



Joint Action  
Antimicrobial Resistance and  
Healthcare-Associated Infections



Co-funded by the  
Health Programme  
of the European Union

# Implementing European incentives

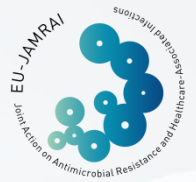
Christine Årdal



EU-JAMRAI is a European Union Joint Action on Antimicrobial Resistance (AMR) and Healthcare-Associated Infections (HCAI) that brings together 44 partners from 28 countries and more than 30 stakeholders. Our mission is to **foster synergies** among EU Member States by **developing and implementing effective *One Health* policies** to fight the rising threat of AMR and to reduce HCAI.

1. To ensure that national processes for research and innovation priority-setting are grounded in a broad *One Health* approach and that both EU **Member States' research priorities and knowledge gaps** are addressed in the development of strategic research agendas
2. To explore and detail **European strategies to implement mechanisms to increase innovation** and other means to fight against AMR and HCAI
3. To ensure that national procedures are in place to **translate research findings into public health policies and practices** related to combating AMR and HCAI

# Technologies and practices needed to combat AMR



Public awareness



Sanitation and hygiene



Antibiotics in agriculture and the environment



Vaccines and alternatives



Surveillance



Rapid diagnostics



Human capital



Drugs



Global Innovation Fund



International coalition for action

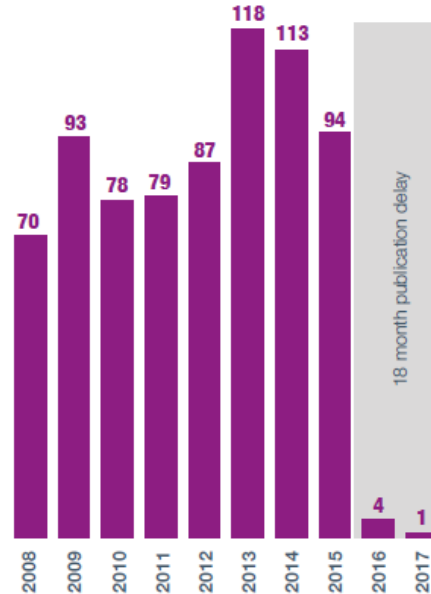


EU-JAMRAI WP9 aims to promote *One Health* innovation across many technologies and practices, including the broader focus on healthcare-associated infections.

## Longitude Prize, October 15, 2018:



Filing figures 2008 – 2017



Struggling to attract adequate funding because:

- Investors are concerned that price expectations are too low to assure return on investment
- Not convinced that financing will be available either from health systems or funders to help create this new market

