Consultation: The Antimicrobial Products Subscription Model

Introduction

The BIA is responding to this consultation on behalf of our members, a number of which are engaged in efforts to tackle the threat posed by antimicrobial resistance (AMR) by developing novel antimicrobials. Over the past decade, the UK has established itself as a leader in addressing the AMR challenge, working across government and industry to deliver outstanding science, collaborative policy leadership and committed funding. The BIA has strongly supported these efforts, including by drawing attention to the challenge of AMR and working with policymakers to deliver solutions.

Following the launch of the pilot scheme for the antimicrobial products subscription model in 2022, the BIA welcomes this consultation on the proposals to extend this approach to more antimicrobial products and across the four nations of the UK. The UK is the first country in the world to implement a subscription-based payment model for antimicrobials, and this represents a significant step forward in developing the necessary global pull incentive to stimulate the required investment.

About the BIA

The BioIndustry Association (BIA) is the trade association for innovative life sciences and biotech industry in the UK, counting over 500 companies including start-ups, biotechnology, universities, research centres, investors and lawyers among its members. Our mission is to be the voice of the industry, enabling and connecting the UK ecosystem so that businesses can start, grow and deliver world-changing innovation.

The BIA represents the interests of its members to a broad section of stakeholders, from government and regulators to patient groups and the media. We also work with organisations at an international level to ensure that UK biotech is represented on the global stage including EuropaBio, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Council of Biotechnology Associations (ICBA).

The BIA is the key thought leader for the sector, operating across a wide range of areas such as policy, finance, science, regulatory, legal, skills and talent as well as genomics, engineering biology and techbio.

Summary of recommendations

The BIA strongly supports the purpose of the antimicrobial products subscription model in stimulating investment into R&D for novel antimicrobials. To make sure that the model is as effective as possible, the BIA has made a number of recommendations, set out in the consultation response below. These recommendations include:

- Revising the proposed non-clinical eligibility criteria to ensure that they do not inadvertently exclude smaller companies
- Making changes to the proposed scoring system to ensure that the non-standard and narrow-spectrum approaches are not undervalued
- Revising the proposed evidence requirements to ensure that they are realistic for companies to deliver
- Enabling a greater dialogue between the authorities and companies throughout the both the tendering and scoring process to reduce the risk of process failing
- Introducing a pre-qualification mechanism to flag pipeline products as potentially being eligible for the subsciption model and stimulate early-stage investment

Consultation questions

Section 2: Introduction

i. To what extent do you agree or disagree with purpose of the Antimicrobial Products Subscription Model? *Strongly agree*

Comments: The BIA strongly agrees with the purpose of the Antimicrobial Products Subscription Model. AMR poses a significant threat to public health, both in the UK and globally, and new antimicrobials are urgently required to replace those drugs which are no longer effective. UK researchers and biotech companies are helping address this challenge by developing next-generation antimicrobial drugs. However, the traditional market model fails to provide sufficient incentives for R&D into novel antimicrobial drugs, and it is therefore imperative that other models are developed which reward innovation in this area. As well as providing a signficiant pull incentive for antimicrobial development, the model has the potential to encourage greater early-stage investment into antimicrobial R&D, thereby increasing the push incentive too.

The UK will be the first country in the world to implement a subscription-based payment model for antibiotics, and it is very positive that the proposed model will include all four nations of the UK. By determining the price of each drug based on its value to the NHS, the UK is leading the way in the global fight against AMR through the development of system which incentivises investment into novel antimicrobials. Health systems across the world will be learning from UK experience as they develop their own systems to incentivise antimicrobial development, hopefully leading to more investment, start-ups and product launches in the antimicrobial space.

Section 3: Key features of the Antimicrobial Products Subscription Model

Route to commissioning

i. To what extent do you agree or disagree with the overall procurement process outlined in the Guidance on Commercial Arrangements for Antimicrobial Products? *Neither agree nor disagree*

ii. To what extent do you agree or disagree with having an eligibility stage prior to the procurement process? *Agree*

iii. To what extent do you agree or disagree that the eligibility criteria should be based on WHO priority pathogens? *Agree*

Comments:

The BIA agrees that an eligibility stage prior to the procurement process is necessary, however we do not agree with all the criteria included in the eligibility stage.

