

Milestone 9.2

Meetings to discuss implementation of incentives with the first-mover volunteer countries, Member State forums and other participating countries.

WP9 | Prioritizing and implementing research and innovation for public health needs

Leader acronym | INSERM, FHI

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Table of Contents

Objectives of the meetings.....	3
Questions asked during the country visits.	4
1. Areas of greatest concern or vulnerability regarding research, innovation, and access.....	4
2. Areas of greatest financial concern related to AMR and HCAI?	4
3. National processes to determine national research priorities.	4
4. Incentives.	4
5. Financing national positions and ambitions.	6
6. Guidelines.	7
7. National processes to update clinical guidelines, IPC routines, and other AMR and HCAI-related policies and practices.	7
Countries interviewed.....	8
Main findings of the meetings.....	9
Acknowledgments	10

Objectives of the meetings.

The purpose of the meetings is to gain a better understanding of current political willingness and barriers to implement actions in line with the mandate of EU-JAMRAI work package 9. This includes (i) national processes to determine national research priorities, (ii) incentives to support research and innovation of new antibacterial treatments, old antibiotics, infection prevention and control, and veterinary vaccines and (iii) national processes to update clinical guidelines with scientific evidences. The intent of these meetings is to have frank, open and informal conversations to design more granular incentives in line with country expectations.

All data gathered through these meetings are handled confidentially and anonymously (Chatham House Rule). All answers were understood to represent personal opinion and not government commitment. The results will be synthesized and published in a peer-reviewed journal.

Questions asked during the country visits.

1. Areas of greatest concern or vulnerability regarding research, innovation, and access.

- Briefly describe your country's biggest concerns regarding AMR & HCAI research, innovation, and access?
- What are your greatest concerns or vulnerabilities regarding AMR and HCAI within animal and plant health?
- What are your research priorities?
- Do you feel like research priorities are being adequately funded and researched?

2. Areas of greatest financial concern related to AMR and HCAI?

- Has your country assessed the cost of AMR?

3. National processes to determine national research priorities.

- What national processes do you use to determine your research priorities? (including priority technologies, infection prevention and control (IPC) knowledge gaps, and behavioral change interventions)

4. Incentives.

- Incentives for new antibiotics and other treatments
 - Access - What steps are your country pursuing (if any) to secure access to new antibiotics (or other treatments)? Are you concerned that your country will not have access to the newest antibiotics developed by small companies?
 - Pull - What focus does your country have on pull incentives? What are the biggest barriers to implementation?
 - Pooled funds - Would your country be willing to pool funds with other European countries? If so, which facilities are considered the strongest candidates for a pooled fund? (European Investment Bank?)

- Selecting products worthy of a reward - Does your country feel that the priority pathogens identified by WHO are aligned with your unmet public health need?
- Higher unit prices - Is your country open to assessing the societal value of a new antibiotic as a part of the health technology process in order to award a higher unit prices?
- Pilots - Sweden and the UK are moving forward on pull incentive pilots.
 - How open is your country to attempting to pilot new incentives within well-defined parameters and financing constraints? For example, an innovative new antibiotic for WHO critical pathogen.
 - Or would your country prefer a European-based pilot? If so, how many other countries would need to commit?
 - What are the barriers and influencing factors?
 - What might be the first steps towards a pilot?
- Incentives/measures to maintain access to older antibiotics
 - Are you experiencing shortages of antibiotics?
 - Is your country pursuing measures to secure availability of older antibiotics?
 - Which older antibiotics are you most concerned about? Do you have a list of critical antibiotics?
 - Is your country attempting to grow its consumption of older antibiotics through expanded susceptibility testing?
 - Is there a willingness to pay higher unit prices for older antibiotics? Or what other incentives might your country be interested in? Netflix models?
 - Piloting
 - How open is your country to attempting to pilot new incentives within well-defined parameters and financing constraints?
 - Or would your country prefer a European-based pilot? If so, how many other countries would need to commit?
 - What are the barriers and influencing factors?

- What might be the first steps towards a pilot?
- Are you experiencing shortages of veterinary antibiotics and/or vaccines?
- Are there any incentives or regulations in place to support veterinary vaccinations?
- Might your country be open to attempting to pilot new incentives for veterinary vaccines within well-defined parameters and financing constraints? What are the barriers and influencing factors?
- Incentives/measures to support IPC
 - OECD has demonstrated that significant cost savings can be achieved by improving IPC measures. Do you feel that this is relevant for your country?
 - If so, these often require upfront financing to achieve the savings. Are there mechanisms in your country to finance these efforts?
 - Could economic incentives be useful for infection prevention and control? For example, upfront financing in line with expected outcomes, followed by sharing of cost savings between the healthcare institution and government?

