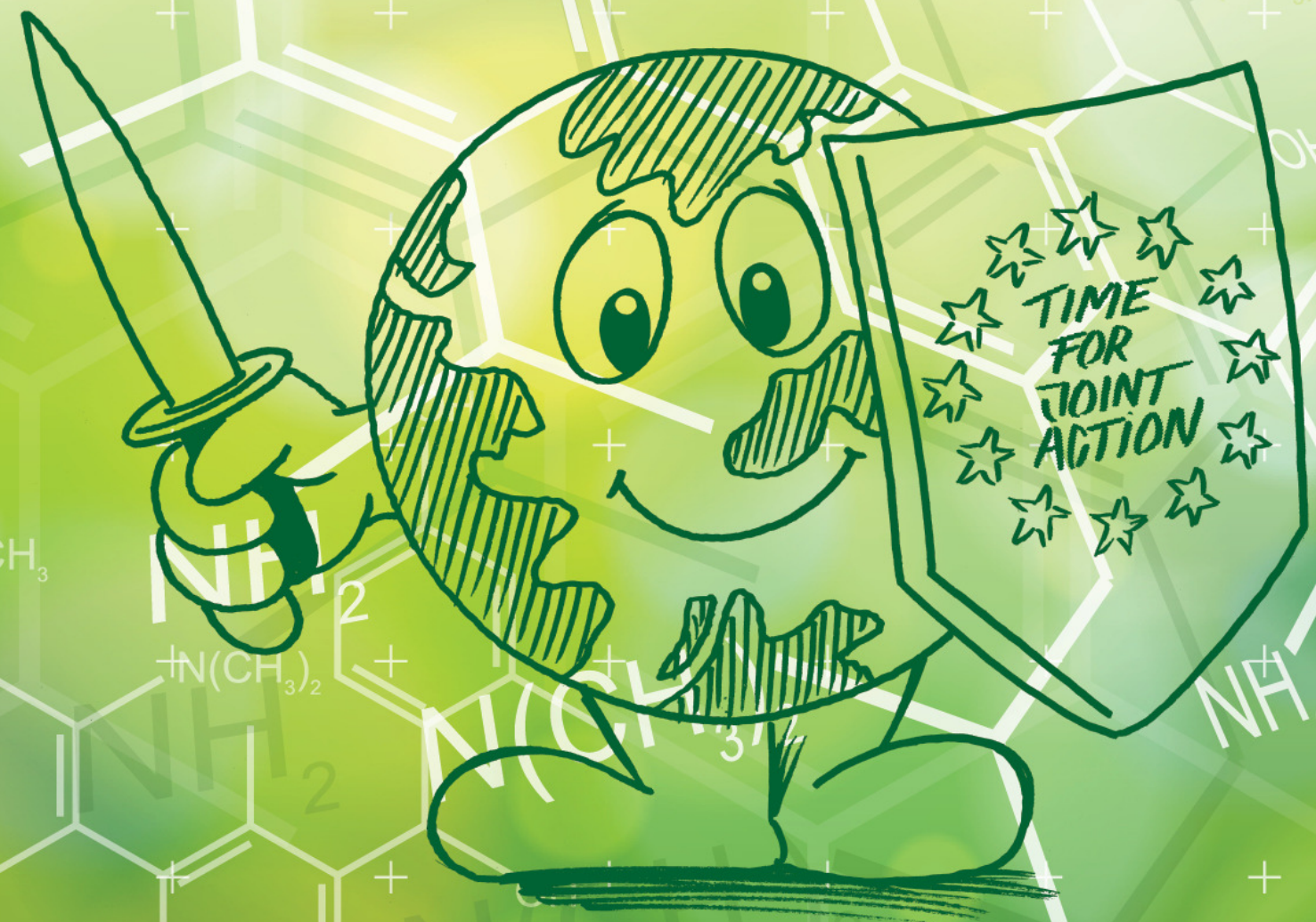
COMBATING ANTIMICROBIAL RESISTANCE



MINISTRY OF HEALTH

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Ministry of Food, Agriculture and Fisheries

European Commission

Content

Executive Summary

In Europe and globally resistance towards lifesaving antimicrobials is a growing problem. The increasing development of resistance against antimicrobials is a major threat to human and animal health as it is the cause of significant morbidity and mortality in Europe and in the rest of the world. It results in immense costs for the society in many ways.

The Danish Presidency finds it worrying that more than 25,000 EU citizens die each year due to infections caused by resistant bacteria, and that still more bacteria continue to develop resistance. Existing antimicrobials are currently losing their efficiency and the development of new effective antimicrobials is not keeping pace with the development of the resistant bacteria.

Antimicrobial treatment is an essential basis for both our health and our medical progress, and antimicrobials are indispensable when treating different diseases such as pneumonia and bacterial abdominal infections, and in connection with major surgery. If antimicrobials lose their effect, we lose a fundamental basis for modern society.

To combat antimicrobial resistance (AMR) immediate action is needed, and the conference held in Copenhagen 14 – 15 March 2012 has sought to inspire to such action.

The conference included plenary sessions and workshops, each addressing the challenges of antimicrobial resistance and possible means of tackling the microbial threat through reviews and overviews, the exchange of best practices and subsequent debates on possible solutions.

The ideas presented at the conference have contributed to the drafting of Council conclusions which will be presented for adoption by the ministers of health at the meeting of the Employment, Social Policy, Health and Consumer Affairs Council (EPCSO) on 22 June 2012.

"*Action is the real measure of intelligence.*"

Napoleon Hill (Author, 1883-1970)

Foreword

A matter of life or death

Antimicrobials have saved millions of human lives since the 1940s and are successfully used in many health related areas for both humans and animals. The use of antimicrobials has become an integrated precondition for modern life to such a degree that most people do not spare it a thought. But the very use of antibiotics includes the potential for bacteria to develop resistance. The more antimicrobials we use – the more resistant bacteria we get. And this is exactly what is happening before our very eyes. More than 25,000 European citizens die each year due to infections involving resistant bacteria.

It goes without saying that we need to take action in order to stop the development of antimicrobial resistance. We need joint action across sectors and across borders. We need to focus on prudent and restricted use of antimicrobials; we need to save critically important antimicrobials for specific uses; and we need everyone to be aware of the importance of this matter.

We need joint action now and therefore the Danish Presidency has made it a key priority to focus on antimicrobial resistance, including organizing this conference where experts and officials have had the opportunity to discuss this important matter and to share knowledge and best practices.

The conference generated many innovative and feasible ideas that we are pleased to present in this report.

The ideas brought forth during the conference have contributed to the drafting of Council conclusions which will be presented for adoption by the ministers of health at the meeting of the Employment, Social Policy, Health and Consumer Affairs Council (EPCSO) on 22 June 2012.

It is time for joint action – it is literally a matter of life or death!

Mette Gjerskov

Minister for Food, Agriculture and Fisheries

Astrid Krag

Minister for Health

Acknowledgements

The conference was organised in close collaboration between the Danish Ministry of Health and the Danish Ministry of Food, Agriculture and Fisheries, including experts from the Danish Medicines and Health Authority, Statens Serum Institut and the Danish Veterinary and Food Administration and with assistance from experts from the Technical University of Denmark (DTU).

The Danish Presidency of the Council of the EU would like to thank the European Commission, Directorate General Health and Consumers (DG SANCO), for co-financing the conference.

In addition, we would like to thank the European Centre for Disease Prevention and Control (ECDC) for sponsoring the participation of members from relevant ECDC networks.

Introduction

On 14- 15 March 2012, the Danish Presidency hosted the conference, *Combating Antimicrobial Resistance – Time for Joint Action*, which focused on the increasing global threat of antimicrobial resistance and the use of antimicrobials from a 'One Health' perspective.

The conference took place at the Bella Centre in Copenhagen and gathered approximately 300 experts and civil servants from EU Member States, candidate countries and EEA countries, the European Commission, EU agencies and other stakeholder organizations and institutions.

The conference moderator was journalist and Climate Director of Monday Morning, Per Meilstrup.

The starting point for the discussions at the conference was that a holistic approach encompassing both human and veterinary medicine is relevant because of the links between disease in animals and health in humans.

In order to prevent further increase of antimicrobial resistance we need to take action now, ensuring treatment for both humans and animals in the future.

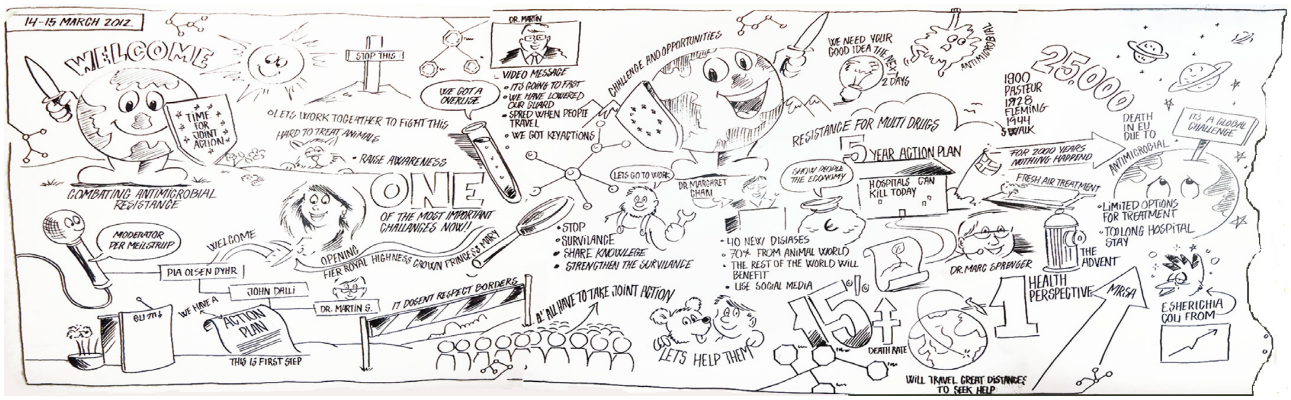
The main focus of the conference was to discuss ways to:

- Improve data collection and surveillance of antimicrobial use and resistance for both animals and humans throughout the EU
- Stop overuse of antimicrobials in humans and animals with focus on a rational use
- Reduce the use of critically important antimicrobials in humans and animals

Based on these three main focus areas, the conference included plenary sessions and workshops, which addressed the challenges of antimicrobial resistance and possible means of tackling the microbial threat through reviews and overviews, the exchange of best practices and subsequent debates on possible solutions.

The aim of the conference was to raise awareness of the microbial threat and motivate Member States and stakeholders to instigate joint action.

The following is the editorial reproduction of the conference.



Visualizations of the conference by Jørn Nielsen, Creative Support

1. Opening of the conference / welcoming address

Her Royal Highness Crown Princess Mary opened the conference by stressing that the problem of antimicrobial resistance is a threat to the health and wellbeing of humans and animals, and thus a matter of great concern. The continuous misuse and overuse of antimicrobials are contributing to an increased development of resistance to antimicrobials which every year leads to the death of thousands of people. Her Royal Highness welcomed the conference and the focus on the escalating problem of antimicrobial resistance – underlining the necessity of focusing on prudent use and raising awareness of the need of limiting the use of certain antimicrobials to dire cases.

