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)

Stakeholders' Workshop 2: Summary report

RAND Europe

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Prepared for Directorate General for Health and Food Safety (DG SANTE)

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Introduction

As part of the '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),' a one-day workshop for EU-level stakeholder organisations was held on 16 February at European Commission premises in Brussels, Belgium. The evaluation was commissioned by the Directorate General for Health and Food Safety (DG SANTE) and is being delivered by RAND Europe. This report provides an overview and summary of the main messages from discussions that took place during the workshop.

Workshop objectives:

1. Inform stakeholders about the evaluation results and conclusions.
2. Obtain feedback from stakeholders about the findings and recommendations, in order to further test the validity of the findings and refine the recommendations.

Participants:

A total of 38 individuals representing 36 organisations and companies attended the workshop (Appendix 2). Of these 38 individuals, six were active in areas mainly related to animal health and veterinary medicine; 11 in human health and medicine; seven in food safety, consumer interests or the livestock trade; and 13 in research and innovation. Three RAND Europe facilitators[1] and three observers from DG SANTE[2] also attended.

Structure:

The morning session focused on the findings and conclusions from the evaluation, while the afternoon focused on the preliminary recommendations. In the morning, the facilitators presented the findings and then had an open plenary discussion, which enabled participants to comment on or ask about the findings. In the afternoon, the facilitators presented their draft recommendations and then facilitated two discussion sessions. First, participants were assigned to one of six small groups based on interest area (group allocations are listed in Appendix 2) and

[1] C. Lichten, E. Smith, E. Dujso.

[2] R. Horgan, K. Kielar, E. MacDonald.

asked to discuss specific recommendations and questions (a sample group activity sheet is in Appendix 5). Next, in a plenary session, participants reported the outcomes of their group discussions and discussed the recommendations. For a detailed agenda, see Appendix 1.

This report presents the main points that arose during the plenary discussions and in additional written feedback submitted by some participants to the facilitators. It does not present all comments made throughout the day, but rather aims to capture the main ideas that were discussed.

Feedback received from the participants about the workshop itself – including what they found useful and areas for improvement – is summarised in Appendix 3.

The main points discussed during group and plenary sessions

Morning session: Findings

This section is organised according to the headline findings presented, with comments grouped according to each set of findings.

Headline findings:

- The EU Action Plan was important as a symbol of political commitment to tackling AMR.
- The holistic and 'One Health' approaches were necessary to address AMR.

Comments:

- The holistic approach was achieved, but there should be more focus on research and development (R&D) to ensure the supply of antimicrobials is maintained.

Headline finding: The issues covered by the Action Plan were relevant, but there were some gaps on environmental issues and international cooperation.

Comments:

- Conservation of existing antibiotics is also important, and should be linked to innovation and stewardship.
- One source of antibiotics in the environment is their use in plant products.
- Efforts to address environmental issues related to AMR could be linked to existing EU and Member State (MS) initiatives, such as existing studies on wastewater treatment, the Innovative Medicines Initiative (IMI) CHEM21 project on sustainable manufacturing of medicines,[3] and LeSPAR[4] cross-sector work on open innovation.
- Given the migration occurring in the EU now (a population prone to disease/infection), there is a need to look at epidemiological impacts in collaboration

[3] http://www.imi.europa.eu/content/chem21

[4] Learned Society Partnership on Antimicrobial Resistance

with the World Health Organisation (WHO) and ensure care is available to these vulnerable populations.

Headline finding: Monitoring and surveillance activities were generally a success, but more could have been done.

Comments:

- The European Association of Hospital Pharmacists (EAHP) has performed surveys on practices in hospital pharmacies;[5] they found that little improvement had taken place in AMR surveillance and see a need for challenges to communication and implementation to be addressed, particularly in Eastern Europe.

Headline finding: There were challenges with addressing the public health dimension given diversity of Member State approaches.

Comments:

- Conservation issues relate to availability: there are shortages of antibiotics and some are not being marketed in all countries.
- When comparing data on antimicrobial usage across countries, it is important to consider the reasons why some countries may use more antimicrobials than others. Reasons could include differences in context such as climate conditions or bacterial strains present in a given country.
- Given that the EU has limited power in human health, other ways to encourage MS to act include benchmarking studies and making some funding contingent on action being taken or progress being made.
- It is important that MS develop Action Plans and also implement them.
- Education is very important, especially in primary care.
- There is a need to engage with hard-to-reach groups, and these groups require a different approach than the general public.
- There is a need to distinguish interventions that change behaviour from those that merely provide information, particularly for patients.

[5] Full data for surveys done in 2005 and 2010 available at: http://www.eahp.eu/publications/surveys

- It may be helpful to make it clearer to patients (through labelling) which medications are antibiotics.

Headline finding: Research and innovation funding was sufficient and wide-ranging but several issues still need to be addressed.

