

<b>EVALUATION ROADMAP</b>			
<b>TITLE OF THE EVALUATION/FC</b>	Evaluation of the Commission's Communication to the European Parliament and the Council on the Action Plan against the rising threats from Antimicrobial Resistance (AMR) (COM (2011) 748)		
<b>LEAD DG RESPONSIBLE UNIT</b>	DG SANTE / UNIT G4	<b>DATE OF THIS ROADMAP</b>	26 May 2015
<b>TYPE OF EVALUATION</b>	Evaluation Ex-post Mixed	<b>PLANNED START DATE</b>	June 2015
		<b>PLANNED COMPLETION DATE</b>	January 2016
		<b>PLANNING CALENDAR</b>	<a href="http://ec.europa.eu/smart-regulation/evaluation/index_en.htm">http://ec.europa.eu/smart-regulation/evaluation/index_en.htm</a>
<b>This indicative roadmap is provided for information purposes only and is subject to change.</b>			

<b>A. Purpose</b>
(A.1) Purpose
<p>The purpose of the present evaluation is to produce an evidence based report to assess the impact of the implementation of the Commission's Communication to the European Parliament and the Council on the Action Plan against the rising threats from Antimicrobial Resistance (AMR) (COM (2011) 748)<sup>1</sup>, published in November 2011 in line with the "One Health" principle. More specifically, the purpose of this evaluation is to analyse whether the 12 key strategic actions contained in the Action Plan were the most appropriate actions to be taken to combat AMR, which elements worked well or not, if the objectives are still relevant to the needs in tackling AMR and if the approach was holistic. As the Action Plan will expire in 2016, the results of this evaluation will provide the Commission with the basis to make informed decisions on what new or additional policy measures should be taken in the medium and long term strategy to combat AMR in the European Union and globally.</p>
(A.2) Justification
<p>AMR is a complex global problem and the EU Action Plan is one of many initiatives being implemented worldwide to address the problem. However, despite all the activities at local, regional, MS, EU and global levels, the problem is getting worse and so it has become even more urgent than before to ensure that actions continue to directly target the problems at the appropriate level.</p> <p>The Progress Report on the Action Plan<sup>2</sup>, dated 11 March 2015, presented the progress made on the implementation of the Action Plan and demonstrated that initiatives under many of the actions have either been started, are ongoing and some have even been completed. However, it highlighted that despite the progress on many initiatives, much still needs to be done and there are still many challenges ahead in combatting AMR. This progress report refers to the conclusions of the Commission's Joint Conference on AMR of December 2013 where experts agreed that two key elements in fighting AMR are taking a holistic approach, ensuring that all key players carry out their responsibilities, and global cooperation. Experts also acknowledged that close attention should be paid to balancing competing needs and interests such as for example the long term need to keep antimicrobials effective with the short term need of treating infections in humans and animals. The lack of appropriate data to evaluate the economic and health impacts of AMR and the fact that harmonised comparable data on resistance and use of antimicrobials, both in human and veterinary medicine are of critical importance for risk management decisions were also acknowledged. Finally, it was agreed that Europe should take the lead in a global dialogue on AMR and on the development of a global research agenda to promote a coordinated research programme to</p>

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

<sup>2</sup> [http://ec.europa.eu/health/antimicrobial\\_resistance/docs/2015\\_amr\\_progress\\_report\\_en.pdf](http://ec.europa.eu/health/antimicrobial_resistance/docs/2015_amr_progress_report_en.pdf)

complement national and European initiatives.

As the Action Plan expires in 2016, it is therefore appropriate to assess whether the Action Plan is still achieving its main objectives, whether the actions taken are relevant to tackling the problems related to AMR and whether the approach taken is holistic, thus enabling the future EU strategy on AMR to be more clearly defined.

## B. Content and subject of the evaluation

### (B.1) Subject area

The 2001 Community Strategy against AMR (COM (2001) 333 final) provided a policy instrument to address the problem of AMR at a European level in four distinct areas: surveillance, prevention, research and product development and international cooperation. In line with the "One Health" initiative, this commitment was renewed in 2011 with the Action Plan against the rising threats from AMR (COM (2011) 748).