The Danish Minister for Food, Agriculture and Fisheries, Mette Gjerskov, and the acting Danish Minister for Health, Pia Olsen Dyhr, welcomed the participants to the conference. They emphasized the problem of antimicrobial resistance and the need for feasible solutions.

Minister Gjerskov pointed out that antimicrobial resistance is a serious problem in both the human health sector and the agricultural sector, and that we therefore must look to both sectors for solutions using the 'One Health' approach. This calls for us to communicate, share and cooperate and it is crucial that everyone contributes with knowledge from their specific area of expertise. Minister Gjerskov urged everyone to talk, share and learn from one another and last but not least to take joint action.

Acting minister Olsen Dyhr highlighted the aim of the conference, i.e. to raise further awareness of AMR and to create a forum for EU Member States and EU institutions to discuss durable action-oriented solutions. For this purpose three workshops had been organised, each dealing with one of the specific focus areas of the conference, which would give participants an opportunity to exchange thoughts and ideas on possible actions for implementation at national and/or European level.

Following the ministers, there was a video-address by Mr. John Dalli, Commissioner for Health and Consumer Policy, followed by a presentation by Dr. Martin Seychell, Deputy Director-General. DG SANCO, European Commission. Both speakers underlined the seriousness of antimicrobial resistance and elaborated on the Commission's focus in the field, especially the Commission's five year Action Plan on antimicrobial resistance, which was launched in November 2011.

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2. Setting the scene – challenges and opportunities

Dr. Margaret Chan, Director-General of the World Health Organisation (WHO) presented an overview of the global problem of antimicrobial resistance. Worldwide larger quantities of antibiotics are used in healthy animals than in unhealthy humans and this is cause for great concern.

Dr. Chan emphasized how the EU and individual countries can and have contributed to finding solutions to address the problem of antimicrobial resistance. Dr. Chan highlighted surveillance as a significant tool, and acknowledged the remarkable ways that the EU has moved forward, as reflected in several networks for surveillance, not least the work of the European Centre for Disease Prevention and Control (ECDC) in so quickly

conducting risk assessments of the spread of NDM-1 producing bacteria within Europe.

Furthermore Dr. Chan acknowledged measures taken by both Denmark and other EU countries in achieving low domestic antibiotic consumption

Referring in particular to the EU Commissions 5-year action plan, Dr. Chan stressed that the EU is seeking solutions which include actions in line with those in the WHO's European strategic action plan on AMR, launched last year.

Dr. Marc Sprenger, Director of the ECDC gave a presentation on European challenges on antimicrobial resistance from a 'One Health' perspective.

Antimicrobial resistance is a threat to patient safety due to limited options for treatment, thus resulting in increased duration of hospital stays, patient morbidity and mortality, and Dr. Sprenger emphasised that each year, 25 000 deaths in EU countries are directly attributable to multidrug-resistant infections.

Dr. Sprenger stressed the importance of a prudent use of antibiotics and underlined that everyone is responsible with a reference to both human and veterinary medicine and the 'One Health' perspective.

It was underlined that awareness is important, and in this context the European Antibiotic Awareness Day, November 18, was highlighted.

Dr. Sprenger concluded with three focal points essential to tackling the AMR challenges:

- Prudent use of antimicrobials
- Infection control
- New antibiotics

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3. The antimicrobial resistance threat (MRSA, ESBL, CPE)[1]

Jan Kluytmans, Professor in Microbiology and Infection Control at the Amphia hospital, Breda, Netherlands, provided an overview of the microbial threat with emphasis on the human problem of MRSA and ESBL, including the zoonotic aspect. Under the headline 'MRSA and ESBL – A tale of humans, animals and antibiotics' Professor Jan Kluytmans gave us an overview of the current situation in Europe regarding antimicrobial use and antimicrobial resistance, specifying that most antibiotics are used in animals and that most animals that receive antibiotics are healthy. And this then leads to consequences; MRSA and ESBL.

Professor Kluytmans elaborated on MRSA, including livestock associated MRSA, which may be adapting to humans, and ESBL, which is increasing everywhere, and concluded by encouraging participants to take home the message of the need for a 'One Health' approach.

Timothy Walsh, Professor in Medical Microbiology and Infectious Diseases at the Cardiff University School of Medicine, the UK, spoke specifically about the global emergence of Carbapenemases, including the distribution of NDM-1[2] that has great potential of becoming a worldwide public health problem.

[1] Methicillin-resistant *Staphylococcus aureus* (MRSA), Extended-spectrum beta-lactamase (ESBL), Carbapenemase-producing Enterobacteriaceae (CPE)

[2] New Delhi metallo-β-lactamase-1 (NDM-1)

With reference to a new WHO publication (2012) "The evolving threat of antimicrobial resistance - Options for action", Professor Walsh highlighted the need for

- Surveillance of antimicrobial resistance and use
- Rational antimicrobial use and regulation,
- Focus on antimicrobial use in animal husbandry
- Infection prevention and control
- Fostering innovations, and
- Political commitment.

Furthermore it was pointed out that if we are to tackle AMR in a comprehensive manner, environmental aspects also needs to be considered.

Professor Walsh concluded by stressing that initiatives must be global, transparency must be mandatory and as money is an issue, perhaps global funds should be used for surveillance on AMR. Coordinated international surveillance is desperately needed.

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4. Best Practices

This session was aimed at inspiring to possible actions through presentations on best practices from different Member States and sectors.

The session was opened by Dr Niels Frimodt-Møller, Professor and MD at Department of Clinical Microbiology at Hvidovre Hospital, Denmark, who presented different initiatives taken in the health care sector to reduce antimicrobial resistance in Denmark and in the EU. These included:

- Implementation of prudent use recommendations and initiatives in most EU Member States and several third-countries
- Major advances in the understanding and awareness of the antibiotic resistance threat among governments, health care professionals and the general public
- Success in significantly reducing antibiotic consumption through campaigns and interventions

Dr. Susan Hopkins from the UCL Division of infection and Immunity, HCAI[3] and AMR Department at the Health Protection Agency in the UK, presented the British experiences with management of MRSA. This included a review of the national intervention strategies for England, Northern Ireland, Scotland and Wales for managing and reducing healthcare associated infections.

The UK National Health Service has successfully reduced meticillin-resistant Staphylococcus aureus (MRSA) bloodstream infections, and Dr. Hopkins concluded that health policy may contribute to reduce HCAI. In the future studies will be conducted to assess the impact of national interventions.

Frank Møller Aarestrup, Professor and research manager at the Division for Epidemiology and Microbial Genomics, the National Food Institute at the Technical University of Denmark, continued the session by giving a presentation on the Danish experiences on applying surveillance data and monitoring to reduce the use of antimicrobials.

Professor Aarestrup spoke of Danish actions taken to reduce consumption in animals and humans since the mid 1990's, and underlined that effective actions have included elements such as non profit, restrictions and control measures based on monitoring of consumption.

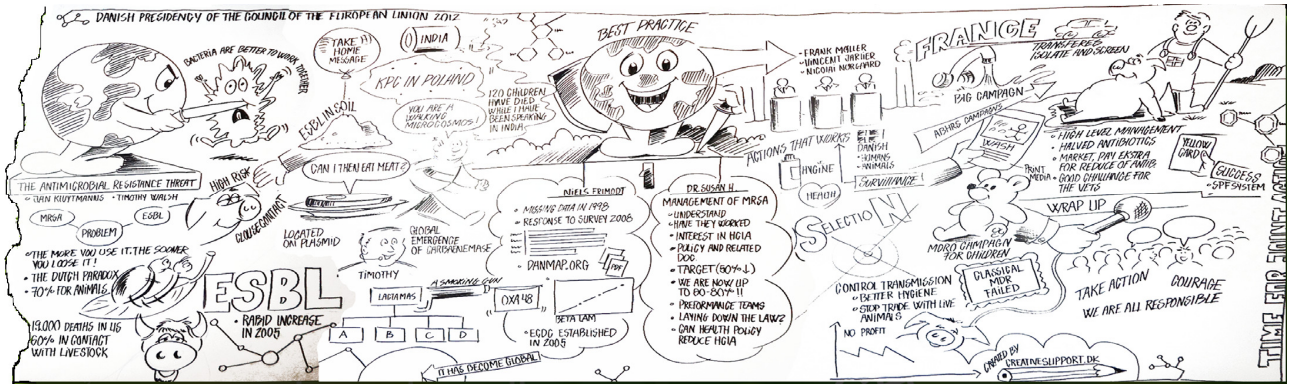
[3] Healthcare Associated Infections

Professor Aarestrup specified that future actions should include focus on targeting the worst antimicrobials, preventing diseases and always combining surveillance with chosen interventions.

Vincent Jarlier, Professor in Microbiology and Infection Control at the Pitie-Salpetriere hospital, France, presented the French experiences with successfully decreasing a number of infections concerning ESBL and MRSA.

To close the session, Nicolaj Nørgaard, Director of the Pig Research Centre (VSP), Agriculture and Food Council, Denmark, presented the voluntary efforts made by the Danish agriculture industry, for instance the voluntary ban on use of Cephalosporins from July 2010 with the aim of reducing potential risk of resistance in human pathogens.

Mr Nørgaard stated that the reduced use of antimicrobials has not had impact on the Danish position in the pork market and has only had minor impact on productivity and economics. Furthermore 'the yellow card' scheme and the awareness of AMR of the Danish pig producers have had great effect in reducing consumption of Antimicrobials.



Visualizations of the conference by Jørn Nielsen, Creative Support

5. Antimicrobial resistance – Socio-economic and health consequences

Hajo Grundmann, Professor at the Centre for Infectious Disease Epidemiology, National Institute for Public Health, the Netherlands, started the second day of the conference by giving a presentation on the socio-economic and health consequences of antimicrobial resistance, under the headline "cost and burden of antibiotic resistance: The population attributable fraction in Europe".

Professor Grundmann gave a review of the direct and indirect costs compared to the perspectives; hospital, patient and society.

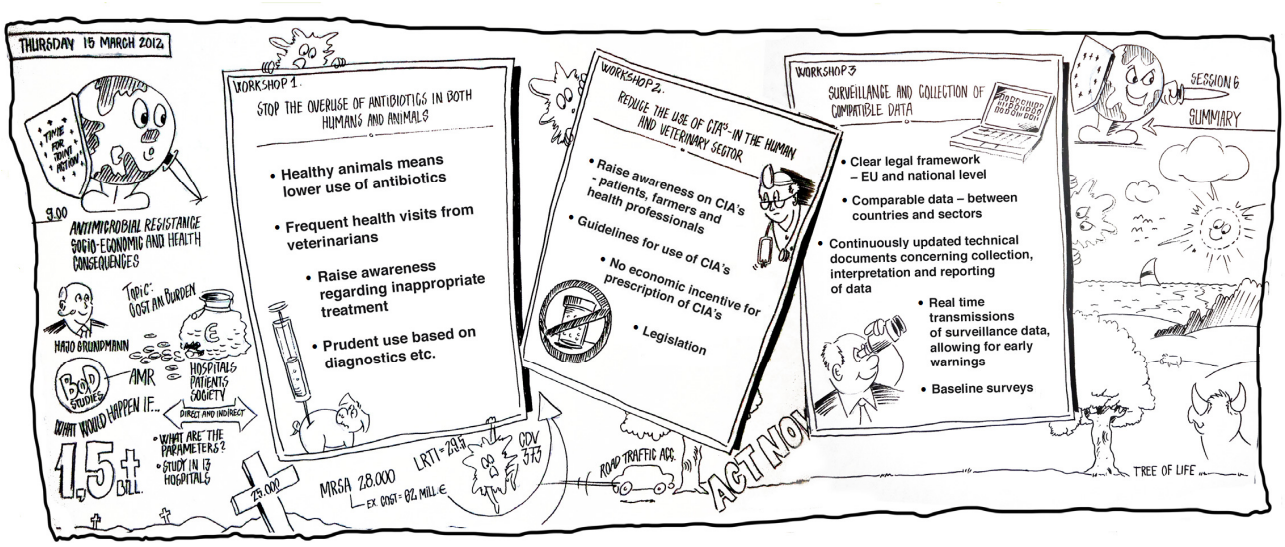
Professor Grundmann concluded by stressing, among other things, that:

- No studies have so far addressed cost and burden from all relevant perspectives.