Comments:

- 'Alternatives' (including diagnostics, vaccines, and other alternative and complementary approaches) are important and may be inadequately addressed in the Action Plan.
    - In addition to R&D, there is a need for existing vaccines and vaccination programmes to be used.
    - There is a need to develop treatment alternatives for mild urinary tract infections (UTIs), sore throats, etc. (for patients who are not severely ill).
    - It is important to consider the sociological issue that a patient expects something when they visit the doctor. Good communication with patients is essential. When the best alternative is doing nothing, there is a challenge in convincing the patient.
    - There is a need to develop evidence-based recommendations on the use of different forms of complementary medicine; there is evidence that integrative medicine settings have lower rates of antibiotic prescriptions but overall current studies in this area are weak.
    - However, a recent Lancet infections disease article suggested there is still a need for new traditional antibiotics.[6]
- Progress has been made including increased funding and development of regulatory guidance by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA). However, while money has gone into R&D over the last five years, it is still early in the cycle so this improvement is fragile.
- A vision is needed for antimicrobials development for treating animals. Stakeholders such as the European Federation for Animal Health and Sanitary Security (FESASS) expect new ingredients will be used in humans first and do not think incentives for development of veterinary antimicrobials have improved in the EU.

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[6] 'Alternatives to antibiotics: a pipeline portfolio review' by L. Czaplewski et al. Lancet Infectious Diseases, 12 January 2016.
http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(15)00466-1/abstract

- For human health, the IMI collaboration has been constructive for those involved, and was linked to the Joint Programming Initiative's (JPI's) activities. The IMI could also consider providing data access for people outside its consortia.
- Given that it takes 10-12 years for new drugs to be developed, there is a need for a longer-term plan to sustain support for the pipeline of innovation.
- Small- and Medium-sized Enterprises (SMEs) are under-funded relative to U.S. competitors; innovative funding (from the EU) is needed to lure back private investors.
- An ERIC or IRIC (European or International Research Infrastructure Consortium) could be used to support information technology (IT), biobanking, etc. required for bringing together AMR researchers across the EU.
- It is important to have a diverse range of solutions. While public money should not be wasted, there needs to be some allowance for failure to encourage risky ideas to be explored.

Headline findings:

- Policies to address the use of antimicrobials in human medicine improved, but volumes of antimicrobials consumed did not change
- Animal health legislation and guidance represent major Action Plan achievements and overall sales of veterinary antimicrobials decreased

Comments:

- Comments on the need to reduce use of antimicrobials were mixed.
  - The final goal is to reduce AMR, not just focus on reducing antimicrobial use, so there is a need to improve prudent use (as well as communication and education), and see what factors drive increased usage in different countries.
  - If there is too much emphasis on reducing use, veterinarians could become reluctant to take necessary steps when infections do arise.
  - The EMA's strategy on use indicated that there is a need for decreasing use and increasing prevention infection through biosecurity, vaccines, etc.[7]
  - Usage must be reduced, and this requires farmers to be able to implement biosecurity measures.

7 http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/11/WC500196645.pdf

- If intensive farming systems exacerbate the problem, a different farming model is needed, but it is unclear how much evidence on the link between AMR and farming practices is available.

Afternoon session: Recommendations

In this section, the recommendations that were presented to the participants are listed, followed by a summary of the comments made for each set of recommendations.

1	Conclusion	The holistic approach adopted by the Action Plan was essential to tackling AMR. The EU played an important role in providing political leadership and encouraging the intersectoral collaboration necessary to pursue a holistic approach to addressing AMR.
	Recommendations	• The holistic and 'One Health' approaches should be reinforced and could be strengthened through cross-sector initiatives. The EU should take further action to enable greater engagement between sectors. • Reach and relevance could be expanded by dedicating resources to an EU-level coordinating mechanism on AMR. This could increase visibility of intra-Commission engagement, encourage more and faster action by Member States, encourage cross-sectoral interactions among stakeholders, raise AMR awareness in the EU.

There were no comments made about this set of recommendations during the afternoon discussion session.

2	Conclusion	A gap was identified in the Action Plan in addressing environmental issues.
	Recommendations	Environmental issues could be better integrated into future EU action on AMR through an approach involving: • Research to better understand the role of AMR transmission from the environment to humans (through animal, human and manufacturing waste); • Supporting the development of monitoring and surveillance systems that capture data on AMR circulation in the environment; • Using this improved understanding to inform how environmental policies could help reduce the spread of AMR; • Identify ways to involve DG Environment in future AMR action; and • Coordinating with ongoing Commission work on a strategic approach to addressing the risks of pharmaceuticals in the environment.