AMR is the resistance of micro-organisms to antimicrobial drugs so that these originally effective standard treatments become ineffective and infections persist which increases the risk of spread. AMR is a serious and increasing worldwide health concern for both humans and animals requiring commitment and action from all governments and society. The direct consequences of infection with resistant micro-organisms can be severe, including longer illnesses, increased mortality, prolonged stays in hospital, loss of protection for patients undergoing operations and other medical procedures, and increased costs.

The emergence and spread of resistant bacteria is a natural biological phenomenon but it is amplified and accelerated by a variety of factors, namely:

- Inappropriate or over use of therapeutic antibiotics in human and veterinary medicine;
- Poor hygiene and infection prevention measures in healthcare settings and at farm level;
- Transmission of resistant bacteria from animals to humans through the food chain or direct contact;
- Environmental spread caused by contaminated food and water systems and international trade and travel;
- Lack of new effective antimicrobials or alternatives.

In Europe, it is estimated that around 25,000 patients die annually as a result of infections caused by resistant bacteria translating into estimated costs of EUR 1.5 billion per annum, due to loss of productivity and an increase in healthcare expenditure costs. Methicillin-resistant *Staphylococcus aureus* (MRSA) is a well-known example of a bacterium that is resistant to a number of antibiotics and is the main cause of hospital-acquired infections (HAI) all across the EU.

EU funds are already spent in several interventions aimed at improving knowledge and promoting research on AMR. In 2014-2015, funds were allocated to Member States for implementing harmonised surveillance of AMR in animals and food and this financial support will be maintained beyond 2015. Research on AMR has been financially supported by the Commission services under the EU's Seventh Framework Programme for Research and Technological Development. The new EU framework programme Horizon 2020 continues to give research on infectious diseases including AMR a high priority. The European Commission has also joined forces with SMEs and large pharmaceutical industries to spur the development of new antibiotics, which led to new EU funded research projects.

### (B.2) Original objectives of the intervention

The objectives of the Action Plan are reflected by the 7 areas covered and are as follows:

- Making sure antimicrobials are used appropriately both in humans and animals;
- Developing new effective antimicrobials or alternatives for treatment;
- Preventing microbial infections and their spread;
- Cooperating with international partners to contain the risk of AMR;
- Improving monitoring and surveillance in human and animal medicine;
- Reinforcing research and innovation;
- Improving communication, education and training.

The Action Plan has been the basis for EU action from 2011 until now and the Commission progress report<sup>2</sup>,

published in March 2015, has outlined the state of play of implementation by listing the initiatives undertaken or completed to date.
(B.3) How the objectives were to be achieved
See annexed intervention logic.

<b>C. Scope of the evaluation/FC</b>
<p>(C.1) Topics covered</p> <p>The evaluation should assess the relevance of the areas covered by the Action Plan in addressing the problems related to AMR and in establishing a holistic approach at EU level. It should assess the achievements of the 12 key strategic actions in terms of effectiveness, efficiency, EU added-value, and coherence on the basis of relevant measurable indicators.</p> <p>Actions which have not been started are excluded from the scope of this evaluation.</p> <p>The evaluation should at least cover all MS of the EU, plus third countries and international organisations if relevant, and the period to be evaluated is 2011-2015.</p>
<p>(C.2) Questions/issues to be examined</p> <p>The evaluation should address the following questions (indicative list, the contractor will be invited to propose reformulations and additional questions in the offer – wherever considered justified):</p> <p><u>Relevance</u></p> <p>EQ1: To what extent do the objectives of the action plan still address the problems identified in 2011? How well do these objectives still correspond to the current needs of tackling AMR within the EU?</p> <p>EQ2: Are the areas for EU action appropriate in view of the distribution of EU and national competences?</p> <p><u>Effectiveness</u></p> <p>EQ3: To what extent have the actions been effective at improving treatment of infections in humans and animals?</p> <p>EQ4: To what extent have the actions aimed at containing the risks of spreading AMR been effective?</p> <p>EQ5: To what extent has the coverage of actions across different services (DGs) within the European Commission been effective in capturing the holistic approach and in delivering results?</p> <p><u>Efficiency</u></p> <p>EQ6: Has the EU budget been efficiently used to address the objectives of the Action Plan?</p> <p><u>Coherence</u></p> <p>EQ7: To what extent is the Action Plan coherent with Member States' national (or regional) strategies and action plans and with similar initiatives at International level?</p> <p>EQ8: To what extent are the actions contained in the Action Plan coherent with other EU policies on environment, human health, animal health and welfare, food safety, agriculture, research, competitiveness and SMEs?</p> <p><u>EU added value</u></p> <p>EQ9: What is the added value resulting from the EU Action Plan compared with what could be achieved by Member States at national and/or regional levels? Did the EU Action Plan identify the actions which should be best dealt with at EU level?</p> <p>EQ10: To what extent can any observed improvements in the situation on AMR in the EU be associated with the development and implementation of the EU Action Plan?</p>