**Report recommendation:**  
Purchase commitments



Review

## Analysis of the clinical antibacterial and antituberculosis pipeline

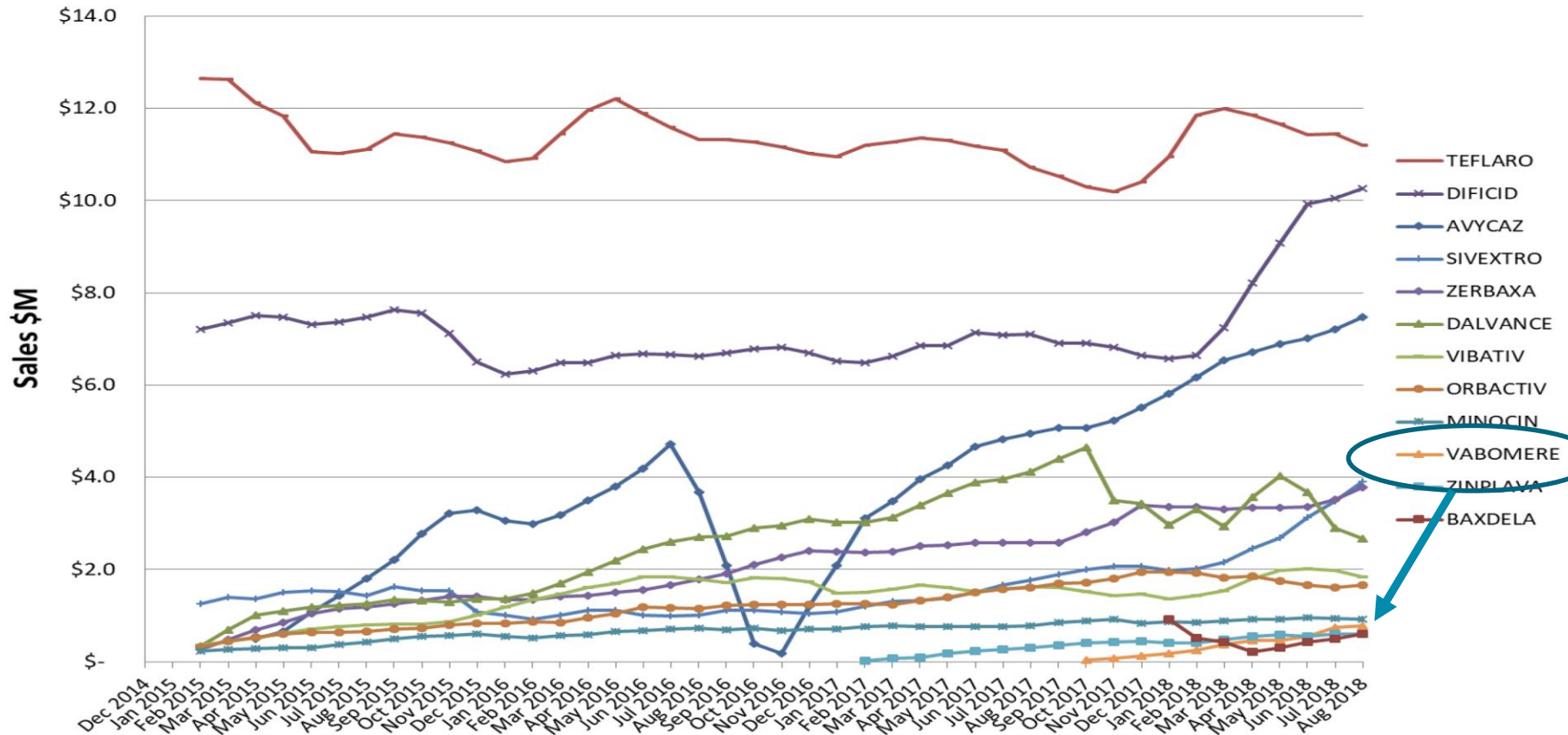


Ursula Theuretzbacher, Simon Gottwalt, Peter Beyer, Mark Butler, Lloyd Czaplewski, Christian Lienhardt, Lorenzo Moja, Mical Paul, Sarah Paulin, John H Rex, Lynn L Silver, Melvin Spiegelman, Guy ETHwaites, Jean-Pierre Paccoud, Stephan Harbarth

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“As of July 1, 2018, **30** new chemical entity (NCE) antibacterial drugs, **ten** biologics, **ten** NCEs against *Mycobacterium tuberculosis*, and **four** NCEs against *C difficile* were identified...The clinical pipeline is dominated by derivatives of established classes and most development candidates display limited innovation.”

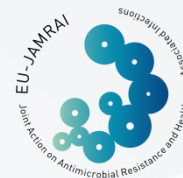
# IMS Monthly Sales 3-Month Moving Average: Antibiotics (FDA approvals since 2009)



Source: Alan Carr, Needham & Co.



# Stimulating therapeutics innovation



Review on Antimicrobial

COMITÉ INTERMINISTÉRIEL POUR LA SANTÉ

1<sup>re</sup> RÉUNION DU COMITÉ INTERMINISTÉRIEL POUR LA SANTÉ  
MAÎTRISER LA RÉSISTANCE BACTÉRIENNE AUX ANTIMIOTIQUES

13 GRANDES MESURES INTERMINISTÉRIELLES  
40 ACTIONS

17 novembre 2016

1

TACKLING DRUG RESISTANT INFECTIONS GLOBAL FINAL REPORT AND RECOMMENDATIONS

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

BCG  
THE BOSTON CONSULTING GROUP

Federal Ministry of Health

FOLLOW-UP REPORT FOR THE GERMAN GUARD INITIATIVE  
**Breaking through the Wall**  
A Call for Concerted Action on Antibiotics Research and Development

Full Report

Silvia Stern (Project Leader)  
Simon Charzwick (Consultant)  
Lucie Franklin (Associate)  
Simon Viller (Principal)  
Heinrich Randmeisler (Partner and Co-Leader)  
Dr. Benjamin Groch (Partner and Co-Leader)

Berlin, February 2017

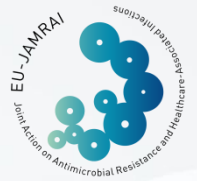
DRIVE-AB REPORT

**Revitalizing the antibiotic pipeline**

Stimulating innovation while driving sustainable use and global access

DRIVE AB  
RE-INVESTMENT  
IN R&D AND RESPONSIBLE  
ANTIBIOTIC USE

# Need for both “push” and “pull” incentives



- Push reduces the R&D costs and removes risk.
- Pull incentivizes the private sector to invest.
  - Public sector financing of antibiotic R&D = \$ 550 million per year (OECD, 2017)
  - Private sector financing = \$ 2 billion in 2016 (AMR Industry Alliance, 2018)

