Work Package n°7:
Appropriate use of antimicrobials in human and animals:
WP leaders:
FHI (Norway) & AEMPS (Spain)
WP objectives. By task

Work description, progress and achievements towards WP objectives

Timeline: Tasks, Deliverables & Milestones status

Stakeholders involvement

Risks encountered

Next steps for Year 2
<table>
<thead>
<tr>
<th>Tasks</th>
<th>Leader</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.1 - Guidelines, tools and implementation methods for antibiotic stewardship</td>
<td>FHI (Norway)/AEMPS (Spain)</td>
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<tr>
<td>7.2- Workshop involving all the registered partners to discuss models of implementation</td>
<td>FHI (Norway)/AEMPS (Spain)</td>
</tr>
<tr>
<td>7.3- Qualitative evaluation of the level of implementation and acceptance of antibiotic stewardship at different levels of healthcare and in animals. Identify success factors and barriers</td>
<td>FHI (Norway)/AEMPS (Spain)</td>
</tr>
<tr>
<td>7.4.1 -Surveillance of AMR and AMC in humans</td>
<td>AEMPS (Spain) and SAS (Spain)</td>
</tr>
<tr>
<td>7.4.2. Surveillance of AMR in animals</td>
<td>ANSES (France) / ISS (Italy)</td>
</tr>
</tbody>
</table>
Work description, progress and achievements
7.1 - Guidelines, tools and implementation methods for antibiotic stewardship
7.1 - Guidelines, tools and implementation methods for antibiotic stewardship

Contributors

- Norwegian Directorate of Health;
- Conselleria de Salud del Govern de les Illes Balears (Spain);
- Fundación para la Formación e Investigación Sanitarias de la Región de Murcia (Spain);
- The National Medicines Institute (Poland),
- The Norwegian Veterinary Institute;
- University of Foggia (Italy);
- Dutch Ministry of Health, Welfare and Health;
- Statens Serum Institut (Denmark);
- University of Medicine and Pharmacy "Iuliu Hatieganu” Cluj-Napoca (Romania);
- Robert Koch-Institute (Germany);
- Austrian Public Health Institute;
- Instituto Superiore Di Sanita (Italy);
- French Agency for Food, Environmental and Occupational Health & Safety (France);
- Croatian Institute of Public Health;
- The Hospital of Lithuanian University of Health Sciences Kauno Klinikos;
- National Public Health Centre (Lithuania).
- Federal Public Service Health, Food Chain Safety and Environment (Belgium)
7.1 - Guidelines, tools and implementation methods for antibiotic stewardship.

<table>
<thead>
<tr>
<th><strong>Aims</strong></th>
<th><strong>Methods</strong></th>
</tr>
</thead>
</table>
| **Human Health:**  
Update and expand the information available on the ECDC website to include information on existing guidelines, implementation methodology and work at different levels of the healthcare system. | ➢ Survey ➢ Revision of available materials on the implementation of Antibiotic Stewardship Programmes |
| **Animal Health:**  
Identify guidelines or tools that have been successful in controlling the consumption and resistance of antimicrobials in the animal population and what is needed next. | ➢ Survey |
Calls to Action

Questionnaire for associations, vets, farmers and other professionals related to animal health

Survey to map the Antibiotic Stewardship Programmes in primary care, long-term care and hospitals in Europe

As part of the WP7, appropriate use of antimicrobials in human and animals, we are developing a tool that implies to collect information resources to assist in planning and implementing Antibiotic Stewardship Programmes at all levels of healthcare and with different levels of available resources. Therefore, we have designed a survey to complement the information already available on this topic. The survey is currently being distributed to relevant respondents within the Member States and Associated Countries. In order to identify what has been effective and what hasn’t worked, we need to know what has already been implemented, under what conditions this occurred and what the outcomes were.

