



Joint Action
Antimicrobial Resistance and
Healthcare-Associated Infections



Co-funded by the
Health Programme
of the European Union

Work Package n° 9 :

Research and innovation:

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WP objectives



Work description, progress and achievements towards WP objectives



Timeline: Tasks, Deliverables & Milestones status



Stakeholders involvement



Risks encountered



Next steps for Year 2

Achieve a coordinated European response in regards to priority AMR research and innovation

- **Priority-setting:** Identify public health needs, gaps and priorities in AMR research and innovation and ensure linkages and coordination between national, European and international research programmes
- **Incentives:** Explore and detail European strategies to implement mechanisms to increase antimicrobial innovation and maintain access
- **Evidence-informed policies:** Contribute to ensuring that evidence-informed public health policies and practices related to combatting AMR are implemented

9.1 Priority-setting

Documented a national case study



Case study: Identifying AMR knowledge gaps and research priorities

Norway

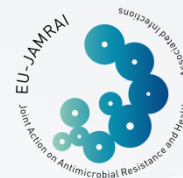
The European Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI) aims to contribute to a coordinated European response in regards to prioritizing and assisting in the implementation of research and innovation expected to help achieve public health-related AMR and HCAI goals and objectives. The first task of work package 9 (WP9) is defined as:

Task 9.1: Work with Member States to ensure that national processes for research and innovation priority-setting are grounded in a broad One Health approach and that both Member State research priorities and knowledge gaps are addressed in the development of the update of the JPIAMR SRA

The first step of this task is to gather best practices of national efforts to identify knowledge gaps and research priorities for antimicrobial resistance (AMR). Norway was suggested as a useful case study

- Ad-hoc process aligned with important documents
- Otherwise entrusted to experts through organizations like JPIAMR and IMI

Work description, progress and achievements



9.1 Priority-setting

Gathered and summarized participating countries (7 of 9) national research priorities

		Country						
		France	Greece	Netherlands	Norway	Slovenia	Spain	UK
Incentives	<i>Work on new economic incentives or funding to foster research and innovation</i>							
Interaction	<i>Work to encourage International/European research collaborations</i>							
	<i>Work to encourage private/public research collaborations</i>							
	<i>Work to encourage interdisciplinary research collaborations</i>							
Structuring	<i>Development of a "national steering committee" to structure and coordinate actions regarding AMR</i>							
Development of new tools	<i>Development of new antibiotic molecules</i>							
	<i>Development of new alternatives to antibiotics (vaccine, phages, antibodies, peptides ...)</i>							
	<i>Development of new diagnostic tools</i>							
Fundamental research	<i>Research on the bacterial mechanisms involved in resistance</i>							
	<i>Research on the causes and consequences of the appearance and dissemination of AMR</i>							
	<i>Other specific research unrelated to animals nor environment</i>							
	<i>Investigating new technologies to help developing antimicrobial molecules or diagnostic tools.</i>							
ICP in healthcare	<i>Implementation, testing and evaluation of diverse ICP measures in the human health sector</i>							

- Common priorities:
- Basic research on mechanisms and consequences of resistance
 - Effectiveness of IPC measures

