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GLOBAL ANNUAL MEETING | 14-18

Securing European patient access to antibiotics

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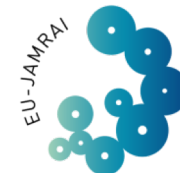
Co-chair, Research and Innovation

EU Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI)

@Christinerdal



Co-funded by the
Health Programme
of the European Union



Joint Action
Antimicrobial Resistance and
Healthcare-Associated Infections

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Disclosures

- ▶ Christine Årdal is a senior advisor at the Norwegian Institute of Public Health (NIPH) and the co-lead of the research and innovation work package of the EU Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI).
- ▶ The views expressed in this presentation should not be considered to reflect the positions of NIPH, the Norwegian government, or participating governments in EU-JAMRAI.
- ▶ I am currently receiving external grant financing from the European Union (EU-JAMRAI, grant number 76129) and the Norwegian Research Council (grant number 300867).



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About EU-JAMRAI

- ▶ Joint Action's mission is to foster synergies related to AMR and HAI among EU Member States (28 participating countries)
- ▶ In research and innovation work package, one of our aims is to:

Explore and detail **European strategies to implement mechanisms to increase innovation** and other means to fight against AMR and HAI



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Calls for antibiotic innovation incentives



Review on Antimicrobial Resistance
Tackling drug-resistant infections globally

TACKLING DRUG-RESISTANT INFECTIONS GLOBAL FINAL REPORT AND RECOMMENDATIONS

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

COMITÉ INTERMINISTÉRIEL DE SANTÉ
MAÎTRISER LA RÉISTANCE BACTÉRIENNE AU NIVEAU NATIONAL

1^{ère} RÉUNION DU COMITÉ INTERMINISTÉRIEL DE SANTÉ
MAÎTRISER LA RÉISTANCE BACTÉRIENNE AU NIVEAU NATIONAL

13 GRANDES MESURES INTERMINISTÉRIELLES
40 ACTIONS

17 novembre 2016

BCG
The Boston Consulting Group

Federal Ministry of Health

FOLLOW-UP REPORT FOR THE GERMAN GUARDIAN
Breaking through
A Call for Concerted Action on Antibiotic Innovation