Comments from the Farming, Food and Consumers group:

- There could be a benefit to research by understanding AMR's role in the environment, but a problem needs to be identified first, and then work backwards to identify its source.
- There are many issues to be researched, so it would be important to weigh the relative importance of research in this area against them.
- It may be premature to implement environmental surveillance before doing more research. Monitoring and surveillance is costly, and it could be more relevant to improve existing systems first. Monitoring and surveillance should only be done if the data would be used to make a difference.

Comments from others:

- There is a need for a proper risk assessment framework before taking these actions. There are multiple potential reservoirs for AMR in the environment, but we do not yet have a quantitative understanding of the importance of each or how they interact. One must first work out what to monitor before doing costly monitoring.

3	Conclusion	International cooperation was effective but more could be done to address AMR as a global issue and support developing countries.
	Recommendations	• Work with WHO towards a global approach to monitoring and surveillance, building EU leadership in developing approaches that brought together data from many national systems. • Continue work with international organisations such as the WHO, TATFAR, World Organization for Animal Health (OIE) and the UN FAO, including support for the Joint Programming Initiative on AMR mapping of AMR research activities, highlighted by the WHO • Support countries with limited capacity to address AMR including education and awareness, strengthening health systems and training health professionals.

There were no comments made about this set of recommendations during the afternoon discussion.

4	Conclusion	Monitoring and surveillance activities focusing on human and animal health issues improved under the Action Plan. The EU could build on these successes at multiple levels.
	Recommendations	• The EU could build a more holistic system for monitoring AMR issues, linking data on resistance, consumption and sales of antimicrobials to prescribing trends and other factors. • Environmental data should be included in future monitoring and surveillance efforts. • The EU could contribute to building a global monitoring and surveillance system.

Comments from the Human Health 2 group:

- It is currently unclear what the role of healthcare professionals is in monitoring and surveillance. Surveillance should not be used to question diagnoses.
- The group members disagreed about whether global monitoring is a priority and/or feasible.
- Coordinate with others on waste management, e.g. the Meds Disposal Campaign.
- The EU *should* (not could) build on current successes.

Comments from the Animal Health group:

- The recommendations seem suitable, but any intervention needs to be applicable, practical, and proportionate.
- Veterinary monitoring currently includes EFSA data on foodborne pathogens but nothing on veterinary pathogens themselves so this is an area where more could be done.[8]
- In terms of global monitoring, the EU can do a lot in terms of advising, but the OIE and FAO are mainly responsible for this work.
- While there is emphasis on reducing antimicrobial usage, there is a need for some context in monitoring to understand why some countries may show higher levels of antimicrobial sales. For instance, if a country faced a disease outbreak one year, they

[8] For instance, there is currently a project led by Peter Borriello (Veterinary Medicines Directorate, UK) on this issue.

would need to use more antimicrobials; higher usage should not be interpreted as poor practice before contextual factors were considered.

Comments from others

- Some countries supply hospital use data, but not all; there could be improvement in data coverage for hospitals.
- In general, there is a benefit in having a holistic system that could put data more into context.
- Global monitoring is unrealistic. The EU role should focus more on supporting countries with difficulties collecting data and encouraging sharing of best practices across MS.
- If EU legislation required countries to provide data to the ECDC, ECDC maps would have accurate information, which would help the global health situation across Europe.

5	Conclusion	There was considerable variability in the extent to which Member States addressed AMR, particularly in the context of human health. Different countries also faced diverse issues.
	Recommendations	• The Commission should continue providing guidance and support to Member States to encourage good practice in public health services and surveillance. • The Commission should continue to support awareness-raising activities through European Antibiotic Awareness Day, and continue to monitor their impacts. • Targeted attention could be paid to specific areas where a Member State is struggling and understanding the specific challenges blocking progress. A one-size-fits-all approach will be insufficient. Both funding and technical support are likely to be required for lagging countries.

Comments from the Human Health 1 group:

- Generally the recommendations are suitable, but may not be feasible. There is a need for tailored guidelines, but MS contexts vary a lot. Without knowing how to ensure good clinical practice is achieved, it will be difficult to reduce variability across MS.
- It could be helpful to identify best practice in some countries and how it is implemented, then encourage other countries to adopt those approaches.
- Recommendations and guidance are weak; in some cases (such as the need for MS to implement rules about antibiotics being given only on prescription) there may be a need for stronger legislation.[9]
- There may also need to be action taken to reduce the online availability of antibiotics.[10]
- There is a need for research on integrated remedies to ensure medical practice is evidenced-based.
- The recommendations should place more emphasis on good diagnostic practice; there is a need for guidance based on best practices that can be easily implemented.

[9] The Research group also made this comment

[10] The Research group also made this comment.

- Awareness is not enough. There is also a need to support education for patients and healthcare professionals, and to monitor results of those interventions.
- There is more knowledge about infection prevention and control within hospitals than outside them, so infection prevention and control outside hospitals (e.g. in schools and migrant centres) should be improved.