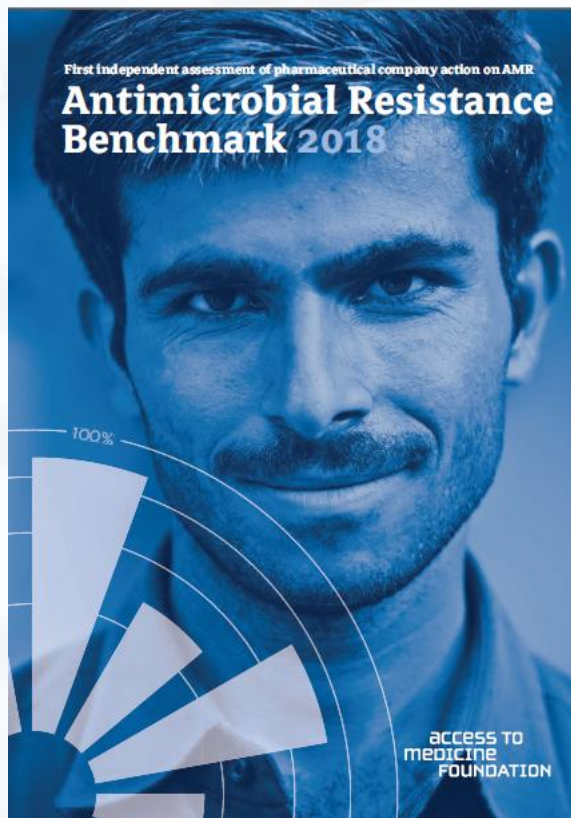
9.1 Priority-setting

Identified an important gap - HCAI/IPC research gaps and priorities

Core component	Identified research needs and gaps
Organization of IPC programmes	<ul style="list-style-type: none">• Lack of high quality studies addressing the effectiveness of IPC programmes• Investigation needed on the impact and ideal composition of an IPC programme• Evaluation of the minimum standard required for the recruitment and training of ICP professionals• More studies needed on the cost-effectiveness of IPC programmes for appropriate budgeting• More insight needed on the impact of an effective IPC programme in support of strategies to improve hygiene and IPC in the community• Need more studies in a low resources setting• Develop tools for the effective documentation and dissemination of successful local initiatives regarding IPC programmes
IPC guidelines	<ul style="list-style-type: none">• Additional evaluation tools needed to assess the effectiveness of local adaptation and implementation of technical guidelines• Need of several situational analysis of guidelines in different countries and their mechanisms for implementation
IPC education and training	<ul style="list-style-type: none">• Tools needed to evaluate IPC training programmes and implement them• Evaluation of the impact of e-learning, self-directed training modules and mentorship on IPC education• Additional studies needed to better understand the impact of patient and family education on HCAI

- Have not identified any consolidated research priorities for HCAI/IPC
- Potential for EU-JAMRAI contribution and impact

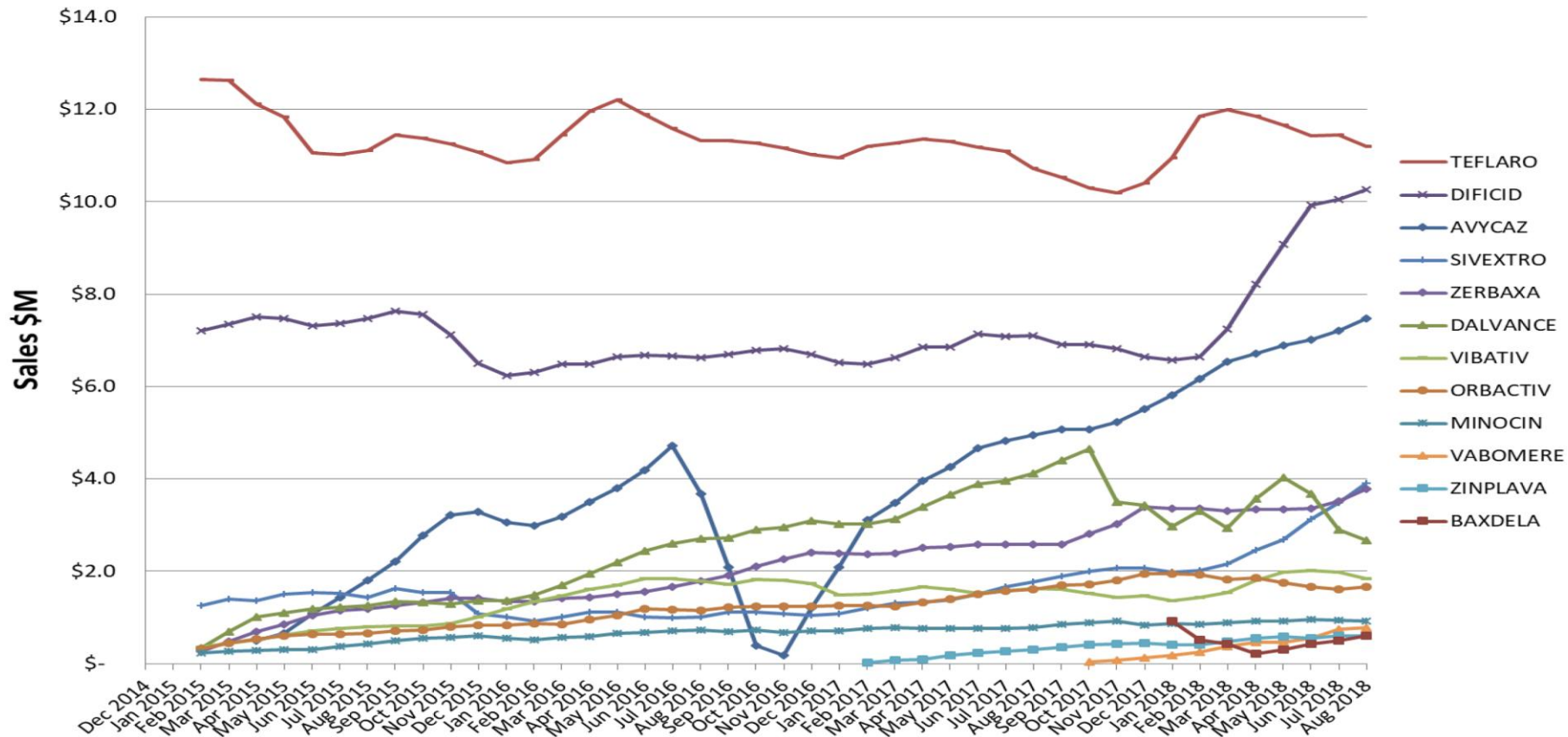
9.2 Incentives



Published in January 2018 and now:

- 5 of 29 (17%) antibiotic companies have left the market, including...
 - 1 of 10 (10%) generic companies
 - 2 of 12 (17%) SMEs
 - 2 of 7 (29%) large pharmaceutical companies

IMS Monthly Sales 3-Month Moving Average: Antibiotics (FDA approvals since 2009)



Source: Alan Carr, Needham & Co.

