technical industry, governmental bodies and patient organisations. Proposal 1 of a June 2014 NRI report on Future Nordic Cooperation on Health was on Antibiotic resistance and stated: ‘Nordic countries ... must set up their own targets to rapidly – in the next 5 years – reduce consumption of antibiotics to the lowest European level, which is currently that of the Netherlands.’

http://nordicnetworks.org/about-nri/  
http://nordicnetworks.org/news/2014/06/20/the-future-nordic-co-operation-on-health/

National

Australia

Antimicrobial stewardship  
- Antimicrobial stewardship is one of the criterion of National Safety and Quality Health Service (NSQHS) Standard 3: Preventing and Controlling Healthcare Associated Infections. The standard aims to ensure appropriate prescribing of antimicrobials by requiring the implementation of antimicrobial stewardship programs to influence prescribing and use of antimicrobials.


- Antimicrobial Stewardship in Australian Hospitals has been produced to assist hospitals develop and implement antimicrobial stewardship (AMS) programs.


- Importance Ratings and Summary of Antibacterial Uses in Humans in Australia (the ‘Antibacterial Importance Ratings’) provides guidance to clinicians and the pharmaceutical industry about the importance of antibacterial agents available for human use, and on the current ways in which antibacterials are used in humans in Australia. Link available at:


- The Government has also utilised the Pharmaceutical Benefits Scheme (PBS) as a mechanism to ensure that the approvals for antibiotics subsidised under this scheme encourage judicious and appropriate use.


Therapeutic Guidelines:  Therapeutic Guidelines: Antibiotic is produced by Therapeutic Guidelines Limited, an independent not-for-profit organisation that aims to

**Australian Veterinary Association (AVA)**


**China**

In 2011 the Chinese Ministry of Health launched a special campaign to promote the rational use of antimicrobials in healthcare settings. This mainly consisted of establishing mandatory management strategies, such as target setting, taskforce organization, and the development of audit and inspection systems. The Ministry held several national medical education programs each year and conducted twice yearly inspections. [http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001556](http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001556)

**Sino-Swedish Bilateral Cooperation on Management of Antibiotic Resistance**

A cooperation framework was drafted in 2010, which later formed the basis of the Plan of Action (for the period 2011-2014). Among the five sub-projects, which were all successful, were:

- Antibiotics in education for sustainable development
- Comparative study on antibiotic prescribing in Sweden and China
- Investigation among medical facilities in China and Sweden on the current situation on bacterial drug-resistance and the rational use of antibiotics.