Contact person for the survey:

Liv Storehagen (Norwegian Institute of Public Health – NIHP), Oliva Kacznik (NIHP), Paloma Crespo Robledo (Spanish Agency of Medicines and Medical Devices – AEMPS) and Antonio López Navas (AEMPS)

Contact: live.storehagen@hi.no and pcrpso_esterno@aemps.es

Deadline: 30 July 2018
7.1 - Guidelines, tools and implementation methods for antibiotic stewardship

Human health

✓ Survey:
  ▪ Description:
    ▪ Identification of respondents for the questionnaire
    ▪ Development questionnaire and partner feedback
    ▪ Utilisation of electronic tools (QuestBack)
    ▪ Distribution of questionnaire, 14 May - 20 July 2018
  ▪ Progress: finished
  ▪ Achievements:
    ▪ Presented and discussed in WS held yesterday (7/11/18).
Short summary of survey

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of respondents:</td>
<td>95</td>
</tr>
<tr>
<td>Number of countries:</td>
<td>28</td>
</tr>
<tr>
<td>Number of respondents - hospitals</td>
<td>60</td>
</tr>
<tr>
<td>Number of respondents - primary care</td>
<td>56</td>
</tr>
<tr>
<td>Number of respondents - long-term care</td>
<td>22</td>
</tr>
</tbody>
</table>

Who is responsible for the content of programmes in hospitals:

- National Ministry of health
- Hospitals (A teams)
- Hospitals (IPC or micro)
- Local/regional authorities
- Specialised national body

Graph showing responsibilities:
- ABS
- Clinical guidelines
Human health

✓ Revision of available materials on the implementation of Antibiotic Stewardship Programmes
  ▪ Description:
    ▪ Perform protocol for development of the task
    ▪ Increase involvement from partners in this task: videoconference, minutes and presentation
    ▪ Mapping
    ▪ Layout and publication in website
  ▪ Progress: finished
  ▪ Achievements:
    ▪ First deliverable release on EC portal: 7.1
    ▪ Directory available and downloadable in eu-jamrai.eu/results
# Guidelines, tools and implementation methods for antibiotic stewardship

Below is a collection of documents about implementation of antibiotic stewardship at different levels of care. Inside each list you can access the original documents. This is not an exhaustive list but is intended as a resource-bank. The links are correct at the time of publication but may change over time.

## Lists by Level of Care

<table>
<thead>
<tr>
<th>Level of Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>All levels of care (Hospital care, Community/primary care and Long-term facility care)</td>
</tr>
<tr>
<td>Hospital care</td>
</tr>
</tbody>
</table>

Animal health

✓ Survey:
  ▪ Description:
    ▪ Identification of respondents for the questionnaire
    ▪ Development questionnaire, partner stakeholder feedback
    ▪ Utilisation of electronic tools (Survey Monkey)
    ▪ Distribution of questionnaire: 16 March - 15 June 2018
  ▪ Progress: finished
  ▪ Results: will need to be publish analysing the guidelines and opinions gathered


Distribution of the survey

1) EPRUMA All contacts

2) All WP7 Partners National Focal points

Collaborating stakeholders, CVMP members
Animal health Survey. Title: Questionnaire for Associations, vets, farmers and other professionals related to Animal Health

- 5 min spent to fill
- 7 items
- 522 responders
- 26 countries
### Sector

- Academia, scientific society or association: 65%
- Animal healthcare provider: 14%
- Competent authorities: 11%
- Farmers and animal keepers: 4%
- Food industry: 4%
- Pharmaceutical Veterinary Industry: 2%

### Sector/Type of animal expertise

<table>
<thead>
<tr>
<th>Sector/Type of animal expertise</th>
<th>Fish</th>
<th>Pigs</th>
<th>Poultry</th>
<th>Large Ruminant (milk)</th>
<th>Large Ruminant (meat)</th>
<th>Small ruminant (milk)</th>
<th>Small ruminant (meat)</th>
<th>Rabbit</th>
<th>Horse (meat)</th>
<th>Cat</th>
<th>Dog</th>
<th>Exotic</th>
<th>Horse</th>
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<tbody>
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<td>42</td>
<td>35</td>
<td>43</td>
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<td>136</td>
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<td>246</td>
<td>251</td>
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<td>3</td>
<td>6</td>
<td>5</td>
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<td>60</td>
<td>298</td>
<td>307</td>
<td>104</td>
<td>129</td>
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</table>

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5. Which of the following tools has been most useful to you to decrease antimicrobial consumption and improve the prudent use?

