Alliance Round-Up

AMR Industry Alliance Round-Up, Issue No.1, June 2019

This is the first issue of "Alliance Round-Up" written for the more than 100 biotech, diagnostic, generic and pharma companies who are members of the AMR Industry Alliance, as well as people interested in collaborating with the Alliance to accelerate efforts to combat antimicrobial resistance. In the Alliance Round-Up, we will provide updates and share opinions that demonstrate the importance of putting our recently adopted commitments into action, further cementing this unique community of the willing. We will also give you tips on how to spread the word via social media channels. Please feel free to distribute the Alliance Round-Up within your respective organizations and send us suggestions of people to add to our distribution list. We look forward to hearing from you.

Magdalena Babinska,Secretariat Lead AMR Industry Alliance

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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 a friend
- Spread the word via social media
- Join the new "AMR Industry Alliance" LinkedIn group (only for the member companies and associations)
- Check out "What it means to be an Alliance Member in 2019"
- Don't forget to share any new case studies

Expert view

Achaogen's failure increases urgency to address antimicrobial market challenges, *by Gregory Frank, Director of Infectious Disease Policy, Biotechnology Innovation Organization (BIO.org), and board member of the AMR Industry Alliance*

In the 2018 Progress Report of the AMR Industry Alliance, many of the members of the Alliance argued that there was a serious threat to the life science industry's investment and growth posed by numerous market challenges for products that can address antimicrobial resistance (AMR). In the report, they called for urgent adoption of substantial and sustainable pull incentives by national governments. One example, in particular, highlights the scale of the problem: in June 2018, Achaogen, a U.S. based biotech company received an approval from the US Food and Drug Administration for its lead antibiotic, plazomicin, intended for the treatment of complicated urinary tract infections. This antibiotic was also a key addition to the armamentarium that can help treat carbapenem-resistant Enterobacteriaceae infections.

Unfortunately, due to the unique market challenges in the development of antimicrobial agents, the company was unable to demonstrate a sustainable return to stay viable. In April 2019, less than a year after receiving the approval, Achaogen announced it was filing for bankruptcy, which put a question mark over the future availability of this key antibiotic. What makes this situation even more troubling is the fact that the company received significant push funding from various sources, including the U.S. Biomedical Advanced Research Development Authority (BARDA), to support its plazomicin research and development program. While these funds were instrumental in helping Achaogen reach a successful commercial approval, they did not address the key market challenges only delaying Achaogen's "valley of death." Such a market failure should have never taken place. Nonetheless it did, serving as clarion call for the global AMR stakeholder community to redouble its efforts to offer biotech companies meaningful, sufficient and practical pull mechanisms to allow them to thrive rather than barely survive.

Further reading: STAT, The Economist, Wired, CIDRAP

Like or retweet: What does it take to establish robust incentives for pharma companies to develop new #antibiotics?

Two sides of the same coin: access and stewardship. New report helps better understand the barriers to access in LMIC

Lack of access to antibiotics now kills more people than antibiotic resistance. The problem has been overlooked for far too long and the question why the barriers to access still exist has not been sufficiently explained. Researchers from the Center for Disease Dynamics, Economics & Policy (CDDEP) in their new report "Access Barriers to Antibiotics" attempted to shed light on this overlooked and under-appreciated problem in high-, middle- and low-income countries by presenting data collected through field interviews with key stakeholders in Uganda, India, and Germany, as well as data gathered through literature reviews.

The report, based in part on the research supported by the AMR Industry Alliance, identifies key access barriers to antibiotics and recommends actions to address this issue. The barriers include: weak drug discovery, difficulties in market entry and poor stewardship, which altogether lead to irrational selection and use of antibiotics. The second barrier identified was limited government funding for public health infrastructure and healthcare coverage on the one hand, and high cost of antibiotics on the other hand, which often force patients to pay out-of-pocket for the medication they require. The third and last barrier singled out by the authors of the report was the failure of governments to deliver antibiotics to patients in need due to weak health systems and unreliable supply chains. In addition, poor inventory management, storage systems, and poor quality control leads to frequent shortages of antibiotics and increased consumption of substandard or falsified antibiotics.

