

Antimicrobial Resistance Benchmark: The role of industry to mitigate environmental AMR

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Presidential Advisory Council on Combating Antibiotic Resistant

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The Antimicrobial Resistance Benchmark

- A new tool that assesses and compares what pharmaceutical companies are doing to limit AMR
- Fully independent
- Funded by the UK and Dutch governments
- 2-year cycle (first publication in 2018, update methodology in 2019, 2nd iteration 2020)



What the Benchmark does

BUILD CONSENSUS

on the role and responsibilities of pharmaceutical companies, to guide company action on AMR



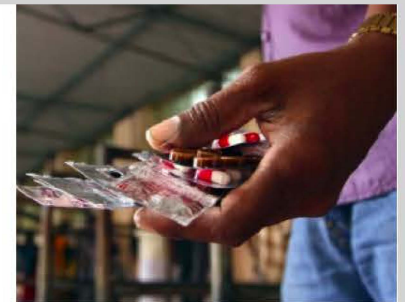
TRACK PROGRESS

covering priority areas in R&D, Manufacturing & Production and Stewardship & Access



DIFFUSE PRACTICES

within companies, governments and investors.



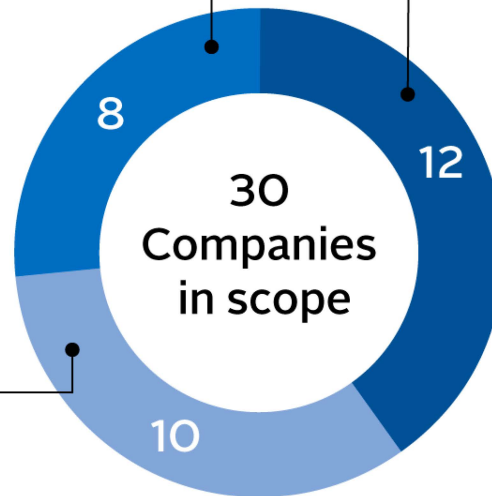
30 companies across three sub-sectors analysed

Large research-based pharmaceutical companies

GlaxoSmithKline plc
Johnson & Johnson
Merck & Co., Inc.
Novartis AG
Pfizer Inc.
Roche Holding AG
Sanofi
Shionogi & Co., Ltd.

Generic medicine manufacturers

Aspen Pharmacare Holdings Limited
Aurobindo Pharma Ltd.
Cipla Inc.
Dr. Reddy's Laboratories Ltd.
Fresenius Kabi AG
Lupin Limited
Macleods Pharmaceuticals Ltd.
Mylan NV
Sun Pharmaceutical Industries Ltd.
Teva Pharmaceutical Industries Ltd.



Biopharmaceutical companies with priority R&D projects

Achaogen Inc.
Cempra Inc.
Entasis Therapeutics Inc.
Melinta Therapeutics Inc.
MGB Biopharma
Motif Bio plc
Nabriva Therapeutics plc
Polyphor Ltd.
Summit Therapeutics
Tetraphase Pharmaceuticals Inc.
The Medicines Company
Wockhardt Ltd.

Analytical framework: 3 Technical Areas, 17 metrics

A RESEARCH & DEVELOPMENT



- A.1 R&D Investments
 - A.2.1 Pipeline size
 - A.2.2 Novelty of pipeline
 - A.2.3 Vaccines in pipeline
- A.3 R&D Collaborations
- A.4 Facilitating access and stewardship

B MANUFACTURING & PRODUCTION



- B.1 Environmental risk-management strategy
- B.2 Disclosure on environmental risk management
- B.3 Manufacturing high-quality antibiotics

C ACCESS & STEWARDSHIP



- C.1 Registration of antibiotics
- C.2 Pricing of antimicrobials
- C.3 Ensuring continuous supply
- C.4 Supporting educational stewardship activities
- C.5 Ethical promotional activities
- C.6 Brochure and packaging
- C.7 AMR surveillance
- C.8 Reducing uncontrolled use

Industry commitments: The Davos Declaration (+100)

“Commitments by signatory companies ...

Work to reduce the development of antimicrobial resistance ...

We support measures to reduce environmental pollution from antibiotics, along with a ‘one health’ approach towards prudent and responsible use, including a global reduction of unnecessary antibiotic use in livestock, and we applaud moves from major food groups to work towards this goal.”

Industry commitments: The Industry Roadmap (13)

“We support measures to reduce environmental impact from production of antibiotics, and will:

1. Review our own manufacturing and supply chains to assess good practice in controlling releases of antibiotics into the environment.
2. Establish a common framework for managing antibiotic discharge, building on existing work such as PSCI, and start to apply it across our own manufacturing and supply chain by 2018.