Other comments:

- Important issues include disparities in access to antibiotics across Europe.
- In addition to EU-level coordination, it may help to have initiatives that encourage coordination at a regional level (involving a few countries), so that countries facing similar challenges can work together.
- An EU mechanism should be introduced to ensure that all antibiotics that should be available in countries are available.

6	Conclusion	Critical funding extended to research activities was catalysed by the Action Plan.
	Recommendations	• The roles of the EU and the Member States should be clarified. • The EU should consider how to focus more attention on the development of alternative treatments in addition to new antimicrobials. • The EU should consider widening AMR research activities to encompass behavioural and social aspects of AMR, for example, regarding prescribing behaviours in veterinary medicine and reasons patients do not use antibiotics as prescribed (as in the ARNA project). • Continue to identify incentives for developing veterinary medicines.

Comments from the Research group

- There is a need to improve coordination in research and development, but not to clarify roles.
- The JPI is an existing mechanism that effectively promotes coordination. An inventory of projects could further improve coordination.
- Specific suggestions for recommendations:
  - Develop research infrastructure (perhaps using an ERIC or IRIC mechanism), e.g. a clinical trials network for recruiting patients with persistent infections, or a primary care network (also linked to social science to look at behavioural aspects).
  - Benchmark research expenditure on AMR. It can be useful to show policymakers how little funding actually goes into AMR research compared to other areas.
  - It may be helpful to look at old products, re-evaluate them in modern clinical practice, and make them available again, or to explore alternatives that have been developed in countries where antibiotics are not readily available.
  - There is more to do in encouraging open collaboration, though this has started within the IMI.
  - R&D collaboration should go beyond Europe to the U.S., Russia, China, etc.
  - More young researchers should be encouraged to work in microbiology and on AMR topics.

- Alternative treatments would relate to 1) different technologies and 2) alternatives to treatment that avoid use of antibiotics (e.g. topical dressings like honey).
    - There are many potential alternatives, and it is unclear how to encourage research investment in this area. The focus of research/investment should not be dictated from the EU level.
    - There may be gaps regarding how alternative treatments would be assessed for regulation, and the route to market may be unclear.
- There is a need for incentives for all antimicrobials (not just veterinary antimicrobials), as featured by the G7 statement,[11] and this issue is missing from the Action Plan and recommendations.

Comments from the Innovation group

- Coordination is key, but not just for funding, also for the research agenda.
- 'Alternatives' should also encompass diagnostics and prevention.
- Before widening AMR research to look at social factors, wait for the outcome of the current Action Plan. That is, review existing data before doing more research.
- Regarding incentives for development of veterinary antimicrobials, there is a need for public-private partnerships and consideration of alternatives to veterinary antimicrobials. The issue is broader than research, encompassing business models, reimbursement, intellectual property, and tax rebates (see O'Neill review for further discussion).

Comments from others

- There is a need for support for vaccine development, innovation in technologies and treatment alternatives, and measures to prevent infection (in humans and animals).
- In veterinary medicine, the lack of incentives for innovation is still an issue. There is support in the new regulation on Veterinary Medicinal Products, but the option to reserve a new antibiotic for human use is a new barrier.
- There is a need for alternative treatments when antibiotics are not appropriate, so research should focus on relief of upper respiratory infections and UTIs.
- There is also a need for research to answer questions in everyday practice, e.g. doctors often cannot say they won't treat a patient; they must offer alternatives.

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[11] http://www.bmg.bund.de/fileadmin/dateien/Downloads/G/G7-Ges.Minister_2015/G7_Health_Ministers_Declaration_AMR_and_EBOLA.pdf

- There is a need for evidence about the complementary medicines that are in use in Europe.

Additional suggestions about the conclusions and recommendations, and general comments about the Action Plan and its role

Vaccines and infection prevention:

- The Action Plan should cover vaccines, not only in terms of R&D, but also in terms of their use, helping with access to vaccines and implementation of vaccine programmes. There are existing, effective vaccines that are underused. The EU could help monitor vaccine coverage and encourage countries to implement vaccination programmes.

Innovation:

- Overall, the EU approach for R&I should take a long-term view. The Action Plan lasts five years, but drug discovery takes much longer, so support needs to be sustained.
- The European Commission needs to take an innovation systems approach, going from basic research to how antibiotics, vaccines and diagnostics could be used. The JPI is making progress but challenges remain in ensuring the market encourages innovation.
- Universities, SMEs (e.g. around 30 companies in the BEAM alliance are developing about 100 products related to AMR) and research performing organisations are important players, and they are also working with big pharmaceutical companies.
- There is a need for more on-site diagnostic tools (and biosecurity) in farming.

