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NHS England

The Antimicrobial Products Subscription Model: Consultation on Proposals

Version 1, 10 July 2023

Contents

How do I make my views known?

This consultation is published by NHS England on behalf of all nation of the UK who may participate in the Antimicrobial Products Subscription Model. We welcome your comments on our proposals for the Antimicrobial Products Subscription Model. There are three accompanying documents:

- Antimicrobial Products Subscription Model: Guidance on Commercial Arrangements;
- Antimicrobial Products Subscription Model: Product Award Criteria;
- Antimicrobial Products Subscription Model: Model Contract from Pilot Project

This public engagement is open for 12 weeks, from 10th July 2023 until midnight on 2nd October 2023. You can respond by:

(a) completing the online engagement at www.engage.england.nhs.uk
(b) downloading and printing a copy of the consultation response form at www.engage.england.nhs.uk, and sending your completed form to Medicines Policy and Analysis Team, NHS England, Wellington House, 133-135 Waterloo Road, London, SE1 8UG.

Alternatively, you can ask for a copy of the consultation response form to be posted to you. Please contact: england.antimicrobialsubscriptionmodel@nhs.net.

We would like to hear from anyone with an interest in the subject of the engagement. We expect that the majority of interest will come from the pharmaceutical industry. We are always committed to involving patients and potential future patients in the development of our policies and are keen to hear from patients, carers and patient representatives on these proposals for an Antimicrobial Product Subscription Model.

Your responses will be public documents and all, or any part, of a response may be publicly available. If you wish to refer to confidential information in your response, please provide it in a separate document and clearly mark each page ‘confidential’.

NHS England is subject to the Freedom of Information Act. While we respect the confidentiality of any information provided to them, you should be aware that we may be obliged to release even confidential information under that Act. Please do not include sensitive personal data in your response.

Post-engagement

Following this engagement, NHS England, NICE and the Devolved Governments will consider all relevant feedback. We are expecting a large number of responses and because of this, we expect to publish feedback on the NHS England website in the form of a thematic report summarising all the material issues raised. The feedback will be used to amend the final guidance document which will also be subject to legal review.

Anyone responding to this engagement should note that engagement responses may be published in full as part of NHS England's, the Devolved Government's and NICE's commitment to openness and transparency.

Engagement questions

Engagement questions are included in annex A. We look forward to receiving your responses.

1. Background and purpose

1. This document sets out our proposals for establishing an Antimicrobial Products Subscription Model. The subscription model will offer a contract with a fixed annual fee, that is delinked from the volume of the product used, for products that meet the eligibility criteria and offer value for money to the NHS.

2. No new classes of antibiotic have been discovered since the 1980s. This, together with the increased, and inappropriate, use of the drugs we already have, means we are heading rapidly towards a world in which our antibiotics no longer work.

3. For most antimicrobials, there are few replacements or alternative products in development and even fewer that target priority pathogens. Investment in novel antimicrobials is widely seen as commercially unattractive, because high research and development costs and low returns (due to restrictions in uptake to slow down resistance) have led to market failure, i.e. companies do not see the return on investment seen with other innovative products where uptake is encouraged rather than restricted.

4. The ideal scenario would be for companies to develop and manufacture new antimicrobials which are used optimally in line with good stewardship. However, this is not currently a viable commercial model for companies.

5. The commissioning authorities recognise that the characteristics of the market for antimicrobial products – specifically the need for clinical stewardship – undermines the normal business model for pharmaceutical companies developing antimicrobials. While good stewardship means prescribing the right antimicrobial to treat the right pathogen at the right time, strategies to preserve the effectiveness of new products often means that they are used very little in the first few years after they have received marketing authorisation.

6. Low usage means low sales revenue for companies in those early years and mainstream use may only be achieved many years later when the patent protection and marketing exclusivity period may have expired. As a result, many large pharmaceutical companies have scaled back their research and

development programmes for antimicrobial products and small companies find it difficult to raise finance for product development, further contributing to a reduced pipeline of new products.

7. The UK Government's national action plan for antimicrobial resistance includes the commitment to lead the way in testing solutions that address the failure of companies to invest in the development of new antimicrobials, by evaluating and paying for selected antimicrobial products in a different way from other medicines. To meet this commitment, in a world first, the NHS in England, in partnership with NICE, implemented a pilot project to test an innovative model that pays companies a fixed annual fee for antimicrobials based primarily on a health technology assessment of their value to the NHS, as opposed to the volumes used.

