



Action Plan Against the rising threats from Antimicrobial Resistance: **Road Map**

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A. Appropriate use of antimicrobials

Action n° 1:

Strengthen the promotion of the appropriate use of antimicrobials in human medicines in all Member States.

Operational objectives	Concrete activities	Milestones/Deadline
Support the implementation of the provisions of the Council Recommendation 2002/77/EC ¹ in Member States, notably regarding: <ul style="list-style-type: none"> • Prescription only requirements • Nursing homes and long term care facilities • Education and training programme 	Launch of the 2012-2014 preparatory action on Antimicrobial Resistance (grant from European Parliament) addressing <ul style="list-style-type: none"> • Misuse of antimicrobial agents in human medicine • Awareness across the whole chain of stakeholders: prescribers, pharmacists and patients. • Sales of antimicrobial agents without a prescription 	2 nd quarter – 2014, start of the preparatory action.
	Consultation with MS on the implementation of Council Recommendation 2002/77/EC.	Presentation of results 2nd half 2015.
	Through the Antibiotic Prescribing and Resistance in European Children (ARPEC) ² project 2010-2013 funded under Health Programme: development of web-based training providing educational modules on optimal antibiotic prescribing in children and antimicrobial resistance	Completed mid-2014.
Stimulate the appropriate use of antimicrobials in human medicines	Workshop “Best use of medicines legislation to bring new antibiotics to patients and combat the resistance problem”, organised by EMA (8 November 2013, London)	Workshop conclusions published (December 2013) ³

¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:034:0013:0016:EN:PDF>

² <http://www.arpecproject.eu/>

³ http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2013/09/event_detail_000781.jsp&mid=WC0b01ac058004d5c3

Research on improving the appropriate use of antimicrobials	The project " Genomics to combat Resistance against Antibiotics in Community acquired low respiratory tract infections in Europe" GRACE ⁴ project funded under the EU Framework Programme for Research demonstrated that antibiotics should not be generally prescribed to patients with uncomplicated lower respiratory tract infections (non-pneumonic infections).	Publication in The Lancet Infectious Diseases ⁵
	The EU Framework Programme for Research funded project "The appropriateness of prescribing antibiotics in primary health care in Europe with respect to antibiotics resistance" (APRES) ⁶ assesses the appropriateness of prescribing antibiotics in primary care in 9 European countries.	Project started in 2009 and final results due in summer 2014
Action n° 2:		
Strengthen the regulatory framework on veterinary medicines and on medicated feed.		
Operational objectives	Concrete activities	Milestones / Deadline
To address Antimicrobial Resistance related to the use of veterinary medicinal products	Revision of the Veterinary Medicines Legislation ⁷	Veterinary Medicines legislation: Commission proposal adopted in 2014 and sent to the EP and the Council. Negotiations between the two institutions should take place at least until 2016.
To address Antimicrobial Resistance related to the use of medicated feed	Revision of the Medicated Feed Legislation ⁸ .	Medicated Feed legislation: Commission proposal adopted in 2014 and sent to the EP and the Council.

⁴ <http://www.grace-irti.org/portal/en-GB/homepage>

⁵ Amoxicillin for acute lower-respiratory-tract infection in primary care when pneumonia is not suspected: a 12-country, randomised, placebo-controlled trial. Lancet Infect Dis. 2013 Feb;13(2):123-9

⁶ http://ec.europa.eu/research/health/public-health/clinical-outcome-into-practice/projects/apres_en.html

⁷ http://ec.europa.eu/health/veterinary-use/rev_frame_index_en.htm

⁸ http://ec.europa.eu/food/food/animalnutrition/labelling/medicated_feed_en.htm

To verify on-the-spot that Member States meet all of their obligations with respect to the existing and revised regulatory framework on veterinary medicines and medicated feedstuffs.	In relation to the distribution and use of antimicrobial veterinary medicinal products (including medicated premixes for animal feedingstuffs), the Food and Veterinary Office (FVO) shall send a questionnaire on this issue to all Member States in the second half of 2015 and, carry out a series of fact-finding missions in selected Member States in 2016. This FVO project will generate an overview report.	All Member States to receive the questionnaire by October 2015; a minimum of six fact finding missions to be completed by September 2016; Overview report to be drafted before end of November 2016.
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Action n° 3:

Introduce recommendations for prudent use in veterinary medicine, including follow-up reports.