The role of the Action Plan and the EU's approach to AMR:

- The Commission should be more visible. It is doing a lot, but not talking about its work very much.
- The Action Plan should be compared to other work, such as the O'Neill review, G7 statement, and the national action plans posted on the ECDC website, so Commission work doesn't happen in isolation.

Education and training for patients and healthcare professionals, and the role of antimicrobial stewardship:

- Patient groups[12] haven't been targeted enough in the Action Plan. They are a good way to share information, inform attitudes, and build pressure from consumers.

[12] Such as the International Alliance of Patient Organizations (IAPO) and European Patients Forum

- Education and training are very important, including education of the community, healthcare workers and future healthcare workers to not over-prescribe antibiotics. There needs to be more emphasis on antimicrobial stewardship in the Action Plan.

Conclusion

The main points that emerged from the workshop are summarised below. These points reflect the experiences and views of the participants present. Some issues may have received more emphasis than others, in part due to the mix of participants in attendance and their interests.

1. There is a need for greater focus on **collaboration and communication between doctors and patients, and veterinarians and farmers.**
    a. Primary care doctors have a particularly important role in discussing AMR and appropriate usage of antibiotics with their patients, as do veterinarians with farmers.

2. **Reducing the use of antimicrobials should happen through both reductions in inappropriate use and implementation of measures to prevent infections**, which would reduce the need for antimicrobials.
    a. It is important that pressure to reduce antimicrobial usage does not interfere with appropriate treatment of infections.
    b. Data on usage should be considered in light of contextual information that could help explain why certain usage patterns occurred.
    c. A more holistic approach to monitoring could help put data into context.

3. **Research and innovation are clear priorities, but require a longer timescale to achieve progress** than other interventions, such as infection prevention and improvements in the appropriateness of usage.
    a. Consultees may have prioritised research and innovation less than the areas of AMR that appear more able to bring immediate impacts.
    b. EU efforts to address AMR must factor in this longer timescale, ensuring support is sustained and covers the entire research and innovation system (including training the research workforce and the full pipeline from basic research to the final stages of product development and marketing).

4. **Research should not focus only on traditional antimicrobials;** there is a need for support to develop diagnostics (particularly point-of-care diagnostics) and vaccines, to improve the evidence base for alternative and complementary medicine approaches that are already in use in Europe, and to improve our understanding of social factors that affect the use of antimicrobials.
    a. There is still no clear future seen for the role of innovation in veterinary antimicrobials.

5. **There is potential to further improve coordination of AMR research and innovation**, but it is important to support a diverse range of ideas and research actors.

a. Coordination and collaboration in AMR research has improved, in part driven by the JPI and IMI.
b. An inventory of AMR research projects could help map the AMR research landscape.
c. European research infrastructures could help support AMR research by supporting research networks and biobanking, and helping to enable clinical trials.
d. The sharing of IMI data outside of the consortia could help that research investment go further.
e. The EU should consider developing research collaborations in AMR with a range of third countries, including China and Russia as well as the U.S.

6. In addition to developing new treatments, **it is important to use the drugs we have effectively.**
    a. There is a need to ensure access to existing antimicrobials and vaccines across MS.
    b. Stewardship is important for the appropriate use of antimicrobials and should be further emphasised in the Action Plan.

7. **More needs to be done to ensure progress across MS**, particularly in public health and on issues such as the availability of antibiotics without prescription.
    a. Approaches that could be taken at EU level to address the disparities that persist could include:
        i. Benchmarking studies across MS,
        ii. Funding that is contingent on AMR action,
        iii. Encouragement of collaboration and sharing of best practice at regional level (as opposed to EU-level),
        iv. Facilitation of exchange of best practice among MS.

8. **Efforts to address AMR in the environment and waste management should build on existing initiatives, and on research** about what type of environmental monitoring or other intervention would be appropriate.
    a. Monitoring systems should not be introduced until it is clear what data would be useful and how such data would be used.

9. **The EU should focus on improving monitoring and surveillance data within the EU.** Global monitoring efforts are a lower priority.
    a. Monitoring of non-foodborne veterinary pathogens could be introduced.
    b. There is a need to improve coverage of human health data across the EU.