8. The project team launched a joint pilot project in July 2019, and selected two antimicrobial products for the pilot in December 2020. In Spring 2022, the project reached a major milestone by completing the evaluation process and publishing NICE guidance which informed commercial discussions between NHS England and the two antimicrobial companies involved in the pilot. The project delivered a global first of awarding subscription style contracts in July 2022 in which payments are delinked from volume used. The pilot has proven to be a success and demonstrates a route to commissioning antimicrobial products that may be adopted by other countries. This work supports the need to explore "practical market incentive options" as mandated by the G20 leaders' statement in 2017 to address the urgent issue of bringing new antibiotics to market by stimulating the pipeline for antimicrobials.

9. The pilot project provided the first health economic quantification of the full value of two important antimicrobial products, by capturing the population health benefits that extend beyond the benefits for people receiving the drug. Despite several sources of uncertainty, the pilot showed that products targeting difficult-to-treat drug-resistant pathogens, designated as a global priority by the World Health Organisation (WHO), can have sufficient value to the NHS to justify subscription-style contracts. In light of this important conclusion and other lessons learnt from the joint pilot, NHS England and NICE have developed a more pragmatic approach to determine the value of the contract payments for products that qualify for the Antimicrobial Products Subscription Model. This should shorten the time between products coming to

market and contracts being in place. The approach to evaluating products will use clinical award criteria with a points-based scoring system, which are provided in a separate document *Antimicrobial Products Subscription Model: Product Award Criteria* accompanying this consultation.

10. This document consults on proposals for the commissioning route for antimicrobials that offer exceptional value to the NHS based on meeting a set of clear clinical criteria. This route will delink payments from the volume used while having appropriate contractual requirements to guarantee surety of supply. Not all products will qualify for a subscription style contract. Companies with products that do not qualify should follow the standard routes to market for launching a medicine in the UK. Products that are not eligible for a subscription style contract will not require a health technology assessment by NICE.

11. **Section 2** of this document introduces the Antimicrobial Products Subscription Model and **Section 3** outlines its key features, including detail on how the routes to evaluating and commissioning will work in practice. **Section 4** gives information on the need for the process to comply with Public Contract Regulations.

2. Introduction to the Antimicrobial Products Subscription Model

12. The Commercial Framework for New Medicines gives more detail on how NHS England work in partnership with NICE and companies on commercial medicines activity to deliver patient access to proven, affordable and transformative medicines in a financially sustainable way.

13. Typically, new branded pharmaceuticals in England are expected to undergo an appropriate NICE health technology assessment (HTA) unless there is a clear rationale not to do so. The HTA typically leads to a recommendation for routine use if deemed clinically- and cost- effective, which is accompanied by a funding mandate.

14. The route to commissioning antimicrobial products differs from other medicines. For antimicrobial products, a NICE HTA is not normally undertaken. Instead, the standard route is simply to seek a price listing from the Department of Health and Social Care (DHSC) once marketing authorisation has been granted.

15. Under the proposed new arrangements, companies with antimicrobials that offer significant value to patients and the NHS may apply for a subscription style contract. These will be assessed against eligibility and award criteria that have been co-developed by NICE and NHS England and will be published by the Lead Authority. The Lead Authority will run the procurement process of the Antimicrobial Products Subscription Model, in compliance with Public Contract Regulations. In this model, payments are delinked from volume used and contractual requirements guarantee surety of supply.

16. Companies with products seeking to apply for a subscription-style contract will need to provide evidence to demonstrate that the company and product meet clear clinical and non-clinical eligibility criteria. Eligible products will then be assessed against clinical award criteria based on a further evidence submission from the company.

17. This process will be undertaken on a periodic basis to enable new products to apply. NHS England currently anticipate undertaking the process every 12 months. Products that do not meet the eligibility criteria for a subscription style contract will still be able to access the NHS market via the standard route. The steps of the commissioning process for subscription-style contracts are set out in the Guidance on Commercial Arrangements for Antimicrobial Products.

3. Key features of the Antimicrobial Products Subscription Model

18. The Antimicrobial Products Subscription Model has been designed to allow all nations of the UK to take part in the procurement for antimicrobial products. A Lead Authority, from one of the four nations of the UK, will have overall responsibility for the process used to award subscription style contracts. However, each authority will decide if it is a party to a particular contract or not. For the purpose of this document, authorities mean NHS England and corresponding representatives of any participating devolved nation of the UK.

