



Alliance Round-Up

AMR Industry Alliance Round-Up, Issue No.3, November 2019

Welcome to the third issue of the Alliance Round-Up – written for more than 100 biotech, diagnostic, generic and R&D pharma companies that are members of the AMR Industry Alliance, as well as people interested in collaborating with the Alliance to combat antimicrobial resistance. Through this newsletter, we aim to share news, updates and expert opinions that show the importance of putting our recently adopted commitments into action. We also give Alliance members tips on how to spread the word via social media channels. Please feel free to distribute the Alliance Round-Up to your networks and encourage your colleagues to subscribe using the button at the bottom of this newsletter or by writing to us at roundup@amrindustryalliance.org. We look forward to hearing from you!

Magdalena Babinska, Head of the Secretariat, [AMR Industry Alliance](#)

In this issue

- [US FDA report finds economic forces at the root of generic antibiotic shortages](#)
- [Boosting R&D to fight superbugs: getting the risk-reward ratio right](#)
- [What leads to drug shortages and how to tackle the problem?](#)
- [AMR remains high on G20 agenda](#)
- [World leaders endorse Health For All, including AMR control](#)
- [EU-JAMRAI takes stock of European cooperation on AMR](#)
- [Alliance action](#)
- [Media mentions](#)
- [Progress update on our progress report](#)
- [Making antibiotics responsibly. A common manufacturing framework to tackle AMR](#)
- [One Health Global Leaders Group on Antimicrobial Resistance: feedback](#)

TO DOs

Call on all digital natives to spread the word about what the life science industry is and what it can do to tackle antimicrobial resistance, we invite you to:

- Share [this email with your colleagues and friends](#)
 - Follow us on twitter [@AMRAlliance](#) and use/adapt the tweets proposed in this Round-Up
 - Join the new [“AMR Industry Alliance” LinkedIn group](#) (for the member companies and associations)
 - Check out new [“AMR Industry Alliance manufacturing booklet – Making antibiotics responsibly”](#)
 - Don't forget to share with the Alliance any [new case studies!](#)
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- [Get social during World Antibiotic Awareness Week](#)

Expert views



US FDA report finds economic forces at the root of generic antibiotic shortages, by *Generic companies of AMR Industry Alliance*

Generic antibiotics underpin recommended prescribing guidance for most infections, accounting for between 80% and 90% of prescriptions in primary healthcare [worldwide](#). However, increasing costs and inadequate incentives for quality-assured manufacturers is feeding through into shortages of these essential medicines for patients, according to a wide-ranging investigation into the root causes of drug shortages by the US inter-agency Drug Shortage Task Force, led by the US Food and Drug Administration.

The [report](#), commissioned in response to a request from 31 US senators and 104 US congressional representatives, lays the blame for drug shortages on several key economic root causes, including a dearth of incentives for manufacturers to produce less profitable drugs, a failure to reward manufacturers for mature manufacturing and supply chain management, and a challenging logistical and regulatory landscape in which to solve supply disruptions.

The FDA study looked at shortages across all drug classes between 2013 and 2017, but the scale of the problem is arguably greatest in the generic antibiotic sector. In 2015, a study in [Clinical Infection Diseases](#) reported that 148 antibacterial drugs were classed as “on shortage” in the US between 2001 and 2013. The authors also found that there has been a dramatic rise in shortages since 2007 – a finding echoed in the FDA study. And the problem is global. Shortly after the publication of the *Clinical Infectious Disease* study in 2015, the Medicines Evaluation Board of the Netherlands [raised the alarm](#) about a complete stock-out of three vital penicillins, warning that “as these penicillins are no longer available, doctors will start using broad-spectrum antibiotics. This contradicts the aim of counter-acting resistance against antibiotics.”

When market conditions limit manufacturers’ profitability, they reduce a firm’s motivation to maintain a presence in, or enter the market for older prescription drugs, and to invest in manufacturing quality and redundant capacity. Manufacturers of older generic drugs, in particular, face intense price competition, uncertain revenue streams, and high investment requirements, all of which limit potential returns. Current contracting practices contribute to a “race to the bottom” in pricing.

The absence of incentives via the procurement process for manufacturers to maintain robust quality-management systems compounds these issues. Generic manufacturers are also expected to meet new environmental standards, such as the AMR Industry Alliance Framework and predicted no effect concentrations

to minimize the potential risk of antimicrobial resistance developing as a result of antibiotic manufacturing emissions. However, current procurement practices attach no value to the attainment of such standards.