- Improvements in biosecurity
- Increase vaccination
- Nutrition optimization
- Routine diagnostic tests
- A clear action plan
- Antibiotics
- Guidelines and/or recommendations

Tools that have been useful to decrease AB consumption
7. Specific measures needed to help to decrease antimicrobials consumption and to increase the prudent use. Indicate from 0 (strongly disagree) to 10 (strongly agree).

<table>
<thead>
<tr>
<th>Measures needed</th>
<th>Scale</th>
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<tr>
<td>Good practice guidelines</td>
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<tr>
<td>Autoconsumption Control Tools</td>
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<tr>
<td>Legislation</td>
<td>0</td>
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<tr>
<td>Training</td>
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<tr>
<td>Biosecurity measures</td>
<td>0</td>
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<tr>
<td>Prescription guidelines</td>
<td>0</td>
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<tr>
<td>Regional epidemiological maps for resistance of clinical pathogens</td>
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<tr>
<td>Reduction / ban to use of specific AM on voluntary basis (for eg. Spanish Voluntary agreement to reduce colistin consumption to 5 mg/PCU)</td>
<td>0</td>
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<tr>
<td>Rapid diagnosis test</td>
<td>0</td>
</tr>
<tr>
<td>Sensitive test (to help to choose the best antimicrobial and avoid the use of CIAs)</td>
<td>0</td>
</tr>
<tr>
<td>Prevention tools such as vaccination or optimised nutrition</td>
<td>0</td>
</tr>
</tbody>
</table>

Measures needed: Good practice guidelines, Autoconsumption Control Tools, Legislation, Training, Biosecurity measures, Prescription guidelines, Regional epidemiological maps for resistance of clinical pathogens, Reduction / ban to use of specific AM on voluntary basis (for eg. Spanish Voluntary agreement to reduce colistin consumption to 5 mg/PCU), Rapid diagnosis test, Sensitive test (to help to choose the best antimicrobial and avoid the use of CIAs), Prevention tools such as vaccination or optimised nutrition.
7.2- Workshop involving all the registered partners to discuss models of implementation
7.2 - Workshop involving all the registered partners to discuss models of implementation

- Human health WS in Vienna, 7 Nov 2018
- Animal health WS was cancelled due to lack of participants.

Aims

• Discuss the findings of the JA survey on AS implementation
• Identify success factors in different settings
• Identify barriers to implementation
• Compile a report from the meeting to guide further interviews (task 7.3)
• Aid implementation of effective stewardship in Europe at all levels of health care
7.2- Workshop involving all the registered partners to discuss models of implementation
7.2- Workshop involving all the registered partners to discuss models of implementation

Primary care - Barriers
- Motivation
- Public vs private sector tension /incentives
- LTCF under variable control
- LTCF many different doctors
- Poor sharing of information and data
- Very few with electronic prescribing
- Diagnostic uncertainty
- Lack of diagnosis
- Lack of education of university students (AMR and HCAIs)

Primary care - Success factors
- Leadership
- Central institutional support – coordination HR, funding, expertise, skills sets
- Better awareness / education
- Uniform cross-systems guidelines / SOP / Software / Guidelines
- Education / Peer to peer programmes
- Indicators linked to incentive
- Good communication across primary care, LTCF and inter-professional groups
- Access to hospital expertise (microbiologist etc.)
- Small integrated systems
- Good quality data systems
- Public slogans and campaigns
- Electronic alert system

Hospital care - Barriers
- AMS team looked as a threat
- Fatigue, time and finance / HR
- Changing / Flow of staff / continuity of care / 24 hours availability
- Lack of priority by leadership
- Access to ATBs and communication
- Non-medical professionals
- Lack of accountability to targets
- AMR training across all healthcare professionals and public
- Involvement of different professional societies
- Integrating clinical informatics into clinical decision making process
- Dedicated resources for quality audit and feedback
- IT and connectivity

