

“Delivering the SDGs: Focus on Industry’s Actions in the Fight against AMR”

18 January 2018, Geneva

This document provides a summary of the discussion at the event “[Delivering the SDGs: Focus on Industry’s Actions in the Fight against AMR](#)”, convened by the [AMR Industry Alliance](#) and [SustainAbility](#) on 18 January 2018 at the Graduate Institute of International and Development Studies in Geneva. A list summarizing the proposals and recommendations made by stakeholders is featured below.

Proposals/recommendations to the AMR Industry Alliance:

- Martha Gyansa, Lutterodt, Director of Pharmaceutical Services and Chief Pharmacist of Ghana, and Co-Convener of the IACG:
 - o Recognition that the AMR Industry Alliance has set an example of what the private sector can do and called the interagency coordination group – IACG – to take it into consideration for future decisions.
 - o Recommendation to the Alliance to issue a Communiqué to share with the IACG.
 - o The Alliance should set a target for 2020 to achieve a 70 to 80% of response rate.
 - o The life sciences industry should look at environmental audits of effluents in the soil.
 - o The fight against AMR could broaden to many other private sector industries in particular the food, fishery and meat industries.

- Marc Sprenger, Director of the AMR Secretariat, World Health Organization:
 - o Complimentary about the AMR Industry Alliance Report but noted the low rate of progress report survey completion by the Alliance SMEs, encouraged to explore ways to facilitate biotech engagement.
 - o Need for further transparency in the Alliance progress report results’ reporting, for example, disclosing data per company and not just aggregated.
 - o WHO is aware of the market “inefficiencies” with regards to the unique dynamic of the antibacterial market. WHO will make sure these challenges are relayed at the “political level”.
 - o WHO Global Antimicrobial Resistance Surveillance System (GLASS) report will advocate for more R&D of antibiotics based on the information on resistance trends collected in countries.

- Other relevant input from participants:
 - o Last November, an appeal was launched to the Swiss Federal Council to put in place a dialogue especially for new incentives. Three meetings are now scheduled with three federal councilors (ministers) of the governments, out of seven (Prof. Dr. J.-C. Piffaretti).
 - o Recommendation that the Alliance bring together its stewardship and access work under one heading. (Dr. Manica Balasegaram, Director, Global Antibiotic Research & Development (GARDP))
 - o Call for a stronger governance mechanism for AMR (Dr. Ilona Kickbusch, Graduate Institute)
 - o Private sector, in particular life sciences industry needs to be involved in the international debate, and in particular the IACG (Thomas Cueni, AMR Industry Alliance).

Introductory Speeches

The opening remarks from **Ilona Kickbusch** reflected the general facts on AMR: it is as considerable a challenge as climate change, only without the governance mechanisms to approach it. She welcomed the AMR Industry Alliance report as it helps identify where the life sciences industry can add value and what is needed to move forwards.

The strong link between AMR and the delivering of the SDGs was underlined even though AMR is not specifically mentioned in any of the Development Goals. Kickbusch noted the impact AMR can have on SDG 3 (healthy lives), but also SDG 1 (AMR affects poor people the most), SDG 2 (food security), SDG 6 (antibiotic residues in water), SDG 8 (economic growth), and SDG 12 (sustainable production and consumption).

Thomas Cueni explained that the multi-faceted nature of the AMR challenge drove the life sciences industry sector to form an Industry Alliance which would help break intra industry silos. Mr Cueni emphasized three main points: the need for stronger collaboration between the public and private sector, the industry willingness to be held accountable and track its progress and the need to have realistic expectations given the combination of challenges existing for AMR.