**Denmark**

- In order to reverse the trend of the constantly increasing (therapeutic) antibiotic consumption in the pig production and the risk posed by increasing antibiotic resistance, the Danish Veterinary and Food Administration (DVFA) established the yellow card initiative in 2010. The initiative operates on three levels: yellow card, increased supervision, and red card. The yellow card initiative is designed to target the highest consumers of antibiotics in the pig production. The goal was to achieve a 10% reduction on 2009 consumption levels as measured in kg by 2013.
<table>
<thead>
<tr>
<th>Country</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>France</strong></td>
<td>Guidelines on Antibiotic therapy and prevention of bacterial resistance in healthcare organisations</td>
</tr>
</tbody>
</table>
| | Haute Autorité de Santé has published guidelines to ensure proper use of antibiotics, and in particular to facilitate the introduction by healthcare organisations of the most effective antibiotic strategies that will prevent the emergence of bacterial resistance. They cover:  
| | • Prescription of antibiotics  
| | • The role of hospital staff in the proper use of antibiotics  
| | • Information and training. |
| **Germany** | National legislation |
| | • [Manual on the Oral administration of veterinary medicines in the livestock sector through feed or drinking water](http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/Leitfaden-Orale-Medikation.pdf?__blob=publicationFile)  
| | • [Guidelines for the prudent use of veterinary antimicrobial drugs](http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/Antibiotikaleitlinien.pdf?__blob=publicationFile) (revised 2010)  
| | • [Systematic recording of antibiotics used in animal husbandry](http://www.bmel.de/SharedDocs/Downloads/EN/Agriculture/AnimalProtection/Antibiotikaleitlinien.pdf?__blob=publicationFile) (introduced 2014): Amendment to the Drug Act establishes a new system for the nationwide minimization of the use of antibiotics in animal husbandry. From July 2014, farms keeping cattle, pigs, chickens and turkeys for fattening purposes must report to the competent authority every six months on what antibiotics they have (therapeutically) administered to which animals in this period and in what quantities. If a farm’s individual index exceeds the federal average, the animal keepers and veterinarians will have to jointly identify the causes and take steps to curb antibiotic use. |
| **India** | Chennai Declaration |
| | Since March 2014, under the Chennai Declaration national five year plan to tackle antimicrobial resistance, 24 antibiotics and 11 anti-tuberculosis drugs can no longer be dispensed without a prescription and pharmacies have to retain details of the prescription in a register for three years. The target is for 90% of antibiotics to be on the restricted list by the end of five years. |
| | [http://www.ijmm.org/article.asp?issn=0255-0857;year=2014;volume=32;issue=3;spage=221;epage=228;aulast=Team](http://www.ijmm.org/article.asp?issn=0255-0857;year=2014;volume=32;issue=3;spage=221;epage=228;aulast=Team)  
| | [http://www.ijmm.org/article.asp?issn=0255-0857;year%3D2014;volume%3D32;issue%3D1;spage%3D1;epage%3D2;aulast%3DGhafur](http://www.ijmm.org/article.asp?issn=0255-0857;year%3D2014;volume%3D32;issue%3D1;spage%3D1;epage%3D2;aulast%3DGhafur) |
| **Ireland** | Start Smart, Then Focus’ and guidelines |
| | • ‘Care bundle’ on Antibiotics for hospital prescribers - ‘Start Smart, Then Focus’. |
| | [http://www.hpsc.ie/A-Z/MicrobiologyAntimicrobialResistance/CareBundles/](http://www.hpsc.ie/A-Z/MicrobiologyAntimicrobialResistance/CareBundles/) |
### Guidelines for Antimicrobial Prescribing In Primary Care In Ireland

[www.antibioticprescribing.ie](http://www.antibioticprescribing.ie)

### Guidelines for the Prevention and Control of Multi-drug resistant organisms (MDRO) excluding MRSA in the healthcare setting


---

### Japan

**Japanese Ministry of Agriculture, Forestry and Fisheries (JMAFF)**

- Veterinary medical products (VMPs) including antimicrobial products used for therapeutic purposes are regulated by the Pharmaceutical Affairs Law. These VMPs cannot be used without diagnosis and instruction by a veterinarian. The distribution and use of VMPs, including veterinary antimicrobial products, is routinely inspected by the regulatory authority (MAFF).
- Feed additives (FAs), which include antimicrobial products used for growth promotion, are regulated by the Law Concerning Safety Assurance and Quality Improvement of Feed. Compared with the antimicrobial VMPs, FAs are used at lower concentrations and for longer periods. Antimicrobial growth promoters in the animals cannot be used for SEVEN days preceding slaughter for human consumption.


### Kenya

**National Medicines and Therapeutic Committee**

The third and current National Medicines and Therapeutic Committee was appointed in April 2014. It is anchored in the Kenya National Pharmaceutical Policy (KNPP) of 2012 and the draft Kenya Health Sector Strategic Plan of 2012. It is anticipated that the revitalized multidisciplinary Committee, by executing its mandate across the various areas under its scope, will have a big impact in improving use of medicines and other health products in the country.