- Current figures from the ECDC are based on multiple assumptions.

- Most studies determine risk estimates for single pathogens/infections in single centres and do not provide population-based estimates.

In conclusion, Professor Grundmann found that additional studies are required to provide a more comprehensive estimate of the socio-economic impacts of AMR; studies including more pathogens and more infections.



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6. Workshops

On the second day of the conference three workshops were conducted:

Workshop 1: Stop the overuse of antimicrobials in both humans and animals – Rational use

Workshop 2: Reduce the use of critically important antimicrobials in humans and animals

Workshop 3: Data collection and surveillance of antimicrobial resistance and antimicrobial consumption in humans and animals

To guide the discussions material had been prepared and distributed prior to the workshop sessions, see annex I-III. The material included a short introduction to the subject, background information and questions, concerning both the human health sector and the veterinary sector, to facilitate the workshop table discussions.

Workshop 1 *– Stop the overuse of antimicrobials in both humans and animals – Rational use*

The workshop was chaired by Jørgen Schlundt, DVM, Ph.D, and Director of the National Food Institute at the Technical University of Denmark, who also acted as rapporteur.

There were approximately 85 participants in the workshop.

Introductory presentations were given by Dominique Monnet, Senior Expert, the European Centre for Disease Prevention and Control (ECDC) and by Annette Cleveland Nielsen, Ph.D., Chief Veterinary Advisor, the Danish Veterinary and Food Administration (DVFA), on how to stop the overuse of antimicrobials in humans and animals, respectively, with a focus on rational use and actions which have shown effectiveness.

The introductory presentations were followed by table discussion in groups consisting of approximately 10 participants. The main question for the discussion was: How can we reduce overuse of antimicrobials and ensure prudent use in both humans and animals?

After the table discussions, the groups presented the main points of their discussions in workshop plenary.

***Workshop 2** – Reduce the use of Critically Important Antimicrobials in humans and animals*

The workshop was chaired by Kåre Mølbak, Ph.D., Department Director at Epidemiological Surveillance, the National Institute for Health Data and Disease Control, Denmark, who also acted as rapporteur.

There were approximately 55 participants in this workshop.

Introductory presentations were given by Christina Greko, Ph.D. and Associate Professor from the department of Animal Health and Antimicrobial Strategies, the National Veterinary Institute, Sweden, on reducing the use of critically important antimicrobials – veterinary medicine, and by Jenny Dahl Knudsen, Senior Hospital Physician, MD, Dr.M.Sci., Department of Clinical Microbiology, Copenhagen University Hospital, Denmark, speaking on antimicrobial treatments with a minimum risk of resistance – and critical important antimicrobials.

The introductory presentations were followed by table discussion in groups of approximately 10 participants. The main question for the discussion was: What are the possible options for reduction and control of the use of critically important antimicrobials in the human and the veterinary field?

After the table discussions, the groups presented the main points of their discussions in workshop plenary.

***Workshop 3** – Data collection and surveillance of antimicrobial resistance and antimicrobial consumption in humans and animals*

The workshop was co-chaired by Professor Frank Møller Aarestrup and Robert Skov, MD, Head of Bacteriologic Surveillance and Infection Control, the National Institute for Health Data and Disease Control, Denmark. Robert Skov also acted as rapporteur.

There were approximately 120 participants in this workshop. The workshop was divided into two main groups; so that approximately 30 persons discussed surveillance on consumption and approximately 90 persons discussed the surveillance on resistance

Introductory presentations were given by Herman Goossens, Professor of Microbiology at the University of Antwerp and Director of the Department of Clinical Pathology of the University Hospital, Belgium, and by Kari Grave, Professor and coordinator of the ESVAC project at the European Medicines Agency.

Both presentations concerned consumption of antimicrobial agents, as the resistance threat had been presented the day before.

The introductory presentations were followed by table discussions in groups of approximately 10 participants. The main question for the discussion was: How can we strengthen surveillance and improve data collection throughout the EU?

After the table discussions, the groups presented the main points of their discussions in workshop plenary, cf. annex III.

7. Presentation of main points from workshop discussions

The main points from each workshop plenary session were presented in conference plenary by each workshop rapporteur in turn.

The following summarize the main points from the three workshop discussions and do not necessarily represent a common view shared by all participants but seek to reflect the scope of the discussions.

See annex IV for the notes from workshop discussions.

Workshop 1 – Stop the overuse of antimicrobials in both humans and animals – Rational use

- Healthy animal production systems means reduced need for antimicrobials
- Strengthen veterinarians position:
  - Increase importance of consultancy role and preventive role of veterinarian
  - Mandatory regular health visits from veterinarians
  - Veterinarians income based on health consulting work, not from sale of antimicrobials
- Good examples promoting prudent use of antimicrobials in humans in EU Member States
- Develop and strengthen guidelines at national level: in hospitals, primary health care sector, long term care institutions and at herd level of food production animals
- National legislation and enforcement to prevent Over the Counter sales of antimicrobials
- Raise awareness of inappropriate treatment and sales without prescriptions

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Workshop 2 – Reduce the use of critically important antimicrobials in humans and animals

- The need to educate and raise awareness: patients, farmers, health professionals
- Guidelines are needed!
  - Common European, but adapted to local situations
  - Avoid off-label use of critically important antimicrobials
- Legislation
  - For example ban of 3rd and 4th generation cephalosporins for food production animals
  - Analyse consequences and possibilities of enforcement
  - EU regulation will be important to support initiatives at Member State-level
- There should be no economic incentive of prescribing critically important antimicrobials for both veterinarians and doctors
- Monitoring of use, including indications for prescribing, via audits or supervision
- Importance of microbiological surveillance, standard methods, building laboratory capacity

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Workshop 3 – Data collection and surveillance of antimicrobial resistance and antimicrobial consumption in humans and animals

- Clear legal framework (with existing frameworks EFSA/EMA/ESVAC/ECDC /EARS-Net/ESAC-Net)
  - EU level
  - National level
- Continuously updated technical documents (for consumption/resistance/human/veterinarian)
  - Clear definitions
  - Data collection/interpretation and Reporting
- Comparable data
  - Between countries
  - Within Sectors
- Real time Reporting
  - Surveillance data
  - Early warning (use of existing frameworks)
- Baseline surveys
  - Some by point prevalence – some repeatedly
    - Selected pathogens
    - Indicator bacteria from Normal flora
    - Use the existing EFSA model
- Obstacles
  - Risk of blame
  - Financial constrains

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8. Closing of the conference

The Danish Minister for Food, Agriculture and Fisheries Mette Gjerskov closed the conference and stressed the need for a joint effort to tackle the problem of antimicrobial resistance.

Minister Gjerskov highlighted the commitment of the Danish Presidency to combating antimicrobial resistance

Addressing the challenges of antimicrobial resistance – taking actions at EU level as well as Member State level – is of paramount importance in order to ensure effective antimicrobials in the future.

On behalf of the Danish Presidency Minister Gjerskov warmly thanked the participants and speakers for participating in the Conference and ensuring fruitful discussions and ideas for future actions.

Annex I – Workshop 1 material

Workshop 1

Stop the overuse of antimicrobials in both humans and animals – Rational use

1. Introduction

Treatment with antimicrobials is in many cases essential for human and animal health, but overuse of antimicrobials can lead to antimicrobial resistance (AMR) resulting in lost efficacy of treatment and thereby complicate disease or even lead to death.

Because some types of antimicrobial resistance can be transferred between bacteria, the development of antimicrobial resistance in any kind of bacteria may constitute a problem.

In the EU an estimated number of 25,000 people die each year due to infections involving resistant bacteria with extra costs of 1.5 billion Euros yearly due to increased healthcare expenses and productivity losses[4].

There is a need to agree on risk management interventions regarding overuse of antimicrobials in both the human and animal sector.

Overuse can be defined as unnecessary use of antimicrobials such as:

- for infections not caused by bacteria, or
- for bacterial infections curable without antimicrobials, or
- unnecessary prophylactic/preventive use of antimicrobials

Overuse often arises from:

- Lack of proper diagnosis, for instance treating viral infections with antimicrobials or treating with a less or non-efficacious antimicrobial due to lack of diagnosis of the disease and bacteria involved.
- Non-prudent use and not following dosage and treatment period.
- Flock medication (water or feed) of animals in whole sections or stables thus inevitably also treating healthy animals.
- Preventive or prophylactic treatment of both animals and humans.
- Prescription of unnecessary broad spectrum antimicrobials
- Doctors and veterinary practitioners relying on sales of antimicrobials for a significant part of their income.
- Lack of vaccination strategies, prevention strategies and infection control precautions in both sectors.

[4] http://ecdc.europa.eu/en/publications/Publications/0909_TER_the_Bacterial_Challange_Time_to_React.pdf

2. Basis for discussion

2.1 Questions regarding the veterinary sector

How is an incentive structure that will minimize continuous/preventive medication of flocks of animals created?

Continuous antimicrobial treatment occurs probably because of lack of microbiological diagnosis or lack of preventive measures such as vaccination or hygienic precautions (all-in all-out production etc.).

Diagnostic testing:

- How do you ensure justification for choosing either flock or individual treatment by current diagnostic testing and epidemiological descriptive data (mortality rate etc.)?

Reducing the number of treated animals without jeopardizing animal welfare:

- Establishing legislation on the period of validity of a prescription following a vet consultation?

- No flock medication in whole sections/stables, but only to separated diseased animals?

Reducing the need for treatment and giving the best animal treatment with respect to human health concerns:

- By an incentive structure favouring vaccination strategies for instance by price regulation?

- By vet advice on preventive management strategies (AI/AO, use of sick pens, alternatives to antimicrobial treatment etc.)?

- Establishing national animal species treatment guidelines for production animals and best practice manuals, knowledge groups etc.

How are systems to decouple the vets prescription practices from profits from sales of antimicrobials established?

Antimicrobial overuse has been shown to be linked to a system that allows the veterinarian to make an income from selling antimicrobials.

- Establishing a one to one relationship between farmer and vet?

- Introducing minimum annual herd health consultations with focus on preventive veterinary strategies?

- Allow/enforce legislation on a realistic and increased payment of vet services?

- Enforce legislation on separate charge for consultations and for medication, no profit from sales and no return payment.

- Which changes in the pharmacy structure will be needed, if the vet no longer sells medicine, but only prescribes it?

