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Antimicrobial Resistance; Access challenges and addressing the stagnating pipeline of new products in development.

Introduction

AMR occurs when microbes protect themselves from the effects of the antimicrobial drugs that are designed to destroy them. The World Health Organization (WHO) has declared it a top ten global public health threat[1].

AMR was linked to almost five million deaths in 2019, more than both malaria and HIV[2]. In the OECD and EU/EEA, around 1 in 5 infections are now drug resistant, complications caused by AMR is costing almost US$30 million to treat, and the impact on workforce participation and productivity is estimated to be almost US$37 billion[3]. Globally, AMR is on track to put a cumulative US$100 trillion of economic output at risk if no action is taken by 2050[4].

The impact of the COVID-19 pandemic is a stark reminder of the need to focus on global health security and has demonstrated the importance of strengthening preparedness for global health threats such as the one posed by AMR.

Global health security is completely reliant on effective antibiotics. Not only are they needed to treat infection, they also represent the foundation of our health system by ensuring surgeries, transplants, caesarean sections, chemotherapy treatment, and other health procedures that rely on effective infection prevention and control, remain viable.

However, the WHO has warned that the pipeline of antimicrobials in development is "insufficient to tackle the challenge of increasing emergence and spread of AMR"[5].

Key to this is a market failure that makes it economically unviable for companies to develop and bring new antibiotics to patients. As a result, 15 of 18 of the largest pharmaceutical companies have discontinued their antibiotic R&D in the last 30 years. Small companies, often pre-revenue, which have developed new treatments, have gone bankrupt due to the low rates of return and significant costs. For profit venture capital firms are not interested in investing in the sector; in 2020, companies making cancer therapies raised almost 45 times more capital than those making antibiotics.

[1] World Health Organization. 2014. Antimicrobial Resistance Global Report on Surveillance. https://apps.who.int/iris/bitstream/handle/10665/112642/9789241564748_eng.pdf;jsessionid=FAA9126AD29D83C9BD29A1B8EA167FD8?sequence=1

[2] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/fulltext

[3] https://www.oecd-ilibrary.org/docserver/ce44c755-en.pdf?expires=1695866921&id=id&accname=guest&checksum=35C935B7CE102CE4A0BCAEEB1C5FCBA9

[4] Review on Antimicrobial Resistance. https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf

[5] World Health Organisation, (2019), 2019 Antibacterial Agents in Clinical Development – An analysis of the antibacterial clinical development pipeline

The critical need to combat AMR through measures such as addressing antibiotic market failure and strengthening AMR antibiotic R&D is being increasingly acknowledged by leading intergovernmental organisations such as the G7[6,7,8], APEC[9] and the G20[10].

There is now widespread consensus that a combination of 'push' and 'pull' incentives are required to support new discovery, early clinical trials and, for medicines that show promise, suitable reimbursement assessment.

'Push' incentives are critical to help early-stage R&D, and can come in the form of grants and tax incentives. Several global public-private partnerships delivering 'push' incentives have had a positive impact on the antimicrobial R&D pipeline, including the world leading Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) and the AMR Action Fund. More is needed.

Market based, or 'pull' incentives, remain key to creating the sustainable market required that will enable developers to bring their products to the bedside. They are crucial to stimulate the development of new antimicrobials and ensure equitable patient access. 'Pull' incentives work by de-linking payments to companies from the volume of antibiotics sold. Several 'pull' incentives have been trialled or are being considered around the world, including by the National Institute of Healthcare Excellence (NICE) in the UK, and the PASTEUR Act, which has been proposed in the US.

The discussion

The panel will discuss in more detail the critical role antibiotics play in global health security, and discuss the market failure that has resulted in the lack of investment in antibiotic R&D. It will examine the global antibiotic pipeline and explore the roles of both 'push' and 'pull' incentives to impact that pipeline. It will also examine initiatives such as the NICE program and PASTEUR Act, as well as the impact of public-private partnerships focused on the R&D of new therapies, including CARB-X and the AMR Action Fund. The panel will also look at what Australia can do to contribute to global efforts to combat AMR.

About CARB-X

Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) is a global non-profit partnership accelerating antibacterial products to address drug-resistant bacteria. The CARB-X portfolio is the world's most scientifically diverse, early development pipeline of new antibiotics, vaccines, rapid diagnostics and other products. CARB-X is the only global partnership that integrates solutions for the prevention, diagnosis and treatment of life-threatening bacterial infections, translating innovation from basic research to first-in-human clinical trials.

[6] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1040016/AMR_-_G7_Finance_Ministers_statement_on_supporting_antibiotic_development_-_final_-_13_Dec_2021.pdf
[7] https://www.g7germany.de/resource/blob/974430/2042058/5651daa321517b089cdccfaffd1e37a1/2022-05-20-g7-health-ministers-communique-data.pdf?download=1
[8] https://www.consilium.europa.eu/media/57555/2022-06-28-leaders-communique-data.pdf
[9] https://www.apec.org/meeting-papers/sectoral-ministerial-meetings/health/chair-s-statement-of-the-13th-apec-high-level-meeting-on-health-and-the-economy
[10] https://www.consilium.europa.eu/media/66739/g20-new-delhi-leaders-declaration.pdf

About AAMRNet

AAMRNet is Australia's leading multi-stakeholder expert group committed to combating the global threat of AMR. AAMRNet is a public-private-partnership, established and operated by MTPConnect, Australia's life sciences innovation accelerator, with the support of Pfizer ANZ, CSIRO, MSD Australia, GSK Australia, Recce Pharmaceuticals, Botanix Pharmaceuticals, SpeeDx, Medicines Australia, Tenmile, Biointelect, Monash Centre to Impact AMR and Bugworks Australia. Its members and stakeholders include universities, not-for-profits, researchers, SMEs and large multinational companies, industry peak bodies, clinicians, patients, and government. AAMRNet provides a unified voice to support and promote Australia's role in the global fight against the growing threat of drugs resistant infections. By providing this whole-of-sector representation, AAMRNet is uniquely placed to promote Australia's role in the fight against AMR and help inform government priorities and strategies.