Appendix 1: Workshop agenda

9:40 – 10:00	**Arrival, registration**
10:00 – 10:50	**Session 1 (plenary presentation): Overview of the Action Plan, agenda for the day** - Welcome: Summary of the Action Plan (objectives, timescale, current status), the evaluation (rationale, scope, approach, timescale, current status), and the plan for the day - Participants introduce themselves
10:50 – 12:00	**Session 2 (plenary presentation and plenary discussion): Present evaluation results** - Presentation: Headline findings - Discussion: Questions and comments, also invited in written form
12:00 – 13:30	**Lunch break**
13:30 – 14:00	**Session 3 (plenary presentation): Present recommendations** - Brief recap on the morning discussions, and afternoon plans - Presentation of recommendations
14:00 – 14:50	**Session 4 (group discussions): Discuss recommendations** Participants discuss the recommendations in groups, focusing on whether they are: - **Suitable** and appropriate for the Action Plan and AMR situation; - **Feasible**; and - **Acceptable** to the actors involved (particularly those represented by the workshop participants).
14:50 – 15:20	**Break** (refreshments, networking)
15:20 – 16:00	**Session 5 (plenary discussion and presentation): Review recommendations discussion, reflection and close** - Each group presents the headlines from their discussions on the recommendations - Discussion of what happens next, how the workshop results will be used in the evaluation, workshop reporting - Completion of workshop review form

Appendix 2: List of registrants and group discussion participants

Colin Adams	ELPHA (European Live Poultry and Poultry Hatching Egg Association)
Leo Aerden*	European Group for Generic Veterinary Products
James Anderson	GlaxoSmithKline
Brendan Barnes	EFPIA (European Federation of Pharmaceutical Industries and Associations)
Elisabeth (Els) Bedert	Eurocommerce
Marie Blanchard	Novartis
Thomas Lothar Breitkreuz	Eurocam (Complementary and alternative medicine)
Dariel Burdass	Microbiology Society
Pauline Castres	BEUC (The European Consumer Organisation)
Rosemary (Rose) Cooper	EWMA (European Wound Management Association); Professor of Microbiology
Jan Dahl*	UECBV (European Livestock and Meat Trading Union)
Asija Delalić	European Federations of Nurses Associations
Olivier Espeisse	European Federation of Animal Health
[name redacted by request]	
César González	COPA-COGECA
Marie Françoise Gros	MedTech Europe
Klaus Hellmann	Association of Veterinary Consultants
Anne Horan	Royal Society of Chemistry
Despoina Iatridou	Federation of Veterinarians of Europe
David John	IFAH-Europe (European Federation of Animal Health)
Robert Johnstone	IAPO (International Alliance of Patients' Organizations)
Olga Kikou	Compassion in World Farming
Elizabeth Kuiper	EFPIA (European Federation of Pharmaceutical Industries and Associations)
Marc Lemonnier	Antabio
Sascha Marschang	European Public Health Alliance
Alessio Gerardo Maugeri	Federation of European Microbiological Societies
Jasna Mesarić	ESQH (European Society For Quality In Healthcare)
Tajda Miharija Gala	EAHP (European Association of Hospital Pharmacists)
Katarina Nedog	EGA (European Generics and Biosimilar Medicines Association)

Jeanette Nenniger	F. Hoffmann-La Roche Ltd
Valérie Oriol Mathieu	Vaccines Europe
Benedikt Pelzer	EMSA (European Medical Students' Association)
Celine Pulcini	ESCMID (European Society of Clinical Microbiology and Infectious Diseases)
Melina Raso**	Health First Europe
Sara Roda	Council of European Dentists
Harald Schliessnig	Association of Poultry Processors and Poultry Trade
Hans Peter Schons	FESASS (European Federation for Animal Health and Sanitary Security)
Katarzyna Świderek	EPSA (European Pharmaceutical Students' Association)
Alike van der Velden	WONCA (The World Organization of Family Doctors)
Otto Arij (Rens) van Dobbenburgh	Federation of Veterinarians of Europe
Rebecca Veale	National Farmers Union

* Registered but did not attend (no reason given)

** Registered but did not attend (due to illness)

Number of registrants	41
Number of attendees	38

Afternoon Discussion Groups

Animal health	**Human health 2**	**Human health 1**
1. Klaus Hellman 2. Olivier Espeisse 3. Despoina Iatridouou 4. Rens van Dobbenburgh 5. David John 6. Hans-Peter Schons	1. Sara Roda 2. Tajda Miharija Gala 3. Katarzyna Swiderek 4. Jasna Mesaric 5. Robert Johnstone 6. Benedikt Pelzer	1. Asija Delalic 2. Rosemary Cooper 3. Thomas Breitkreutz 4. Sascha Marschang 5. Marie-Françoise Gros
Food, Farming & Consumers	**Research**	**Innovation**
1. Harald Schliessnig 2. Cesar Gonzalez 3. Rebecca Veale 4. Olga Kikou 5. Pauline Castres 6. Elisabeth Bedert 7. Colin Adams	1. Celine Pulcini 2. Alessio Maugeri 3. Anne Horan 4. Alike van der Velden 5. Dariel Burdass 6. Brendan Barnes 7. James Anderson	1. Marie Blanchard 2. Marc Lemonnier 3. Elizabeth Kuiper 4. Jeanette Nenniger 5. Valerie Oriol 6. [name redacted by request]

Appendix 3: Feedback about the workshop

Attendees were asked to fill in a feedback form at the end of the workshop. They were asked to rate the workshop overall on a scale from one to ten, state which aspect they liked most and which could be improved, and to write one message about AMR in the EU or the Action Plan they felt was important for the evaluation. (Most of the responses to this last question came up during the workshop itself, and they have been incorporated to the main workshop report). The workshop facilitators received 35 feedback forms.

