NHS England Antimicrobial Products Subscription Model Consultation

The Microbiology Society is a membership charity for scientists interested in microbes, their effects and their practical uses. It is one of the largest microbiology societies in Europe with a worldwide membership based in universities, industry, hospitals, research institutes and schools. Microbiology is the study of all living organisms that are too small to be visible with the naked eye.

Our principal goal is to develop, expand and strengthen the networks available to our members so that the science of microbiology provides maximum benefit to society.

We note that our submission reflects the views expressed by five members of the Microbiology Society who responded to our call for input. We present evidence provided by our respondents and provide recommendations where appropriate.

1. Consultation questions

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / NA
To what extent do you agree or disagree with the purpose of the Antimicrobial Products Subscription Model?	☒	☐	☐	☐	☐	☐
Comments	It was reported to us that the piloted subscription model for antimicrobials has been well received by the clinical community. Pharmaceutical companies have taken note of this new, financially viable route to enter into the antimicrobial development field, and we are optimistic that it could reinvigorate the antimicrobial pipeline moving forward. Most endeavours to screen for new antimicrobials are currently done by not-for-profits and academics, so this initiative could work to re-engage pharmaceutical companies in the screening process. However, the scheme is lacking clear definitions of success, and it is not clear exactly how the subscription model was successful. This means there is a risk that other nations will follow suit before the model has proven to be effective. Designing the framework was a time consuming and expensive process, so it is yet to be seen whether this is a cost-effective way to bring antimicrobials to clinical use. As this model will significantly increase the amount of public money going to pharmaceutical companies, robust metrics of success that are evaluated					

	by external, independent assessors are needed before the scheme can be considered successful. It is also worth noting that, while we strongly support the initiative, it is one of many that could be effective. Until the model proves to be truly transformative, it is important that we continue to investigate alternative mechanisms that could stimulate research and development into novel antimicrobials.					
To what extent do you agree or disagree with the overall procurement process outlined in the Guidance on Commercial Arrangements for Antimicrobial Products?	☐	☐	☐	☐	☐	☒
Comments	N/A					
To what extent do you agree or disagree with having an eligibility stage prior to the procurement process?	☒	☐	☐	☐	☐	☐
Comments	We strongly agree that an eligibility stage is necessary.					
To what extent do you agree or disagree that the eligibility criteria should be based on WHO priority pathogens?	☐	☒	☐	☐	☐	☐
Comments	We recognise that the initiative is expensive and cannot be used to subsidise all drug development research. We therefore agree that the eligibility criteria should be based on WHO priority pathogens. However, the list of priority pathogens does not represent the full plethora of pathogens of concern, so this should not be to the detriment of research into non-priority pathogens. For instance, *Mycobacterium tuberculosis,* the causative agent of tuberculosis, is not currently a priority pathogen, but in 2021, an estimated 10.6 million people fell ill with TB worldwide. The subscription scheme should apply to priority pathogens but we advise making funding readily available through alternative schemes for antimicrobial development targeted at non-priority pathogens. It is also important to consider that future epi/pandemics could be caused by resistant bacteria that are not included in the WHO priority pathogen list. To ensure that the scheme can be applied when new antimicrobials are needed to combat non-priority pathogens in emergency scenarios, there needs to be an element of agility in the eligibility criteria.					
To what extent do you agree or disagree with the opportunity	☐	☒	☐	☐	☐	☐