- **Collaboration.** Cueni reiterated the importance of the strong partnerships referring to SDG 17 and noted that both the private and public sectors should implement it. Cueni underscored the importance of the private sector being more involved in the international debate to find solutions. He said *“we are banging at the door of the IACG.”*
- **Commitments.** Cueni explained that the industry believes its role in the fight against AMR goes beyond innovation. This approach was reflected in the Alliance progress report as industry’s commitments cover a wide range of areas: R&D, but also access, environment and stewardship. The AMR Industry Alliance progress report is a sign that *“we are making progress, but there is a need to be humble as there is still a long way to go”* said Cueni.
- **A combination of challenges** come from AMR:
 - From a scientific angle, scientists are struggling to develop effective medicines (Bacteria are extremely resilient. The “therapeutic window” between ability to kill bacteria and producing side effects in humans) is increasingly narrow. It is also difficult to predict the how, where, or when resistance will develop.
 - From a regulatory perspective, identifying and recruiting patients for trials is extremely challenging.
 - It is also an economic challenge: there is a unique market dynamic for antibiotics where new therapies should be used at a minimum level to ensure their preservation. This dynamic goes against the “traditional” market dynamics which are based on price/volume; innovative incentive mechanisms are therefore needed. The AMR Industry Alliance 1st progress report highlights the fragility of the economic environment hinting that push mechanisms stimulating research are important but that their potential cannot be fully realized without robust pull mechanisms rewarding positive outcomes. Despite these challenges, the report shows the importance of the private sector’s efforts in tackling AMR. In 2016 alone, Alliance members invested at least USD 2 billion in R&D on AMR. This is a conservative estimate, and not much when compared to the possible \$100 trillion damage foreseen. However, Cueni noted *“it is about four times as much as governments provided for push incentives for R&D on antibiotics that same year”*.

Marc Sprenger from WHO commended the AMR Industry Alliance for a very impressive report and the commitment they made to track progress by 2020. He welcomed the continuing commitment by companies that have expressed their public commitment to tackle AMR by signing the Davos Declaration and the Roadmap. He invited more

companies to join this exercise and particularly SMEs to keep this discussion growing. He also encouraged further transparency in the results' reporting, for example, disclosing data per company and not just aggregated.

Dr Sprenger mentioned the series of tools the WHO developed to help the fight against AMR:

- **Pipeline inventory.** WHO released a report "Antibacterial agents in clinical development"¹ describing the current pipeline. The report found that only 42 compounds are being developed, from which only 12 target the gram-negative pathogens (from which one is innovative). Scientists experience important failure rates, which makes it a difficult environment where financial investments can make a difference. Sprenger underscored the need to develop new antibiotics, and this required further investment which would not be "an easy job, as we are aware of the difficulties in the business model". The WHO is prepared to make this problem clear to the "political level" to address it. But in counterpart, industry needs to ensure that new medicines are accessible and affordable.
- **Guiding R&D efforts.** The list of Priority Pathogens² was released early 2017, it is a catalogue of 12 families of bacteria divided into three categories according to the urgency of need for new antibiotics: critical, high and medium priority. This list was developed as a tool to guide and promote research and development (R&D) of new antibiotics.
- **Surveillance.** At the Prince Mahidol Award Conference 2018, the WHO will release its Global Antimicrobial Resistance Surveillance System (GLASS) report³, and based on the findings in the report the WHO will advocate for more R&D in specific areas. The IACG will be meeting in Bangkok, where they will begin to formulate their recommendations for the future.
- **Access and Stewardship.** WHO also reviewed the Essential Medicines List (EML)⁴ section on antimicrobials and created three categories (Access, Watch, Reserve) to provide guidance on the appropriate use of antibiotics. Sprenger explained that it was crucial to balance the access, innovation and conservation aspect of antimicrobials to contain AMR.
- **Awareness.** Finally, Sprenger noted an increase of 60% in participating countries to the antibiotic awareness week and 130 countries actively developed an awareness campaign. Sprenger underscored the need to educate people that they should not apply pressure on doctor to give them antibiotics when they are not needed – there are some simple, low cost solutions that the WHO is exploring and hopes to further encourage their use as well as continuing to find adapted, low cost solutions to diagnosis.

Denise Delaney presented the AMR Industry Alliance 1st progress report⁵ and explained the methodology which was used to collect information. SustainAbility developed metrics into a survey tool and invited the Alliance members to report on their AMR activities. While responses cover all sub-categories of the industry (R&D manufacturers, generics, biotechs and diagnostics) Delaney explained the Alliance is only subset of the entire life science industry. It currently represents 30 to 40% of volume of global antibiotics. Key findings of the report include:

¹ WHO Antibacterial agents in clinical development, September 2017

http://www.who.int/medicines/news/2017/IAU_AntibacterialAgentsClinicalDevelopment_webfinal_2017_09_19.pdf

² WHO List of Priority Pathogens, February 2017 <http://www.who.int/medicines/news/bacteria-antibiotics-needed/en/>

³ WHO GLASS Report Early Implementation 2016 -2017, January 2018

<http://apps.who.int/iris/bitstream/10665/259744/1/9789241513449-eng.pdf?ua=1>

⁴ WHO Model List of Essential Medicines, 20th List, March 2017

http://www.who.int/medicines/publications/essentialmedicines/20th_EML2017_FINAL_amendedAug2017.pdf?ua=1