### Netherlands

**Veterinary Medicines Authority**

- The Netherlands Veterinary Medicines Authority (SDa) is an independent agency established in 2010 to promote responsible drug use in Dutch animal husbandries in general and especially usage of antibiotics.
- In 2008-2011 the Netherlands drafted a policy for a substantial reduction and a more responsible (therapeutic) use of antibiotics in the livestock industry. By 2012 the sales of veterinary antimicrobials had already dropped by 50%, so the target set for 2013 was achieved one year earlier. Moreover, the sales of third and fourth generation cephalosporins had dropped by more than 90%.
- Since 2011, the SDa has monitored antibiotic use at Dutch livestock farms by means of benchmark indicators. In 2014, the SDa published ‘The Veterinary Benchmark Indicator (VBI): towards a transparent and responsible prescribing pattern of antibiotics in veterinary practice’. This indicator describes prescription patterns of veterinarians and identifies those whose patterns exceed defined thresholds.
### Norway

**Norwegian Food Safety Authority**

In Norway, the introduction of effective vaccines in farmed salmon and trout in 1987 and improved health management reduced the annual use of antimicrobials in farmed fish by 98% between 1987 and 2004, while salmon and trout production increased tenfold over the period.


### Senegal

**Rapid diagnostic test for malaria**

In Senegal, the Government prioritized accurate diagnosis by introducing RDTs as the first-choice diagnostic for malaria-suspected patients. As a result, presumptive treatment based on clinical symptoms decreased and antimalarial artemisinin combination therapy medicines correctly targeted patients with confirmed malaria.


### Sweden

**Treatment recommendations**

- For the treatment of infections in outpatient care, national recommendations are published by the Swedish Medical Products Agency. One objective has been to define more clearly when the use of antibiotics is indicated – and when it is not.
- For the management of infections in hospital care, there are national, evidence-based care programmes developed by Infektionsläkarföreningen (the Swedish Society of Infectious Diseases).
- Strama groups and pharmaceutical committees are key players through their systematic work to implement treatment recommendations into the healthcare system.


**Ban on antimicrobial growth promoters**

Sweden banned the use of antibiotics for growth promotion in animals in 1986. The ban was initiated by Swedish farmers.


### Thailand

**National Drug Policy on Rational Use of Medicine**

The 2011 National Drug Policy on Rational Use of Medicine and AMR Containment comprises national strategies for the containment of antimicrobial resistance, as well as other policy movements.

[http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3524958/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3524958/)

Government actions to influence the use of antibiotics include:

- Reclassification of critically important antibiotics from non-prescription drugs to prescription drugs
- Prohibition of direct-to-consumer advertising of antimicrobials
- Policies to promote rational use of antibiotics and improve infection control.

[http://www.fhi.no/dokumenter/be0137d708.pdf](http://www.fhi.no/dokumenter/be0137d708.pdf)
### Antibiotics Smart Use (ASU)

The Antibiotics Smart Use (ASU) programme was introduced in Thailand as a model to promote the rational use of medicines, starting with antibiotics. The programme’s first phase consisted of assessing interventions intended to change prescribing practices; the second phase examined the feasibility of programme scale-up. The third phase centred on sustainability. To change antibiotic prescription practices, multifaceted interventions at the individual and organizational levels were implemented; to maintain behaviour change and scale up the programme, interventions at the network and policy levels were used.

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3524958/
http://www.who.int/bulletin/volumes/90/12/12-105445/en/

### Turkey

**Rational Drug Use National Action plan**

The Rational Drug Use National Action plan (2013–2017) includes quantitative targets to reduce antibiotic use.

http://www.euro.who.int/__data/assets/pdf_file/0006/246471/Lancet-article-Antibiotic-use-in-eastern-Europe-a-cross-national.pdf?ua=1

### United Kingdom

**Antimicrobial Prescribing for General Dental Practitioners**

The Faculty of General Dental Practice (UK) was formed in 1992 and is based at The Royal College of Surgeons of England (RCSEng). It helps dental professionals working in primary care ('high street') dental practices to improve the standard of care that they deliver to their patients. *Antimicrobial Prescribing for General Dental Practitioners* provides simple and practical guidance on when to prescribe antimicrobials, what to prescribe, in what dose and for how long.

http://www.fgdp.org.uk/content/publications/antimicrobial-prescribing-for-general-dental-pract.ashx

**8-point plan for the responsible use of antimicrobials in veterinary practice**

The British Veterinary Association (BVA)'s 8-point plan for the responsible use of antimicrobials in veterinary practice, which is outlined in an easy-to-f0llow poster, ranges from reducing the need for antimicrobials in the first place and avoiding inappropriate use to selecting the correct antimicrobials to use, keeping accurate records and reporting suspected treatment failures to the Veterinary Medicines Directorate (VMD).