Like or retweet: [Incentivizing and rewarding quality manufacturing could provide companies with an impetus to achieve greater reliability in drug production, thus reducing the risk of supply disruptions and shortages: https://bit.ly/370p2Xk](https://bit.ly/370p2Xk)



Boosting R&D to fight superbugs: getting the risk-reward ratio right, by *Thomas Cueni, Chair, the AMR Industry Alliance*

Discovering new antibiotics is imperative to overcoming the threat of AMR. Yet approvals for new antibiotics have declined for many years. The last new class of antibiotics was introduced in the 1980s. While the pharmaceutical industry has been extremely successful in introducing transformative new therapies in general, it is exiting the field of antibiotics. In this area, the classic business model – high-risk research with reward in case of success – simply does not work.

Experts agree that incentives for innovations are needed; and there are a number of initiatives underway. So far, governments have focused on push incentives such as grants, tax credits or public-private collaborations. These are designed to lower the risks that come with the early stages of research and development. But the bankruptcy of the antibiotic-focused biopharmaceutical company [Achaogen](#) shows that subsidizing research is not enough. Solutions are needed along the whole value chain to crack the AMR problem.

There is a slow but positive shift in the policy landscape acknowledging the need for broader, more sustainable solutions, including market-based pull incentives. For example, in July 2019, the [United Kingdom launched a pilot program](#) to reimburse companies based on how valuable their drugs are to the National Health Service (rather than on the quantity of antibiotics they sell). And in the [United States](#), the Centers for Medicare & Medicaid Services is also making changes to the way it reimburses hospitals for antibiotics and the treatment of AMR.

This is a good start, but given the exponential threat to life that AMR poses, it is not enough; we need to go a lot further to get the risk-ratio right and ensure the continued investment we need to find and develop new antibiotics.

This is an abbreviated version of a story originally published (in German) in the print edition of Frankfurter Allgemeine Zeitung (FAZ) on October 29, 2019.

Further reading: [IFPMA Global Health Matters](#)



Like or retweet: [URGENTLY NEEDED: 1\) incentives for antibiotic R&D 2\) powerful global movement of governments, industry & biotech companies. Both are critical to overcome the threat of #AMR and address the current challenge in discovering novel #antibiotics: http://bit.ly/2ozsEOU](#)

Policy highlights

What leads to drug shortages and how to tackle the problem? ([FDA](#))

A report published by the US inter-agency Drug Shortage Task Force titled “[Drug Shortages: Root Causes and Potential Solutions](#)” has identified three significant causes of drug shortages. Firstly, there is a lack of incentives in place for manufacturers to produce less profitable drugs. Secondly, there is a lack of recognition and rewards for manufacturers that engage in mature manufacturing and supply chain management. Thirdly, there are logistical and regulatory challenges. The report recommends the development of a rating system in order to incentivize drug manufacturers to invest in quality management maturing for their facilities. In addition, it recommends promoting sustainable private sector contracts to ensure that there is a reliable supply of medically important drugs.

AMR remains high on G20 agenda ([HPW](#) | [CIDRAP](#))

G20 Health Ministers reaffirm “commitment to take urgent action to address the global threat of AMR”.

G20 Health Ministers met in Okayama, Japan, on 19 and 20 October 2019, in a bid to accelerate progress towards the 2030 Agenda for Sustainable Development. In a meeting dominated by discussions around Universal Health Coverage, AMR nevertheless remained high on the agenda. In addition to renewing the commitments on AMR made under the Chinese, German and Argentine G20 Presidencies, Ministers pledged to strengthen efforts to “fund, implement monitor and update” National and Regional Action Plans under the One Health approach.

Ministers also called for new thinking on the economics of addressing AMR. Whilst expressing their approval for investment in research and development for new antimicrobials, diagnostic technologies, and preventative measures such as vaccines, Ministers also reiterated previous calls for more action to identify the best models for AMR R&D. Ministers concluded by reaffirming the need to further examine “practical market incentives to guarantee sustainable access to both new and existing essential antibiotics”.

Further reading: [G20 Health Ministers Declaration](#)

World leaders endorse Health For All, including AMR control ([UN](#))

At the [UN High-Level Meeting on Universal Health Coverage \(UHC\)](#) in September 2019, UN heads of state committed to the Health for All agenda, calling for stronger primary healthcare and a more coordinated approach to antimicrobial resistance.

The [political declaration](#) that they adopted marks the most comprehensive agreement ever reached on global health. Paragraph 76 of the declaration specifically addresses AMR, committing world leaders to enhanced national, regional and global cooperation, using a “One health” approach. It highlights the links between AMR and UHC, and calls for various approaches to address them, including health system strengthening, capacity-building, and effective stewardship and equitable access to affordable, safe, effective and quality medicines, vaccines, and diagnostics.