(C.3) Other tasks
No other tasks.

D. Evidence base
(D.1) Evidence from monitoring
Data needed for this evaluation should be gathered from the different EU surveillance systems that have been developed so far to monitor AMR prevalence and antimicrobial consumption. In particular, relevant reports and corresponding data from ECDC (ESAC-Net <sup>3</sup> , EARS-Net <sup>4</sup> , HAI-Net <sup>5</sup> ), EFSA (EUSR <sup>6</sup> ), EMA (ESVAC <sup>7</sup> ) should be used for this purpose. Those data have been gathered by the above-mentioned scientific agencies and are considered to be the most robust and reliable data available so far.
(D.2) Evidence from assessing the implementation of research activities
Relevant information on research calls can be found on the websites of DG RTD ( <a href="http://ec.europa.eu/research">http://ec.europa.eu/research</a> ), the Innovative Medicines Initiative (IMI) <sup>8</sup> and the Joint Programming Initiative on AMR <sup>9</sup> (JPIAMR). Information on coordination activities can be obtained from JPIAMR, published workshop reports, and comments published in scientific journals.
(D.3) Previous evaluations and other reports
The Commission progress report <sup>2</sup> on the Action Plan published in March 2015 and the latest version of the Commission roadmap against AMR <sup>10</sup> should be used as basis documents gathering all links and references to previous evaluations and other relevant reports. Those reports should be used to define, as far as possible, the relevant measurable indicators aiming to help answering the evaluation questions, in particular those related to effectiveness.
(D.4) Evidence from assessing the implementation and application of legislation (complaints, infringement procedures)
Not applicable.
(D.5) Consultation
An open public consultation of 12 weeks will be held at the end of 2015 to verify preliminary findings. Moreover, the main stakeholders (e.g. farmer associations, pharmaceutical industry representatives, animal and human health care providers, patients and consumers representatives) will be consulted through dedicated workshops during 2nd half of 2015, in order to get their feedback on experiences gained with the action programme either through active participation or because they were a target group that would be impacted by the results of the programme. The list of stakeholders that will be consulted will be further refined through stakeholders mapping exercise.
(D.6) Further evidence to be gathered
Other evidence may be gathered by the contractor taking into account the objective and the scope outlined above. This may request, where relevant, to conduct surveys, interviews or case studies.

<sup>3</sup> <http://ecdc.europa.eu/en/activities/surveillance/ESAC-Net/Pages/index.aspx>

<sup>4</sup> [http://ecdc.europa.eu/en/healthtopics/antimicrobial\\_resistance/database/Pages/database.aspx](http://ecdc.europa.eu/en/healthtopics/antimicrobial_resistance/database/Pages/database.aspx)

<sup>5</sup> <http://ecdc.europa.eu/en/activities/surveillance/HAI/Pages/default.aspx>

<sup>6</sup> <http://www.efsa.europa.eu/fr/efsajournal/pub/4036.htm>

<sup>7</sup> [http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000302.jsp](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jsp)

<sup>8</sup> <http://www.imi.europa.eu/>

<sup>9</sup> <http://www.jpiaamr.eu/>

<sup>10</sup> [http://ec.europa.eu/dgs/health\\_food-safety/docs/road-map-amr\\_en.pdf](http://ec.europa.eu/dgs/health_food-safety/docs/road-map-amr_en.pdf)