What are the major obstacles to categorize herds with respect to antimicrobial consumption?

Benchmarking of antimicrobial consumption at herd level has been used to decrease antimicrobial overuse.

- Can herd categorization relative to antimicrobial consumption be based on individual records from the veterinarian or is some sort of herd monitoring necessary?

- Is herd categorization relative to antimicrobial consumption possible for all animal species (which species are most important)?

2.2 Questions regarding the human sector

How can prescriptions of antimicrobials be reduced by doctors in the primary healthcare sector?

Auditing of primary care physicians has been shown to both reduce antimicrobial use and improve prudent use. Rapid diagnostic microbiology testing has also been shown to improve prudent use of antimicrobials.

- Implement regular auditing of antimicrobial use in primary health care?

- Establish national guidelines for rational use of antimicrobials based on diagnostics?

- Implement use of point of care laboratory tests (bedside tests) for use by general practitioners?

- Introduce reimbursement as an instrument for reduction of antimicrobial use; “medical” taxes, e.g. pricing of antimicrobials, taxes on use of generics?

- Educate and employ regional risk managers monitoring antimicrobial prescription activity of GP’s, with regular feedback and benchmarking?

- Enforce education/best practice manuals of professionals and patients concerning treatment of infectious diseases, especially which infections can be treated with antimicrobials, and how to dose?

How can the use of antimicrobials in the healthcare sector be reduced?

Overuse in hospitals, especially of broad-spectrum antimicrobials, has been shown to select for resistant bacteria that can spread among patients, i.e. cause hospital epidemics, which result in prolonged hospitals stay and increased mortality.

- Update and implement national guidelines for antimicrobial therapy in the hospital sector?

- Focus and prioritize rational use e.g. only after laboratory testing, and a prescribed course of treatment should be re-evaluated by a specialist within 24/48 hours or as soon as the test result is available?

- Discuss relevance of campaigns; are campaigns cost effective in relation to reduction of antimicrobial consumption?

Which instruments can be used to ensure that legislation on antimicrobials labelled "prescription only" is followed?

It has been shown that up to 15-20 % of antimicrobial use in some European countries is due to over-the-counter sales without prescription.

- Which changes in the organisation of pharmacy structure or organisation are needed? (Centralised registration of pharmacies/pharmacists; Permits for pharmacies/pharmacist positions/education of pharmacists)

- Implement monitoring, quality assurance, auditing, control of pharmacy sales; control visits; reporting on sales with/without prescription?

- Implement rules for the pharmaceutical industry's influence on pharmacy sales?

3. Background information

As every use of antimicrobials gives rise to development of resistant bacteria, unnecessary overuse give rise to unnecessary loads of resistant bacteria, which threatens efficacy of treatment in both humans and animals and increased mortality rates in humans infected with resistant bacteria. Specifically patients infected with S. typhimurium resistant to ampicillin, chloramphenicol, streptomycin, sulfonamide and tetracycline were approximately 5 times more likely to die, whereas patients infected with quinolone resistant S. typhimurium were approximately 10 times more likely to die than the general population. It should be noted that patients infected with totally sensitive S. typhimurium are only 2 times more likely to die than the general population[5]. Studies have also indicated that the use of antimicrobials for food animals is a major contributing factor for the selection and dissemination of resistant *Salmonella*[6] and recently the increasing use of antimicrobials, *particularly fluoroquinolones, in humans* has been shown to be associated with an increase in incidence of infections caused by drug-resistant *Salmonella*[7].

Present EU recommendations

Humans

Council recommendations on prudent use and health care associated infections in the human sector are part of the Community strategy against AMR[8]. Specific strategies such as strengthening the surveillance systems, control implementation, preventive measures, education etc. have been reported from 18 Member States (MS) and 6 MS are preparing such strategies. Council recommendations from June 2009 aim at strategies and specific proposals to improve patient safety in healthcare systems[9].

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[5] Helms M, Vastrup P, Gerner-Smidt P, Mølbak K. Ugeskrift for Laeger. 2003 Jan 13;165(3):235-9); Helms M, Vastrup P, Gerner-Smidt P, Mølbak K., Emerg Infect Dis. 2002 May; 8(5):490-5 Excess mortality associated with antimicrobial drug-resistant Salmonella typhimurium.; Helms M, Simonsen J, Molbak K., J Infect Dis. 2004 Nov 1;190(9):1652-4. Epub 2004 Sep 21.

[6] Emborg, H.D., Vigre, H., Jensen, V.F. *et al.* (2007). Tetracycline consumption and occurrence of tetracycline resistance in *Salmonella* typhimurium phage types from Danish pigs. Microb. Drug Resist.; 13: 289-294.

[7] Koningstein M, Simonsen J, Helms M, Mølbak K. (2010). The interaction between prior antimicrobial drug exposure and resistance in human Salmonella infections J Antimicrob Chemother, 17 May, doi:10.1093/jac/dkq176

[5] Communication from the Commission of 20 June 2001 on a Community strategy against antimicrobial resistance (COM(2001) 333 final, Volume 1 –not published in the Official Journal).

[9] Council Recommendation of 9 June 2009 on patient safety including the prevention and control of healthcare-associated infections (OJ L 1541, 3.7.2009, p. 1)

Animals

Since 2006 the EU has banned the use of antibiotic growth promoters (AGP) in feed and this should reduce the consumption of antimicrobials, if this is not compensated with an increase in therapeutic use. Medicated feed is only available on prescription from a veterinarian and can only be produced in authorised and controlled premises[10].

MS medicine agencies adopted a strategic plan on antimicrobial usage[11], which supports CVMP's[12] strategy on antimicrobials (AM). Currently the Commission has started a referral procedure on all quinolones and fluoroquinolones used for food producing animals, aiming at a prudent use of these antibiotics in MS[13].

In applications for marketing authorisations of veterinary medical products for food-producing species, applicants are requested to address AMR issues and limitations to development of AMR when using the medical product[14].

Use of AM to control *Salmonella* is prohibited in poultry (Commission Regulation (EC) No 1177/2006) and other measures to control *Salmonella* are expected to reduce both Salmonella prevalence and AMR strains, whereas control programmes for *Salmonella* in pigs and *Campylobacter* in poultry are lacking.

[10] Council Directive 90/167/eec (Medicated feed directive)

[11] Heads of Medicines Agency (HMA) Strategic Plan on antimicrobial issue, June 2010. In November 2011, HMA revised the Strategic Plan and adopted "HMA Action Plan on antimicrobial issues

[12] Committee for Medicinal Products for Veterinary Use (CVMP)

[13] Link to EMA: www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/veterinary/referrals/Quinolones_containing_medicinal_products/vet_referral_000039.jsp&mid=WC0b01ac05800986a1

[14] International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; VICH GL27 (Antimicrobial Resistance: Pre-Approval), December 2003

Annex II – Workshop 2 material

Workshop 2

Reduce the use of Critically Important Antimicrobials in humans and animals

1. Introduction

Critically Important Antimicrobials (CIAs) have been defined first by the WHO for humans and later by OIE for veterinary use. The primary parameter was scarcity of therapeutic alternatives for treatment of serious diseases.

In recent discussions three main classes have been identified as antimicrobials for which special precautions should be taken in order to maintain their efficacy for the future:

1) Fluoroquinolones (widely used in both human and veterinary medicine)
2) Cephalosporins (widely used in both human and veterinary medicine)
3) Carbapenems (only authorised for human use)

Antimicrobial resistance against the CIAs is particularly worrying, as they are "the last resort" treatment for a number of very serious diseases. A strictly prudent use of CIAs should therefore be agreed internationally as resistant bacteria can spread via global movements of persons, animals, and food products. The goal could be to reduce the use of CIAs to the lowest possible level while maintaining the option for necessary, lifesaving treatments.

There is a need to agree on risk management interventions regarding the use of CIAs for humans and animals. A number of possible options and practises exist in individual EU member states, and these have the potential to greatly affect the efficacy of CIAs for the future and may be implemented without big public sector investments in databases, surveillance systems, etc.

2. Basis for discussions

2.1 Conditions for use of CIA

Q.1: Should there be certain conditions for use of CIAs?

Statements for discussion:

General conditions:

- CIAs should only be used for treatment of serious cases, which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials.
- If CIA treatment is initiated due to serious health condition prior to the result of a susceptibility test, the treatment should be re-evaluated immediately after the test result is available, and amended if necessary.
- CIAs should only be used in combination with diagnostic/susceptibility tests.
- Duration of treatment should be limited to the minimum required time for cure of diseases.

- The use of products with combinations of active substances in situations where products with a single active substance would be enough, unnecessarily increases selection pressure for antibiotic resistance and should be avoided.
- Preventative use of CIAs (e.g. pre-surgery or metaphylactic treatment of patients/animals in the incubation phase) should be minimised and always be carefully considered and preserved for specific circumstances.
- Carbapenems should not be introduced into the veterinary field.
- Off label use of CIAs should be strongly discouraged.

***Regarding use of CIAs in humans**:*

- CIAs should only be used in hospitals. Do CIAs have a role in general practise at all? This is in particular relevant for fluoroquinolones, which today at least in some countries are widely used for treatment of uncomplicated urinary tract infections and for travel prophylaxis.
- Carbapenems should only be used in human therapy if the infection is caused (or in very serious cases suspected to be caused) by multi-resistant bacteria.

Regarding use of CIAs in animals (Fluoroquinolones and 3rd and 4th generation cephalosporins):

- Fluoroquinolones should be used ONLY after a diagnostic/susceptibility test showing that there is no other treatment option.
- Fluoroquinolones should only be used in flock treatments when individual treatment is not possible (e.g. poultry production) and only in serious incidents when no other option is available.
- 3rd and 4th generation cephalosporins should be restricted to avoid preventative treatment and flock treatment as far as possible.

2.2 Restricted use of CIA's in human and animals

Q.2: Which actions should be taken to ensure restricted use of CIAs in humans and animals?

Statements for discussion:

- Treatment guidelines for choice of correct antimicrobial for relevant diseases (and animal production forms) should be developed on national/international level, and implemented in all member states. The national guidelines should take internationally recognised code of practice of rational and prudent use of antimicrobials into account.
- The national guidelines should be communicated effectively to the prescribers.
- When authorising CIAs, doses should be selected considering AMR related risks. In case of existing products where data on dose selection are sparse, doses should be reviewed and in case they are too low (e.g. compared to other products containing the same active substance) this should be addressed by the competent authority.

- The competent authorities should ensure that distribution of antibiotics follow strict rules and that no antibiotic can be bought without a prescription from a diagnosing doctor or vet.
- Doctors and vets should have no economic incentive to prescribe antibiotics, i.e. their payment should be related to diagnosing the clinical condition rather than to the prescription of antibiotics (neither amount nor frequency).
- Contracts between a doctor/vet/farmer and distributors/manufacturers of medicines should be prohibited, i.e. no return-payment to influence the choice of/preference for certain products should be allowed.
- Advertisement of CIAs should not be directed to animal owners or patients.

2.3 Monitoring data and control measures to ensure a restricted use of CIA's

Q.3: Which basic monitoring data and control measures are necessary to ensure restricted use/compliance with guidelines?