Full Report

Value-based strategy for encouraging new development of antimicrobial drugs

DRIVE-AB REPORT

Revitalizing the antibiotic pipeline

Stimulating innovation while driving sustainable use and global access

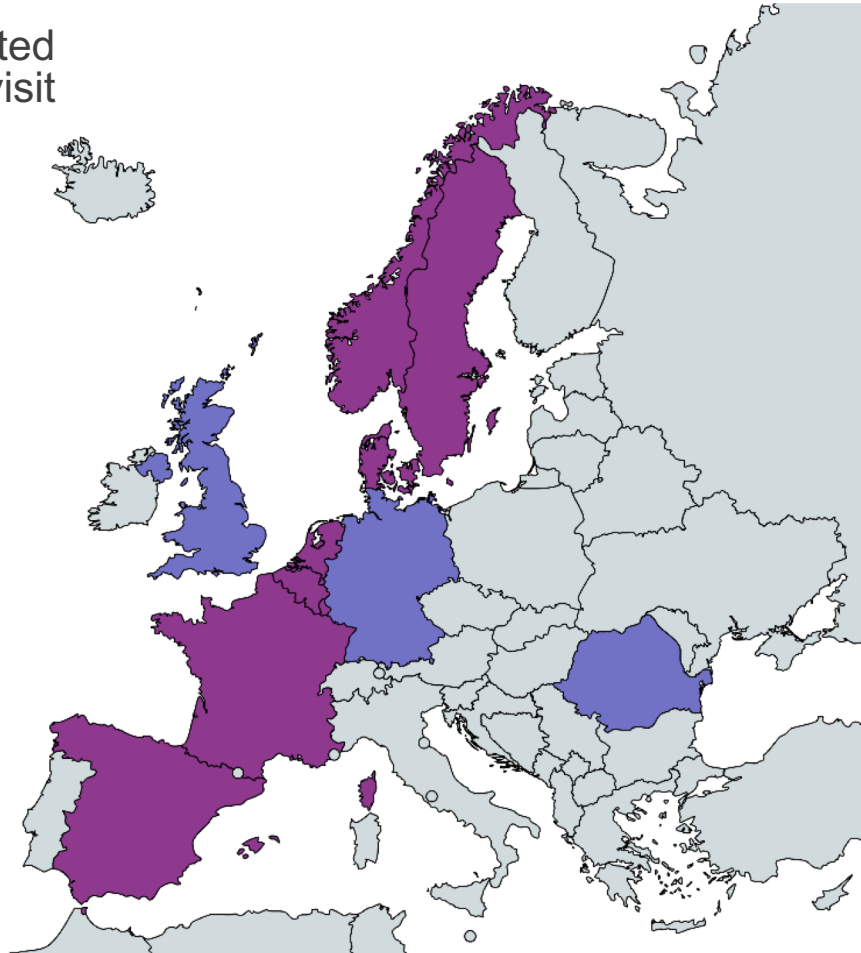
DRIVE AB
RE-INVESTMENT IN R&D AND RESPONSIBLE ANTIBIOTIC USE

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Country interviews



- Countries visited
- Countries to visit



Objective: To gain a better understanding of current political willingness and barriers to implement actions regarding:

- ▶ Innovation of **new** antibacterial treatments
- ▶ Access to **existing** antibiotics

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Preliminary results...

- 1. Strong desire to find common solutions for both existing and new antibiotics**
 - Shortages of existing antibiotics are more pressing concern than lack of new antibiotics
 - Shortages result in potentially suboptimal treatment



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Shortages are increasing



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Meeting Report
*Antibiotic Shortages: Magnitude, Causes
and Possible Solutions*

Norwegian Directorate of Health, Oslo, Norway
10-11 December 2018



“The experiences of several European countries indicate that **shortage of antimicrobial agents is common**, and the frequency of shortages seems to be **increasing...**”