**Advertising restrictions for antimicrobials**

- It is an offence under the Veterinary Medicines Regulations for a product available on prescription to be advertised to the public. Advertising of all antimicrobial products authorised in the UK is restricted to veterinary surgeons, veterinary nurses and pharmacists. [https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/364405/PCDOCS-_406736VMD_VMGN_004_A_-_Controls_on_Advertising.PDF](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/364405/PCDOCS-_406736VMD_VMGN_004_A_-_Controls_on_Advertising.PDF)
- Advertising of prescription only human medicines (such as antibiotics) to the public is prohibited.

**Antimicrobial prescribing and stewardship competencies**

The *Antimicrobial prescribing and stewardship competencies* aim to improve the quality of antimicrobial treatment and stewardship. They can be used by any independent prescriber to help develop their prescribing practice at any point in their professional development in relation to prescribing antimicrobials.

### British Dental Association (BDA)

Dentists are responsible for approximately 10% of all antibiotic prescriptions in the UK and evidence suggests that many patients could be treated more appropriately without antibiotics. The BDA is working to present recommendations on how dentistry can contribute to the fight against AMR antibiotic use for publication at its Annual Conference in May 2015, based on its expert summit in November 2014.


### Guidance to optimize prescribing in animal health

- The British Veterinary Association (BVA), the British Small Animal Veterinary Association (BSAVA), and the British Equine Veterinary Association (BEVA) have all published information for prescribers and animal keepers/owners to guide prescribing and use of antimicrobials in veterinary practice.
- BEVA is also calling on its members to introduce clinical audit into responsible antimicrobial use and has created a flexible framework allowing veterinary surgeons to undertake effective clinical audit without significantly impacting on working practices.

http://www.bva.co.uk/News-campaigns-and-policies/Policies/Medicines/Antimicrobials/
http://www.bva.co.uk/You-and-your-vet/BVA-advice-leaflets/
http://beva.org.uk/useful-info/Vets/Guidance/AMR

### Initiatives to optimize prescribing in human health in primary care

- The *Treat Antibiotics Responsibly, Guidance and Education Tool (TARGET)* Antibiotics toolkit is a freely available resource for clinicians, their patients and commissioners to promote safe, effective, appropriate and responsible antibiotic prescribing. The tools can be used by all primary care staff.
- The *Scottish Reduction in Antibiotic Prescribing (ScRAP) Programme* is an educational toolkit to help prescribers to reduce unnecessary prescribing of antibiotics.

### Initiatives to optimize prescribing in human health in secondary care

- *Antimicrobial stewardship: Start smart - then focus*, Guidance for antimicrobial stewardship in hospitals (England), aims to help reduce inappropriate prescribing and optimise antibiotic use.
  https://www.gov.uk/government/publications/antimicrobial-stewardship-start-smart-then-focus
- *Antimicrobial stewardship: an evidence-based, antimicrobial self-assessment toolkit (ASAT)* for acute hospitals offers a checklist for hospitals to self-assess their organizations' levels of antimicrobial stewardship.
  http://www1.imperial.ac.uk/resources/F40CE444-9A71-4D5D-B985-1A90D3CE44F/9cookeetaljantichem.pdf
- The *Scottish Antimicrobial Prescribing Group (SAPG)*'s primary objective is to co-ordinate and deliver a national framework for antimicrobial stewardship to enhance the quality of antimicrobial prescribing and management.
  http://www.scottishmedicines.org.uk/SAPG/SAPG_Reports