The report recommends: acting on antibiotic and diagnostics research and development, strengthening regulatory capacities, supporting registration of antibiotics according to clinical need, exploring innovative funding of essential antibiotics to reduce out-of-pockets payments, encouraging development and diversification of quality local manufacturing, improving clinical treatment guidelines and, lastly, educating patients and prescribers about appropriate use of antimicrobials.

Further reading: CIDRAP, Deccan Herald

Like or retweet: Lack of access to #antibiotics currently kills more people globally than #AMR. This new @CDDEP report explains the key access barriers to #antibiotics in developing nations. Read it here ☞ http://bit.ly/2HHSAOV

Alliance's Science Team makes great progress in environmental manufacturing: The history behind the Predicted No-Effect Concentrations (PNECs) values, *by Steve Brooks, Chair of the Manufacturing Working Group, AMR Industry Alliance*

A lot of attention is being given to the environmental aspects of AMR and much of that attention is focused on manufacturing and risks associated with waste water emissions from manufacturing plants, especially in such countries as India and China. Many stakeholders have called for the industry to take action to better address those risks. In September 2016, the AMR Industry Alliance made a Roadmap commitment, against a backdrop of evolving science, to develop a method that would allow for establishing "safe discharge targets" from manufacturing facilities by 2020.

Jump forward to 2018 and the Science Team, a sub-committee of the AMR Industry Alliance Manufacturing work group, led by Joan Tell of MSD and primarily comprising ecotoxicologists from Alliance member companies, delivered on this commitment ***two years early!*** Having diligently reviewed relevant scientific literature on approaches to setting "safe discharge targets ", including the important work of the Swedish researcher Dr Joakim Larrson, and having shared (under a confidentiality agreement) eco-toxicity data generated by member companies on their products, the Science Team selected what they considered to be the most appropriate method to determine discharge targets. They took into account potential risk to the environment and potential antibiotic resistance risk. They then consulted with their scientific peers at a meeting of the Society of Environmental Toxicologists and Chemists (SETAC), who confirmed that the proposed approach was robust. With this positive feedback, the Science Team applied their approach to the data available for ~120 antibiotics and published the results as Predicted No-Effect Concentrations (PNECs) on the website of the Alliance in September 2018.

Recognizing the importance of this development, the US Secretary of State for Health and Human Services, Alex Azar, in his opening remarks at the CDC AMR event in NYC on the margins of the United Nations General Assembly in 2018, proclaimed the publication of both the Alliance "Common Antibiotic Manufacturing Framework" and the Alliance's manufacturing antibiotic discharge targets as signs of real progress being made to address AMR by the industry.

The story does not stop in 2018, however. The members of the Science Team have recently published their work entitled "Science-based Targets for Antibiotics in Receiving Waters from Pharmaceutical Manufacturing Operations" in a peer-reviewed journal. The paper, which was widely welcomed by various stakeholders (listed here), summarizes the current state of the science and the various approaches considered in setting discharge targets. It provides the rationale for the selected approach and includes a table of discharge targets.

Kudos here to Joan and all members of the Science Team (listed below) for their excellent collaboration, which resulted in a significant step forward that has improved our ability to better understand antibiotic environmental risk in proximity to manufacturing plants.

Science team members and their company affiliation: Dr. Daniel J. Caldwell, J&J; Dr. Andreas Häner, Roche; Dr. Jutta Hellstern, Novartis; Dr. Romain Journel, Sanofi; The late Dr. Frank Mastrocco, Pfizer; Dr. Jim J. Ryan, GSK; Dr. Jason Snape, Astra Zeneca; Dr. Jürg Oliver Straub, Roche; Mr. Tim Swenson, Pfizer; Dr Joan Tell, MSD; Dr. Jessica Vestel, MSD.