Medicine shortages in Norway

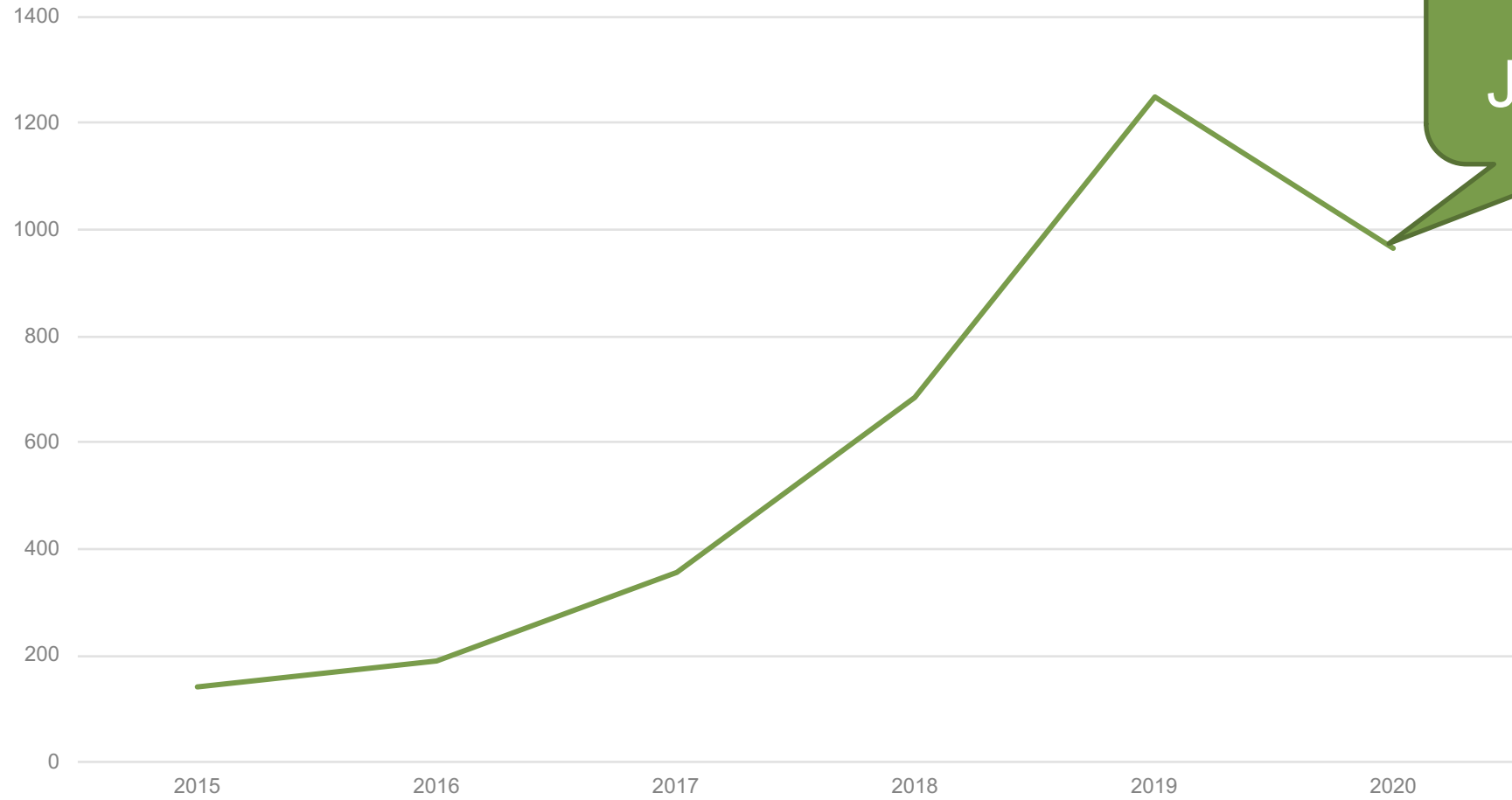


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Registered medicine shortage



As of
June 10th

Uncertainty about where the risks lie.

Difficult to prevent supply disruptions because of lack of transparency

“To give a real-life example, a global shortage of the key antibiotic piperacillin-tazobactam was caused by an explosion at a Chinese factory – **the single producer of the API** needed to produce the medication.”

Shortages, stockouts and scarcity
The issues facing the security of antibiotic supply and the role for pharmaceutical companies

WHITE PAPER 31 MAY 2018

Three of the main issues are: growth comes from the past; there's low profitability and the supply chain has weak links.

GLOBAL ANTIBIOTIC SUPPLY IS PATCHY, COMPLEX AND AT RISK OF COLLAPSING

This white paper unpacks the systematic factors making antibiotic supply so fragile. For example, a global penicillin shortage now affects 39 countries. The paper links the causes of antibiotic shortages to recommendations for governments, regulators, the pharmaceutical industry and others.

To show where action is possible, the paper identifies examples of how some pharmaceutical companies are already strengthening supply chains. It identifies three further areas where action is needed.

Supply chain collapses lead to antibiotic shortages, which are linked to disease outbreaks and antimicrobial resistance. Commercial incentives underpinning the market are weak: few pharmaceutical companies are willing or able to invest in rebuilding supply chains.

- 1 Pharmaceutical companies must bring a step change in their practices for antibiotic 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 A unified approach – led by governments and supported by regulators and the industry – is needed to ensure there are multiple suppliers competing at critical links in the chain.
- 3 Success will depend on the development of stronger incentives for pharmaceutical companies to enter and stay in the market.

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Transparency also has environmental benefits



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Regulatory Toxicology and Pharmacology 53 (2009) 161–163



ELSEVIER

Contents lists available at ScienceDirect

Regulatory Toxicology and Pharmacology

journal homepage: www.elsevier.com/locate/yrtph



Commentary

Transparency throughout the production chain—a way to reduce pollution from the manufacturing of pharmaceuticals?

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ARTICLE INFO

Article history:

Received 3 November 2008

18 December 2008

Available online 29 January 2009

Keywords:

Bulk drugs

ABSTRACT

Recent findings have shown that wastewater from bulk drug production can be a source of very high environmental concentrations of drugs in certain locations. The release of active ingredients is often not specifically regulated, and thus rapid initiatives from the industries themselves are warranted. Possible ways to stimulate action include changes in local and international regulations, including the implementation of appropriate environmental standards within existing industry guidelines as well as demands from prescribers and consumers of medicines. The lack of readily available information regarding the origin of drugs and the environmental impact of the production, however, prevents consumers

Transparency becoming more common



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Supplier List

The Apple Supplier List details our top 200 suppliers based on spend, and outlines the supplier facilities which provide services to our supply chain.