On the whole, feedback from participants was positive (Figure A1). Attendees reported that the opportunity to have discussions in small groups and with a range of stakeholders were positive aspects of the workshop. Several participants highlighted the small group discussions as being useful while others referred to the plenary discussions. The opportunity to obtain information on the preliminary results and recommendations was also seen as a positive aspect. Some participants said the workshop had been well organised with good time management, and some said it was a good networking opportunity.

Among areas for improvement, the two main issues identified were i) that the slides were not visible in the morning session due to an IT problem and ii) that it would have been helpful to receive the conclusions and recommendations in advance of the workshop to enable more reflection on them. Several participants said the morning session should have been more structured and focused, and several commented that it would have been helpful to hear from the European Commission about the wider context of the Action Plan and future plans. Among practical considerations, participants suggested it would have been helpful to have participants' organisations printed on their badges and to have name-cards on the tables at each person's seat.

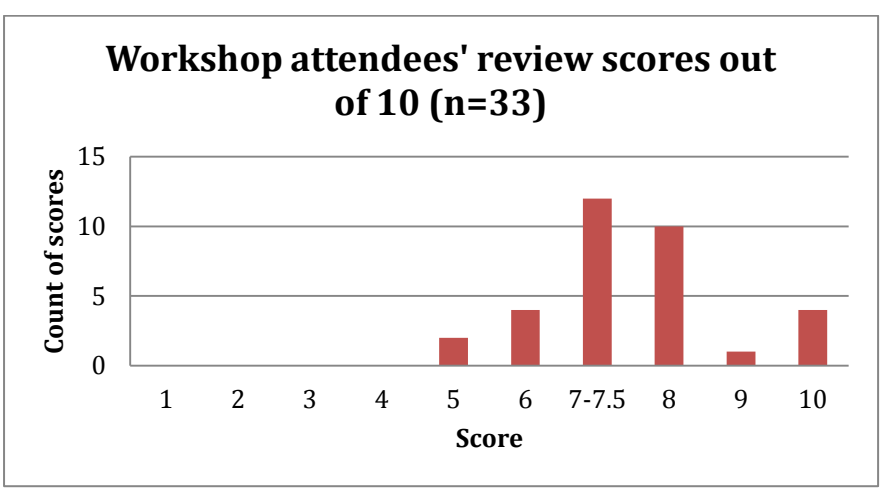

Figure A1 Scores from workshop feedback question: 'How would you rate the event? (1-10, with 10= excellent)'. Mean score= 7.5.

Appendix 4: Documents, events and initiatives mentioned during the workshop

Documents:

- Czaplewski et al. 'Alternatives to antibiotics: a pipeline portfolio review'. *Lancet Infectious Diseases*, 12 January 2016. http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(15)00466-1/abstract
- EAHP surveys on hospital pharmacies (2005 and 2010; 2015 data to come http://www.eahp.eu/publications/surveys)
- EMA: CVMP strategy on antimicrobials 2016-2020 (DRAFT), 6 November 2015
- http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/11/WC500196645.pdf
- EMA and FDA regulatory guidance: EMA: http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500194333
- EUROCAM. 'The role of CAM in reducing the problem of AMR'. Brussels, November 2015.
- G7 declaration on AMR http://www.bmg.bund.de/fileadmin/dateien/Downloads/G/G7-Ges.Minister_2015/G7_Health_Ministers_Declaration_AMR_and_EBOLA.pdf
- O'Neill AMR Review (ongoing; multiple reports, www.amr-review.org)

Organisations and initiatives

- BEAM alliance of SMEs (http://beam-alliance.eu/)
- IMI Chem21 project on drug manufacturing waste http://www.imi.europa.eu/content/chem21
- Learned Society Partnership on Antimicrobial Resistance (LeSPAR, http://www.microbiologysociety.org/policy/campaigns.cfm/learned-society-partnership-on-antimicrobial-resistance)
- Meds Disposal Campaign
- One Health Commission (www. OneHealthCommission.org)
- Patient groups, e.g. the International Alliance of Patients' Organizations and European Patients Forum
- Small World Initiative (citizen science project for antibiotics discovery, www.smallworldinitiative.org)
- A project led by Peter Borriello (Veterinary Medicines Directorate, UK) on monitoring veterinary pathogens

Appendix 5: Activity sheet for small group discussions (sample)

Group: Human health 1

Part I: Recommendation discussion

Please discuss the recommendation(s) outlined in the table.