(continues...)

Industry commitments: The Industry Roadmap (13)

(...continued)

3. Work with stakeholders to develop a practical mechanism to transparently demonstrate that our supply chains meet the standards in the framework.
4. Work with independent technical experts to establish science-driven, risk-based targets for discharge concentrations for antibiotics and good practice methods to reduce environmental impact of manufacturing discharges, by 2020.

Manufacturing & Production Company performance

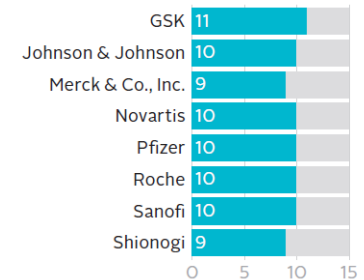
B MANUFACTURING & PRODUCTION



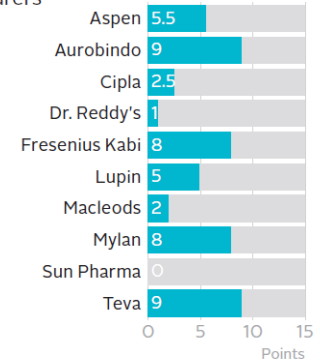
- B.1 Environmental risk-management strategy
- B.2 Disclosure on environmental risk management
- B.3 Manufacturing high-quality antibiotics

Company performance

Large research-based pharmaceutical companies



Generic medicine manufacturers



● Manufacturing & Production
● Remaining potential score

Environmental AMR risk-management strategies

		Breadth			Third party manufacturing sites of API and Drug Products			External waste treatment plants		
		Depth			Strategy	Audits	Limits	Strategy	Audits	Limits
		Strategy	Audits	Limits						
Large research-based pharmaceutical companies	GSK	●	●	●	●	●	●	●	●	
	Johnson & Johnson	●	●	●	●	●	●			
	Merck & Co., Inc.	●	●		●	●				
	Novartis	●	●	●	●	●		●	●	
	Pfizer	●	●	●	●	●	●			
	Roche	●	●	●	●	●	●			
	Sanofi	●	●	●	●	●		●	●	
	Shionogi	●	●	●						
Generic medicine manufacturers	Aspen	●	●							
	Aurobindo	●	●				●	●		
	Cipla									
	Dr. Reddy's	●								
	Fresenius Kabi	●	●							
	Lupin									
	Macleods	●	●							
	Mylan	●	●							
	Sun Pharma									
	Teva	●	●	●	●					

Disclosure on environmental risk-management

- 15/18 companies assessed have ERMS - 12 disclose strategies publicly
- 8 companies in scope report to have set limits for antibiotic discharge
- 4/8 require upstream suppliers of antibiotic APIs and drug products to adhere to same limits.
- Yet, no company discloses publicly its limits and/or the levels of antibiotic discharge.

	Signed Industry Roadmap	Sets discharge limits	Publishes discharge levels	Applies limits to suppliers' sites	Audits strategy implementation
GSK	●	●		●	●
Johnson & Johnson	●	●		●	●
Novartis	●	●			●
Pfizer	●	●		●	●
Roche	●	●		●	●
Sanofi	●	●			●
Shionogi	●	●			●
Teva		●			●

New Common Antibiotic Manufacturing Framework

- Published in January 2018 by the AMR Industry Alliance
- “While the overall contribution of pharmaceutical manufacturing to PIE is relatively low, there is the potential for localized impacts to be created in cases where manufacturing emissions are inadequately managed.”
- “No untreated discharge of manufacturing waste containing antibiotic.”
- “Audit reports will remain confidential.”

AMR Industry Alliance Antibiotic Discharge Targets

- Published 25 September 2018 AMR
- Predicted No-Effect Concentrations (PNECs) for use in environmental risk assessments of antibiotics
 - PNEC-Environment (PNEC-ENV)
 - Values intended to be protective of ecological species and incorporate assessment factors consistent with standard environmental risk methods
 - The PNEC- Minimum Inhibitory Concentration (PNEC-MIC)
 - Values intended to be protective of resistance promotion
- Updated periodically as new data become available.

Key takeaways

Companies should:

- Take account and implement published “ PNEC-ENV” and “PNEC-MIC” extend limits across supply chain
- Move forward with practical ways to disclose more information about suppliers and levels of antibiotic discharge

Governments should:

- Consider explicit inclusion of environmental standards in GMP assessments
- Include green criteria into procurement of antibiotics

Academia should:

- Collaborate with governments to further refine evidence base for safe antibiotic discharge limits
- Collaborate with companies & governments in environmental surveillance and assessment of the human health impact of antibiotic discharges

Thank you

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