⁵ Tracking Progress to Address AMR, AMR Industry Alliance, January 2018

https://www.amrindustryalliance.org/wp-content/uploads/2018/01/AMR_Industry_Alliance_Progress_Report_January2018.pdf

Write-up

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- **R&D:** The report found that the R&D pipeline is active but is not sufficient in view of the challenge AMR represents (there are 10 antibiotics with activity against WHO priority 1 or 2 pathogens; 13 AMR-relevant vaccines candidates; 18 AMR-relevant diagnostic products). Since only 22 members of the Alliance disclosed their financial investments made into AMR for 2016, the USD 2 billion is a conservative estimate of the industry financial investment in total. Half of the companies also explained that they would consider decreasing their research if no incentives were established.
- **Appropriate use:** 70% of the respondents said they were engaged in or were planning to engage in surveillance, education and promotion programs dedicated to AMR.
- **Access:** The report also found that more than 75% of companies have access strategies covering some or all products marketed AMR-relevant.
- **Environment:** Finally, the report shows companies developed a common framework on the management of antibiotics discharge in the environment, to share knowledge, standards and greater transparency.
- **Next steps:** For the future, Alliance members would like to increase collaboration in the R&D, develop a consensus priority lists for vaccines and diagnostics, and solid incentives. Regarding appropriate use, progress should be made in harmonizing surveillance approaches, increase public awareness, and promote wider use of vaccines. Companies are also working on developing further access programs dedicated to antibiotic, and increase dialogue with all actors in that area. In 2018, they will also start the implementation of their common framework for managing antibiotic discharge, and for establishing science-driven, risk based targets for discharge concentrations for antibiotics.

Panel I

The first panel of discussion presented findings from the report and good practices.

A. Innovation: the key role of partnerships and pull incentives

The biotechnologies sector is where most of the innovation in discovery and development of antibiotics is.

Sanjay Kakkar, CEO of the biotech company Peptilomics underlined that biotechs added value in the fight against AMR is mostly on pre-clinical innovation. Biotechs are particularly focusing on “novel approaches” and bringing products to pre-clinical development and then seek to partner with larger pharmaceutical companies as those products move into clinical development phases. Today, bringing a product from early clinical development to a market is a challenge.

Kakkar explained that successes come from a **new type of collaboration** between start-ups, large pharmaceutical companies and venture capital investors and these are directly dependent on the existence of robust incentives at the market end because there is a high rate of failure. From a market perspective, to succeed “*we need two stakeholders: investors i.e. venture capitalists and larger pharmaceutical companies*”. Both stakeholders will be looking for return on their investment: “*We need to see a market dynamic that will enable those investments and those partnerships to work*”. Push incentives helped, however the challenge for biotechs is to ensure that once their product is at the early clinical phase, there is enough of prospect of return so that larger pharmaceutical companies will be interested to partner and move this product through the different phases of clinical development. This is a fragile balance because if larger companies are not partnering, then venture capitalist will stop funding biotechs. Hence it is crucial to **ensure robust incentives exist at the market end**. Kakkar concluded: “*innovative pull incentives will address the way new technologies are deployed and how society gets access to them*”.

B. Industry’s multi-pronged engagement on appropriate use

Bruce Altevogt explained the different proactive steps the industry is taking to address the fight against AMR. Industry is investing in prevention, developing **new vaccines** as the most powerful tool to prevent new bacteria to develop. The industry is also partnering with public authorities for **educational campaigns** for healthcare professionals about appropriate use of antibiotics and the rational manner to cure patients. Altevogt also explained that **promotional activity** with regards to antibiotics was now focusing on removing sales-based incentives. The industry could engage more and make progress in identifying the gaps in the **surveillance area**.

In addition, Thomas Cueni emphasized that none of the **incentives** the private sector was considering link the volume of antibiotics consumed with the amount of the reward received by companies. These incentives can help support stewardship as they are decoupled from sales.

Diagnostics are also instrumental to ensure that antibiotics are used appropriately. Gary Cohen said: “*You cannot practice antimicrobial stewardship without diagnostics; diagnostics enable you to determine the cause of infections and the resistance profile so that you choose the appropriate therapy*”. For example, in the United States about 50% of antibiotics prescriptions concern misdiagnosed cases despite the availability of cost-effective tests. In many cases, if the patient has a resistant strain and no diagnostic device is used, the patient is given a broad-spectrum antibiotic, which generally worsens his condition. Cohen emphasized that “*diagnostics are highly cost-effective*” as knowing precisely the cause of an infection would help health care professionals choose the right treatment and therefore prevent the costs associated to the worsening health conditions of patients with resistant infections. In some cases, the low prices of antibiotics could act as a disincentive to use diagnostics and their underutilization.