The BIA agrees eligibility criteria should be based primarily on WHO priority pathogens. However, to ensure that the UK model maintains broad equivalence with the US PASTEUR Act and other international models, it will be important for the UK to also consider the pathogens prioritised by the US Centers for Disease Control and Prevention (CDC). It is also important that for the model to consider UK-specific priority pathogens and that there is flexibility for the model to be adapted in response to urgent local threats.

The BIA is concerned that some of the non-clinical eligibility criteria could present significant challenges for small and medium-sized companies. For example, the eligibility criterion for "surety of supply" risks inadvertently excluding many SMEs from the model, as it will be very difficult for many smaller companies to demonstrate that they have enough capacity to supply the NHS under any circumstances. Some flexibility is required on this criterion with regard to smaller companies and exceptional circumstances, otherwise the model will not be a commercially viable option for many companies.

Similarly, the requirement for companies to demonstrate sufficient "economic and financial standing" could also result in the exclusion of many smaller biotechs with low levels of capitalisation and cash reserves. This is especially concerning when most R&D into novel antimicrobial drugs is being conducted by biotechs, with a 2021 report from the Access to Medicines Foundation finding that 75% of all projects active in late-stage antibacterial R&D are developed by SMEs. SMEs in the AMR space face significant barriers to growth due to low levels of investment and high R&D costs, and there needs to be recognition of this in the model to ensure that it works for companies of all sizes.

The opportunity to tender should be open to new and existing antimicrobials, and not limited to products that obtained UK market authorisation since the previous annual invitation to tender or expect UK marketing authorisation within 12 months. Given evidence is generated throughout a

product's lifecycle, this would allow companies to submit at a time where their evidence dossier is strongest.

Throughout the proposed process, there are limited opportunities for companies to engage with the authorities. The BIA recommends that a greater dialogue between the authorities and stakeholders is enabled, as this would allow the authorities to seek necessary clarifications and reduce the risk of the process failing. An element of the process that would particularly benefit from greater engagement is the decision on the target population and place in therapy. The proposals states that "Applicants will be advised of the proposed scope, which must be accepted as a condition of progressing to the award stage". Given that this step takes place prior to the company submission of the full evidence package, it will require a dialogue between the company and authorities to avoid situations where the company is unable to accept the proposed scope. A meeting could be held between the company and the eligibility panel to allow the applicant to present their proposed population and the rationale behind it, which would then allow for a discussion of the issues before a decision is made.

The subscription model could be complemented by the introduction of a pre-qualification mechanism, similar to the US Qualifying Infectious Disease Product (QIDP). The mechanism would help to flag pipeline products as potentially being eligible for the subsciption model, providing an important signal to industry and investors that an early-stage product has strong potential to be moved through the clinical pathway, supporting investment into AMR research. It would also help to support horizon scanning for novel antimicrobials, encouraging early engagement between developers and the authorities. This could work similarly to the UK's Innovative Licensing and Access Pathway (ILAP), which aims to accelerate patient access to innovative medicines. It would be important that such a mechanism for antimicrobial drugs has sufficient resources and expertise behind it. The pre-qualification mechanism would also need appropriate methodology to evaluate novel approaches, such as phage therapies and monoclonal antibodies, to ensure that viable novel approaches are not inadvertently excluded or undervalued.

Opportunities for companies to obtain clarification

i. To what extent do you agree or disagree with the opportunity for companies to obtain clarification? *Neither agree nor disagree*

Comments:

It is important that companies can obtain clarification from the authority to fully understand the requirements. It is also important that the process is as transparent as possible, and the BIA therefore agrees that any clarification information provided to a company in response to a question received during the eligibility or evaluation stage may be shared with all companies applying for a contract. It is important that confidentiality requirements are maintained, and companies are able to request that certain company-specific information is redacted.

The BIA believes that the process would benefit from more extensive engagement between the authorities and companies beyond the opportunity for companies to obtain clarification, as proposed in the comments provided in the previous section.

Award criteria and scoring mechanism

i. To what extent do you agree or disagree that the three main categories describe the main areas of value? *Agree*

ii. To what extent do you agree or disagree that the criteria in each category will allow for differentiation between products? *Neither agree nor disagree*

iii. To what extent do you agree or disagree with the scoring approach for each criteria? *Disagree*

iv. To what extent do you agree or disagree with the weighting attributed to each criteria? *Neither agree nor disagree*

Comments:

The BIA agrees on the need to develop a scoring mechanism and that the three main categories (relative effectiveness and unmet clinical need; pharmacological benefit; and health system benefit) describe the main areas of value.