Operational objectives	Concrete activities	Milestones / Deadline
Use existing legal tools to the utmost to ensure prudent use of antimicrobials in the veterinary	Commission decision on referral in relation to 3rd and 4th generation cephalosporins	Adopted on 13 January 2012, C(2012)182 ⁹
	Scientific recommendations of the Committee for Medicinal Products for Veterinary Use (CVMP) on the need for further referrals of critically important antimicrobials ¹⁰	July 2013
	To initiate referrals on veterinary medicinal products taking into account the updated priority list for referrals as established by European Medicines Agency (EMA)	Referral initiated on colistin (2014)
	CVMP-reflection paper of November 2011 on the use of macrolides, lincosamides and streptogramins	June 2013 ¹¹
To have scientific recommendations on the use in the veterinary sector of last resort antimicrobials for humans (e.g. tigecycline and colistin) sector	Request for scientific advice (based on Article 57 of Regulation 726/2004) of Agency Committee for Medicinal Products for Veterinary Use (CVMP) and the Committee for Medicinal Products for Human Use (CHMP) on the use of last resort antimicrobials in the veterinary sector.	February 2013 ¹²
	Follow-up of the scientific recommendation published in 2014 prepared by the Antimicrobial Advice Ad Hoc Expert Group (AMEG) ¹³	2015-2016

⁹ http://ec.europa.eu/health/documents/community-register/2012/20120113113370/dec_113370_en.pdf

¹⁰ http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/07/news_detail_001859.jsp&mid=WC0b01ac058004d5c1

¹¹ http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/11/WC500118230.pdf

¹² http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/04/WC500142070.pdf

¹³ http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000385.jsp&mid=WC0b01ac058004a585

<p>To reduce the overall use of antimicrobials in veterinary medicine (better targeted treatments, use according to best practices, etc)</p>	<p>In addition to the legal provisions, development of a guidance document to provide overview of practical examples of prudent use principles to be considered implemented by Member States when developing national strategies on prudent use. Follow up reports of the implementation by Member States.</p>	<p>Development guidance document on prudent use of antimicrobials by mid 2015</p>
<p>Guarantee responsible and efficient use of medicated feed</p>	<p>Raising awareness of the control authorities to risks due to different routes of oral administration of antimicrobials in order to detect misuse and to take remedial action.</p>	<p>Current and follow-on to Action 2</p>
<p>To verify on-the-spot that the Member States have acted upon whatever Commission recommendations are proposed for the prudent use of antimicrobials in the Member States.</p>	<p>Questionnaire and fact-finding missions in selected Member States – see FVO project undertaken pursuant to Action No 2. How the Member States put the Commission's and/or national guidelines on prudent use into practice will be one of the elements of the FVO project referred to above.</p>	<p>All Member States to receive the questionnaire by October 2015; a minimum of six fact finding missions to be completed by September 2016; Overview report to be drafted before end of November 2016.</p>
<p>In the course of evaluating Member States residue monitoring plans, focus on the ability of the national laboratories to effectively monitor for residues of antimicrobials of concern (critically important antimicrobials including fluoroquinolones, third and fourth generation cephalosporins and macrolides).</p>	<p>Evaluation of EU Member States' residue monitoring plans and supplementary assessment of Member States' screening methodology by the EU Reference Laboratory for antimicrobial residues</p>	<p>The evaluation of the 2013 residues monitoring plans was completed in November 2013 and the EURL assessment was provided in February 2014. An FVO discussion document has been completed and will be launched formally in the first semester of 2015</p>
<p>Verify in audits the measures taken by the Member States to reduce the carry-over of Veterinary Medicines Products in non-target animal feed</p>	<p>A desk study and audits by the Feed Hygiene Sector in the Member States</p>	<p>Overview report by January 2016.</p>

B. Prevent microbial infections and their spread

Action n° 4:

Strengthen infection prevention and control in healthcare settings.

