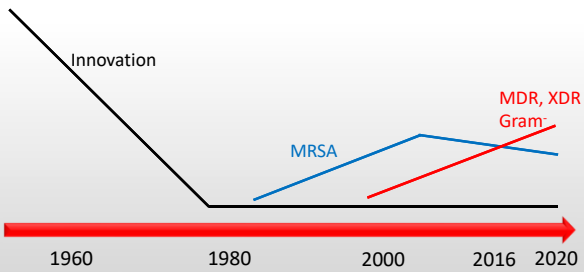
NSCMID 2016

Inadequate antibiotic pipelines and international initiatives to stimulate innovation and sustainable use of antibiotics

U. Theuretzbacher – Center for Anti-Infective Agents, Vienna, Austria

ReAct

Trends

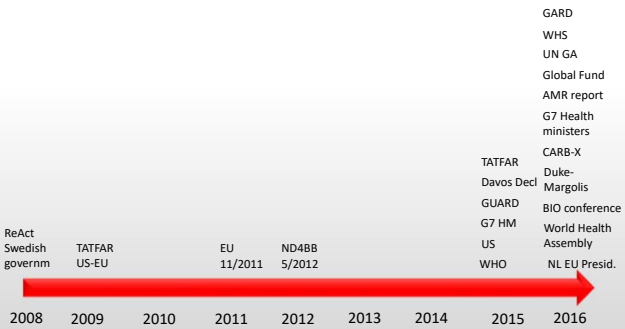


Antibiotics R&D

Compound	Class	Discovery of class	Fail at FDA	Pass at FDA
Linezolid	Oxazolidinone	1978		2000
Ertapenem	Carbapenem	1976		2001
Cefditoren	Cepahlosporin	1948		2001
Gemifloxacin	Fluoroquinolone	1961		2003
Daptomycin	Lipopeptide	1987		2003
Telithromycin	Macrolide	1952		2004
Tigecycline	Tetracycline	1948		2005
Faropenem	Penem	1978	2006	
Retapamulin	Pleuromutilin	1952		2007
Doripenem	Carbapenem	1976		2007
Cethromycin	Macrolide	1952	2009	
Iclaprim	Trimethoprim	1961	2009	
Telavancin	Glycopeptide	1953		2009
Ceftaroline	Cephalosporin	1948		2010
Fidaxomicin	Macrocyclic	1975		2013
Dalbavancin	Glycopeptide	1953	2007	2014
Oritavacnin	Glycopeptide	1953	2008	2014
Ceftobiprole	Cephalosporin	1948	2009	2014 (EU)
Tedizolid	Oxazolidinone	1978		2014

Modified:
L Silver 2011

International initiatives



Events 9/10 2016

- G20 Leaders Summit, China
- UN General Assembly in New York, High-level AMR meeting
- G7 follow-up Health Ministers meeting, Japan
- World Health Summit in Berlin
  - Global Expert Networks on innovations in antimicrobial R&D meeting (German Ministry of Health)
  - WHO R&D priority list project
  - Clinical Trials Network Conference
- Trilateral WIPO, WHO, WTO symposium on AMR, Geneva
- WHO/DNDi Global Antibiotic Research and Development Partnership
- Global innovation fund

Convergence of principles

- Better use of existing antibiotics
- Prevention, infection control
- Surveillance
- Education, training
- Stimulate R&D of new antibiotics: innovation + sustainable use and equitable access provisions
- Global collaboration and coordination







G20 Leaders' Communiqué, Hangzhou Sept 2016

- We affirm the need to explore in an inclusive manner to fight antimicrobial resistance by developing evidence-based ways to prevent and mitigate resistance, and unlock **research and development into new and existing antimicrobials** from a G20 value-added perspective, and call on the **WHO, FAO, OIE and OECD to collectively report back in 2017** on options to address this including the economic aspects. In this context, we will promote **prudent use of antibiotics** and take into consideration huge **challenges of affordability and access of antimicrobials** and their impact on public health. We strongly support the work of the WHO, FAO and the OIE and look forward to a successful high-level meeting on AMR during the UN General Assembly.

UN General Assembly Sept 2016

- On 21 September 2016, the President of the UN General Assembly convenes an one-day high-level meeting at the UN Headquarters in New York on **Antimicrobial Resistance**, with the participation of Member States, non-governmental organizations, civil society, the private sector and academic institutions, in order to provide input.

DRIVE-AB www.drive-ab.eu @DRIVE_AB

- **DRIVE-AB** is the ND4BB project focusing on economics and responsible use
- Stimulate antibiotic innovation and ensure that new antibiotics are used sustainably and available equitably
- 16 public and 7 private partners from 12 countries
- Project duration: 3 years (Oct 2015 – Sept 2017)

DRIVE-AB www.drive-ab.eu @DRIVE_AB

- All incentives to stimulate innovation will be paired with
  - Sustainable use policies, conservation measures
  - Equitable access provisions

Pipelines - What to expect?

- **Adjunctive therapies**
  - Require an active antibiotic
  - Virulence factors, biofilm formation, persisters
  - Immune system stimulation, microbiome modifying
  - Phages
- **Potentiators**
  - Resistance determinants (e.g. beta-lactamase-inhibitors, efflux pump inhibitors)
  - Facilitating penetration
  - Changing the sensitivity of the bacterial cell
- **Targeted therapies**
  - Traditional antibiotics, antibodies
  - Single pathogen, especially S. aureus or P. aeruginosa
- **Prevention**

UK AMR Report

Physicians, microbiologists

- Old antibiotics
  - Optimise their use
  - Access if needed
- New antibiotics
  - Sustainable use policies
  - Access if needed

Future of anibacterial therapy

- Mandatory stewardship requirements
- Optimised use of old antibiotics: individualised therapy
- Increased implementation of diagnostic tools
- Targeted therapies
- Sustainable use of new antibiotics
  - Jusification of empirical use
  - Authorisation by specifically trained staff
- Infection control
- Monitoring of consumption and resistance, documentation
- Policies for hospital waste water treatment
- Classify as potentially hazardous pharmaceutical waste