5	Conclusion	There was considerable variability in the extent to which Member States addressed AMR, particularly in the context of human health. Different countries also faced diverse issues.
	Recommendations	• The Commission should continue providing guidance and support to Member States to encourage good practice in public health services and surveillance. • The Commission should continue to support awareness-raising activities through European Antibiotic Awareness Day, and continue to monitor their impacts. • Targeted attention could be paid to specific areas where a Member State is struggling and understanding the specific challenges blocking progress. A one-size-fits-all approach will be insufficient. Both funding and technical support are likely to be required for lagging countries.

Questions about the recommendations:

1. Is the recommendation a suitable response to the conclusion?
2. Is it feasible to implement in practice?
3. Is it acceptable to you? (Do you have any concerns?)
4. What specific actions could be implemented as part of this recommendation?
5. Would you change the recommendation(s) proposed?

Part II: Recommendation discussion:

Please select the recommendation(s) to discuss from the list below.

Questions about the recommendations:

1. Is the recommendation a suitable response to the conclusion?
2. Is it feasible to implement in practice?
3. Is it acceptable to you? (Do you have any concerns?)
4. What specific actions could be implemented as part of this recommendation?
5. Would you change the recommendation(s) proposed?

Part III: Additional questions to discuss:

1. Overall, do you think the conclusions and recommendations have missed any important issues? What and why?
2. Should the EU maintain its current role in addressing AMR or take a different approach?
3. Do you have any recommendations related to animal health issues?

Conclusions and recommendations: Summary

1	Conclusion	The holistic approach adopted by the Action Plan was essential to tackling AMR. The EU played an important role in providing political leadership and encouraging the intersectoral collaboration necessary to pursue a holistic approach to addressing AMR.
	Recommendations	• The holistic and 'One Health' approaches should be reinforced and could be strengthened through cross-sector initiatives. The EU should take further action to enable greater engagement between sectors. • Reach and relevance could be expanded by dedicating resources to an EU-level coordinating mechanism on AMR. This could increase visibility of intra-Commission engagement, encourage more and faster action by Member States, encourage cross-sectoral interactions among stakeholders, raise AMR awareness in the EU.

2	Conclusion	A gap was identified in the Action Plan in addressing environmental issues.
	Recommendations	Environmental issues could be better integrated into future EU action on AMR through an approach involving: • Research to better understand the role of AMR transmission from the environment to humans (through animal, human and manufacturing waste); • Supporting the development of monitoring and surveillance systems that capture data on AMR circulation in the environment; • Using this improved understanding to inform how environmental policies could help reduce the spread of AMR; • Identify ways to involve DG Environment in future AMR action; and • Coordinating with ongoing Commission work on a strategic approach to addressing the risks of pharmaceuticals in the environment.

3	Conclusion	International cooperation was effective but more could be done to address AMR as a global issue and support developing countries.

	Recommendations	• Work with WHO towards a global approach to monitoring and surveillance, building EU leadership in developing approaches that brought together data from many national systems. • Continue work with international organisations such as the WHO, TATFAR, World Organization for Animal Health (OIE) and the UN FAO, including support for the Joint Programming Initiative on AMR mapping of AMR research activities, highlighted by the WHO • Support countries with limited capacity to address AMR including education and awareness, strengthening health systems and training health professionals.

4	Conclusion	Monitoring and surveillance activities focusing on human and animal health issues improved under the Action Plan. The EU could build on these successes at multiple levels.
	Recommendations	• The EU could build a more holistic system for monitoring AMR issues, linking data on resistance, consumption and sales of antimicrobials to prescribing trends and other factors. • Environmental data should be included in future monitoring and surveillance efforts. • The EU could contribute to building a global monitoring and surveillance system.

5	Conclusion	There was considerable variability in the extent to which Member States addressed AMR, particularly in the context of human health. Different countries also faced diverse issues.
	Recommendations	• The Commission should continue providing guidance and support to Member States to encourage good practice in public health services and surveillance. • The Commission should continue to support awareness-raising activities through European Antibiotic Awareness Day, and continue to monitor their impacts. • Targeted attention could be paid to specific areas where a Member State is struggling and understanding the specific challenges blocking progress. A one-size-fits-all approach will be insufficient. Both funding and technical support are likely to be required for lagging countries.

6	Conclusion	Critical funding extended to research activities was catalysed by the Action

		Plan.
	Recommendations	• The roles of the EU and the Member States should be clarified. • The EU should consider how to focus more attention on the development of alternative treatments in addition to new antimicrobials. • The EU should consider widening AMR research activities to encompass behavioural and social aspects of AMR, for example, regarding prescribing behaviours in veterinary medicine and reasons patients do not use antibiotics as prescribed (as in the ARNA project). • Continue to identify incentives for developing veterinary medicines.