Statements for discussion:

- In each country the use patterns of CIAs should be analysed via surveillance of data of doctors, vets, clinics, hospital sections and farmers (diagnosis and animal species).
- If CIA-use is above certain defined levels, the competent authority could inspect and advice on options for reduction.
- For prescribers and users of CIAs (farmers, clinics and hospitals) a system of documentation and own check should be installed and this could be audited by a competent authority.
- The competent authority could have an inspection team that would visit farms, vets, etc to investigate correct use, documentation of medicine use, illegal medicine supply etc.
- Emergence of resistance to CIAs in pathogenic and indicator bacteria should be monitored and the need for interventions should be continuously evaluated (The European Commission, EFSA, ECDC, Community Reference Laboratory, National Reference Laboratories and routine laboratories).

3. Background information

The use of CIAs selects for resistance in bacteria in both humans and animals. The resistance is generated in both pathogenic bacteria and commensal bacteria of the normal flora. Several of the resistance mechanisms are transferable between bacterial species, thus leading to dissemination of resistance especially in antibiotic containing environments. This may reduce the treatment options for serious infections in humans and animals.

Reports of increased resistance against CIAs in life-threatening bacterial diseases in humans have emerged from many places in Europe. Most of the problems with resistance in human medicine are related to use of antimicrobials in humans, and must be managed by measures applied to the use of antimicrobials in humans. However, resistance in zoonotic and other transferred bacteria may be a result of the veterinary use of antimicrobials; hence there is a need for prudent use in veterinary medicine as well.

For animals, fluoroquinolones and some cephalosporins are also critically important, efficacious and valuable antimicrobials to treat serious animal diseases. If such antimicrobials lose their activity or are no longer available for the treatment of animal diseases, antimicrobial therapy of some diseases will be complicated and may result in animal welfare and public health concerns, and economical losses.

Annex III – Workshop 3 material

Workshop 3

Data collection and surveillance of antimicrobial resistance and antimicrobial consumption in humans and animals

1. Introduction

The aim of this workshop was to generate ideas and recommendations to improve data collection and strengthen surveillance of antimicrobial consumption and antimicrobial resistance (AMR) in humans and animals throughout the EU.

Accurate and comparable data on antimicrobial consumption and resistance in both humans and animals is an important prerequisite to visualize the extent of the problem of AMR and to implement targeted measures to combat resistance. Such data will further provide the EU and the individual Member States (MS) with fundamental tools to enable them to take concrete action to combat antimicrobial resistance and to measure the effect of these actions.

Organisations like the World Health Organisation (WHO), the Codex Alimentarius and the World Organisation for Animal Health (OIE) have prepared guidelines on monitoring and surveillance of antimicrobial consumption and AMR in humans, animals and food. These guidelines contain useful information and advice on strategies and practical implementation.

Several programs e.g. EARS-Net, EFSA, ESAC-Net and ESVAC are already running in Europe with the purpose of collecting accurate and comparable data from all MS. However, at present, participation by MS in most of these programs is voluntary and as a result, data are not reported by all MS. There is therefore a need for political initiatives to bring about the implementation of these programs in all MS.

Furthermore, it is not certain that all the data from these programs are completely adequate or comparable. The purpose of this workshop was therefore to discuss what constitutes optimal surveillance and data collection and how this can be most easily and efficiently achieved by all MS. In addition, there is a need to determine how the results of surveillance can best be communicated to relevant stakeholders so that they may be encouraged to take appropriate action to curtail or arrest the development of AMR.

2. Basis for discussions

2.1 Surveillance and collection of comparable data on antimicrobial consumption in humans and animals

Q.1: What is the optimal level of surveillance of antimicrobial consumption?

What is needed to optimize the present surveillance programs on consumption?

- What should the next level be and what are the obstacles to achieve this level?

Veterinary medicine (ESVAC)

- In regard to consumption data on farm level, animal species and age group?
- In regard to antimicrobial sub groups/substances?
- In regard to indications and/or diagnosis?

Human medicine (ESAC)

- With regard to continue the collecting overall sales data at package level?
- With regard to the number of bed days an age group?
- In regard to antimicrobial sub groups/substances?
- In regard to information on indications and/or diagnosis?
- In regard to human consumption data for the individual general practice and hospital (department level)?

- Should consumption of antimicrobial agents to companion animals be included in surveillance programs?
- Should consumption of antimicrobial agents for other purposes (e.g. plants) be included in surveillance programs

Q.2: How do we get all Member States included?

How do we get all the Member States to collect data on consumption in the human and veterinary field and to not only provide these data to the ECDC, EFSA and EMA but also use them at a national level?

- What are the obstacles preventing collection and reporting of data to ESAC or ESVAC, respectively?
- What kind of tools and incentives would support a continuous EU wide surveillance of antimicrobial consumption?
- Should the goal be commitments by MS or should surveillance and reporting be mandatory for Member States?

Q.3: How can we present data in a way to facilitate action?

How should data be presented to stakeholders and the general public, both at a national level and internationally, in order to visualize the situation and enable and facilitate action?

- To ensure the exchange of comparable data between Member States – should it be mandatory to report national data on consumption to ESAC and ESVAC, respectively?
- What are the prerequisites for comparing data on antimicrobial resistance and antimicrobial consumption in real-time?
- How do we develop integrated surveillance and reporting of the data on consumption from the human and veterinary sector in order to facilitate an integrated approach?

2.2 Surveillance and collection of comparable data on antimicrobial resistance in humans and animals

Q.1: What is the optimal level of surveillance of resistance?

What is needed to optimize the present surveillance programs?

- What should the next level be and what are the obstacles to achieve this level?
  - In regard to resistance data on animal species, age group and bacteria species?
  - In regard to resistance data among bacteria isolated from community or hospital acquired infections?
  - In regard to which antimicrobial agents that should be tested?
  - In regard to specific pathogens / resistance mechanisms (MRSA, ESBL, CPE, incl. NDM-1)
  - In regard to phenotype or genotype?
  - In regard to methodology (MIC, disk diffusion, clinical breakpoints/cut off values)
- Should antimicrobial resistance in companion animals be included in surveillance programs?

Q.2: How do we get all Member States included?

How do we get all the Member States to collect data on antimicrobial resistance in the human and veterinary field and to not only provide these data to the ECDC and EFSA but also use them at national level?

- What are the obstacles preventing collection and reporting of data?
- What kind of tools and incentives would support a continuous EU wide surveillance of antimicrobial resistance?
- Should the goal be commitments by Member States or should surveillance and reporting be mandatory for Member States?

Q.3: How can we present data in a way to facilitate action?

How should data be presented to stakeholders and the general public, both at a national level and internationally, in order to visualize the situation and enable and facilitate action?

- To ensure the exchange of comparable data between Member States – should it be mandatory to report the data that are available?
- Should we establish an early warning and reaction system for specific resistance mechanisms?
- What are the prerequisites for comparing data on antimicrobial resistance and antimicrobial consumption in real-time?
- How do we develop integrated surveillance and reporting of the data on AMR from the human and veterinary sector, respectively, in order to facilitate an integrated approach?

3. Background information

In the following please find a short status on each of the programs ESAC-Net, EARS-Net, EFSA and ESVAC.

European Surveillance of Antimicrobial Consumption Network (ESAC-Net)

Status on ESAC-Net prepared by Klaus Weist

The European Surveillance of Antimicrobial Consumption Network (ESAC-Net, formerly ESAC project) is a Europe-wide network of national surveillance systems, providing European reference data on antimicrobial consumption. ESAC-Net collects and analyses data on antimicrobial consumption from 28 EU and EEA/EFTA countries, both in the community and in the hospital sector[15].
The coordination of ESAC-Net was transferred from the University of Antwerp, Belgium, to the European Centre for Disease Prevention and Control (ECDC) in July 2011. ESAC-Net continues to collect and analyse data from EU and EEA/EFTA countries, both in the community (primary care) and in the hospital sector, and thus provides independent, reference information on antimicrobial consumption in Europe.

The data sources for ESAC-Net are national sales and reimbursement data, including information from national drug registers. The WHO Anatomical Therapeutic Chemical (ATC) classification system is used for the allocation of antimicrobials into groups. Data on antimicrobial consumption will be collected at the product level for antibacterials for systemic use (ATC group J01), antimycotics for systemic use (ATC group J02), antimycobacterials (ATC group J04), and antivirals for systemic use (ATC group J05). In addition, data on a few other antimicrobials outside of ATC group J are also collected.

The national networks upload their data to The European Surveillance System (TESSy) at ECDC on a yearly basis. The first data call for 2010 EU reference data was performed in January 2012. After uploading, each country approves its own data and the results are made available from the ECDC website. Antimicrobial consumption data are expressed as a number of WHO Defined Daily Doses (DDD) per 1,000 inhabitants and per day. Complementary to this measurement unit, the number of packages per 1,000 inhabitants and per day is also reported depending on the availability of data on packages. Since the ATC/DDD system cannot take into account changes in package content, information on packages is deemed to improve the understanding and interpretation of differences in the levels and trends in antimicrobial consumption observed between and within countries. For the denominator, population data from EUROSTAT, or from national statistical reports, are used. When consumption data do not cover the whole population, countries provide data on the population covered by antimicrobial consumption surveillance data.

To maintain and facilitate data reporting, ECDC ensures:

[15] http://ecdc.europa.eu/en/activities/surveillance/ESAC-Net/Pages

- Validation of community and hospital sector data, analysis of the trends in antimicrobial consumption overall and in the different ATC groups;
- Public access to information on antimicrobial consumption in Europe through an ESAC-Net interactive database;
- Timely information and feedback to EU Member States and EEA/EFTA countries on indicators of antimicrobial consumption. These indicators provide a basis for monitoring the progress of EU Member States and EEA/EFTA countries towards prudent use of antimicrobials.

Cooperation of ESAC-Net and ECDC with the European Food Safety Agency (EFSA) and the European Medicines Agency (EMA) on the integrated use and reporting of data on consumption of and resistance to antimicrobial agents in humans, animals and food in the EU is currently underway.

European Antimicrobial Resistance Surveillance Network (EARS-Net)

Status on EARS-Net prepared by Ole Heuer and Liselotte Diaz Högberg

The European Antimicrobial Resistance Surveillance Network (EARS-Net) is a network of national surveillance systems providing European reference data on antimicrobial resistance for public health purposes. EARS-Net is the largest publicly funded system for surveillance of antimicrobial resistance in Europe[16]. The coordination of EARS-Net was transferred from the Dutch National Institute of Public Health and the Environment (RIVM) to the European Centre for Disease Prevention and Control (ECDC) in January 2010.

How are the data collected and processed?

Antimicrobial susceptibility test results are collected by national surveillance networks from clinical laboratories in the participating countries. At present, more than 900 public health laboratories serving over 1400 hospitals are providing data to EARS-Net. The participating hospitals and laboratories provide services to an estimated population of 100 million European citizens.

The national surveillance networks upload their data to The European Surveillance System (TESSy) at ECDC on a yearly basis. After uploading, each country approves its own data and the results are made available from the ECDC website. In order to facilitate data reporting, ECDC provides:

- Validation of antimicrobial susceptibility data reported by the countries;
- Analysis of trends in the occurrence of antimicrobial resistance over time and between different countries and regions;
- External quality assessment (EQA) and protocols on testing methods to improve the consistency and quality of the data.

Which surveillance data are collected?

