

## Member State Medicines Regulatory Agency Activities in the area of Antimicrobial Resistance (AMR) – Overview of collected data (November 2011)

<b>Member States</b>	Austria, Belgium, Bulgaria, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Netherlands, Norway, Poland, Slovakia, Slovenia, Spain, Sweden, Romania, UK (25) <i>(The MHRA have also completed a questionnaire covering information on activities in the UK relevant to human medicines. The information is not included in the summary below)</i>
<b>Activities where the medicines agency has direct responsibility relating to AMR</b>	Agencies within the HMA network have a range of responsibilities. All are involved in authorisations and pharmacovigilance and most are directly involved in collection of sales data for antimicrobials and policy. The minority of Agencies (5) are involved directly in surveillance activities and even less are involved in commissioning research.
<b>Collection of information on antimicrobial sales</b> <ul style="list-style-type: none"> <li>- Collected?</li> <li>- Published?</li> <li>- Member of ESVAC?</li> </ul>	<p>With two exceptions, all respondents have started, or will shortly start, the collection of antimicrobial sales data. Six countries are members of the ESVAC Technical Consultancy Group and a further 9 are ESVAC members. In one case the collection of data currently only relates to imported antimicrobial veterinary products. In the case of Liechtenstein the data are combined with the Swiss sales data.</p> <p>A number of countries have been collecting and publishing information for 10 years or more. Other countries have started to collect data relatively recently and most plan to publish.</p> <p>The data are collected from different points according to the country. Sources of the data include: Marketing Authorisation holders, manufacturers, wholesalers, pharmacies.</p>
<b>Collection of information on antimicrobial prescriptions</b> <ul style="list-style-type: none"> <li>- Systematic collection?</li> <li>- Surveys?</li> </ul>	<p>Two countries (Denmark and Sweden) have an established system for the systematic collection of prescription information for all products. Slovenia collect information on prescriptions for all types of veterinary medicines. One country has such a system for fish medicines, but is developing a system to cover all medicines. A further two countries are in the process of putting in place a system. Otherwise, generally there are not centralised systems to collecting prescribing information. Seven countries have conducted surveys of varying scope on prescribing.</p>
<b>Collection of information on factors influencing prescription habits</b> <ul style="list-style-type: none"> <li>- Have you studied this?</li> <li>- Is the work published</li> </ul>	<p>One country has studied this by means of a specific survey and published their findings. A further four countries are in the process of collecting such information, in some cases relating to a single species (two countries are specifically examining pigs). Those countries with systems to collect prescribing information are able to interrogate the information collected to help understand prescribing habits.</p>