C. Access challenges: price, continuity of supply and availability of old antibiotics

With regards to access challenges, Altevogt explained that **price and intellectual property (IP) are not the main barriers** as 95% of antibiotics are generic which means those medicines are not protected by IP. He added that all antibiotics listed in the WHO Essential Medicines List in the access category are generic and therefore emphasized the central role of strong health care systems to ensure patients can access the right treatment. Partnerships between the public and private sectors are key to strengthen health infrastructures.

Panelists also discussed how **shortages** can hamper the continuity of antibiotics supply. Susana Goncalves explained how they can be a source of resistance as patients cannot have access to the specific antibiotics they need. She explained that one of the reasons for shortages is the **demand fluctuation**: Companies are not able to forecast manufacturing costs and maintain needed manufacturing lines because there is too much uncertainty. To mitigate the impact on the healthcare system, a strong dialogue at country level should be reinforced to promote **regulatory changes**, for example, by allowing that new clinical guidelines to be issued quicker.

Goncalves also explained that there is a range of therapeutic options for every disease, which means access to both – new and old antibiotics – is necessary. However, when the demand for a certain product decreases, their manufacturing costs also change. To prevent this situation of shortages, a proper **pricing and reimbursement mechanism** should be thought through.

Panel II

The second panel addressed potential collaboration paths across parties and targets.

A. Political commitment and local implementation

The Director of Pharmaceutical Services and Chief Pharmacist of Ghana, Martha Gyansa, Lutterodt provided a powerful example of how AMR ultimately needs to be addressed at the national level. In Ghana, all players in the AMR space were invited to join in an Alliance to **change the narrative** on this disease area. One of the strategies was to determine the **knowledge, attitude, beliefs and processes** in place regarding antibiotics use and resistance at every stage of the disease occurrence. This evaluation formed the basis for any intervention for all players. **Evidence** was generated regarding the role of civil society, and of different industrial sectors (aquaculture, veterinary, among others) and published in a study accessible [here](#). This created a political momentum across the country that led to the development of a national action plan against AMR. WHO, but also OIE – World Organisation for Animal Health and FAO – Food and Agriculture Organisation all supported this endeavour.

For Martha Gyansa-Lutterodt, the AMR Industry Alliance is setting a best practice example. She called the Inter-Agency Coordination Group (IACG) to take it into consideration for future decisions. She also recommended to issue a Communiqué from the AMR Industry Alliance report to share with the IACG for support. She finally suggested to set a target for 2020 that the report should reach 70 to 80% of responding rate, to ensure every actor is committed. Industry should also look at environmental audits, to have a better understanding of the effluents in the soil, and impact of their activities on the environment. The fight against AMR could be broadened to many other private sector industries in particular the food, fishery and meat industries.

B. Innovative Product Development Partnerships

GARDP⁶ – the Global Antibiotic Research & Development Partnership (between WHO and DNDi) – works bringing different actors together (governments, private sector, academia) and facilitating their collaboration. Their objective is to accelerate the introduction of new products and improve the use of existing and old antimicrobials. GARDP is not

⁶ <https://www.gardp.org/> (Accessed February 2018)

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just a funder, it is also actively developing R&D strategy and sponsoring clinical trials. GARDP strategy is to look at medical needs, identify the most promising avenues to address them, whilst building access and stewardship strategy into it. Manica Balasegaram explained that **both push and pull mechanisms are needed** and emphasized “*we need to align these incentives to ensure we bring products to pipeline (...) ultimately what is needed is a much bigger societal investment in AMR*”.

FIND⁷ – the Foundation for Innovative New Diagnostics – recent strategy review concluded that despite significant investment into AMR early stage development for diagnostics, there is **no clear access pathway in LMICs**. For example, simple diagnostics that can reduce antibiotic overuse by 40% in malaria programs, such as CRP, are not in use. This shows the lack of strong global national policies and of procurement mechanisms for diagnostics which could do forecasting and help reduce the price of diagnostics. Catharina Boehme said: “*We don’t see enough collaboration in the diagnostics space*”. She explained that FIND, in addition to working with companies and building R&D portfolio, aims at catalyzing access and address market failures for example through the creation of a “diagnostic use accelerator”.