for companies to obtain clarification?						
Comments	We agree that providing an opportunity for companies to obtain clarification will accelerate and smooth the application process. However, if companies are able to repeatedly change their applications throughout the process, this could result in a heavy administrative load. A potential solution could be providing opportunities for clarification in the pre-application process, rather than throughout the entire application process. New companies applying for the scheme must be thoroughly assessed and scrutinised to ensure that they have good track records for antimicrobial development, infrastructure for research and in-house clinical expertise. This will prevent misappropriation of public funds.					
To what extent do you agree or disagree that the three main categories describe the main areas of value?	☐	☒	☐	☐	☐	☐
Comments	We agree with the three main categories outlined in the document.					
To what extent do you agree or disagree that the criteria in each category will allow for differentiation between products?	☐	☒	☐	☐	☐	☐
Comments	We agree that the criteria outlined are comprehensive, however it was noted that the health system benefits could be broadened, for instance to include improved health of patients, long-term quality of life, and benefits to international development. We do however recognise that these may be difficult to quantify. It is worth considering that certain effective antimicrobial products might not fulfil the criteria. For instance, there are antibiotics that reduce virulence rather than kill bacteria (e.g., beta-lactam antibiotics that interrupt cell wall formation), that wouldn't fulfil the criteria despite being effective. If the initiative seeks to encourage novelty, expanding the criteria could allow for inclusion of these non-traditional antimicrobial agents.					
To what extent do you agree or disagree with the scoring approach for each criteria?	☒	☐	☐	☐	☐	☐
Comments	We strongly agree with the scoring approach for each criteria.					
To what extent do you agree or disagree with the weighting attributed to each criteria?	☐	☒	☐	☐	☐	☐

Comments	While we mostly agree that the weighting attributed to each criteria makes sense, it was noted that 'adverse events' is critical and could be rated higher. Our members also expressed concerns that novelty (both 'chemical entity novelty' and 'target site novelty') is underscored, which could stifle innovation. For instance, novel products such as topical antimicrobials might not score well using this framework. Giving more weight to these criteria could further incentivise innovation. To verify that the weighting makes sense, we suggest scoring well known antibiotics using the criteria to determine whether the score accurately reflects their value to the NHS.					
To what extent do you agree or disagree with the four value bands being proposed for the contract?	☐	☐	☐	☐	☐	☒
Comments	N/A					
To what extent do you agree or disagree with key performance indicators on surety of supply and compliance with good stewardship practice?	☒	☐	☐	☐	☐	☐
Comments	We strongly agree with the key performance indicators outlined in the document. Additionally, if we are to keep pace with the emergence of resistant organisms, it is crucial that the pipeline is always full of new antimicrobial agents that are continuously being developed. We recognise that this is difficult to achieve, and that the global pipeline needs significant reform before this can be realised. We suggest introducing an additional indicator to ensure companies are continuing to innovate and develop new antimicrobials, even after the contract has been awarded. This will encourage companies that are locked in to the scheme to continue to invest in developing new antimicrobial products. We also re-iterate that evaluating the true impact of the scheme will require robust, clearly defined, independently measured metrics of success.					
To what extent do you agree or disagree with the length of contract being proposed?	☐	☒	☐	☐	☐	☐
Comments	We agree with the length of contract being proposed. It is worth considering that if the contract period is too long, this could de-incentivise companies to continuously innovate by screening for and developing new antimicrobials throughout the 15-year lifespan of the contract. It is important that, once contracts are awarded, companies do					

	not cease their antimicrobial discovery and development activities, and instead continue to invest in innovation and bringing new antimicrobial drugs to market. There is also the possibility that a 15-year contract will be awarded for a drug that could become obsolete due to the emergence of resistance. Incremental renewal and review processes would ensure that the drug is still fulfilling the eligibility requirements and meeting the agreed criteria.
Are there any aspects of the Antimicrobial Products Subscription Model that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation?	No comment.
Conflict of interest disclosures: have you or the organisation you represent received any payments, grants or other funding from the pharmaceutical and life science industry in the last three years?	Yes. The Microbiology Society has received approximately £500,000 from the pharmaceutical and life science industry in the last 3-years. These payments were primarily to sponsor or exhibit at Society events, and do not fund or influence other Society activities. Individual members that contributed to this consultation response have in the last three years received: • ~£900 from *Bayer* • ~£400,000 from *GlaxoSmithKline* • ~£180,000 from *CC Bio* through *Innovate UK* • ~£1,500 from consultations with the pharmaceutical industry