Since the network started in 1999, the participating laboratories have collected antimicrobial resistance data on approximately 500,000 invasive bacterial isolates. EARS-Net performs surveillance of antimicrobial susceptibility in seven bacterial pathogens of public health importance:

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- *Streptococcus pneumoniae*
- *Staphylococcus aureus*
- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Escherichia coli*
- *Klebsiella pneumoniae*
- *Pseudomonas aeruginosa*

In addition, EARS-Net collects denominator data on laboratory/hospital activity.

How are the data made available?

EARS-Net results represent an important source of information on antimicrobial resistance for policy makers, scientists, doctors and the public. These results are made available through:

- The **EARS-Net interactive database** providing user friendly display of selected results in various downloadable formats, such as tables, figures, and maps[17]
- The **EARS-Net annual reports** with interpretations and conclusions regarding trends in the occurrence of antimicrobial resistance across Europe[18],
- Scientific publications in peer review journals.

Monitoring of AMR in zoonotic and indicator bacteria from humans, animals and food in the EU (EFSA)

Status on EFSA prepared by Pierre-Alexandre Beloeil and Pia Mäkelä

Bacterial resistance to antimicrobials occurring in food-producing animals can spread to people via food-borne routes but also by environmental routes, such as surface water, and by direct animal contact. The monitoring of antimicrobial resistance (AMR) in zoonotic and commensal bacteria in humans, food-producing animal reservoirs and food thereof is a pre-requisite for the understanding of the development and dissemination of AMR and the identification of the emergence specific patterns of resistance. Under the existing European Union (EU) legislation, Member States are required to establish monitoring systems of AMR in the major food-producing animal species (poultry, turkeys, pigs and cattle) and related meat. The AMR monitoring in zoonotic Salmonella and Campylobacter is mandatory, while that in indicator commensal E. coli and enterococci is made on a voluntary basis. The European Food Safety Authority (EFSA) has been assigned a key role in collecting the data reported by the EU Member States and in monitoring AMR in animals and food at EU level.

On a yearly basis, EFSA analyses the AMR data reported by Member States and publishes an EU Summary Report displaying an overview of the levels of resistance for the zoonotic Salmonella, Campylobacter, and indicator E. coli and enterococci, monitored in animal species and food at both Member State and EU levels. AMR is interpreted using harmonised epidemiological cut-off values (ECOFFs) in order to early detect reduced susceptibility. Temporal trends in the occurrence of resistance are also followed and analysed, to detect changes over time. Additionally, a move

[17] http://ecdc.europa.eu/en/activities/surveillance/EARS-Net/database/Pages/database.aspx
[18] http://ecdc.europa.eu/en/activities/surveillance/EARS-Net/publications/Pages/documents.aspx

towards an integrated approach in the monitoring of resistance has started since 2009, when resistance data from zoonotic Salmonella and Campylobacter collected and analysed by the European Centre for Disease Prevention and Control (ECDC) from human cases of salmonellosis and campylobacteriosis have been included in the EU Summary Report, and an attempt made at jointly analysing them in conjunction with those deriving from animals and food.

In order to enhance the comparability of data reported to EFSA, technical specifications on the monitoring and reporting of AMR in animals and food have been developed and published in 2007 and 2008. These specifications cover the sampling strategies to be used for the selection of isolates, the methods for susceptibility testing, the panel of antibiotics to be used and also the criteria to define resistance. As observed in the last reporting years, data transmitted to EFSA are now mostly obtained through standardised dilution methods, and reporting of MIC distributions has made possible to interpret the occurrence of resistance using both epidemiological cut-off values and, when a comparison with human data was made, clinical breakpoints used in human medicine.

The main general findings conclusions of data collection and analyses at EU level are that resistance to antimicrobials was commonly found in isolates from humans, animals and food, although disparities in the occurrences of resistance were frequently observed between Member States. High resistance levels were recorded to ampicillin, tetracyclines and sulphonamides in Salmonella isolates from human cases, while resistance to third-generation cephalosporins and fluoroquinolones, both critically important antimicrobial groups for human medicine, remained low. In Salmonella and indicator E. coli isolates from fowl, pigs, cattle and meat thereof, resistance to tetracyclines, ampicillin and sulphonamides was also commonly found, while resistance to third-generation cephalosporins was low. Moderate to high levels of ciprofloxacin resistance was observed in Salmonella and indicator E. coli isolates from fowl, broiler meat and pigs. In Campylobacter isolates from human cases, resistance to ampicillin, ciprofloxacin, nalidixic acid and tetracyclines was high, while resistance to erythromycin, a critically important antimicrobial, was recorded at a low level. High resistance to ciprofloxacin, nalidixic acid and tetracyclines was also observed in Campylobacter isolates from fowl, broiler meat, pigs and cattle, whereas erythromycin resistance was at lower levels. Among the indicator enterococci isolates from animals and food, resistance to tetracyclines and erythromycin was commonly detected.

As a next step, EFSA is in the process of moving from the traditional reporting of aggregated data to isolate-based data, thus improving the level of granularity of the data submitted and the potential analyses that can be conducted. AMR isolate based data enable to analyse and report on the multi-resistance by investigating co-resistance patterns and identifying emerging new multi-resistance patterns. Moreover, it is expected that the more detailed information that will become available with reporting at isolate level could be used to better characterise the occurrence of AMR in particular defined animal populations so that this information could also be linked to antimicrobial consumption data. In collaboration with European Medicine Agency (EMA), which is in charge of monitoring consumption of antimicrobials in animals, the intention is indeed to analyse the relationship between antimicrobial use and antimicrobial resistance in animals.

European Surveillance of Veterinary Antimicrobial Agents (ESVAC)

Status on ESVAC prepared by Kari Grave, Jordi Torren & David Mackay

The European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project was launched by the European Medicines Agency in September 2009[19], following a request from the European Commission to develop a harmonised approach for the collection and reporting of data on the sales of antimicrobial agents in animals from the Member States (MSs). The major deliverables to be delivered by the ESVAC project as described in the terms of references (TOR) from the Commission were

- To identify the existing data/surveillance systems established for collection of sales and use of antibacterial drugs in the Member States
- To develop a harmonised approach for the collection and reporting of data based on national sales figures combined with estimations of usage in at least major groups of species (poultry, pigs, veal, other ruminants, pets and fish);
- To collect the data from Member States and manage the data base;
- To draft a summary annual report with the data from Member States.

An appendix to the terms of reference sets out the following intended uses for the collected data on usage of veterinary antimicrobial agents:

- To aid interpretation of patterns and trends regarding antibacterial resistance
- To serve as a basis for risk profiling and risk assessment regarding antibacterial drug resistance.
- To serve as a basis for setting risk-management priorities.
- To serve as a basis for evaluating the effectiveness of control measures being implemented.
- To aid in identifying emerging use of antibacterial drugs, e.g. of specific drug classes such as critically important antibiotics.
- To aid in comparing usage of antibacterial drugs between and within countries, and between time periods, etc.
- To assess the spread and effects of environmental pollution through use of antibacterial drugs.
- To serve as a basis for focused and targeted research and development.

In response to the TOR already existing data on the sales of veterinary antimicrobial agents from the 9 European countries (of which 8 were EU/EEA countries) that had already established surveillance programs were collected and reported in a harmonised manner20. This included the development of a population correction unit (PCU) in order to normalize the annual sales figures in each country by the animal demographics. PCU is the estimated weight at treatment of livestock and of slaughtered animals in the relevant year and serves as a proxy for the animal population.

[19] European Medicines Agency, 2009 .European Surveillance of Veterinary Antimicrobial Consumption. (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580153a00)

[20] European Medicines Agency, 2011. Trends in the sales of veterinary antimicrobial agents in nine European countries (2005-2009); EMA/238630/2011. (http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/09/WC500112309.pdf)

During the first part of the pilot phase (2010-2012) an ESVAC protocol and data collection form in order to ensure standardized data were developed and tested together with experts from the MSs as well as with three MSs collecting data on veterinary antimicrobials agents for the first time. In parallel, the ESVAC data program for the logical validation of the data in terms of standardization has been developed and tested and the ESVAC data base is established.

The ESVAC project has now collected harmonised and detailed data on sales of veterinary antimicrobial agents at package level for 2010 by use of the ESVAC data collection from 19 EU/EEA countries that volunteered to participate in the pilot study. Of these 17 are MSs, and the sales data from these represent a coverage of the major food animal species (cattle, pigs, poultry, sheep and goat) in the MSs close to 75 %. The data will be published the second half of 2012. It is expected to increase the numbers of MSs providing data for 2011 by at least three countries. In contrast to the aggregated data, the data collected according to the template will for example give information on administration form such as premixes and differ between herd and individual treatment; these data will allow for a more in-depth analysis of the sales of veterinary antimicrobial agents in the EU. However, in order to perform proper risk analysis data by species are required.

It should be emphasised that many of the MSs are collecting the data for the first time and that it is generally acknowledged that it takes at least three years to establish a valid baseline; consequently the 2010 data should not be used alone as a basis for setting management priorities, but should always be complemented by data from other sources.

According the ESVAC project plan the collecting of data by animal species from the MSs will be implemented in 2014. In order to prepare for this, an ad hoc working group consisting of experts from the MSs has recently been nominated with the task to propose a model on how to establish a sustainable surveillance program for the collection of standardized and representative data by species.

Furthermore, in order to take into account the differences in the dosing and the number of treatment days for the veterinary antimicrobial agents when reporting the data by species an ad hoc working group of experts from the MSs has been established and is asked to propose technical units of measurement applicable for analysing surveillance data.

Annex IV – Notes from workshop discussions

The contents of this annex summarises the workshop discussions and is a condensed list of the ideas that were brought forward in connection with the group discussions. The ideas below do not reflect a common view shared by all participants.

Workshop 1

The following questions were the basis of the discussions:

1. How is an incentive structure that will minimize continuous/preventive medication of flocks of animals created?
2. How are systems to decouple the veterinarians prescription practices from profits from sales of antimicrobials established?
3. What are the major obstacles to categorize herds with respect to antimicrobial consumption?
4. How can prescriptions of antimicrobials be reduced by doctors in the primary healthcare sector?
5. How can the use of antimicrobials in the healthcare sector be reduced?
6. Which instruments can be used to ensure that legislation on antimicrobials labeled "prescription only" is followed?

General statements

Antibiotics in animal health should only be used in the context of biosecurity, good nutrition, good housing, herd health plans and vaccinations being in place.

All sectors should work together.

One way forward could be to expand the existing AMR-Working Group in the European-Commission on the veterinary side to include the human side. This would support the 'One-Health' approach, i.e. experts from each Member State, to enforce implementation of the Commissions action plan on AMR in the EU.

<u>Questions regarding the veterinary sector</u>

How is an incentive structure that will minimize continuous/preventive medication of flocks of animals created?

Possible initiatives:

- Healthy animal production systems are needed. Healthy animals equal lower use of antibiotic
- Preventive treatment should be avoided; Metaphylaxis/flock medication should be reduced
- There is a need for guidelines for the treatment in certain species
- To reach the goal of responsible use a combination of data collections (on farm level), best practice guides and restriction policies are needed
- Incensement of the importance of consultancy role and preventive role of veterinarians

- Mandatory frequent health visit from vets should be encouraged. Veterinarians should base their income from health consulting work and not from sale of antibiotics
- Ensure the professional independency of the veterinarians

Obstacles:

- No or small economic incentive for producers to have better production systems
- In some countries farmers cannot access antibiotic drugs from pharmacies
- The veterinarians buy the drugs from the industry and store it
- A change in rules needs to be followed by change in logistics

How are systems to decouple the vets prescription practices from profits from sales of antimicrobials established?