## Coordination

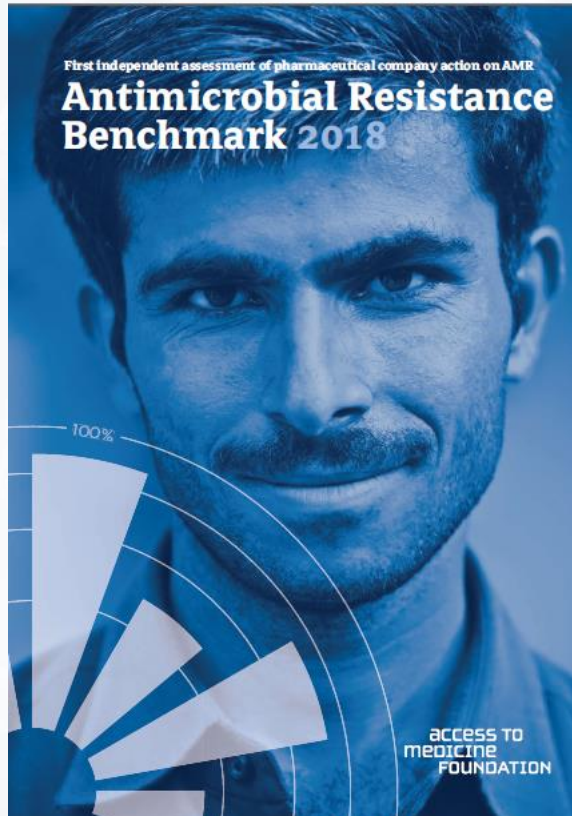
- G20 AMR R&D Hub

## Push

- JPIAMR (€230m)
- IMI (€700m)
- CARB-X grants (USD 500m)
- GARDP partnerships (ca. € 270m)
- EIB InnovFin loans (€20m + €20m)
- REPAIR by Novo Nordisk loans (USD 165m)
- And more

## Pull

- Potential national pilots in Sweden and UK



Published in January 2018 and now:

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

## Shortages, stockouts and scarcity

The issues facing the security of antibiotic supply and the role for pharmaceutical companies

WHITE PAPER

31 MAY 2018

WHAT IS THE ISSUE?

WHAT ARE PHARMACEUTICAL COMPANIES

“Supply chain collapse leads to antibiotic **shortages**, which are linked to disease outbreaks and antimicrobial resistance.”

Authors: Denise Cogan, Japann K. Iyer  
Sponsor: Access to Medicine Foundation  
Funding: Wellcome Trust, The Netherlands  
Contact: [info@access-to-medicine.org](mailto:info@access-to-medicine.org)  
Website: [www.access-to-medicine.org](http://www.access-to-medicine.org)

ACCESS TO  
MEDICINE  
FOUNDATION



RESEARCH ARTICLE

### Shortages of benzathine penicillin for prevention of mother-to-child transmission of syphilis: An evaluation from multi-country surveys and stakeholder interviews



OPEN ACCESS

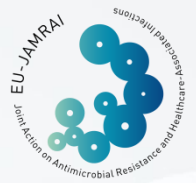
**Citation:** Nurse-Findlay S, Tay Melo MB, Saliyou S, Lavayen Shortages of benzathine penicillin for prevention of mother-to-child transmission of syphilis: An evaluation from multi-country surveys and stakeholder interviews. PLoS One. 2018 May 31;13(5):e0190247. <https://doi.org/10.1371/journal.pone.0190247>

**Academic Editor:** Nicola Low, University of Bath, SWITZERLAND

“Congenital syphilis remains a significant contributor to early infant mortality, particularly in low- and middle-income countries. There are several reasons for this, but one of the most important is a **global shortage of [benzathine penicillin G]**.”

evaluation was undertaken to quantify countries that have experienced shortages in the past 2 years and to describe factors contributing to these shortages.

# Member Countries' aims for increasing innovation



- “**Provide** innovative products and technologies contributing to the control of antimicrobial resistance with a set of regulatory and financial incentive mechanisms.” - **France**
- “The government will participate actively in the international **debate** about incentive schemes for the development of new antibiotics, while supporting efforts to develop vaccines.” - **Norway**
- “**Study** incentive mechanisms for research projects based on the identified needs.” - **Spain**
- “Sweden to contribute to the **development of knowledge** about new business models and financial incentives to stimulate the development of new antibiotics and other treatment options.” - **Sweden**
- “Actions needed...are...addressing the commercial viability issues that are hampering investment in antibiotic development, **assessing the relative merits** of possible incentives to stimulate research and development in new antibiotics and other products, and fast-track priority review arrangements for new antimicrobials.” - **United Kingdom**

- **Potential pilots:** Devising financing mechanisms with cost/benefit analyses
- **Country visits:** Closed door, informal session under Chatham House Rule to determine appetite to implement incentives

# Thank you!

[www.eu-jamrai.eu](http://www.eu-jamrai.eu)



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Health Programme  
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**Inserm**

La science pour la santé  
From science to health



Norwegian Institute of Public Health

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