Operational objectives	Concrete activities	Milestones / Deadline
Monitor and support the implementation of the Council Recommendation on patient safety incl. healthcare associated infections (HAI) with emphasis on: <ul style="list-style-type: none"> • Development of guidance on infection prevention and control • Strengthened surveillance of HAI • Education and training of healthcare workers • Information to patients 	1st Report of the Commission on the implementation of the Council Recommendation on patient safety, including healthcare associated infections.	Adopted and published November 2012 ¹⁴
	2nd Report of the Commission on the implementation of the Council Recommendation on patient safety, including healthcare associated infections.	Adopted and published 2014. ¹⁵
	Support via the Health Programme projects/actions to follow up the priority areas on which future work should focus include, as identified in the Commission's implementation report	HAI prioritised in the Third Health Programme Project call issued in 2014
	Continue fostering with European Centre for Disease Prevention and Control (ECDC) the development of guidance on infection prevention and control, strengthening of Health Associated Infections (HAI) surveillance and the development of training curricula for healthcare workers.	Several guidance reports published ¹⁶ Directory of existing guidance and other documents on the prevention and control of AMR and HAI online on ECDC website ¹⁷

¹⁴ http://ec.europa.eu/health/patient_safety/docs/council_2009_report_en.pdf

¹⁵ http://ec.europa.eu/health/patient_safety/docs/ec_2ndreport_ps_implementation_en.pdf

¹⁶ <http://www.ecdc.europa.eu/en/Pages/home.aspx>

¹⁷ http://www.ecdc.europa.eu/en/healthtopics/Healthcare-associated_infections/guidance-infection-prevention-control/Pages/guidance-prevention-control-infections-caused-by-multidrug-resistant-bacteria-and-healthcare-associated-infections.aspx

Action n° 5: Adoption of a proposal for an EU Animal Health Law.		
Operational objectives	Concrete activities	Milestones / Deadline
<ul style="list-style-type: none"> To create an animal health legal framework based on the principle "prevention is better than cure". 	<p>Animal Health Law proposal will foresee to:</p> <ul style="list-style-type: none"> Increase responsibilities of operators to ensure the required level of animal health and biosecurity; clarify the responsibility of veterinary and aquatic animal health professionals to adopt effective measures to prevent the spread of pathogens and to raise awareness; clarify responsibility of competent authorities to protect animal health, human health and the environment through reduction of the risks arising from the emergence, introduction or spread of pathogens; provide for an assessment, prioritisation and categorisation of diseases or disease agents, including where appropriate, the ability to generate resistance to treatment as criterion to decide about appropriate measures; clarify obligations to ensure appropriate monitoring, surveillance and early detection of pathogens. 	<p>Final proposal was adopted by Commission on 6 May 2013¹⁸, it is in ordinary legislative procedure. The European Parliament adopted a resolution on its first reading position on 15 April 2014¹⁹, confirmed it after elections in September 2014. Council agreed its position in December 2014. Trilogues between the three Institutions started in February 2015. Further details are foreseen in subsequent delegated and implementing acts as appropriate</p>

¹⁸ COM(2013) 260 final, http://ec.europa.eu/food/animal/animal-health-proposal-2013_en.htm

¹⁹ http://ec.europa.eu/prelex/detail_dossier_real.cfm?CL=en&DosId=202630

C. Develop new effective antimicrobials or alternatives for treatment

Action n° 6:

To promote, in a staged approach, unprecedented collaborative research and development efforts to bring new antibiotics to patients.

Operational objectives	Concrete activities	Milestones / Deadline
To re-activate research and development by Industry for new antibiotics and related issues	Calls for proposals via the Innovative Medicine Initiative (IMI) , a public-private partnership between the Commission and the industry. IMI ²⁰ projects are funded by the Commission, via Framework Programme 7, and the European Federation of Pharmaceutical Industries and Associations (www.imi.europa.eu)	On 11 December 2013 IMI launched its 11th Call
	To support the IMI project improving tests for appropriate use of antibiotics ²¹	The project started in April 2011 for a duration of 60 months
	<p>The launch of a large IMI programme "new Drugs 4 Bad Bugs" that aims to bring new antibiotics to patients and currently covers:</p> <ol style="list-style-type: none"> 1) innovative trial design and clinical drug development 2) learning from success and failure and getting drugs into bad bugs, and 3) discovery and development of new drugs for combating Gram-negative infections 4) Driving re-investment in R&D and responsible use of antibiotics 5) Clinical development of antibacterial agents for Gram-negative antibiotic resistant pathogens <p>This programme has a budget of more than €600 million</p>	<p>Two IMI Projects of the 6th call were launched in February 2013. COMBACTE pioneers new ways of designing and implementing efficient clinical trials for novel antibiotics²² and TRANSLOCATION aims to increase the overall understanding of how to get antibiotics into multi-resistant Gram-negative bacteria²³ Project ENABLE²⁴ puts in place an antibiotic drug development platform. The project aims to advance the most promising early discovery stage of novel antibiotic molecules from the academic and SME sector to early clinical development.</p> <p>ND4BB project DRIVE-AB²⁵ , launched October 2014, will develop concrete recommendations for new commercial models that provide industry with an incentive to invest in antibiotic development while ensuring that new antibiotics are used wisely.</p>