Work description, progress and achievements

9.2 Incentives

Country visits to understand barriers and appetite for incentives



COMITÉ FRANÇAIS DE L'ANTIBIOTIQUE
1^{ère} RÉUNION DU COMITÉ MAÎTRISER LA RÉSISTANCE
13 GRANDES MÉDICATIONS

BCG
The Boston Consulting Group
FOLLOW-UP REPORT FOR THE GERMAN GUARD
Breaking through
A Call for Concerted Action on Antibiotics
Full Report

TACKLING DRUG-RESISTANT INFECTIONS GLOBALLY: FINAL REPORT AND RECOMMENDATIONS

THE REVIEW ON ANTIMICROBIAL RESISTANCE
CHAIR BY JIM O'NEILL
MAY 2016

DRIVE-AB REPORT
Revitalizing the antibiotic pipeline
Stimulating innovation while driving sustainable use and global access

WHITE PAPER
Shortages, stockouts and scarcity
The issues facing the security of antibiotic supply and the role for pharmaceutical companies
21 MAY 2016

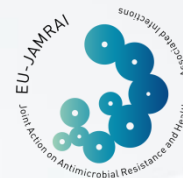
WHAT IS THE ISSUE?
There is an emerging crisis in the global anti-infectious market – antibiotic supply is getting complex and at risk of collapsing.
> An important form of penicillin has been unavailable in six countries since early 2014 including Australia, Canada, Germany, India and the United States.
For many antibiotics, supply chains rely on just a handful of producers per active pharmaceutical ingredient (API).
> The current global shortage of broad spectrum antibiotic piperacillin-tazobactam was caused by an explosion of the only facility producing the API needed.
Supply chain collapse leads to antibiotic shortages, which are linked to disease outbreaks and antimicrobial resistance.
Commercial incentives underpinning the market are weak.
> Unlike on-patent antibiotics, some manufacturers (e.g. Becton Dickinson), individual cancer medicines can generate twice that annual revenue.
Few pharmaceutical companies are willing or able to invest in rebuilding supply chains, and besides other slim margins, reach to high end segments and growth in demand comes mainly from the poor.

WHAT ARE PHARMACEUTICAL COMPANIES DOING NOW?
The white paper pinpoints key factors that make antibiotic supply so fragile, to show where action is possible. It identifies examples of how some pharmaceutical companies are already strengthening supply chains, grouped into three broad tactics:
1. Central planning
2. Strategic softwares, vendor-agnostic supply and
3. Strengthening the distribution chain

WHAT SHOULD HAPPEN NEXT?
1. Pharmaceutical companies must bring a sharp change in their practices for stock and inventory management, improve their agility (e.g. in response to shortages), and communicate information about their plans and stock data earlier and in more detail to more partners.
2. Multiple players at critical links in the chain are needed to rebuild a healthy antibiotic market.
3. Success will depend on the development of stronger incentives for pharmaceutical companies to enter and stay in the market.

ACCESS TO MEDICINE FOUNDATION

Timeline: tasks, deliverables & milestones status



Milestone 9.1 Gathering of national priorities to provide input to SRA from at least 5 countries

- Deadline was originally Feb 2019 (M18) but already done in Sept '17 (M13)
- 7 countries included instead of 5

Milestone 9.2 Inter-governmental meeting to discuss DRIVE-AB and AMR Review recommendations with regards to AMR and HCAI

- Deadline was originally Feb 2018 but moved to Nov 2018
- All WP9 members were invited to DRIVE-AB meeting in Brussels in Sept '17
- Presented yesterday (Nov 7, 2018) at WP9 workshop



Task 1: Priority-setting



On schedule

Task 2: Incentives



On schedule

Task 3: Evidence-informed policies



On schedule

One-on-one telephone conferences with 5+ stakeholders to inform them of the objectives and tasks of WP9

Presentations and discussions of WP with following stakeholders:

- **Policymakers:** European Health Parliament, February 20, 2018, Brussels
- **Policymakers:** Transatlantic Taskforce on Antimicrobial Resistance (TATFAR), March 8, 2018, Atlanta, Georgia
- **Policymakers and industry:** European Policy Center, June 5, 2018, Brussels
- **Academics and industry:** ESCMID/ASM, September 6, 2018, Lisbon
- **Policymakers, academics, and industry:** World AMR Congress, October 25-26, 2018, Washington DC

Description of risk	Proposed risk mitigation measures
Overshadowing HCAI	Defined core piece of work with IPC research priorities
Cost of incentives is significant	Document the counterfactual costs, financing methods, and points of negotiation
Balancing diverse needs	Build in flexibility in incentives

Next steps for Year 2

Priority-setting: Publish a research agenda for IPC/HCAI with endorsement from Member States and related organizations like JPIAMR, and report on national approaches for priority-setting

Incentives: Publish granular incentives with financing plan in line with Member States' expectations

Evidence-informed policies: Produce a policy brief of best practices on evidence-informed policies

Thank you !

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Inserm

La science pour la santé
From science to health



Norwegian Institute of Public Health

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