There is a risk that the scoring system could inadvertently under-value non-standard and narrow-spectrum approaches, which could disadvantage innovative biotechs. For example, some novel antimicrobial pipeline agents offer value by renewing existing antimicrobials coverage against the most resistant pathogens. However, the current scoring system assumes that a product is only valuable on its own or as part of a particular fixed combination and can only be scored as such. The scoring system should be adapted to ensure that it captures the value of these innovative products.

The BIA is concerned that the guidance on some evidence requirements is unrealistic or would be very challenging to deliver, especially for smaller companies. For example, in Criterion 1C, the requirement for companies to provide a systematic review of all evidence on UK unmet need, would be particularly burdensome. The scoring system could instead assess UK unmet need based on the latest data from the English surveillance programme for antimicrobial utilisation and resistance (ESPAUR) report. Furthermore, for Criterion 1D, the four highest scoring levels include randomised clinical trial evidence which is not possible to attain for highly resistant infections due to international regulatory standards. This criterion could risk devaluing antimicrobials for the most resistant pathogens and should be revised to avoid this.

More detail is required on the extent to which the evaluation panel is able take into account benefits of the product which are not adequately captured by the scoring system, especially as this was necessary during the pilot. For example, clarification is required on what evidence the committee will be able to consider other than the results from the scoring system.

The BIA believes that there should be a mechanism for companies to appeal decisions made by the evaluation panel. There should also be scope for the evaluation panel to engage with companies throughout the scoring process, including to ask questions and seek clarifications about the evidence provided. The scoring process should follow NICE best practices in medicines evaluation, allowing for companies and other stakeholders, such as patient advocacy groups, to engage in the process.

Model contract

i. To what extent do you agree or disagree with the four value bands being proposed for the contract? *Neither agree nor disagree*

ii. To what extent do you agree or disagree with key performance indicators on surety of supply and compliance with good stewardship practice? *Neither agree nor disagree*

iii. To what extent do you agree or disagree with the length of contract being proposed? *Neither agree nor disagree*

Comments:

The BIA welcomes the decision to increase the maximum value band to £20m per year as this will enable the UK to contribute its fair share of the global pull incentive required. It is important that the scoring system enable products of significant value to the NHS to be awarded the higher value bands. With the proposed scoring system, there is a danger that many products would be undervalued as there are significant differences in value between the bands and scores are rounded down rather than up. This issue could be addressed by using more granular value bands, for example in intervals of £2m.

While the BIA understands the need to ensure that companies to be able to meet NHS demand for their product, we are concerned that the key performance indicators on "surety of supply" will inadvertently exclude many SMEs from the model. The example contract from the pilot scheme stipulated that the suppliers had to "maintain physically within England, sufficient stock to satisfy at least 6 months of the anticipated demand in England". Such a requirement may be challenging for many SMEs due to limited financial headroom. Given that most R&D into novel antimicrobial drugs is being conducted by biotechs, it could severely undermine the effectiveness of the model if it is only accessible to large pharmaceutical companies. Furthermore, it could raise ethical concerns for the UK to hold so much stock of antimicrobials when they could be used in other countries with more urgent need. The BIA recommends that there is a degree of flexibility on the key performance indicators for surety of supply for SMEs, to recognise the environment in which these companies operate. Support could also be provided to these companies to help them to ensure that they are able to meet future NHS demand for their product. Flexibility should also be provided with regard to exceptional circumstances of unexpectedly high demand, such as during a global pandemic.

The BIA agrees with the requirement for companies to comply with good stewardship practice and supports companies playing a role in the education of healthcare professionals regarding

appropriate use of the antimicrobial. However, it is important that smaller companies are not penalised for conducting fewer educational events and activities than larger companies.

The BIA agrees that the contracts should be able to cover a maximum total period of up to 15 years to cover the patent exclusivity period of the product. However, the BIA is concerned that the proposal for an initial three-year contract with the authorities retaining the right to terminate the contract could create uncertainty, thereby undermining the aim of the subscription model to enable companies to reliably forecast their return on investment and encourage private investment into companies developing new antimicrobials. The model could also be undermined by the authorities having the ability to move products between the value bands at any time. Further detail should be provided on the circumstances in which the authorities would terminate the contract or move the product into a different value band.