Hospital care - Success factors
- Leadership
- AMS leader position of authority
- Broad clinical engagement
- Agreed guidelines / SOP and vision
- Training on stewardship on clinical meetings
- Joining a EU mentor programme
- Reputation / Senior leadership
- Accountability and responsibility
- Regular audit and feedback
- IT and connectivity
- Multidisciplinary
- Set and short-term and long term goals
- Accreditation
- Giving the pharmacist a review role
- Integration of the AMS and IPC Team
- Good lab and epidemiology
- Clinically meaningful epidemiology data
7.3. Qualitative evaluation of the level of implementation and acceptance of antibiotic stewardship at different levels of healthcare and in animals. Identify success factors and barriers
7.3. Qualitative evaluation of the level of implementation and acceptance of antibiotic stewardship at different levels of healthcare and in animals. Identify success factors and barriers

Contributors

- Norwegian Directorate of Health;
- Austrian Public Health Institute;
- The National Institute of Public Health (Czech Republic)
- Statens Serum Institut (Denmark)
- Robert Koch-Institute (Germany)
- The Hospital of Lithuanian University of Health Sciences Kauno Klinikos;
- The National Medicines Institute (Poland)
- Servicio Andaluz de Salud (Spain)
- Dirección General de Ordenación Profesional y Regulación Sanitaria. Departamento de Salud de la Generalitat de Cataluña (Spain)
- Agence Nationale de la Securite Sanitaire de l’alimentation de l’Environnement et du travail (France)
- Folkhälsomyndigheten - Public Health Agency of Sweden
- Conselleria de Salud del Govern de les Illes Balears (Spain)
- National Center of Infectious and Parasitic Diseases (Bulgaria)
- Federal Public Service Health, Food Chain Safety and Environment (Belgium)
Aims

• To evaluate level of implementation of antimicrobial stewardship
• To identify barriers and success factors for implementation of antimicrobial stewardship
• To deliver a report of compliance of indicators of antibiotic use and resistance
7.4. Develop and test near real time surveillance of antimicrobials and multidrug resistant bacteria

7.4.1 Surveillance of AMC and AMR in humans

7.4.2 Surveillance of AMR in clinical pathogens of animals
Aims

- To develop a simple surveillance system of antibiotic use and resistance including feedback mechanisms for a shorter time-lag
- Select basic indicators for surveillance of antimicrobial consumption
- Select basic indicators for surveillance of antimicrobial resistance
- Reinforce participants surveillance systems to:
  - provide data on a quarterly basis
  - from Hospitals and/or Primary Care
  - at Regional or National scope
7.4.1- Surveillance of AMC and AMR in humans

Collaborators

11 countries (19 institutions)

- Bulgaria (1)
- Croatia (1)
- Czech Republic (1)
- Denmark (1)
- Germany (1)
- Greece (2)
- Italy (2)
- Lithuania (2)
- Poland (1)
- Portugal (1)
- Spain (6)

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<th>Geo scope</th>
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<td>Regional scope</td>
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<td>63%</td>
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<td>Hospitals+Primary Care</td>
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</tr>
<tr>
<td>Hospitals only</td>
<td>8</td>
<td>42%</td>
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<tr>
<td>Primary Care only</td>
<td>4</td>
<td>21%</td>
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<table>
<thead>
<tr>
<th>Indicators</th>
<th>n</th>
<th>Rate</th>
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</thead>
<tbody>
<tr>
<td>Antibiotic use only</td>
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<td>16%</td>
</tr>
<tr>
<td>Antimicrobial resistance only</td>
<td>1</td>
<td>5%</td>
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<tr>
<td>Both AMC+AMR</td>
<td>15</td>
<td>79%</td>
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</table>
7.4.1- Surveillance of AMC and AMR in humans

**Progress**

- Indicators for surveillance of AMC and AMR selected - Dec/2017
- Guidelines developed and disseminated - Dec/2017 (v.3 - Feb/2018)
- Database and website developed - Dec/2017
- Piloting 2018-2020 ongoing