- Enforcement!
- Regular visits of veterinarians
- Cooperation with the industry in the development of new drugs should be strengthen; Develop and strengthen national level guidelines for rational use of antimicrobials based on diagnostics and develop fast track procedure for their adoption
- Another option: Important to have inspections and surveillance systems of veterinarians - not a requirement to decouple veterinarian prescription from economic incentives as long as you have a good and very effective surveillance systems. (Different opinions around the table!)

What are the major obstacles to categorize herds with respect to antimicrobial consumption?

Obstacles:

- Reporting systems not reliable
- Lack of political willingness
- Lack of good surveillance systems

Initiatives:

- Guidelines on how to start surveillance programmes should be encouraged
- The systems should be usable for both veterinarians and farmers

<u>Questions regarding the human health sector</u>

How can prescriptions of antimicrobials be reduced by doctors in the primary healthcare sector?

Initiatives:

- Permanent Working Party standards and guidelines, NETHMAP, inspections (NL)
- Good examples are important for promoting prudent use in other EU countries
- Visit different countries to get inspired by best practices

- Guidelines should be made for primary health sector and for the hospital sector
- Guidelines should be set at EU level but with special parts for each MS
- Laboratory test (bed side) should be developed and used much more and be a part of the guidelines
- Reinforce and reorganise the curriculum of medical staff at university level to include AMR and infection prevention and control all along their courses
- Develop and strengthen at national level guidelines for rational use of antimicrobials based on diagnostics and develop fast track procedure for their adaptation
- Auditing including considerations according to quality indicators
- Incentive systems to regulate antibiotic use by general practitioners
- Better control of antibiotic use in the long term care institutions, which use a lot of antibiotics. Infection control in long term care institutions
- Reinforce infection control – hand hygiene in primary care (children's institutions, schools, long term care institutions)

How can the use of antimicrobials in the healthcare sector be reduced?

- Focus on hygiene and prudent use to diminish transmission
- Reinforce prevention and control of infection in healthcare settings
- Through the European Antibiotic Awareness Day, reinforce and make it systematic to address communication and awareness among the healthcare professionals (in all healthcare settings)

Which instruments can be used to ensure that legislation on antimicrobials labeled "prescription only" is followed?

- Enforcement of national legislation to prevent over-the-counter sales of antibiotics!
- Raise awareness among the public about the problems of sales without prescriptions, including internet sales
- Raise awareness about the problems for the individual arising from inappropriate treatment with antibiotics
- EU-legislation against under-the-table sales; better enforcement of rules/fines
- Enforce prescription only sales of antibiotics
- Guidelines for practitioners
- Training and education for pharmacists
- Socio-economic-cultural factors explaining over the counter sales of antibiotics

Obstacles:

- Economic incentives for pharmacies to sell prescription drugs in some countries - antibiotics can then be sold illegally
- No enforcement of present laws. You only dispense what the doctor ordered

Workshop 2

The following three questions were the basis of the discussions:

1. Should there be certain conditions for use of CIAs?
2. Which actions should be taken to ensure restricted use of CIAs in humans and animals?
3. Which basic monitoring data and control measures are necessary to ensure restricted use/compliance with guidelines?

Framing the situation

- The concept of CIAs is developing as resistance is increasing
- Second line drugs (cephalosporins) are used as first line treatment, and colistin as the last resort
    - Colistin/polymyxin needs to be included
- In some countries, little difference between practices in the primary health care system and in hospitals
    - Important to focus on primary health care with overuse of fluoroquinolones and carbapenems
- Often little microbiological support
- There should be certain conditions for the use of CIA's

Q 1: Should there be certain conditions for use of CIAs?

- CIA's should be used in combination with microbiological diagnosis and sensitivity tests
- Allowed for early empirical treatment of severe infections, expected to respond poorly to other classes of antimicrobials
- In animals: CIAs may be limited to few situations of acute illness
    - Carbapenems should not be used for animals
- In general practice: CIAs has a very limited role to play
- In general, do not use CIAs as prophylaxis

Actions

- Need to educate and raise awareness
    - Patients, farmers, health professionals
- Guidelines are needed!
    - European, but adapted to local situations
    - Avoid off-label use of CIAs
- Legislation may be necessary, e.g., ban of 3rd and 4th generation cephalosporins for food animals
    - Analyse consequences and possibilities of enforcement
    - EU regulation will be important to support initiatives at the MS level

- There should be no economic incentive of prescribing CIAs for both veterinarians and medical doctors

Implementation

- Monitoring of the use including indications to prescribe
    - Audits, supervision, ”yellow cards”
- Importance of microbiological surveillance, standard methods, support to build laboratory capacity

Workshop 3

The following questions were the basis of the discussion:

1. What is the optimal level of surveillance of antimicrobial consumption?
2. How do we get all Member States included (consumption)?
3. How can we present data in a way to facilitate action (consumption)?
4. What is the optimal level of surveillance of resistance?
5. How do we get all Member States included (resistance)?
6. How can we present data in a way to facilitate action (resistance)?

Q.1: What is the optimal level of surveillance of antimicrobial consumption?

Need EU-standards for human consumption data collection and denominators

- Age group
- Indications

Focus on the most critical first

- Consumption data on animal species, age group, production type, sub groups/substances should be achieved
- Indication and/or diagnosis should be considered both as an animal health indicator and for actions at the national level; at this state not a high priority on the EU level

Q.2: How do we get all Member States included (consumption)?

- Need EU legislation for collecting data by animal species
- Should be harmonised legal basis for top-down surveillance; e.g. harmonised with ESVAC legislation
- Media campaigns

Q.3: How can we present data in a way to facilitate action (consumption)?

- Need for a common legal basis on what to report to ESVAC. There must be free hand for the countries on how system should be build

- Also national legal framework is necessary for collection in order to obtain harmonized data on species level
    - National action plans
- There should be a possibility for adoption to national structure:
    - Collection of all veterinary prescriptions
    - Recording of each prescription and indication
    - Recording public data base or
    - Recording privately on practice level
- Data must be fully available for national reporting, and should be analyzed nationally; statistically relevant by the scientifically competent body/authority data should be reported with transparency
- Management actions are a national matter; possible actions for improvement of the data collection systems should be identified (e.g. benchmarking of herds)
- Data quality – is all reported. Is medicated feed registered? And transport? It is necessary to describe carefully the distributions systems and find methods to validate
- Capacity building: organizing meeting with countries that have extensive experience in bottom-up systems

Prerequisites for comparing data on resistance and consumption

- Data on consumption should be in harmonized with resistance data
    - That is as a minimum on species level, but for some species also on production type level, e.g. broilers vs. layers and in the future veal calves vs. dairy cattle

Integrated surveillance and reporting on data from human veterinary field

- It is necessary to harmonize the measures, e.g. defining an equivalent to the DDD for the veterinary field; also harmonizing of the denominator
- Also, more than one measure is necessary for each field depending on the purpose of the comparison, to facilitate correct interpretation

Q.4: What is the optimal level of surveillance of resistance?

- Need absolutely clear definitions and collection of quantitative data
- Human surveillance of resistance
    - Bacterial species to include (EARS-Net pathogens extended by: Acinetobacter, S.pyogenes, Haemophilus influenzae (invasive) gastro-enteritis pathogens (Salmonella, Campylobacter) and Helicobacter pylori
    - Hospitals, community, age groups (children), indications (LRTI, UTI, Blood, Skin and soft tissue)

- Denominators
- Ad hoc screening of emerging resistances in healthy humans / groups at risk
- Also monitoring in healthy humans also different syndromes/disease – hospital environment
- Phenotypic and genotypic

- Animal surveillance of resistance
  - Animal/food isolation as close to the consumer as possible - Both food and pets
  - Indicators covering the whole line – vet – food – human – environment – set up from Vet/food could be implemented in human sector – E. coli/Enterococci – description of the load of AMR from food to consumers
  - Stratification of monitoring animal species, production types
- Risk based approach for identifying the most critical points for prioritizing the focus – especially for indicator organisms
  - What is the major hazard to humans (MRSA, CPE, and ESBL)?
  - Which kind of the animal/food production is most risky?
  - Where is the highest consumption?

Recommendation 1:
Suggest to EFSA to include E. coli as an additional pathogen that represent an important reservoir for multiple resistance determinants.

Recommendation 2:
Carry out cross- sectional (human and animal) baseline and repeated surveys to representatively collect isolates (E. coli) from both habitats and explore occurrence of AMR genes.

Q.5: How do we get all Member States included (resistance)?

- High level of transparency – sharing of data – but this is difficult in daily life (especially in human sector)
- Important from the beginning to have a clear goal of a monitoring programming that include agreement on dataflow and ownership (e.g. as the EU baseline studies)
- Need harmonization
- Mandatory to participate and report
- Legislation should define the key element
- All partners need to see the benefit
- Good communication
- Good IT-systems

- Financial constraints (AMR surveillance programme should at least for some countries be supported by: i.e. DG-SANCO grants)
- Expansion to other countries of current systems
- Adaptation of current systems started before harmonisation
- Police function or help when not compliant (Feedback on the results/report: what is the outcome, what improvements can be achieved: gives motivation) – AVOID BLAME
- Need for a stringent legislation
- Long term vision with funding (by EU or countries?)
- Commitments at all levels, EU, countries with prove of outcome
- Media campaigns

Q.6: How can we present data in a way to facilitate action (resistance)?