²⁰ <http://www.imi.europa.eu/>

²¹ <http://www.imi.europa.eu/content/rapp-id>

²² <http://www.imi.europa.eu/content/combacte>

²³ <http://www.imi.europa.eu/content/translocation>

²⁴ <http://www.imi.europa.eu/content/enable>

²⁵ <http://drive-ab.eu/>

		<p>In February 2015, COMBACTE-MAGNET was launched which aims to bring highly innovative studies and activities related to prevention and treatment of infections caused by multi-drug resistant Gram-negative bacteria²⁶.</p> <p>Proposal evaluation/ contract negotiations of additional projects going on in 2015.</p>
To ensure pricing conditions and other "pull" measures needed for the longer term sustainability of new antibiotic development	To set up an agreement with European Federation of Pharmaceutical Industries and Associations (EFPIA) on a "compact" of initiatives to promote a sustainable business model and adequate conditions for the introduction of effective new antibiotics.	
To assess the possibilities for increasing the efficiency of the market authorisation process in relation to new antibiotics	To launch a dialogue with the health authorities of the Member States and other relevant stakeholders in view of a co-ordinated approach to introduce incentives for the development and marketing of new antibiotics	Event on the best use of medicines legislation to bring new antibiotics to patients and combat the resistance problem (15 November 2013)
	To complete an assessment of relevant non-legislative market authorisation process aspects in view of streamlining and accelerating the introduction of new antibiotics	
	In light of the results of the assessment mentioned above, to identify possibilities of simplification/streamlining of testing/assessment requirements/procedures and accelerating the assessment process for new antimicrobials and where relevant launch a revision of the relevant guidelines	

²⁶ <http://www.combacte.com/News/News-Publications/ID/26/Launch-COMBACTE-MAGNET>

Action n° 7: Promote efforts to analyse the need for new antibiotics into veterinary medicine.		
Operational objectives	Concrete activities	Milestones / Deadline
To analyse the need for new antibiotics into veterinary medicine	To have scientific advice of European Medicines Agency (Committee for Medicinal Products for Veterinary Use (CVMP) and the Committee for Medicinal Products for Human Use (CHMP)) whether new classes of veterinary antimicrobials contribute to having a better management of the development of AMR and these new classes could be used in the veterinary sector or should be set aside for human use	Report published 2014 ²⁷ See also Action 3
	Follow-up of the scientific recommendation published in 2014 prepared by the Antimicrobial Advice Ad Hoc Expert Group (AMEG)	2015-2016
To facilitate the use of alternatives that may reduce the need for treatment with antimicrobials	Reducing the need for antimicrobials by using specific feed materials and authorised feed additives e.g. with possible effects on the gut flora	Authorisation of additives is dependent on applications received

²⁷ http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000385.jsp&mid=WC0b01ac058080a585

D. Joining forces with international partners to contain the risks of spreading AMR from international trade and travel and via the environment

Action n° 8:

Develop and/or strengthen multilateral and bilateral commitments for the prevention and control of AMR in all sectors.

Operational objectives	Concrete activities	Milestones / Deadline
Maintain and deepen EU/US transatlantic cooperation addressing AMR.	Implementation of the 17 Transatlantic Taskforce Antimicrobial Resistance (TATFAR) Recommendations ²⁸	TATFAR progress report published May 2014 ²⁹
	Bi-annual TATFAR audio-conference meetings and organisation of a face-to-face meeting with part of the group to review progress and discuss follow-up (depending on available funding)	
	End of 2013, TATFAR was prolonged until the end of 2015, 15 of the recommendations will continue, one new recommendation has been added.	
Discussion with international partners identifying areas of cooperation	Cooperation and joint actions in the fields of surveillance, promotion of prudent use of antimicrobials, awareness/communication and healthcare-related infection prevention and control.	
	Bilateral cooperation China-EU	1st Seminar China-EU (Beijing) March 2013 2nd Seminar China-EU (first half 2015) Comparative studies on policies (by first half 2015)
	Bilateral cooperation Russian Federation-EU	AMR as standing item of meetings of the Russian Federation Sub-group on Communicable Diseases (on hold)

²⁸ <http://www.ecdc.europa.eu/en/activities/diseaseprogrammes/tatfar/Pages/index.aspx?MasterPage=1>