5. Financing national positions and ambitions.

- Are there national mechanisms to assist companies to bring products to market or support small businesses? Could these mechanisms be used to finance potential pilots for new or old antibiotics?
- Are there other mechanisms that may be potentially used to finance pilot for new or old antibiotics?
- Does your country work with the European Investment Bank regarding financing for health research?
- Has your country considered carving out the antibiotic reimbursement from the DRG?
- What are your thoughts about placing a fee onto EMA registrations of all other medicines with the exception of anti-infectives in order to finance antibacterial innovation?

- Is there any consideration of lessening regulatory requirements for SMEs, for example, local office for pharmacovigilance?

6. Guidelines.

- Do you have national stewardship or IPC guidelines?
- In animals and/or plants too?

7. National processes to update clinical guidelines, IPC routines, and other AMR and HCAI-related policies and practices.

- What processes and procedures do you have to update the above? How often? How do you incorporate new evidence?
- Are there any barriers to gathering the evidence and updating the policies/guidelines?

Countries interviewed.

Meetings were organized as follow:

Country visited	Date	Type of meeting
France	23-24 May 2019	Physical
Netherlands	25 June 2019	Physical
Norway	27-28-29 August 2019	Physical
Luxembourg	16-17 October 2019	Physical
Sweden	18-19-20 November 2019	Physical
Denmark	15-16 January 2020	Physical
Spain	29-30 January 2020	Physical
Belgium	11 February 2020	Physical
Romania	04 September 2020	Virtual
Germany	16 September 2020	Virtual

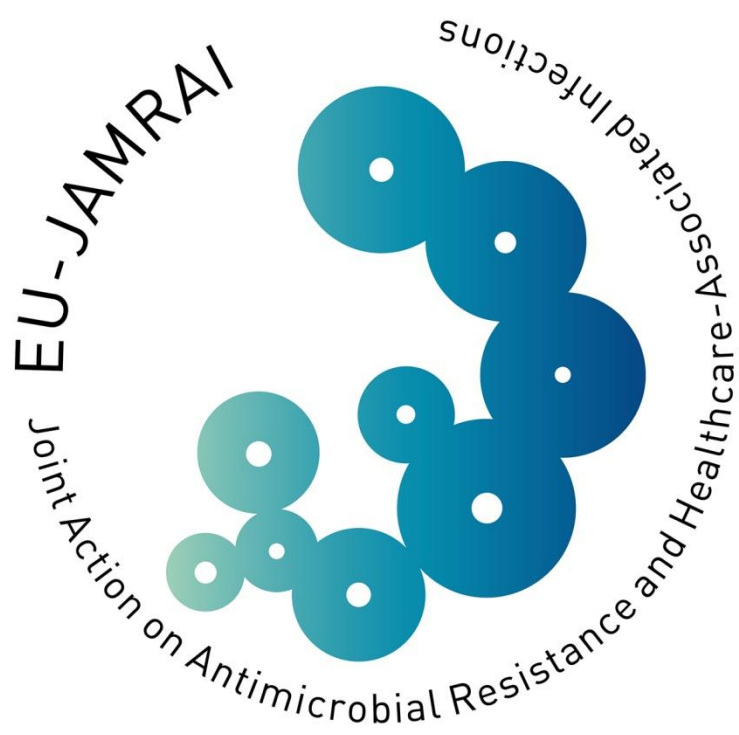
Identity and affiliation of the people interviewed cannot be revealed due to the Chatham House Rule. People interviewed were mostly policymakers and AMR experts from both the human and animal sector.

Main findings of the meetings.

- There is a high support for antibiotic incentives with still uncertainties on how to implement them.
- Currently the most pressing concern for European countries is not the lack of new antibiotics but **unstable supply of existing antibiotics**. Shortages are increasingly common. They result in suboptimal treatment and the reported expanded use of broad spectrum antibiotics, thereby accelerating resistance. However, this only relates to human health. There are almost no reports of shortages of veterinary antibiotics, perhaps due to few controls on pricing.
- At the same time, European countries recognize that new antibiotics will be needed. However, there is general **uncertainty of the value-add** of recently approved antibiotics since the clinical trials are small and conclude only non-inferior status. Countries would like to see new antibiotics demonstrating clinical superiority against resistant pathogens, even through trials with few patients.
- Most European countries prefer a **pan-European** pull incentive, rather than setting up their own national solutions. The main objective of this pull incentive would be to secure sustainable access to important antibiotics across Europe, ideally for both old and new antibiotics.
- Yet this pan-European pull incentive must be **independent** from actual unit pricing and reimbursement processes that are the jurisdiction of individual countries.
- It is appealing that **large pharmaceutical companies contribute** financially to any pull incentive since other therapies, like cancer treatment, are dependent upon effective antibiotics.

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