EU-JAMRAI takes stock of European cooperation on AMR

The Istituto Superiore di Sanità in Rome, Italy, hosted the second annual meeting of the EU joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI) on 16 and 17 September 2019.

The two-day meeting of EU-funded initiative takes stock of progress so far, and brought together 44 partners from 21 countries, and an additional 30 stakeholders from industry and civil society to address future challenges.

The meeting examined the achievements of the first two years of the project, due to run until 2020, with a focus on three key areas: strengthening the national and European response to AMR; filling the gaps in infection prevention and control implementation, research, and communication; and antibiotic stewardship and surveillance. Looking to the future, the stakeholder engagement session explored key questions for the coming years, including appropriate economic models to incentivize innovation and ensure access; challenges to antimicrobial stewardship in animal health; and sustainable integration of the One Health approach to National Action Plans on AMR.

Further reading: [EU-JAMRAI mission](#)



Like or retweet: [The @AMRAAlliance welcomes the #G20 declaration calling for urgent action to be taken to address the global threat of #AMR by investing in R&D for new antimicrobials, diagnostic technologies, #vaccines and alternative measures ↗ <https://bit.ly/2pG9GGk>](#)



Like or retweet: [The #HLMUHC presents a golden opportunity to acknowledge the intrinsic links between #UHC & #AMR and ensure concerted action for both, says @ThomasCueni, the @AMRAAlliance Chair: <http://bit.ly/2kpzx8A8> #HLMUHC](#)

Alliance out and about

Alliance action

Alliance leads public–private partnership discussion at World Health Summit

Discussion in Berlin focused on identifying how to cultivate and develop effective partnerships to increase access and improve stewardship.

The AMR Industry Alliance convened an expert panel in the margins of the World Health Summit in Berlin on 28 October 2019, to discuss one of the main themes of the recent UN Interagency Coordination Group on AMR report: how best to foster collaboration between the public and private sector. The discussion, which put a particular emphasis on access and stewardship, drew on the collective experience of representatives from the Alliance, UNICEF, The Wellcome Trust, the Swiss Agency for Development and Cooperation, and ReAct Africa, to address a number of key questions including why partnerships fail, and how best to structure cross-sectoral partnerships. Suggestions included common ground and agreement about the causes of a problem as an important foundation for engagement between organizations, followed by the importance of arriving at an equal sharing of burdens and risks between collaborating organizations.

Alliance at the World AMR Congress

The world's largest AMR conference drew the crowds at the US capital, with the Alliance playing a central role.

The World Anti-Microbial Resistance Congress took place on 7 and 8 November in Washington, D.C., USA. The "world's largest AMR conference", and the only of its kind with a commercial focus, brought together 600 attendees from 40 countries to compare notes and forge new connections on everything from research and development to infection prevention and control. The Alliance, which was a sponsor of the event, was well represented, with a number of board members and advisers in attendance, and Alliance Chairman Thomas Cueni on hand at the end of the first day to open the drinks reception. The Alliance also had its own booth and was pleased to see a number of prospective companies expressing interest in joining the membership base.

Strengthen the voice of young people in the fight against AMR

The annual [One Young World Summit](#), often referred to as the "Young Davos", convenes the brightest young talent from every country and sector, working to accelerate social impact. For this year's event, AMR Industry Alliance members GSK and Centrient Pharmaceuticals put antimicrobial resistance on the agenda.

Through an interactive workshop aimed at people under the age of 30, GSK and Centrient Pharmaceuticals designed a creative campaign to incentivize young people to act on AMR.

Young people have a unique role to play in combating AMR. Studies have shown that people aged 15-24 years are the highest users of antibiotics; are more likely than other age groups to take them for infections that do not need antibiotics; and 15-34-year-olds have lower knowledge than older groups about antibiotics.

Media mentions

Tackling AMR through sustainable antibiotic production

Alba Tiley, Head of Sustainability at Centrient Pharmaceuticals, explains why a sustainable approach to developing antibiotics is key to combatting antimicrobial resistance. Emphasizing industry's role in sustainable production, Alba points to the AMR Industry Alliance's development of a set of science-based emissions targets that can be used to help reduce the amount of antibiotic discharges in wastewater. The targets, which are used alongside the Alliance's Antibiotic Manufacturing Framework, are an important tool in ensuring companies make

antibiotics in a sustainable way, which when combined with buying antibiotics from responsible sources is critical to ensuring a clean supply chain that minimizes contributions to AMR.