²⁹ <http://www.cdc.gov/drugresistance/tatfar/index.html>

World Health Organisation (WHO)	Cooperation with WHO to support development of WHO Global Action Plan	Participation to WHO meetings related to the development of the WHO Global Action Plan Provide input to WHO consultation on global action plan
Implementation of the World Health Organisation (WHO/EURO)-DG Health and Food Safety “Health Security Roadmap” identifying Antimicrobial Resistance as an area for cooperation”	Annual WHO-EURO / EC Senior officials meetings reviewing WHO/EURO-DG Health and Food Safety “Health Security Roadmap”	WHO-EC meeting May 2013 WHO-EC meeting June 2014 WHO-EC meeting February 2015
	Cooperation to support capacity building (laboratories in charge of surveillance of AMR in the food chain) in non EU Member States	Several workshops and trainings (2014-2015)
World Organization for Animal Health (OIE)	Support to the Conference on Antimicrobial Resistance organized by the World Organization for Animal Health (OIE)	March 2013
	Collaboration revision chapters on AMR of the Terrestrial and Aquatic Codes and participation on ad hoc groups AMR	August 2013, January- July-December 2014
Food and Agricultural Organization (FAO)	Bilateral meeting FAO-EC	September 2014
To identify options for addressing potential risks from pharmaceuticals in the environment	Development of a strategic approach to pharmaceuticals in the environment	As soon as possible after September 2015
Rationale use of medicines through the Renewed Partnership EU-WHO in 15 countries ³⁰	1) Provide technical assistance to countries to update their list of essential medicines, their Standard Treatment Guidelines and their National Formulary 2) Provide technical assistance to countries to survey prescribing, dispensing and use of medicines using WHO methodology- Done in Ghana 3) Provide technical assistance to countries for improving prescribing,	Depends on the countries (x15)- below some examples: a)Burundi: Formation des formateurs sur l'utilisation du Guide des médicaments dans les centres de santé b) DRC: Réaliser une enquête sur les modes de prescription, la délivrance et l'utilisation des antibiotiques dans la Province Orientale.

³⁰ Burundi ; Cameroon ; Congo ; DRC ; Ethiopia ; Ghana ; Guinea-Conakry ; Kenya ; Mali ; Mozambique ; Senegal ; Tanzania ; Togo ; Zambia ; Zimbabwe.

	dispensing and use of medicines in public sector facilities- Tanzania: dispensers and prescribers from 10 districts trained in rational medicine use	c) Ghana: Develop surveillance system for antibiotic use in three in hospitals. Train staff to use the system to collect data on antibiotic use.
Local capacity building and awareness campaigns through a comprehensive support to national policy and Plans	Health is a sector of concentration in 17 countries ³¹ . The DEVCO main approach is to provide a comprehensive and coordinated support to the developing countries. Pharmaceutical strategic plans would cover aspects of medicines regulation, public sector procurement, supply and distribution and medicines use.	On-going with the development of the activities under the 11 th European Development Fund (EFD)

³¹ Burkina Faso ; Guinea-Conakry ; Guinea Bissau ; Mauritania ; Nigeria ; Burundi ; CAR ; DRC ; Ethiopia ; South-Soudan ; Zimbabwe ; Afghanistan ; Tajikistan ; Morocco and Grenada.

E. Monitoring and surveillance

Action n° 9:

Strengthen surveillance systems on AMR and antimicrobial consumption in human medicine.

Operational objectives	Concrete activities	Milestones / Deadline
Strengthen surveillance systems on antimicrobial resistance and antimicrobial consumptions through:	Ensuring the sustainability of the European Surveillance system of Antimicrobial Consumption (ESAC). Transfer of European Surveillance system of Antimicrobial Consumption to European Centre for Disease Prevention and Control	December 2012
	Publication of ESAC reports Publication of EARS-net reports Publication of point prevalence surveys	Several ESAC reports published EARS-net reports published November each year
	Implementation of the newly adopted measures on new case definitions for antimicrobial resistance and healthcare-associated infections (Commission Implementing Decisions 2012/506/EU of August 2012 under Decision No 2119/98/EC of the European Parliament and of the Council). ³²	Decision adopted 2012. Monitor of the implementation: by December 2015
	Addressing the lack of data on antimicrobial resistance and antimicrobial consumption in children: Completion of the Antibiotic Prescribing and resistance in European Children (ARPEC) project ³³	Completed mid-2014.

Action n° 10:

Strengthen surveillance systems on AMR and antimicrobial consumption in animal medicine.

