

Pharma-led fund launch to save antibiotic pipeline, prompts policy-makers to look at incentives

Global launch highlights from Berlin, 9 July 2020

On Thursday, July 9, the <u>AMR Action Fund</u>, a ground-breaking partnership that aims to bring 2-4 new antibiotics to patients by 2030, was launched during a live, virtual event in Berlin.

Novel antibiotics are urgently needed to address the rapid rise of antibiotic-resistant infections - also called antimicrobial resistance, or AMR. More than 20 leading biopharmaceutical companies have stepped up to the challenge and raised nearly US\$1 billion in funding to support R&D of innovative new antibiotics to address the most resistant bacteria and life-threatening infections.



From left: - Hubertus von Baumbach, Boehringer Ingelheim; Thomas Cueni, IFPMA; Stefan Oelrich, Bayer; Stefan Oschmann, Merck; Astrid Frohloff; and on screen Kasim Kutay, Novo Holdings, Nathalie Moll, EFPIA

The concept of the AMR Action Fund was developed in collaboration with the World Health

Organization (WHO), European Investment Bank (EIB), and Welcome Trust. The AMR Action Fund will bridge innovative candidates in the pipeline through the most challenging later stages of drug development, ultimately providing governments time to make the necessary policy reforms to enable a sustainable antibiotic pipeline and safeguard our future.

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The AMR initiative global launch events, led the by International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and in partnership with national and regional industry associations, took place in Washington, DC and Berlin simultaneously on July 9, with an event in Tokyo on July 10. Visit **AMRActionFund.com** for more information on the Fund.

The Berlin event focused on the international and European dimension of the AMR innovation challenge - more information about the event program can be found **here**.

Highlights

The virtual launch event in Berlin featured panel discussions and remarks from an all-star line-up of key pharma players, biotechs and policy-shaping stakeholders – including seven industry CEOs and association representatives joined by five policy-makers from the EU, Germany, France and Denmark and leaders of organizations that collaborated in the creation of the fund: the WHO, EIB and Wellcome Trust – underscoring the importance of tackling AMR.

Thomas Cueni, Director General of IFPMA, kicked-off the event with an introduction to the AMR Action Fund and the recognition by the industry of their role in addressing the AMR innovation pipeline challenge. He opened by saying "this is an initiative health experts around the world have been waiting for" and has been hotly debated since the Jim O'Neill report in 2014. He highlighted the difficult antibiotics innovation context by explaining that "right now the worst which can happen to somebody who invests in antibiotics is that they succeed because then they will lose more money than when they just have to write off the research expenditure." He applauded the 23 companies that have raised nearly US\$1 billion and underscored that the "intention is to respond to public health needs, with a fund that does provide a lifeline for clinical research where up to now there was no funding available for biotech companies, for start-up companies, for SMEs." His opening remarks were followed by panel discussions on the need to bridge the gap from novel antibiotic invention to patients, while at the same time finding a different type of incentive system in the market that acknowledges the fact that, from a public health perspective, any new antibiotic will need to be kept in reserve.

AMR is a serious challenge - and industry first mover with fund for new antibiotics is welcomed

AMR is a looming global crisis that has the potential to dwarf COVID-19 in terms of deaths and economic costs. And, given the virtual nature of the event, the COVID-19 links were impossible to miss. Nearly all panelists noted how the experience of going through the COVID-19 crisis can help prepare better to tackle AMR.

Dame Sally Davies, UK special ambassador on AMR, explained the health and economic toll of AMR, saying: "We know more than 700,000 people die across the world because of resistance to the treatments they are given,

including around probably 60,000 new-born babies in India every year from sepsis. So clearly this cost to people's happiness, to the health system, is immense ... And the World Bank has done some great work, which is terrifically worrying, that by 2050 more than 28 million people will be pushed into extreme poverty if we don't have effective antimicrobials, antibiotics." French Minister for Industry, Agnès Pannier-Runnacher, added "It is not only a question of health, this is also a question of the economic resilience."

Two Ministers of Health, Jens Spahn, German Federal Minister of Health and Magnus Heunicke, Minister of Health and Senior Citizens of Denmark, took time out from overseeing their respective country's response to COVID-19 to acknowledge the importance of tackling AMR. Spahn said that with COVID-19, "If states, business and science join forces, we will make a difference ... And that is encouraging for this new fund and the initiatives around AMR."

Given the nature of resistance, we will always need new antibiotics. However, drug resistant bacteria are developing faster than new antibiotics can reach the market. This can be seen in the data countries are monitoring and reporting on AMR to the WHO. "The data they provide reveals that resistance to essential medicines to treat infections continues to spread across the world at an alarming rate and the current pipeline of the antibiotics is insufficient," said **Dr Tedros Adhanom Ghebreyesus**, **Director General of WHO**, adding "With private shrinking and public investment unable to fully compensate, the AMR Action Fund will be key to reversing that trajectory, strengthening and accelerating research and development of antibiotics through gamechanging investments into biotechnology companies around the world."

Werner Hoyer, President of the European Investment Bank said: "Looking beyond COVID-19, AMR comes as the next challenge and a growing threat to public health. Regrettably, all efforts in the past were not enough to fill an enormous investment gap and to deliver novel treatment options against priority pathogens. It is of utmost importance that we act now to better cope with expected greater resistance in the future." He added that "no success can be achieved without the value created by partnerships ... We are proud of teaming up with you in the Fund's initiation group."