Check out the AMR Alliance Recommended PNECs for Risk Assessments

Policy highlights

New UN report calls for urgent action to avert antimicrobial resistance crisis (WHO | Health Policy Watch | New York Times | WHO PDF Report)

In April 2019, the UN Interagency Coordinating Group (IACG) on AMR released a report calling for immediate, coordinated and ambitious action to avert a drug-resistance crisis that could potentially cause 10 million deaths a year by 2050. The report shared a number of recommendations, which include prioritising national action plans to scale-up financing and capacity-building, strengthening countries' regulatory systems, investing in R&D for new technologies to combat AMR while stopping the use of critically important antimicrobials as growth promoters in agriculture, among many other recommendations. The AMR Industry Alliance submitted a number of comments during the open consultation process and we were pleased to see many of them echoed in the final version of the IACG report.

Thomas Cueni, Chair of AMR Industry Alliance and Director General of IFPMA, said that the current market incentives are simply not sufficient and welcomed the report's recommendation to increase investment and innovation in quality-assured new antimicrobials and novel compounds, diagnostics and vaccines. Echoing the report's call for "sustained investments and collaborations (…) on the part of governments, the private sector and civil society to accelerate research and development, pull new products through to market and ensure effective stewardship", Thomas Cueni stressed that the life science industry stands ready to fulfil its role and wants to be treated as an equal partner, sitting at the table to engage in discussions. The industry believes that moving beyond the long-standing debate about what has not worked so far to developing concrete, practical and sustainable solutions that truly address the limited market potential of antibiotics, diagnostics and vaccines is the next logical step.

AMR and the WHO – The World Health Assembly adopts resolution on steps to follow up on the High-Level Meeting at the UN General Assembly on health-related issues: Antimicrobial resistance (WHA A72/18 | WHO)

At the World Health Assembly in May 2019, the 194 member states adopted the resolution WHA A72/18, which urges members states to strengthen infection prevention and control measures including water sanitation and hygiene, enhance participation in Global Antimicrobial Surveillance System, ensure prudent use of quality-assured antimicrobials, and support multisectoral annual self-assessment surveys. It requests the WHO Director-General to significantly increase support for countries in implementing their national action plans and help mobilize the required financial resources in collaboration with other UN agencies and partners. It also calls on the WHO Director-General to maintain the WHO List of Critically Important Antimicrobials for human medicine and keep Member States informed of WHO's work with the other members of the Tripartite (the Food and Agriculture Organisation and the World Organisation for Animal Health) along with the UN Environmental Program.

The resolution acknowledges the work of the Interagency Coordination Group on Antimicrobial Resistance (IACG) to provide practical guidance on how to scale up global action to address antimicrobial resistance, and stresses the importance of addressing antimicrobial resistance in order to achieve the 2030 Agenda for Sustainable Development.

Like or retweet: Fighting #AMR is a crucial step towards the achievement of the 2030 Agenda and #SDGs 🌍 Take a look at the resolution related to AMR recently adopted by member states at the #WHA72 to tackle future AMR 👉 http://bit.ly/2Mu60mn

Like or retweet: With the new resolution related to #AMR countries have agreed to strengthen infection prevention and #WASH, enhance participation in the Global #AMR Surveillance System, ensure use of quality-assured antimicrobials, and support the self-assessment survey👊

Announcement

WHO is currently developing the **priority list of antimicrobial resistance diagnostics**. This is a landscape analysis of available technologies and promising products for low-and middle-income countries, conducted in order to identify gaps in the diagnostics needed. The list, due to be published by July 2019, will be used to develop target product profiles for the highest priority diagnostics for antimicrobial resistance by the end of 2019. **Stay tuned!**

“I applaud the U.N. for at least putting incentives on the map, but there needs to be more than talk,” said Thomas Cueni, chair of the AMR Industry Alliance. “What’s needed is money.” 29 April 2019, New York Times “U.N. Issues Urgent Warning on the Growing Peril of Drug-Resistant Infections”.

Creating new antimicrobial drugs will require governments working with industry (STAT), Opinion by Thomas Cueni.

