Survey of actors involved in the development of antimicrobials:

High level results – February 2015 published by the Review on Antimicrobial Resistance.

The Review on Antimicrobial Resistance has thus far devoted a large amount of time engaging with the actors involved in AMR and the problems with developing new antimicrobials to understand what problems they face. To facilitate this understanding we sent a survey to a large number of pharmaceutical companies, research funders and investors to gain a better understanding of the decisions they make with regards to antimicrobials. The survey had sixty responses. 40% of responses were from countries where English is not the first language. Responses also came from a wide range of large and small companies, highlighting the survey’s diversity.

While we were happy with the response rate it would have benefited from a larger sample, and there are some inherent self-selection issues in terms of most responses coming from organisations which do have some existing interest in antimicrobials, so while this research was important it is by no means perfect. This is only one small component of the analysis undertaken to to form the Reviews overall recommendations.

Break down of respondents

Here we provide a summary of some of the key findings of this survey:

**Barriers**

- 70% of companies who invested in antibiotics in the early 1990s made a profit from their investments while 30% did not. Therefore there has been profit from past investment.
- However, despite this the biggest barrier to investment was seen as being economic, with almost 80% of companies describing this as the main reason for not investing.
• The scientific challenge was highlighted to be a major factor in the early stages of development with many firms saying there is general difficulty in finding new and novel antibiotics.

• Regulation is perceived to be a problem later in the drug development process. 70% of companies thought the FDA was too rigid and 55% thought the same of the EMA. While recent changes in both organisations were hugely welcomed, many believe that they could go further. Some respondents suggested that the two organisations are too worried about being misled by industry because of previous interactions, and that the FDA in particular is often worried about litigation.

**What is the biggest risk at each stage?**

![Graph showing the biggest risk at each stage (Preclinical, phase 1, phase 2, phase 3)]

- Reimbursement risk
- Regulatory risk
- Scientific risk

**Focus of research and investment decisions**

• Most firms looking at antibiotics were focusing on narrow and broad spectrum drugs.

• All firms looking at antibiotics were focusing on gram-negative antibiotics.

• There were a range of approaches cited with respect to capital allocation. Amongst for profit entities, 40% use a Net Present Value approach, 20% focus of multiple on investment capital, 10% reference an internal rate of return and the remainder use a variety of approaches that typically include an assessment of medical need.

• Discount rates vary widely between companies.

• The US and large EU countries seem to be the main focus for most companies when assessing market potential, though China and India were also viewed by some as important.

**Partnering**

• Almost all respondents wanted more opportunities to partner with other organisations
More than half favour open access systems where organisations share their research, although the consensus within the responding sample is that this should be voluntary and not government enforced.

Many companies stated a particular desire to work with academics doing early stage research. Smaller companies also look to either work with or sell to big pharma.

**Solutions**

Respondents were asked for their opinions on a range of initiatives to increase investment in antimicrobials, per the below graph. Grant funding was particularly popular with smaller companies.

**Our thoughts**

We are hugely grateful to the large number of people who took time to respond to our survey and share their thoughts. As we continue to develop our thinking about how incentives might need to change to encourage research and development of new antimicrobials, we will continue to seek input from industry and academia, along with governments, funders and regulators.

We would also like to thank Joanna Scott in the Wellcome Trust evaluations team, for her help putting the survey together.

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1 Treating certain antibiotics as 'high cost drugs' in hospitals, reimbursed separately from bundled provider payments.