**Preliminary results**

- 47% of the participants (9/19) have provided 1st and 2nd quarters 2018 data
  - 67% of the respondents (6/9) provided complete geographical scope data
  - 33% of the respondents (3/9) provided partial (a sample of) geographical scope data
- 53% of the participants (10/19) have not provided data yet
7.4.2 Surveillance of AMR in clinical pathogens of animals

• Start: April 2018
• General aim: Develop the surveillance of AMR in clinical bacterial pathogens of animals in a One Health approach.
• Contributors:
  – Sweden (SVA)
  – Norway (NVI)
  – Czech Republic (USKVBL)
  – Italy (ISS)
  – Spain (AEMPS & Ministry of Agriculture)
  – Greece (ESDY & Ministry of Agricultural development and Food)
  – France (ANSES)
  – Denmark (?)
Specific objectives

1. Assess the surveillance systems in place - if any - on AMR in animal pathogens in each country
   – Questionnaire to describe national systems and teleconference
   – Evaluation of the French system by the OASIS method
2. Identify the main gaps and appropriate strategies for AMR surveillance in diseased animals depending on the country specificities
   – Questionnaire and teleconferences
3. Select appropriate AMR indicators in diseased animals in coherence with human. The choice of these indicators will allow correlating the animal data with the human data from subtask 7.4.1

- Teleconference with human and veterinary partners
  - Adaptation of the preliminary list of target pathogens of public health relevance to monitor in the animal sector
  - Veterinary specific pathogens will also be included
  - Correlating animal and human data is not a priority
  - One health approach of clinical pathogen surveillance of animals:

« To decrease the public health impact of antimicrobial use in the veterinary sector, surveillance should be able to provide useful data for veterinarians to guide their prescriptions. »
7.4.2 Surveillance of AMR in clinical pathogens of animals

4. Identify laboratory and technical capacities in each country
5. Assess the opportunities to combine the national surveillance systems into a pilot EU network
6. Draw guidelines for uploading, validation and management of the data
7. Provide global and specific recommendations to EU to build a European network covering AMR surveillance in diseased animals, including interface with AMR surveillance in human medicine

Uncovered yet
Timelines, stakeholder status and risk encountered
Timeline: Tasks, Deliverables & Milestones status

Up-to-date letter to partners
16/3/2018

Distribution of survey (human)
14/5/2018

Distribution of animal survey
16/3/2018

Up-to-date letter to partners
31/8/2018

M7.2. Progress check in terms of website
31/8/2018

D7.2. Report on workshop of models for implementation of AMS
31/12/2018

Tasks WP7

7.1 On schedule 1/15/2018 - 8/31/2018

7.2 On schedule

7.3 On schedule

7.4.1 On schedule

7.4.2 On schedule

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<table>
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<tr>
<th>N°</th>
<th>Meeting name</th>
<th>Type</th>
<th>Date</th>
<th>Aim</th>
<th>Expected attendees</th>
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<tr>
<td>1</td>
<td>ECDC-task 7.4.1</td>
<td>TELECONFERENCE</td>
<td>19/10/2017</td>
<td>Inform ECDC about the aim and development of real-time surveillance of AMR and AMC</td>
<td>ECDC, AEMPS, SAS,</td>
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<tr>
<td>2</td>
<td>WP7 - PGEU</td>
<td>TELECONFERENCE</td>
<td>28/02/2018</td>
<td>Present WP7 and discuss possible involvement of stakeholder</td>
<td>FHI, PGEU (Jaime Wilconson), AEMPS</td>
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<tr>
<td>3</td>
<td>Vet+i</td>
<td>Face to Face. Vet+i headquarter</td>
<td>13/02/2018</td>
<td>Develop survey of task and strategy of distribution</td>
<td>Santiago DE ANDRÉS JUÁREZ, María JAUREGUÍZAR REDONDO, Patricia FERNANDEZ MARTINEZ, Pablo Hervás Calle (VET+I) and Paloma Crespo and Sara Sacristan (AEMPS)</td>
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<tr>
<td>3</td>
<td>EPRUMA</td>
<td>TELECONFERENCE</td>
<td>27/02/2018</td>
<td>Organize distribution of the survey. Task 7.1 in animal health</td>
<td>Myriam Alcain (EPRUMA) and Paloma Crespo (AEMPS)</td>
</tr>
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<td>4</td>
<td>Beam Alliance</td>
<td>TELECONFERENCE</td>
<td>23/03/2018</td>
<td>Information about WP7</td>
<td>Live Storehagen (NIPH, WP7), Marie Petit, Christine Årdal (NIPH, WP9) and Marie-Cecilie Ploy (INSERM, WP9)</td>
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## Status of the Stakeholders