Operational objectives	Concrete activities	Milestones / Deadline
Harmonized surveillance systems and monitoring on the occurrence of antimicrobial resistance and consumption of antimicrobials will	European. Surveillance of Veterinary Antimicrobial Consumption (ESVAC) ³⁴ project coordinated by the European Medicines Agency on collection data on the consumption of antimicrobials on a multiphase approach:	

³² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:262:0001:0057:EN:PDF>

³³ <http://www.arpecproject.eu/>

³⁴ http://www.emea.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jsp&mid=WC0b01ac0580153a00

<p>provided the necessary data on the use of antimicrobials and on the impact of antimicrobial consumption on the occurrence of antimicrobial resistance in the food chain (animals and food) in the EU.</p>	<ul style="list-style-type: none"> • Pilot project collecting standardized overall sales data • Collecting and report overall national sales data from all Member States 	<ul style="list-style-type: none"> • 4th ESVAC report October 2014 • From 2014-onwards: collect and report overall national data from participating Member States
<p>Harmonized surveillance systems and monitoring on the occurrence of antimicrobial resistance and consumption of antimicrobials will provided the necessary data on the use of antimicrobials and on the impact of antimicrobial consumption on the occurrence of antimicrobial resistance in the food chain (animals and food) in the EU.</p>	<p>Reinforce legal base for collection of antimicrobials in regulatory framework for veterinary medicines</p>	<p>Legal proposal for review of veterinary medicines 2014</p>
<p>Harmonization of surveillance and monitoring of antimicrobial resistance in the food chain:</p>	<ul style="list-style-type: none"> • Request of scientific and technical assistance to the European Food Safety Authority (EFSA) on harmonizing monitoring in bacteria transmitted through food. 	<p>EFSA opinion on harmonization monitoring AMR published in 2012³⁵</p>
<p>New legal framework for harmonised monitoring of antimicrobial resistance in zoonotic and commensal bacteria in the food chain.</p>	<ul style="list-style-type: none"> • Financial contribution from the Union to the harmonized monitoring of AMR carried out by the Member States. 	<p>Decision 2013/652/EU³⁶ on harmonised monitoring and reporting of antimicrobial resistance in the food chain in the EU.</p>
<p>Request of scientific and technical assistance to the European Food Safety Authority (EFSA) on randomisation of sampling for the purpose of AMR monitoring</p>	<ul style="list-style-type: none"> • Request of scientific and technical assistance to the European Food Safety Authority (EFSA) on randomisation of sampling for the purpose of AMR monitoring 	<p>Decision 2013/653/EU³⁷ financial aid towards a coordinated control plan for AMR monitoring in 2014. Financial aid for 2015: individual grant decision sent to the Member States in February 2015.</p> <p>EFSA opinion on randomisation of sampling for monitoring AMR published in May 2014³⁸</p>

³⁵ <http://www.efsa.europa.eu/en/efsajournal/pub/2742.htm> and <http://www.efsa.europa.eu/en/efsajournal/pub/2897.htm>

³⁶ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1403594558125&uri=CELEX:32013D0652>

³⁷ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1403594663786&uri=CELEX:32013D0653>

³⁸ <http://www.efsa.europa.eu/de/efsajournal/pub/3686.htm>

<p>Surveillance and monitoring of the occurrence of pathogens in the framework of Animal Health Law No treatment of animals without proper diagnosis; in particular treatment should not jeopardize detection of certain major pathogens.</p>	<p>Animal Health Law proposal</p>	<p>The same as for Action nr 5</p>
<p>To verify on-the spot that Member States comply with the legislation on monitoring of AMR. Identify good practices. Gather information on voluntary monitoring systems.</p>	<p>Two pilot audits (to develop approach in this area). A series of targeted audits in 6 representative Member States (issuing of individual reports after each audit with recommendations). Preparation of a final overview report (evaluation of the implementation of Decision 2013/652/EU by Member States /common difficulties/ good practices).</p>	<p>Pilot audits in the autumn 2015 Series of audits in 2016 Overview report by the end of first quarter 2017</p>
<p>The information on antimicrobial resistance and antimicrobial consumption collected by the three agencies EFSA, EMA and ECDC needs to be combined and analysed in order to allow a clear identification and quantification of the risk of developing and spreading antibiotic resistance in the food chain.</p>	<p>Request from the Commission to the 3 Agencies (EFSA, EMA and ECDC) on the establishment of a new organisational structure to improve the analysis of the data on AMR and consumption (Joint Interagency Antimicrobial Consumption and Resistance Analysis Report, JIACRA).</p>	<p>First JIACRA report published January 2015³⁹</p>
	<p>Follow-up of the scientific Joint Interagency Antimicrobial Consumption and Resistance Analysis Report (JIACRA).</p>	<p>2015-2016</p>