Supplier Name	Manufacturing Location
3M Company	905 Adams Street, Hutchinson, Minnesota, United States
3M Company	5500 Oaza Osanagi, Higashine, Yamagata, Japan
3M Company	3406 E. Pleasant Street, Knoxville, Iowa, United States
3M Company	235 Zhongyuan Road, Suzhou, Jiangsu, China
3M Company	18 Jangan-Gongdan 1 Gil, Jangan-myeon, Hwaseong, Gyeonggi-Do, Korea
3M Company	1425 Stokke Parkway, Menomonie, Wisconsin, United States
3M Company	1030 Lake Road, Medina, Ohio, United States
AAC Technologies Holdings Incorporated	No. 8, Fengqi Road, Hi-Tech. Industry Development Area, Wujin District, Changzhou, Jiangsu, China
AAC Technologies Holdings Incorporated	No. 66 Yanghuxi Road, Wujin District, Changzhou, Jiangsu, China
AAC Technologies Holdings Incorporated	Building 5, 6th floor, Nanyou Tianan Industry Park, Dengliang Road, NanShan District, Shenzhen, Guangdong, China
Advanced Semiconductor Engineering Incorporated	No. 2, Chuangyi South Road, Nanzi District, Kaohsiung, Taiwan
Advanced Semiconductor Engineering Incorporated	No. 501 Longgui Road, Jinqiao Export Processing (South) Zone, Shanghai, China
Advanced Semiconductor Engineering Incorporated	No. 188, Su Hong Xi Road, Suzhou Industrial Park, Suzhou, Jiangsu, China
Advanced Semiconductor Engineering Incorporated	No. 1558, Zhang Dong Road, Zhangjiang Hi-Tech Park, Shanghai, China
Advanced Semiconductor Engineering Incorporated	No. 107, Neihuan North Road, Nanzi District, Kaohsiung, Taiwan
Advanced Semiconductor Engineering Incorporated	76, Saneopdanji-gil, Paju, Gyeonggi-Do, Korea
Advanced Semiconductor Engineering Incorporated	73 Kai Fa Road, Nantze Export Processing Zone, Kaohsiung, Taiwan
Advanced Semiconductor Engineering Incorporated	1F, No. 115 Nei-Huan North Road, Nantze Export Processing Zone, Kaohsiung, Taiwan

<https://www.apple.com/supplier-responsibility/pdf/Apple-Supplier-List.pdf>

Preliminary results...

2. Unsure of the actual value of new antibiotics

- Non-inferiority trials
- Clinical trial designs do not always compare against antibiotic(s) most used in practice
- Label is often for skin infections, not resistant infections



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Value uncertainty results in low prices



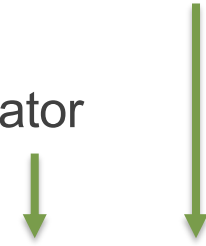
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Lower price than comparator

Price parity with comparator



Recent assessments of Haute Autorité de Santé of antibiotics

Name (molecule)	Date	ASMR I	ASMR II	ASMR III	ASMR IV	ASMR V
XYDALBA (dalbavancine)	2016/12/04					X
ZAVICEFTA, (ceftazidime/avibactam)	2016/11/30				X	
ZERBAXA, (ceftolozane/tazobactam)	2016/07/06					X
DELPRIM (triméthoprime)	2016/06/22					X
ORBACTIV (oritavancine)	2015/11/18					X
SIVEXTRO (tédizolide)	2015/11/04					X

Source: Da Volterra (July 2019)

Preliminary results...

3. Interest in new models to secure access

- European solutions, rather than country-specific
- For antibiotics with demonstrated ability to meet unmet, public health needs (even through small trials)



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European design constraints

National ownership

- ▶ Antibiotic prescribing guidelines and stewardship mechanisms
- ▶ Health technology assessment
- ▶ Medicines unit pricing
- ▶ Medicines reimbursement

European potential

- ▶ EMA guidance identifying “critical” antibiotics
- ▶ Centralized European fund (European Investment Bank?) to pay out “top-up” access payments
- ▶ Stewardship requirements for producers



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Thank You

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