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Acronym</th>
<th>Contribution</th>
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<tbody>
<tr>
<td>European Centre for Disease Prevention and Control</td>
<td>ECDC</td>
<td>Tasks 7.1 and 7.4.1</td>
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<tr>
<td>The Standing Committee of European Doctors</td>
<td>CPME</td>
<td>Human</td>
</tr>
<tr>
<td>DG Health and Food Safety - DG SANTE (former Food and Veterinary Office)</td>
<td>FVO</td>
<td>Animal</td>
</tr>
<tr>
<td>Union of European Veterinary Practitioners</td>
<td>EVPO</td>
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<td>European Platform for the Responsible Use of Medicines in Animals</td>
<td>EPRUMA</td>
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<td>European Union of General Practitioners</td>
<td>UEMO</td>
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<td>Pharmaceutical Group of the European Union (PGEU)</td>
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<tr>
<td>European Pharmaceutical Students Association</td>
<td>EPSA</td>
<td>Human</td>
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<td>European Food Safety Agency</td>
<td>EFSA</td>
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<td>Vet+i Foundation, Spanish Technology Platform for Animal Health</td>
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<td>Animal</td>
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<td>Federation of European Microbiological Societies</td>
<td>FEMS</td>
<td>General</td>
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<td>Federation of Veterinarians of Europe</td>
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<td>MedTech Europe, the European trade association for the medical technology industries</td>
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<td>Proposed risk mitigation measures</td>
</tr>
<tr>
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<td>----------------------------------</td>
</tr>
<tr>
<td>1</td>
<td>Lack of acceptance and cooperation from ECDC</td>
<td>Early dialogue with ECDC</td>
</tr>
<tr>
<td>2</td>
<td>Lack of infrastructure</td>
<td>Pilot only in countries that can deliver data</td>
</tr>
</tbody>
</table>
### Risks encountered

#### Unforeseen

<table>
<thead>
<tr>
<th>Risk n°</th>
<th>Description of risk</th>
<th>Proposed risk mitigation measures</th>
<th>Comments/updates</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Exhaustion from receiving too many surveys</td>
<td>Ask the ECDC Survey Committee to approve it. Make animal survey as short as possible and easy to access</td>
<td>In the end, this was not a problem. Good sample of responders for each survey</td>
</tr>
<tr>
<td>2</td>
<td>Partners’ commitment declines (when leaders request information or collaboration in contents approval)</td>
<td>Identification of communication focal points for each partner. Fix deadlines WP7 leaders close follow-up. Coordinator support.</td>
<td>A document with up-to-date information about the tasks and deadlines was developed and sent to partners (also shared in Sharefile) 2 times during this year. Informal meeting at the ECCMID conference in Madrid. Videoconference for task 7.1 in June, all contributors</td>
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<tr>
<td>3</td>
<td>The evaluation of Resapath was highly time-consuming (around 3 months)</td>
<td>Another methodology should be used for assessing other surveillance</td>
<td></td>
</tr>
</tbody>
</table>
Next steps
Next steps for year 2

- Analyse more in detail findings from animal survey.
- Develop task 7.3: first interviews in human health and contact with WP5 for animal health
- Task 7.4.1: first report of situation of the pilot study published in Website + first Milestone
- Task 7.4.2: the design of a preliminary European surveillance system should be finalized and under review from other European countries and relevant European institutions + first milestone
THANK YOU

Antonio López Navas
(AEMPS)

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