Praising the AMR Action Fund as the biggest single commitment for antibiotic R&D in the last four years, **Jeremy Farrar, Director of the Wellcome Trust,** said it will provide the urgently needed lifeline for innovators who currently struggle to find investors to support late-stage development, adding "We must ensure that promising products have a more dependable path from early stage discovery to patients who need them in all parts of the world."

Much more than a fund - pharma investors will also share knowhow with biotechs

Participants recognized the key role industry has in addressing AMR and highlighted three key benefits of the Fund: putting in place desperately needed financing and know-how for biotechstart-ups and SMEs to bridge the gap between research and patients; providing a fighting chance for the world to prepare for the next global health crisis; and starting a debate on how to improve the antibiotic pipeline in the long-term.

Talking about the in-kind support that the Fund will provide, beyond the US\$1 billion in funding, **Hubertus von Baumbach, Chairman of the Board of Managing Directors of Boehringer Ingelheim**, said: "We understand very well how products are being researched, how they are being clinically developed, then registered and brought to the market. That's one of the assets that we believe can contribute to this fund ... Money is generic. Money can come from anywhere. We as an investor in this Fund understand the risk profile of the industry, and we know what young companies need. We want them to focus on research and give them the necessary support and the experience that we have (built) for such a long time."

Welcoming the launch of the AMR Action Fund, **Florence Séjourné, CEO of Da Volterra and President of the BEAM Alliance**, said: "The Fund is a wonderful opportunity for BEAM Alliance members. It allows us to believe in the path to reach the market. The Fund will also support with clinical development, regulatory, market-positioning advice which is great for biotechs, as you can never have enough of advice in this highly-complex world of drug development, especially on innovative approach to optimize your chances of success. The midterm and long-term exit strategies for biotechs are absolutely key. The support of a collaborative platform with the industry to restore viable business models for AMR innovation is very important."

However, while participants recognized the AMR Action Fund as a necessary and valuable effort, they noted the necessity of policy changes and efforts by other stakeholders.

Policy reform and multi-stakeholder action are urgently needed

Thomas Cueni, Director General of the IFPMA said: "In the long-term, we will not solve the problem with two to four new antibiotics. Bacteria will continue to become resistant. Therefore, we need longer-term market reforms and we need governments to engage," highlighting that "The small biotech companies who, thanks to different initiatives, are bringing new candidates which need funding for clinical research, are desperate for someone to come up with funding and this is where the Fund will play a major role. But, we also need support from the governments as by the end of the day, we need a long-term solution which will make research into antibiotics interesting again."

The pharmaceutical industry is stepping up to bridge the funding gap, but policymakers need to take action, too. Several policymakers spoke about how regulatory reform and new incentives are needed to bring back investment into antibiotic R&D, so that innovation can reach patients.

No single stakeholder can effectively take on the challenge of AMR, and multi-stakeholder action was highlighted as the way forward. **Dr Tedros Adhanom Ghebreyesus, Director General of the World Health Organization**, said: "No one sector can tackle this challenge alone which is why I welcome the collaboration with the pharmaceutical industry, development banks and philanthropic organizations. This is a new model for public-private partnership: using private sector investment to address global public challenges with guidance from the public sector." In a <u>statement</u> the World Health Organization acknowledged the launch of the <u>AMR Action Fund</u> represents an important step towards revitalizing antibacterial drug development and also creates the opportunity to address the much needed reforms of the current procurement and reimbursement systems for new treatments.

Recognizing the importance of the AMR Action Fund to support biotechs in accessing the market and emboldening the efforts to fight against AMR, **Agnès Pannier-Runacher**, **French Secretary of State for Economy and Finance**, said that existing business models are not working well, and are not enough, calling for urgent reform: "We are going to help the consortium and try to find new models.... we have asked Jean Tirole, French economist and Nobel Prize winner to work on new economic models."

Within the context of Germany's Presidency of the EU, **Minister Spahn** said: "Antimicrobial resistance will get the attention it needs during the German Council presidency." He invited ideas on how to set the right

incentives, and noting the UK approach he said: "I will have another look how well it works, but what we need is in the end concrete tools, concrete approaches, this fund is one and if there are others that can be led by public institutions and the states, I'm happy to engage."

During the discussion, the online audience of over 1,200 people, voiced their support for the AMR Action Fund and their desire to engage. Mark Pearson, Deputy Director of Employment, Labour and Social Affairs at the Organisation for Economic Co-operation and Development (OECD) said: "Congratulations on this wonderful initiative. We would be delighted to add our economic expertise to the necessary debate about the need for pull incentives." John Rex, Chief Medical Officer & Director of F2G said: "The AMR Action Fund announcement today was awesome ... indeed, it brought tears to my eyes. This \$1b down payment from Industry will buy us some time in which to create those pull incentives and ensure that we have a sustainable pipeline of new #FireExtinguishersOffMedicine!"

The event closed with panelists welcoming the game-changing potential the AMR Action Fund will bring in the long-run. There was broad agreement that while in the immediate the fund will bridge the gap in financing of antibiotic research and development, it has already inspired a broadening of the debate and collaboration between the industry, philanthropy and global public health sector.

"This is not a solution in itself; it is a bridging solution. The AMR Action Fund aims to provide a bridge to bring two to four new antibiotics to the market, and is a signal of the industry stepping up and responding to the criticism of exiting the field many years ago, and because there is no economic model right now. We strongly believe we need to re-create this economic model, but we are willing to step up. The companies are willing to invest and provide this bridge.

We now need to kick off the debate on how we can achieve success beyond 2050," said **Thomas Cueni, Director General of IFPMA** in conclusion of the discussion.

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