### Responsible Use of Medicines in Agriculture (RUMA)

The Responsible Use of Medicines in Agriculture Alliance (RUMA) was set up in 1997 with the aim of promoting responsible use of all medicines in agriculture. It involves organizations from across the food chain including veterinary bodies, farming organisations, the veterinary medicines industry and retailers. One of the ways that RUMA promotes responsible use is by providing free guidelines for...
farmers and vets. RUMA’s responsible use guidelines stress the need for good farm management and disease prevention strategies to minimise the risk of disease and the need to use medicines and then encourage the proper treatment of animals that become ill. RUMA believes antibiotics can be used responsibly in animal medicine to prevent disease and suffering but does not support the routine preventive use of antibiotics where such disease challenge can be prevented by better husbandry and farm management.


| Royal Pharmaceutical Society (RPS) | The RPS has made a commitment to tackle AMR in *New Medicines, Better Medicines, Better Use of Medicines – A Guide to the Science Underpinning Pharmaceutical Practice* (May 2014). Recommendations include:
|                                 |   • Educate the public and patients on the use of antimicrobials and their place in therapy
|                                 |   • Encourage further development of antimicrobial stewardship by healthcare professionals to maintain the effectiveness of current and any future antimicrobials.

| Veterinary antimicrobial surveillance data | The annual Veterinary Antibiotic Resistance and Sales Surveillance report presents antimicrobial sales data for products sold for use in animals and antimicrobial resistance trends in both veterinary pathogens and zoonotic organisms. It is anticipated that veterinarians and farmers will be able to use the report when prescribing antibiotics or developing health plans.

| United Republic of Tanzania | Accredited drug dispensing outlet (ADDO) program | Public-private partnership in Tanzania launched the accredited drug dispensing outlet (ADDO) program to improve access to quality medicines and pharmaceutical services in rural areas. ADDO dispensers play a potentially important role in promoting the rational use of antimicrobials, which helps control antimicrobial resistance (AMR). The study objectives were to 1) improve dispensing practices of antimicrobials, 2) build ADDO dispensers’ awareness of the consequences of misusing antimicrobials, and 3) educate consumers on the correct use of antimicrobials through the use of printed materials and counseling.

| United States | Agency for Healthcare Research and Quality (AHRQ) | AHRQ has several projects that have addressed optimizing the use of existing antimicrobials and promoting antimicrobial stewardship, for example:
|               |   • Decision support tools to improve antibiotic prescribing for respiratory infections http://www.ahrq.gov/news/newsletters/research-activities/14mar/0314ra31.html
|               |   • Standardized Antibiotic Use in Long-Term Care Settings (SAUL Study) http://www.ahrq.gov/news/events/conference/2012/track_a/62_garfinkel_et-al/garfinkel.html |
| **Centers for Disease Control and Prevention (CDC)** | Example CDC activities in the areas of optimizing prescribing and antimicrobial stewardship include:

- Development and promotion of the ‘Get Smart’ programmes to improve antibiotic prescribing and use (See entries under Objective 1) [http://www.cdc.gov/getsmart/index.html](http://www.cdc.gov/getsmart/index.html)
- **Core Elements of Hospital Antibiotic Stewardship Programs** [http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html](http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html)
| **US Agency for International Development (USAID)** | Examples of USAID activities to promote antimicrobial stewardship and effective use of antimicrobials include:

| **Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals** | • The Food and Drug Administration (FDA) is implementing a voluntary agreement to phase out the use of medically important antimicrobials in food animals for food production purposes, such as to enhance growth or improve feed efficiency, and to phase in veterinary oversight of the remaining appropriate therapeutic uses of such drugs, as outlined in Guidance for Industry (GFI) #209: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals. [http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm216936.pdf](http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm216936.pdf) [http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf](http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf)
- Specific recommendations were published in December 2013 in GFI #213: New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209. These specify a three-year timeframe (until December 2016) for drug sponsors to complete the recommended changes to their antimicrobial products. [http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf](http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf)
<table>
<thead>
<tr>
<th>Resource</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labeling for systemic antibacterial drug products</td>
<td>The Food and Drug Administration (FDA) has had labelling regulations addressing the appropriate use of antibacterial drugs for use in humans since 2003 through the Code of Federal Regulations Title 21, Part 201 Labeling. Sub-part 201.24 &quot;Labeling for systemic antibacterial drug products&quot; requires the label to state the antibacterial drugs should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. In the 'Precautions' section, the labeling must state that prescribing the medicine in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria. The labeling must also state that patients should be counseled that antibacterial drugs do not treat viral infections and that the medication should be taken exactly as directed. <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=201">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=201</a></td>
</tr>
<tr>
<td>Veterinary Antimicrobial Decision Support (VADS)</td>
<td>This site was developed to provide an easily accessible, comprehensive source of guidance in antimicrobial selection for food animal practitioners that addresses regimen design utilizing state of the art techniques and knowledge. The VADS System collaborators hoped the website would serve as a central location for discussion and debate that advances the judicious use of antimicrobials in food animal veterinary medicine. <a href="http://vads.vetmed.vt.edu/index.cfm">http://vads.vetmed.vt.edu/index.cfm</a></td>
</tr>
</tbody>
</table>
| American Veterinary Medical Association (AVMA)              | AVMA developed materials on judicious therapeutic use of antimicrobials targeted to food animal producers. These consist of a series of booklets that explain antimicrobial prudent use in the areas of:  
  - General Guidelines and Resources  
  - Aquatic animals  
  - Companion animals  
  - Equine animals  
  - Food animals (beef cattle, dairy cattle, poultry and swine). [https://www.avma.org/KB/Resources/Reference/Pages/Antimicrobial-use.aspx](https://www.avma.org/KB/Resources/Reference/Pages/Antimicrobial-use.aspx) |
| Infectious Disease Society of America (IDSA) and the Society for Healthcare Epidemiology of America (SHEA) guidelines |  
  - In 2007, the Infectious Disease Society of America (IDSA) and the Society for Healthcare Epidemiology of America (SHEA) released guidelines for developing an institutional program to enhance antibiotic stewardship. The American Society of Health-System Pharmacists (ASHP) provided input and endorsed the guidelines. According to IDSA and SHEA, effective antibiotic stewardship programs (ASPs) are evidence-based and can improve patient care and be financially sustainable.  
  - In 2012, IDSA, SHEA and Pediatric Infectious Diseases Society (PIDS) issued a joint position statement outlining recommendations for the mandatory implementation of antimicrobial stewardship throughout health care, including recommendations to monitor interventions and methods to address current deficiencies in education and research, as well as the lack of accurate data on antimicrobial use in the United States. [http://www.idsociety.org/Stewardship_Policy/](http://www.idsociety.org/Stewardship_Policy/) |
| Antimicrobial Stewardship Toolkit                            | The American Hospital Association (AHA) has compiled a toolkit on antimicrobial stewardship in partnership with seven other national organizations. The toolkit is composed of three sections:  
  - Hospital and Health System Resources  
  - Clinician Resources |
- Patient Resources.

| California antimicrobial stewardship legislation | California is the first and remains the only state to enact antimicrobial stewardship legislation. Since 2008 California law required that general acute care hospitals develop a process for monitoring the judicious use of antibiotics and that the results are monitored by quality improvement committee(s). In September 2014, California Senate Bill 1311 was signed into law, further requiring hospitals to adopt and implement an antimicrobial stewardship policy in accordance with guidelines established by federal government and professional organizations, and to establish a physician-supervised multi-disciplinary antimicrobial stewardship committee. [http://www.cdph.ca.gov/programs/haipages/AntimicrobialStewardshipPrograminitiative.aspx](http://www.cdph.ca.gov/programs/haipages/AntimicrobialStewardshipPrograminitiative.aspx) |