<p><b>Advertising</b></p> <p>Are there national rules or guidance concerning advertising of antimicrobials?</p> <p>Is there any control to limit profit from prescribing antimicrobials?</p>	<p>A number of countries have some form of guidance/best practice guides for the industry to follow with specific reference to antimicrobials. In most cases the industry is self-regulating. However, one country checks advertising prior to use (for all products but with a focus on antimicrobials). According to the country advertising may be to vets only, or at the other extreme may be to all prescribers, pharmacies and professional keepers of animals. In the case of Denmark no advertising of antimicrobials is permitted.</p> <p>Seven countries have specific rules to separate vet practice profit from the supply of any kind of medicine.</p>
<p><b>Surveillance of antimicrobial resistance</b></p> <ul style="list-style-type: none"> <li>- Who is responsible?</li> <li>- Scope of surveillance</li> <li>- Are results published if so where?</li> <li>- Any surveys conducted with diagnostic laboratories for animal pathogens?</li> </ul>	<p>In most countries the surveillance comprises of the statutory requirements for monitoring for salmonella and campylobacter, and in many cases also the recommended monitoring of <i>E.coli</i> and <i>Enterococcus</i> spp. A small number of countries also do some additional surveillance, usually targeted work. One country has an extensive programme on a range of target animal pathogens. Results are generally published.</p> <p>In one country work is underway to standardise laboratory sampling, testing, reporting, and interpretation. In a further country a working group is looking at how the surveillance of target animal pathogens can be improved. In one country (Lithuania) diagnostic laboratories have to report the isolation of pathogens and submit the isolate for further testing.</p>
<p><b>Risk assessment</b></p> <ul style="list-style-type: none"> <li>- Any national assessment?</li> <li>- Assessment of risks posed by different practices</li> </ul>	<p>About one third of the countries have specific groups/taskforces/committees established who consider antimicrobial resistance issues, in most cases considering the implications for animals and humans.</p>
<p><b>Responsible Use</b></p>	<p>Most countries have some form of national or local guidance in place. According to the country the guidance may be very general or may be focused on specific target species, conditions or audiences (e.g. vet, farmer) or route of administration. In some cases the guidance is a “formulary” indicating the preferred antimicrobial in a specific species to treat a specific condition.</p> <p>In one country they have “obligatory” principles of responsible use of antimicrobials which apply to third and fourth generation cephalosporins and all fluoroquinolones intended for food-producing animals. In another country they maintain a list of first choice drugs, ranking veterinary medicines according to the benefit:risk balance and prudent use factors. Most countries have also run workshops and some issue regular communications on the topic.</p>
<p><b>Communication and Education</b></p> <ul style="list-style-type: none"> <li>- For vets?</li> <li>- For the public?</li> <li>- For farmers?</li> </ul>	<p>Various workshops have been held by different countries. Information has been placed on the internet. Reactive communications e.g. press, media. A leaflet and poster aimed at vets is available.</p> <p>One country has set up a “Drug Information Unit” to provide independent advice (on all medicines).</p> <p>One country holds annually a national antibiotic awareness day.</p>

<p><b>Does the national law currently restrict use of antimicrobials for use in animals in any way beyond the EU legislation?</b>  <i>If yes please described these</i></p>	<p>In one country (Czech Republic) there is legislation which states that where a product has a restriction it can only be used if there is no product without this restriction and then only following sensitivity testing.</p> <p>In one country (Finland) use of certain last resort antimicrobials is limited to exceptional conditions or prohibited by national law (Decree of the Ministry of Agriculture and Forestry MMMa 847/2008).</p> <p>In one country (Sweden) there is legislation that a vet must consider the risk for antimicrobial resistance when prescribing. Vets are allowed to hand out antimicrobials to the end user to cover the need in relation to specific farm visit. In addition, under certain conditions the veterinarian may prescribe antimicrobials to be administered to animals for specified diseases by the farmer who have undergone training in medication. Here the vet should supervise the farm every five to eight weeks during the prescription period.</p> <p>In one country (Lichtenstein) a restriction is possible based on article 6 paragraph 6 of the Ordinance on Veterinary Medicines (Tierarzneimittelverordnung TAMV, <a href="http://www.admin.ch/ch/d/sr/c812_212_27.html">http://www.admin.ch/ch/d/sr/c812_212_27.html</a>). Based on this disposition, it would be possible to publish a list of substances or substance groups that might be excluded from any reconversion (as described in the cascade regulation).</p> <p>In one country (Denmark) they issue 'yellow cards' to farmers whose use of antimicrobials exceed a set threshold relative to average use. The yellow card involves a fine and a requirement to correct the pattern of use. Failure to comply can lead to closing a farm.</p>
<p><b>Has the government set out specific targets to reach in terms of reduction of use of antimicrobials to treat animals?</b>  <i>If yes please described these</i></p>	<p>In one country (The Netherlands) a target has been set. The Dutch Minister of Agriculture stated last year that in 2011 a reduction of 20% should be realised as compared to 2009. In 2013 the reduction should be 50%.</p> <p>In one country (France) a target has been set to reduce antimicrobial usage by 25% over 5 years.</p> <p>In a further country (Belgium) work is currently being undertaken with the view to achieving responsible use and a reduction in the use of antimicrobials. There is no clear expectation that a quantifiable target for reduction will be set, but this is a possible outcome of this work.</p>