Further reading: [EMP Magazine](#)



Catch up

Progress update on our progress report

Our second progress report will be published in January 2020.

All the data for the AMR Industry Alliance's second progress report have been duly collected through a member survey and are being analyzed by SustainAbility. In October 2019, our External Advisory Group – including representatives from 12 organizations – gathered in Geneva to review preliminary findings and discuss results.

The group's input was fed into a discussion of the results by the AMR Alliance Board, which worked with SustainAbility in October 2019 to develop a list of recommendations and key messages for the second progress report.

Survey participants can submit case studies to amr@sustainability.com by Friday 22 November 2019. Examples showcasing innovation in the AMR space and those reflecting challenges that companies face in today's marketplace are particularly welcome.

The report is now being drafted and is expected to be ready for publication in January 2020. Stay tuned!

Making antibiotics responsibly. A common manufacturing framework to tackle AMR

The rapid rise in antibiotic resistance threatens to reverse a century of progress made by modern medicine.

Avoiding this post-antibiotic era requires all countries, companies and communities to join forces and change the ways we make, regulate and use antibiotics. One thing that the life sciences industry can do to help is to protect local environments by effectively minimizing the presence of antibiotic residues in pharmaceutical production waste streams. To that end, the AMR Industry Alliance has developed [a common framework for responsible antibiotic manufacturing](#), which lays out the best practices that factories producing antibiotics should follow to minimize the environmental risk of their business. For the first time ever, antibiotic manufacturers also have a set of science-based target concentrations for antibiotics in receiving waters they can use to shape their environmental and waste management strategies and ensure the continued health and safety of people and the planet.

One Health Global Leaders Group on Antimicrobial Resistance: feedback

Following the launch of an [open consultation](#) on the establishment of One Health Global Leaders Group on Antimicrobial Resistance recommended by the United Nations ad hoc Interagency Coordination Group (IACG)

and supported by the Tripartite Joint Secretariat on Antimicrobial Resistance (managed by FAO, OIE and WHO), the AMR Industry Alliance and IFPMA have welcomed the initiative and submitted their joint comments on the composition and role of the Group.

Get social during World Antibiotic Awareness Week

We have developed a suite of engaging social media communications materials that you can use for this year's [World Antibiotic Awareness Week](#) from 18–24 November.

World Antibiotic Awareness Week (WAAW) aims to increase awareness of global antibiotic resistance and to limit its spread by encouraging best practices among the general public, health workers and policymakers. This year, through a selection of engaging visuals designed for social media, the AMR Alliance will use WAAW to reinforce five key messages:

- Investing in research and science is the only way to invent innovative diagnostics and treatments for resistant infections.
- Diagnostic tools and technologies can help with timely antimicrobial interventions, reducing unnecessary use of antibiotics.
- Improving patient access to the most appropriate treatment, vaccine and diagnostic can help slow the spread of AMR.
- Responsible manufacturing practices can reduce emissions from antibiotic production.
- Surveillance informs healthcare professionals around the world on changing resistance trends.

Tune in to Twitter and LinkedIn to follow our participation in WAAW; and get a free copy of our social media materials by contacting: RoundUp@AMRIndustryAlliance.org

See more...

Alliance resources:

- New "[AMR Industry Alliance manufacturing booklet – Making antibiotics responsibly](#)"
- "[Antibiotics: Responsibly Making the Drugs Society Needs](#)", opinion by Steve Brooks, Advisor to the AMR Industry Alliance

Upcoming events

- 18–24 November 2019 (Global). [World Antibiotic Awareness Week](#). AMR Industry Alliance activities are planned.
 - 1–6 March 2020 (Il Ciocco, Tuscany, Italy). [Disruptive Antibiotics and Non-Antibiotic Therapies to Combat Drug-Resistant Bacterial Infections](#). Gordon Research Conference on antibacterial discovery and development.
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- 12–13 March 2020 (Location TBD). [4th Conference on Novel Antimicrobials and AMR Diagnostics](#). This conference is a platform for SMEs, start-ups, big pharma, academia, investors and public institutions to discuss strategies and challenges in bringing new antimicrobial treatments and diagnostics to the market.
- 16–17 March 2020 (London). [BSAC Spring Conference](#). This year's conference is called 'Into clinical practice: Bridging the gap between science, policy and effective antimicrobial use.'

Please let us know of any upcoming events which you would like to see included in this Alliance Round-Up.

Contributions, suggestions and comments from AMR Industry Alliance members are welcome.

For all communications, please contact the Head of the Secretariat, Magdalena Babinska,

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