³⁹ http://www.ema.europa.eu/docs/en_GB/document_library/Report/2009/10/WC500004306.pdf
<http://www.efsa.europa.eu/en/efsajournal/pub/4006.htm>
<http://www.ecdc.europa.eu/en/publications/Publications/antimicrobial-resistance-JIACRA-report.pdf>

F. Additional Research and Innovation

Action n° 11:

Reinforce and co-ordinate research efforts. Innovation.

Operational objectives	Concrete activities	Milestones / Deadline
Reinforce antimicrobial resistance research in a coordinated fashion in three different thematic areas within the last calls of the seventh Framework Programme for Research:	<p>An overview of research projects related to drug resistance can be found: http://ec.europa.eu/research/health/infectious-diseases/antimicrobial-drug-resistance/index_en.html</p> <p>Under the 7th Framework Programme the European Commission has published Research Work Programmes in which call topics on AMR were published in a coordinated manner:</p> <ul style="list-style-type: none"> • HEALTH Work Programme (WP) (ftp://ftp.cordis.europa.eu/pub/fp7/health/docs/fp7-health-wp-2013_en.pdf), • KBBE Work Programme (ftp://ftp.cordis.europa.eu/pub/fp7/docs/wp/cooperation/kbbe/b-wp-201301_en.pdf) and the • NMP Work programme (ftp://ftp.cordis.europa.eu/pub/fp7/docs/wp/cooperation/nmp/d-wp-201101_en.pdf) 	2007 -2013
	The codes below refer to the call topics in the Work Programmes:	
Antimicrobial transfer throughout the food chain	<ul style="list-style-type: none"> • WP2013, call7, topic KBBE.2013.1.3-05 for €9Mio EU contribution 	Project EFFORT, which studies the ecology and transmission of AMR from farm to fork, started Dec 2013
Antimicrobial resistance in farming and animal production	<ul style="list-style-type: none"> • WP2012, call6, topics KBBE.2012.1.2-10 & KBBE.2012.1.4-04; 	Projects on Impact matrix analysis and cost-benefit calculations to improve management practices regarding health status in organic dairy farming ("IMPRO" ⁴⁰) and on Targeted disease prophylaxis in European fish farming ("TARGETFISH" ⁴¹ ;) projects started 4th quarter 2012.

⁴⁰ <http://www.dev.impro-dairy.eu/index.php/fr/>

⁴¹ <http://www.wageningenur.nl/en/show/TARGETFISH.htm>

Development of diagnostic tools for infectious diseases	<ul style="list-style-type: none"> WP2013, call7, KBBE topics KBBE.2013.1.1-01, KBBE.2013.1.3-03, KBBE.2013.3.5-01 for a total of €21Mio EU contribution 	<p>Projects related to "Routine diagnostic tool for urinary tract infections caused by extended spectrum beta lactamase and carbapenamase producing bacteria" (ROUTINE) and to "Rapid identification of respiratory tract infections (RID-RTI) "Development of a handheld antibacterial drug resistance diagnostic device using nanowire technology" (NANOMAL), "Automated next generation sequencing for diagnostic microbiology" (PATHSEEK), "Assured point-of-care device for Syphilis and HIV in pregnant women and new-born" (Preventit), "Rapid Aptamer based diagnostic for bacterial meningitis"(RAPTA Diag) and "Detection of persistent infections by human papillomaviruses" (PIPAVIR) are in particular related to drug resistance and started in 2012.</p> <p>The EC will launch on 26/2/2015 the Horizon Prize - Better use of Antibiotics, which offers a cash reward of €1 million to whoever who can develop a rapid test that will allow healthcare providers to distinguish, at the point of care, between patients with upper respiratory tract infections that require antibiotics and those that can be treated safely without them⁴². Award decision: 2016.</p>
	<ul style="list-style-type: none"> HEALTH.2012.2.3.0-1 	
	<ul style="list-style-type: none"> HOA 8 – 2015: Inducement Prize 	
Mobilise Small and medium enterprise (SME) to develop new antimicrobials and vaccines;	<ul style="list-style-type: none"> HEALTH.2013.2.3.1-1 	<p>7 Projects to support research and development of drugs, vaccines or alternative treatments for bacterial infections have been funded⁴³ The work of 44 innovative SMEs will be directly supported</p>
Research to the use of antimicrobials via personalised approaches	<ul style="list-style-type: none"> HEALTH.2013.2.3.1-2 	<p>4 other funded projects seek to identify better methods to use currently available antibiotics.</p>