(a) Role of NICE in supporting commissioning of antimicrobial products

19. The authorities will commission NICE to support key clinical input to the process:

- To provide representatives for the eligibility panel, established by the authorities, to assess the suitability of an organisation and its product for a contract award based on clinical and non-clinical criteria before it progresses to the evaluation stage. The representatives provided by NICE will include clinical experts from the evaluation panel (see below);

- In addition to making a recommendation to the authorities as to an applicant's eligibility, the eligibility panel may also recommend the population(s) within the marketing authorisation indications to be included within the scope of the award stage and assessed against the award criteria. Applicants will be advised of the proposed scope, which must be accepted as a condition of progressing to the award stage;

- To establish, on behalf of the authorities, a standing panel of clinical experts from across the UK to evaluate each product against clear award criteria; the 'evaluation panel'. The panel will be recruited, hosted and operationalised by NICE, with input from the authorities as appropriate. For example, recruitment of panel members will adhere to typical NICE

processes for committee recruitment, with representatives from the authorities also involved in assessing applications and agreeing appointments.

20. The evaluation panel will be an integral part of the NHS procurement process. The authorities may need to charge an application fee to companies as an entry requirement at each stage of the process to cover the respective administrative costs incurred by NICE. Any charge will be calculated on a cost recovery basis.

(b) Route to commissioning and responding to tender

21. For all antimicrobial products in the standard route, companies would be required to apply for market authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) and seek a list price from the DHSC in the same way as other medicines. This requirement will continue unaltered.

22. To deliver the Antimicrobial Products Subscription Model, in compliance with Public Contract Regulations, organisations will be able to express interest in the advertised selection process.

23. The selection process proposed will be open to all interested organisations and consist of two stages:

Stage 1) an eligibility stage where potential suppliers will be required to demonstrate that they satisfy minimum eligibility criteria to be awarded a subscription style contract; and subject to passing Stage 1, eligible suppliers will be invited to

Stage 2) an award stage where potential suppliers will be required to provide evidence for assessment by the evaluation panel to demonstrate the extent to which their product satisfies the award criteria.

24. Stage 2 will determine if a supplier is awarded a subscription style contract and the quantum of the associated annual fee. The eligibility and award criteria, together with the subscription style contract terms and process instructions for suppliers, will be published when the opportunity is advertised.

25. Under the subscription model, the Lead Authority on behalf of the authorities will issue an invitation to tender approximately once a year. Initially NHS England will act as the lead authority across the four nations of the UK

seeking to offer a subscription contract. Once a product has moved through the evaluation phase of the tender process and has reached the point of contract award, each nation will then decide if they wish to adopt the contract for their respective administration. This process is designed to minimise the administrative burden and ensure consistency while recognising the autonomy of the healthcare systems in each nation.

26. All products receiving a marketing authorisation in the period since the previous window will be able to apply subject to the eligibility criteria. As part of the subscription model, the proposal is also to allow companies to apply for a subscription style contract while the marketing authorisation process is ongoing. The requirement is that the product has a high probability of receiving a marketing authorisation in the 12 months following the date of issuance of the invitation to tender. NHS England, NICE and MHRA will work together to verify that this is the case, where relevant.

27. The authorities reserve the right to limit the number contracts in a given year. When this situation arises, priority will be given to those products that already have a marketing authorisation.

28. The invitation to tender will include documentation on the eligibility criteria, the award criteria and the evidence that companies will need to provide. Companies wishing to apply for a subscription contract will need to complete an application in response to the invitation.

29. The application will require submission of documentation and evidence to demonstrate that the company and product meet the eligibility criteria, which will include both clinical and non-clinical requirements:

    - Product is active against pathogens on the WHO priority list.
    - *Confirm agreement to the model contract terms, including:*
        - *surety of supply* – contractual requirements for companies to provide assurance that they will always have supply, ensuring antimicrobial product availability at the right time and right place to meet need and demand
        - *antimicrobial stewardship*

        - *sales force stewardship* – reinforce appropriate organisational behaviours, delinking remuneration incentives for company sales representatives from antimicrobial sales
        - *promotional activities* – activity on use of products should be informative and educational. For products with a subscription style contract, companies must keep the NHS informed of the activities they intend to undertake through the year.
    - *Performance*
        - *Key performance measures and reporting requirements*
    - *Payment terms*
- *Environmental Standards* - companies must demonstrate, via independent assessment, compliance with specified antibiotic manufacturing standards which aim to reduce the development of resistance and ecotoxicity in the environment as a result of manufacturing operations.
- *Economic and Financial Standing* – it is a standard requirement of all public sector contracts that companies demonstrate they have a sufficient economic and financial standing to justify award of the proposed contract.
- *Probity - companies must demonstrate they don't trigger any of the requirements that would make them ineligible to be awarded a public contract;*
- *Social Value - companies must demonstrate their commitment to specified social value requirement e.g. achieving Net Zero carbon emissions.*

30. Products that are active against pathogens on the WHO priority list will be eligible. The eligibility criteria will be considered and set each year as part of the invitation to tender documentation. The key target will be products that treat infections caused by pathogens designated as 'critical' on the WHO priority list.