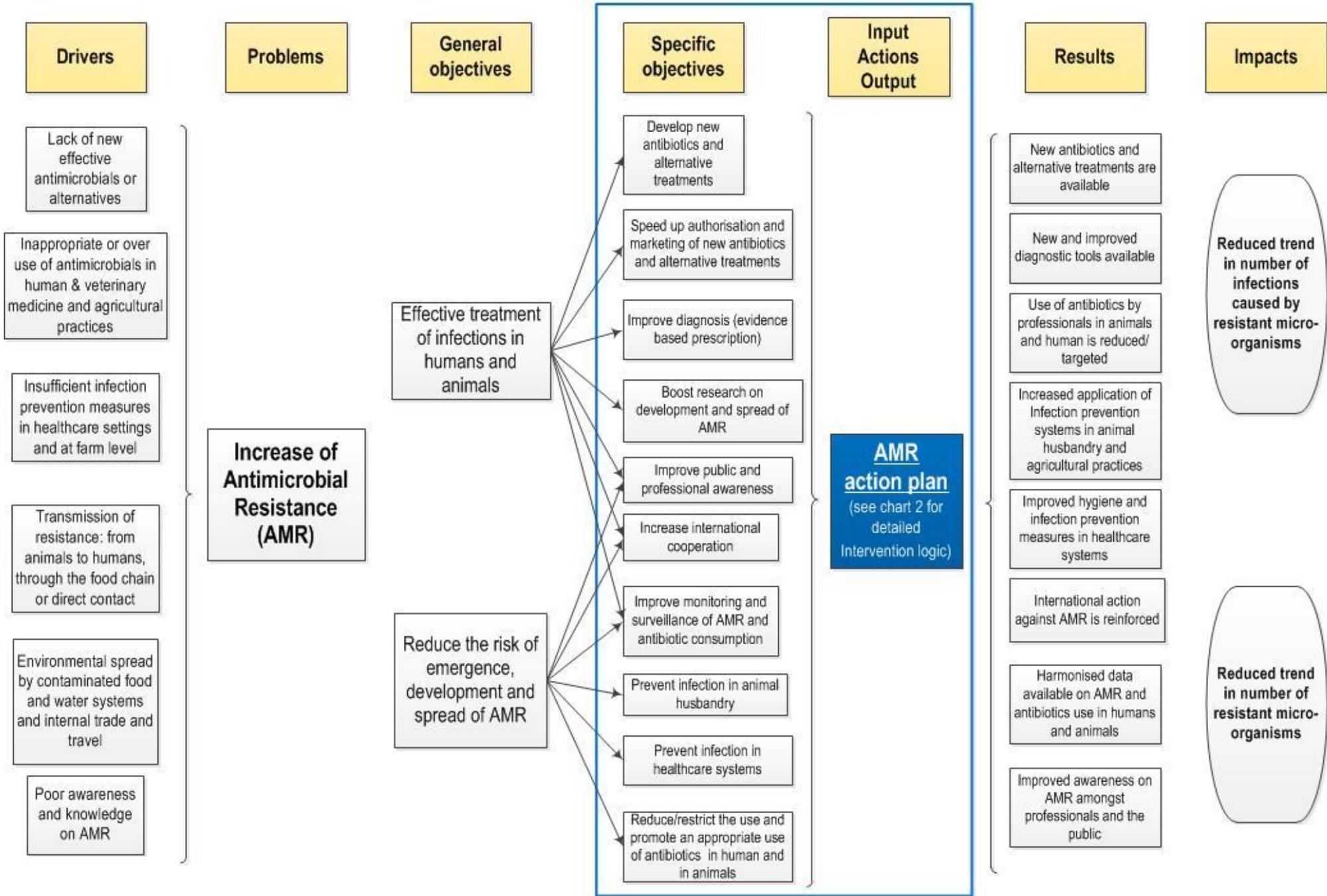
### E. Other relevant information/ remarks

For reference, the following EU legislation in force covers, to varying degrees, certain issues related to AMR:

- Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs (under revision with the co-legislators);
- Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (under revision with the co-legislators)
- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use;
- Commission Decision No 2002/253/EC of 19 March 2002 laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council;
- Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC
- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products
- Commission Implementing Decision No 2013/652/EU of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria
- Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC



**Chart 1: Overview of the AMR issue**





**Chart 2: AMR Action Plan intervention logic**