- Early warning
- Establish a similar system as the rapid early system on food borne outbreaks. This is the ultimate goal
- In the beginning start on establishing expert groups in MS, who should look on data and decide which actions to be taken. They should link up on ECDC, who should be those to decide in the end
- Quick publications
- Combine reporting of consumption data and resistance
- Common database needed. All MS needs an electronic database system for central data recording. Data must be comparable
- Good IT-systems
- To obtain integrated surveillance we need a system to monitor the same bacteria on both the vet and human sides
- The focus must be based on known zoonoses and indicator-bacteria as a starting point. On the long term the choice of bacteria to monitor can be changeable
- Resistance data should be presented with e.g. economical costs / outcome to speak louder for politicians
- Trends in resistance should be presented for each pathogen
- We recommend to include the representatives of the each antimicrobial groups , depending on bacterial species
- Combined reports for actions to tighten the cooperation between medical and veterinary authorities in each Member State

- The existing EWRS reporting should be utilized (extend EWRS for AMR). The veterinary and medical reference labs are expected to cooperate closely and regularly exchange AMR-data collected by their field-laboratories
- Media campaigns

Annex V – List of participants

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Schon	Joseph	Dr.	Agriculture/Laboratoire de Médecine Vétérinaire de l'Etat	Luxembourg	Workshop 3A/B
Zagrebneviene	Galina	Mrs/Ms	Centre for Communicable Diseases and AIDS	Lithuania	Workshop 3A/B

Surname	First name	Title	Ministry/institution	Country	Workshop
Aarestrup	Frank	Prof.	Technical University of Denmark	Denmark	Workshop 3B
Ajufo	Justin	Dr.	Danish Veterinary and Food Administration	Denmark	Workshop 3B
Aspevall	Olle	Dr.	Swedish Institute for Communicable Disease Control	Sweden	Workshop 3B
Baggesen	Dorte	Dr.	National Food Institute, The Technical University of Denmark	Denmark	Workshop 3B
Barkbu	Kjersti	Mrs/Ms	Norwegian Food Safety Authority, Head Office	Norway	Workshop 3B
Babovic	Tatjana	Mrs/Ms	Veterinary Administration	Montenegro	Workshop 3B
Beloeil	Pierre-Alexandre	Dr.	European Food Safety Authority (EFSA)	EU/Europe	Workshop 3B
Bertrand	Sophie	Dr.	Institute of Public Health	Belgium	Workshop 3B
Bjerager	Gitte	Mrs/Ms	Danish Veterinary and Food Administration	Denmark	Workshop 3B
Breck	Karin	Mrs/Ms	The Danish Veterinary and Food Administration	Denmark	Workshop 3B

Surname	First name	Title	Ministry/institution	Country	Workshop
Brtkova	Andrea	Ms	State Veterinary and Food Institute	Slovakia	Workshop 3B
Brådenmark	Anna	Dr.	National Food Administration	Sweden	Workshop 3B
Bukovski-Simonoski	Suzana	Prof.	University Hospital for Infectious Diseases "Dr Fran Mihaljevic" Zagreb	Croatia	Workshop 3B
Butaye	Patrick	Prof.	CODA-CERVA	Belgium	Workshop 3B
Coignard	Bruno	Dr.	Institut de Veille Sanitaire (InVS)	France	Workshop 3B
Dalsgaard	Anders	Prof.	University of Copenhagen	Denmark	Workshop 3B
Danuser	Jürg	Dr.	Swiss Federal Veterinary Office	Switzerland	Workshop 3B
De Frutos	Cristina	Mrs/Ms	Ministry of Agriculture, Food and Environment Affairs	Spain	Workshop 3B
Dumpis	Uga	Dr.	Pauls Stradins University Hospital	Latvia	Workshop 3B
Egervärn	Maria	Mrs/Ms	National Food Agency	Sweden	Workshop 3B
Florek	Karolina	Mrs/Ms	General Veterinary Inspectorate	Poland	Workshop 3B
Gierczynski	Rafal	Dr.	National Institute of Public Health - National Institute of Hygiene	Poland	Workshop 3B
Giessen	Arjen	Dr.	National Institute of Public Health and the Environment	Netherlands	Workshop 3B
Gomes	Carlos	Dr.	Ministry of Health / Directorate-General of Health	Portugal	Workshop 3B
Grundmann	Hajo	Prof.	University Medical Centre Groningen	Netherlands	Workshop 3B
Hald	Tine	Dr.	National Food Institute, DTU	Denmark	Workshop 3B
Hammerum	Anette	Dr.	Statens Serum Institut	Denmark	Workshop 3B
Hengl	Brigita	Mrs/Ms	Croatian Food Agency	Croatia	Workshop 3B
Herrera León	Silvia	Mrs/Ms	Institute of Health Carlos III.	Spain	Workshop 3B
Hopkins	Katie	Dr.	Health Protection Agency	United Kingdom	Workshop 3B
Hryniewicz	Waleria	Prof.	National Medicines Institute	Poland	Workshop 3B
Ivanova	Kate	Mrs/Ms	National Center of Infectious and Parasitic Diseases	Bulgaria	Workshop 3B
Janevski	Blazho	Mr	Food and Veterinary Agency	FYR Macedonia	Workshop 3B
Jarlier	Vincent	Mr	Assistance Publique - Hôpitaux de Paris	France	Workshop 3B
Jernberg	Cecilia	Dr.	Swedish Institute for Communicable Disease Control	Sweden	Workshop 3B

Surname	First name	Title	Ministry/institution	Country	Workshop
Karpiskova	Renata	Dr.	National Institute of Public Health	Czech Republic	Workshop 3B
Koefer	Josef	Prof.	Vetmeduni Vienna	Austria	Workshop 3B
Le Hello	Simon	Dr.	Institut Pasteur	France	Workshop 3B
Levent	Belkis	Dr.	Ministry of Health, Refik Saydam National Public Health Agency	Turkey	Workshop 3B
Lo Fo Wong	Danilo	Dr.	World Health Organization Regional Office for Europe	WHO/Europe	Workshop 3B
Lohman Jankovic	Ivana	Dr.	Ministry of Agriculture-Veterinary Directorate	Croatia	Workshop 3B
López	Gema	Mrs/Ms	Ministry of Agriculture, Food and Environment Affairs	Spain	Workshop 3B
Lund	Arve	Dr.	Norwegian Veterinary Institute	Norway	Workshop 3B
Much	Peter	Dr.	Austrian Agency for Health and Food Safety	Austria	Workshop 3B
Mulhern	Michael	Dr.	Health Service Executive	Ireland	Workshop 3B
Nielsen	Eva	Dr.	Statens Serum Institut	Denmark	Workshop 3B
O'Connor	Lisa	Ms	Food Safety Authority	Ireland	Workshop 3B
Pantosti	Annalisa	Dr.	Istituto Superiore di Sanità	Italy	Workshop 3B
Peetso	Rita	Dr.	Health Board	Estonia	Workshop 3B
Peran Sala	Rosa	Mrs/Ms	European Commission, DG Health & Consumers	EU/Europe	Workshop 3B
Saez Llorente	Jose Luis	Mr	Ministry of Agriculture, Food and Environment	Spain	Workshop 3B
Sahin	Güzin	Mrs/Ms	Ministry of Food Agriculture and Livestock	Turkey	Workshop 3B
Schweickert	Birgitta	Dr.	Robert Koch-Institute	Germany	Workshop 3B
Selderina	Solvita	Dr.	Infectology Center of Latvia	Latvia	Workshop 3B
Sideroglou	Theologia	Mrs/Ms	Hellenic Centre for Disease Control and Prevention	Greece	Workshop 3B
Sigmundsdottir	Gudrun	Dr.	Centre for Health Security and Communicable Disease Control, Directorate of Health	Iceland	Workshop 3B
Siitonen	Anja	Dr.	The National Institute for Health and Welfare	Finland	Workshop 3B
Skov	Robert	Dr.	Statens Serum Institut	Denmark	Workshop 3B

Surname	First name	Title	Ministry/institution	Country	Workshop
Struelens	Marc	Prof.	European Centre for Disease Prevention and Control (ECDC)	EU/Europe	Workshop 3B
Sørensen	Alice	Mrs/Ms	Danish Veterinary and Food Administration	Denmark	Workshop 3B
Tast Lahti	Elina	Dr.	National Veterinary Institute	Sweden	Workshop 3B
Thorsteinsdottir	Thorunn	Mrs/Ms	The Directorate of Health	Iceland	Workshop 3B
Trkov	Marija	Dr.	National Institute of Public Health	Slovenia	Workshop 3B
Unger	Kilian	Mr	Department of Agriculture, Food and the Marine	Ireland	Workshop 3B
Vanholme	Luc	Dr.	Federal Agency for the Safety of the Food Chain	Belgium	Workshop 3B
Vesmes	Ingrid	Mrs/Ms	Ministry of Agriculture	Estonia	Workshop 3B
Vuopio	Jaana	Prof.	National Institute for Health and Welfare	Finland	Workshop 3B
Wallmann	Jürgen	Dr.	Federal Office of Consumer Protection and Food Safety	Germany	Workshop 3B
Wester	Astrid	Mrs/Ms	Norwegian Institute of Public Health	Norway	Workshop 3B
Zemlickova	Helena	Dr.	National Institute of Public Health	Czech Republic	Workshop 3B

Surname	First name	Title	Ministry/institution	Country	Workshop
Angen	Øystein	Mr	National Veterinary Institute, Technical University of Denmark	Denmark	Not participating
Boville	Claire	Mrs/Ms	Department of Health	United Kingdom	Not participating
Chan Fung	Fu Chun Margaret	Dr.	World Health Organization	WHO	Not participating
Gyssens	Ingeborg	Prof.	SWAB	Netherlands	Not participating
Hajlová	Alena	Mrs/Ms	Public Health Authority, Department of Epidemiology	Slovakia	Not participating
Hauksdottir	Vilborg	Mrs/Ms	Nordic Council of Ministers	Denmark	Not participating
Jakab	Zsuzsanna	Mrs/Ms	World Health Organization Regional Office for Europe	WHO/Europe	Not participating
Juul	Mai	Mrs/Ms	European-Parliament	EU/Europe	Not participating
Kunoe	Asja	Mrs/Ms	National Board of Health	Denmark	Not participating
Mancarella	Giovanni	Mr	European Centre for Disease Prevention and Control (ECDC)	EU/Europe	Not participating
Nanda	Arun	Mr	World Health Organization, Regional Office for Europe	WHO/Europe	Not participating

Surname	First name	Title	Ministry/institution	Country	Workshop
Nordvig	Rune	Mr	National Board of Health (Sundhedsstyrelsen)	Denmark	Not participating
Nørgaard	Nicolaj	Mr	Pig Research Centre	Denmark	Not participating
Pedersen	Court	Prof.	Odense University Hospital	Denmark	Not participating
Raka	Lul	Prof.	Ministry of Health, National Institute of Public Health of Kosova	EU/Europe	Not participating
Seychell	Martin	Mr	European Commission, DG Health & Consumers	EU/Europe	Not participating
Smith	Else	Dr.	The National Board of Health	Denmark	Not participating
Søndergaard	Dorthe	Mrs/Ms	Ministry of Health	Denmark	Not participating
Sprenger	Marc	Dr.	European Centre for Disease Prevention and Control (ECDC)	EU/Europe	Not participating
Walsh	Timothy	Prof.	Cardiff University	United Kingdom	Not participating
Walter	Anne	Mrs/Ms	Norwegian Directorate of Health	Norway	Not participating
Worning	Anne Marie	Dr.	World Health Organization	WHO	Not participating

Moderator					
Meilstrup	Per	Mr	Journalist and Climate Director, Monday Morning - a leading independent think tank	Denmark	Not participating

Organisers					
Amelung	Anders	Mr	Ministry of Food, Agriculture and Fisheries	Denmark	Workshop 3
Groth Rasmussen	Line	Mrs/Ms	Ministry of Food, Agriculture and Fisheries	Denmark	Workshop 3
Hansen	Line	Mrs/Ms	Ministry of Health	Denmark	Not participating
Holton	Christina	Mrs/Ms	Ministry of Health	Denmark	Not participating
Knudsen	Charlotte	Mrs/Ms	Ministry of Food, Agriculture and Fisheries	Denmark	Workshop 3
Krohn	Maria	Mrs/Ms	Ministry of Food, Agriculture and Fisheries	Denmark	Workshop 2
Lindgaard	Gitte	Mrs/Ms	Ministry of Health	Denmark	Workshop 2
Strøbæk	Grith	Mrs/Ms	Ministry of Health	Denmark	Workshop 1
Szpakowska	Emilia	Mrs/Ms	Ministry of Health	Denmark	Not participating
Thoustrup	Lisette	Mrs/Ms	Ministry of Health	Denmark	Workshop 1


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