C. Next steps

Broader impact. Thomas Cueni explained that the AMR Industry Alliance wishes to increase its impact by increasing its membership. To that end, he encouraged more companies, for example from India or from China, to join the AMR Industry Alliance as it currently covers less than half of the AMR volume use.

Sustainable eco-system. In addition, Cueni noted “*If we want to address the need for new antibiotics, we need to move from talk to action on incentives*”. The industry invested 2 billion dollars in 2016 in antibacterial R&D which is four times as much as governments provided for push incentives for antibiotic R&D, but this is still “*a drop in the ocean*” compared to what serious scientific progress would need. Therefore, traditional incentives such patent protection remain also crucial to secure the research-based pharmaceutical industry involvement to bring innovative medicine to the market. Cueni explained that the private sector is now better aligned on the need for a suite of incentives⁸ which could include a **Market Entry Reward or a Transferable Extended Exclusivity**. He noted that finding the needed funds might be politically challenging for governments and that the private sector is willing to discuss the use of a funding mechanism that would limit the amount of upfront funding needed from governments.

Governments. A representative from the Swiss roundtable for antibiotics (Prof. J.-C. Piffaretti) explained they were trying to stimulate innovative research on AMR. Last November, the group launched an appeal to Federal Council in Switzerland to install a dialogue especially for new incentives. Three meetings are now scheduled with three federal councilors (ministers) of the governments, out of seven. They hope to progress in this field.

One health. AMR solution requires a holistic approach where every aspect of the disease is looked at. The AMR Industry Alliance is setting an example because the entire life-science community is invited to collaborate. It could also be, as Ilona Kickbusch suggested, that other industrial sectors joined the Alliance – e.g. the agri-food industry.

⁷ <https://www.finddx.org/> (Accessed February 2017)

⁸ Sustainable models to overcome the challenging economics of antimicrobial R&D, IFPMA Position Paper, January 2017
https://www.ifpma.org/wp-content/uploads/2017/01/IFPMA_AMR_Policy_Position_January_2017_FINAL.pdf

Annex

Speakers

Moderator: Dr Ilona Kickbusch, Director of the Global Health Centre and adjunct professor at the Graduate Institute of International and Development Studies

Introduction: Mr Thomas Cueni, Director General, IFPMA, Chair, AMR Industry Alliance

Keynote Speaker: Mr Marc Sprenger, Director of the AMR Secretariat, World Health Organization

Progress Report: Mrs Denise Delaney, Director, SustainAbility

Panel I: Findings and good practices from the 4 commitments areas of the AMR Industry Declaration

- a. Mr Gary M Cohen, Executive Vice President, Global Health and President, BD Foundation
- b. Dr Sanjay Kakkar, MD, MSc, MPH, CEO, Peptilogics, Inc.
- c. Mr Bruce Altevogt, Senior Director of Science Policy and Science Advocacy, Pfizer
- d. Mrs Suzanna Goncalves, Sandoz

Panel II: Setting targets for the future and identifying potential collaborations with the private sector

- a. Mr Marc Sprenger, Director of the AMR Secretariat, World Health Organization
- b. Mrs Martha Gyansa, Lutterodt, Director of Pharmaceutical Services and Chief Pharmacist of Ghana
- c. Mr Thomas Cueni, Director General, IFPMA, Chair, AMR Industry Alliance
- d. Dr Manica Balasegaram, Director, Global Antibiotic Research & Development (GARDP)
- e. Dr Catharina Boehme, CEO, Foundation for Innovative New Diagnostics (FIND)

About the AMR Industry Alliance

The AMR Industry Alliance is a coalition of over 100 biotechnology, diagnostic, generics and research-based biopharmaceutical companies and trade associations that was formed to drive and measure industry progress to curb antimicrobial resistance. The AMR Industry Alliance ensures that signatories collectively deliver on the specific commitments made in the [Industry Declaration](#) on AMR and the [Roadmap](#) and measures progress made in the fight against antimicrobial resistance.

www.amrindustryalliance.org

About SustainAbility

SustainAbility is a consultancy and think tank enabling business to lead on the sustainability agenda.

www.sustainability.com

- Full Progress report: <https://www.amrindustryalliance.org/progress-report/>
- Press release: <https://www.amrindustryalliance.org/mediaroom/report-shows-life-sciences-industry-alliance-taking-action-curb-antimicrobial-resistance/>
- Case studies: <https://www.amrindustryalliance.org/in-action>