“Antibiotics are the cornerstone of modern healthcare, and we need to act now to ensure they stay that way. Step one is to get the incentives right – including the right combination of “carrots” and “sticks” writes Harshika Sarbajna, Global Head Anti-infectives, Sandoz International GmbHl & member of the AMR Industry Alliance in her LinkedIn post.

“Generic manufacturers play a crucial role in ensuring a sustainable supply of antibiotics to patients when they need them, and where they need them. Since access and appropriate use are two of the main work pillars of the Alliance, we need the support of generic manufacturers to address these topics in a meaningful way”, said Thomas Cueni. Alba Tiley, head of the sustainable antibiotics program at Centrient Pharmaceuticals & member of the AMR Industry Alliance, explained that in the fight against antimicrobial resistance we should be “calling on both the manufacturing industry and the entire value chain – suppliers, marketers, buyers, and so on – to act responsibly and ensure we stop buying, using or selling irresponsibly made antibiotics.” *Generics Industry Must Play ‘Crucial Role’ In AMR Industry Alliance*, writes David Wallace, Generics Bulletin, 22 May 2019.

Catch up

Action: Alliance members contributing to the 2nd Progress Report, the hard work is now, *by Magdalena Babinska AMR Industry Alliance Secretariat*

The impact and contribution of the Alliance to the common goal of reducing antimicrobial resistance is demonstrated through the progress made by its individual members and as a collective. For the Alliance to be greater than the sum of its parts, all members must work continuously and diligently towards fulfilling the commitments – and one key aspect of this is to participate in the **member survey**. **The data collected through the survey** will be rigorously analyzed to identify best practice, opportunities and gaps where further efforts may be required by the life science industry and other stakeholders. The survey is managed by SustainAbility, a think tank and advisory firm, who is helping us produce the 2020 report (they also supported compiling the 2018 Progress Report). If you need a helping hand in completing the survey, please send an email to AMR@sustainability.com – Nick Jackson and Rita Sampainho will be more than happy to assist.

The first Progress Report of the AMR Industry Alliance was well received; however, only 36% of Alliance member companies participated in the survey. This time around our key objective is to increase the number of participating companies as much as possible to produce an impactful report that ultimately represents the Alliance as a whole. Big "thank you" to all members of the Alliance for your submissions to the survey! Rest assured that you are helping us share best practices and identify remaining barriers in order to better understand where the industry could add value in the fight against AMR and what more can be done to help the biotech, diagnostic, generic and R&D companies deliver on all the commitments.

See more...

- Alliance resources: What it means to be an Alliance member in 2019

- Alliance – people and places: In February 2019, AMR Industry Alliance elected its Board Members for 2019/2020

Upcoming events

- 20-24 June 2019 (San Francisco): Annual ASM Microbe meeting.
- 9 July, 17:00-18:30 CEST: Webinar "Infection models for antimicrobial R&D: Intracellular models". Speaker: Françoise van Bambeke, Research Director Cellular and Molecular Pharmacology, Louvain Drug Research Institute, Catholic University of Louvain (FR). Moderator: Laura Piddock, Director of Scientific Affairs, GARDP. Register here.
- 2-6 Oct 2019 (Washington, DC): IDSA's annual IDWeek meeting.
- 7-8 Nov 2019 (Washington, DC): The World Antimicrobial Resistance Congress.
- 11-17 Nov 2019 World Antibiotic Awareness Week – AMR Industry Alliance activities planned
- 1-6 Mar 2020 (Il Ciocco, Tuscany, Italy): GRC on Antibacterial Discovery and Development: "Now is the time to re-boot antibiotic R&D before it's too little, too late." Details: here .

- 12-13 Mar 2020: BEAM-, Novo REPAIR-, CARB-X-, DZIF-, ND4BB-, ENABLE. Conference on Novel Antimicrobials and AMR Diagnostics. Final location is TBD, details will appear here, and you should mark your calendar now.
- 16-17 Mar 2020 (London): BSAC Spring Conference entitled: "Bridging the gap between science, policy and effective antimicrobial use." Details here.

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 Secretariat Lead, Magdalena Babinska,
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