⁴² www.ec.europa.eu/horizonprize/antibiotics

⁴³ [http://europa.eu/rapid/press-release MEMO-13-996_en.htm?locale=en](http://europa.eu/rapid/press-release_MEMO-13-996_en.htm?locale=en)

Developing novel nanotechnology enabled therapies for bacterial infectious diseases	<ul style="list-style-type: none"> • NMP.2013.1.2-2 • HEALTH. 2012.2.3.1-1 	Another 4 projects study the usage of novel nano technology for drug delivery.
Support the Joint Programming Initiative (JPI) on Antimicrobial Resistance (AMR)		Participation in the Management Board of the JPI AMR as a non-voting member and funding for the implementation of this JPI via a coordination and support action (since end 2012), first call launched Jan 2014 JPIAMR Strategic Research Agenda launched 3 April 2014
	<ul style="list-style-type: none"> • HCO 12 – 2015: ERA-NET 	First H2020 WP published at the end of 2013 EC support of transnational research call of JPIAMR via ERA-NET Co-fund scheme
	<ul style="list-style-type: none"> • 1st transnational call: InnovaResistance http://www.jpiaamr.eu/activities/open-call/ 	
Contribute to a global mapping of drug resistance	<ul style="list-style-type: none"> • H2020 WP 2014-15 	Meeting between the World Health Organisation (WHO) and the European Commission (EC) in January 2012, participation in WHO Advisory Group 2013
	<ul style="list-style-type: none"> • Cooperation and joint actions in the field of global mapping 	
Foster Innovation-Focus group on reduction of antimicrobials in pig production	Creation of the focus group (20 experts).	2013
	Develop and explore cost-effective integrated strategies to reduce the use of antibiotics. Final report of the focus group.	Publication final report in 2014 ⁴⁴

⁴⁴ <http://ec.europa.eu/eip/agriculture/en/content/animal-husbandry>

G. Communication, education and training

Action n° 12:

Communication, education and training: Survey and comparative effectiveness research.

Operational objectives	Concrete activities	Milestones / Deadline
Assess and improve the impact of the EU awareness and communication initiatives on antimicrobial resistance	European Antibiotic Awareness Day (EAAD) evaluation report	Publication of EAAD evaluation report ⁴⁵
	Annual EAAD stakeholder event and communication activities	EAAD marked annually around 18 th November ⁴⁶
Monitor evolution of behaviour on antimicrobial resistance and prudent use in human medicine	3 rd Eurobarometer Survey on antimicrobial resistance	Eurobarometer published and presented at the occasion of European Antibiotic Awareness Day 2013 ⁴⁷
Monitor evolution of behaviour on antimicrobial resistance and prudent use in veterinary medicine	In collaboration with relevant stakeholders identification of target groups and evaluation, (surveys, enquires, etc) on the impact and implementation of campaigns on prudent use antimicrobials, awareness, etc.	2015
Conference Antimicrobial Resistance: Dissemination of information about EU approach on antimicrobial resistance	Mid-term review of the Commission's 5-year action plan against AMR with competent authorities of member states, international organizations and stakeholders representatives, focussing discussions on the challenges ahead, the drivers and possible limitations of the envisaged measures.	11 December 2013 ⁴⁸
To inform about the progress made so far on the implementation of the Action Plan.	AMR Progress report	Published February 2015 ⁴⁹
To evaluate the impact and effectiveness of the measures taken and goals achieved by the implementation of the 5-year Action Plan	Ex-post evaluation	By mid 2016

⁴⁵ <http://ecdc.europa.eu/en/eaad/Pages/Home.aspx>

⁴⁶ <http://ecdc.europa.eu/en/EAAD/Pages/Home.aspx>

⁴⁷ http://ec.europa.eu/public_opinion/archives/ebs/ebs_407_en.pdf

⁴⁸ http://ec.europa.eu/health/antimicrobial_resistance/events/ev_11122013_en.htm

⁴⁹ http://ec.europa.eu/health/antimicrobial_resistance/docs/2015_amr_progress_report_en.pdf