



Meeting of the All Party Parliamentary Group on Antibiotics held on
Wednesday 30 November 2016, 1600-1800hrs in the Macmillan Suite, Portcullis House

Discovery, Research and Development of New Antibiotics

Chairs: **Julian Sturdy, MP**

Keynote Speakers: **Professor Kevin Outterson, Executive director, Professor of Law and the N.
Neal Pike Scholar in Health & Disability Law, Boston University, USA
Mr Peter Jackson, AMR Centre, UK**

Attendees The meeting was attended by approximately 57 individuals.

Introduction

MP Julian Sturdy opened the meeting with a brief background on the issue of antimicrobial resistance (AMR) and the purpose of the meeting. He introduced the two keynote speakers, Prof Kevin Outterson and Dr Peter Jackson. He highlighted the interest that the APPG has on how the UK government will take forward recommendations by the Review on Antimicrobial Resistance. He reminded the audience that the organizations with which the speakers are affiliated, the Longitude Prize, DRIVE-AB, CARB-X and the AMR Centre, are making great strides in attempting to address the current gaps in antibiotic research and development (R&D).

Economic models to stimulate antibiotic development

Kevin Outterson

Driving innovation

- Prof Outterson emphasized some of the key issues in antibiotic R&D that need to be considered in any long-term solution, including:
 - o the need to pay for antibiotics based on their societal value rather than the volume of sales,
 - o global access to antibiotics is an issue (more children die from lack of treatment of infections than from AMR infections),
 - o conservation and stewardship can undermine innovation,
 - o conservation, access and innovation need to be tackled in parallel,
 - o a One Health approach (human, agricultural and environmental sector collaboration) is important.

- He discussed the necessity of both push (early discovery) and pull (market entry) incentives for antibiotic development, including market entry rewards (a push incentive).

Market entry rewards

Prof Outtersson described the concept of market entry rewards and laid out some recommendations on what these rewards might look like:

- Developers would receive a guaranteed reward for developing a treatment that meets identified unmet public health needs/targets.
- Reward size should vary with the target product profile and quality, be spread over five years regardless of sales volume, and stipulate that commitments must be made to stewardship and global access efforts.
- Estimated reward size should be a minimum of 1 billion USD according to existing research (reports by Sertkaya et al, Sharma and Towse and the Review on Antimicrobial Resistance).
- Funding of these rewards can be based on a number of models including;
 - o “Pay or Play” (as most pharmaceutical products rely on antibiotics to treat infections in the target patient, companies who do not contribute to solving the problem should pay towards the innovation fund),
 - o “User Fees” (users of antibiotics are taxed and revenues are used to fund innovation; this may not be applicable to low- and middle-income countries),
 - o and “Transferable Exclusivity Vouchers” (this may only be appropriate in the United States).

Accelerating the antibiotics pipeline: CARB-X and AMRC

Peter Jackson

- Dr Jackson emphasized the need for push incentives to complement the pull incentives discussed by Prof Outtersson and to address the capacity and capability gap in the UK and other countries with relatively small numbers of researchers focusing on tackling antimicrobial resistance.
- He highlighted that while AMR rates are increasing, available treatment options and innovation are decreasing.
 - o The number of antibiotics approved by regulators has been decreasing over the past four years.
 - o There are fewer than 200 research scientists in the UK currently focusing on AMR, compared to more than 40,000 researchers currently funded by Cancer Research UK.
- He cited two programmes that he is involved in which focus on providing push incentives: CARB-X and the Antimicrobial Resistance Centre.

- Discussing the scale of the challenge and the level of funding required, Dr Jackson reminded the audience of the very high failure rates associated with antibiotic development (of 64 drug development programme, usually one product makes it to market). He indicated that a push incentive of 600 million to 2 billion USD per product would be reasonable.

CARB-X

The CARB-X program is designed to facilitate the translational stage between discovery and clinical trials for treatments for bacterial infections. The first two call rounds have received over 300 expressions of interest and are requesting a total of more than 1 billion USD in funding. Year one of the CARB-X programme will focus on supporting SMEs with innovative approaches to targeting urgent Gram-negative bacterial infections.

UK AMR Centre

The AMR Centre, a part of the CARB-X consortium, was initiated to address the capacity and capability gap in the UK by providing funding and resources to bring pre-clinical ideas from universities and small/medium enterprises (SMEs) through to clinical trials. The Centre also promotes collaboration between academia, SMEs and large pharmaceutical companies.

- The Centre aims to initiate their first five funded programs in 2017, with the first funded project beginning Q1 2017, and have these reach the clinic by 2022.
- The first two call rounds have generated 350 applications.

Discussions of the presentations focused on the need for guaranteed support from governments to provide long-term, sustainable funding.