31. As with all public sector contracts, it will be necessary for companies to provide information about their economic and financial standing when bidding for a contract. The purpose of this requirement is to check that a company is financially robust and able to carry out the terms of the contract.

32. Typically, this involves providing a copy of audited accounts for the last two years. Where this is not possible, then alternatives like a profit and loss account or cash flow forecast can be submitted. As part of the pre-market engagement process for each tender, consideration will be given to the requirements to make sure small and medium sized companies, or those with only a short trading history, are able to comply.

33. The scoring for these criteria is normally “pass” or “fail” depending on whether than company submits the specified information and demonstrates a minimum financial standing.

34. Additional to the eligibility criteria, companies will also need to provide information on the marketing authorisation date (either existing or expected) and the patent expiry date. This will be for administrative purposes and will be for determining:
    a) whether the product is suitable for consideration in that invitation to tender window; and
    b) the maximum number of years for which the contract may run.

35. An eligibility assessment panel will assess the documentation provided by the company against the eligibility criteria. Companies that meet the criteria will be informed of the decision by the panel and progress to the next step of the process.

36. During the eligibility stage, the panel may request companies to clarify details included within their application. No additional evidence or data may by requested or provided at this stage; clarification requests will be restricted to questions to help with the panel’s interpretation and understanding of the evidence submitted.

37. During the eligibility stage, in addition to making a recommendation to the authorities as to an applicant’s eligibility, the eligibility panel will also recommend the population(s) and/or marketing authorisation indications to be included within the scope of the award stage and assessed against the award

criteria. Applicants will be advised of the proposed scope, which must be accepted as a condition of progressing to the award stage.

38. Companies may also be invited to submit information about the scope of the use of the product within the marketing authorisation as part of the initial application. The eligibility panel can take account of any such information when considering their recommendation on scope for the award stage.

39. Companies will be informed by the lead authority on the outcome of the assessment against the eligibility criteria. Those companies whose product meets the eligibility criteria will then be invited to submit evidence showing how the product performs against pre-specified award criteria.

40. A UK panel of clinical experts (the 'evaluation panel'), convened by NICE to provide recommendations to the authorities, will meet in private to assess the documentation provided by the company against the award criteria. During the award process, the evaluation panel may request clarification or additional information or evidence from companies as part of its quality assurance of the evidence.

(c) Opportunity for companies to obtain clarification

41. Companies will have the opportunity throughout the procurement process to seek clarification from the authority to help companies fully understand the requirements. 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 to make sure the process is as transparent as possible.

(d) The award and scoring system

42. The evaluation panel will assess the product against pre-specified award criteria using a points-based scoring system and make recommendations to the authorities. The product's score will determine the value of the contract between each authority and the company, through assignment to one the four possible contract 'value bands'. The top band is for innovative breakthrough products which offer exceptional value to patients and the NHS.

43. The clinical award criteria fall within three main categories:

a) relative effectiveness and unmet clinical need;
b) pharmacological benefit; and
c) health system benefit.

44. Further details on the award criteria and scoring system is provided in a separate document *Antimicrobial Products Subscription Model: Product Award Criteria* accompanying this consultation.

(e) Contract award and model contract including contract payments and invoice prices

45. The lead authority will inform applicants about the outcome of the evaluation panel assessment against the award criteria, whether they will be offered a contract and the relevant value band to be offered. Once companies have been informed of the contract award outcome, the authority will observe the public contract regulations mandatory minimum standstill period of 10 days before entering into a contract with the successful applicant(s). Any applicant may seek clarification or raise any concerns about the award outcome with the authority during this period. Applicants will have up to 30 days to accept the award, if offered, by the authority.

46. A model contract based on the standard NHS contract will be used in the Antimicrobial Products Subscription Model. The contract used will be published as part of the opportunity documentation. An example of the model contract used during the pilot project is provided in a separate document *Antimicrobial Products Subscription Model: Model Contract from the pilot project*. The model contract that will be used will be subject to amendment in light of the consultation and any pre-market engagement exercise.

47. Based on the award criteria a product will be placed into one of four value bands. The more points a product achieves against the award, the higher the value band into which it will be placed. For England, the value bands range from £20m per year to £5m per year. These are shown in figure 1 and more information can be found in the guidance document Guidance on Commercial Arrangements for Antimicrobial Products.

Figure 1. Value bands, linked to the award criteria scoring system

Band 1: £20m per year Breakthrough antimicrobials	Band 2: £15m per year Critical new antimicrobial	Band 3: £10m per year Priority new antimicrobial	Band 4: £5m per year Important new antimicrobial
achieves ≥80% of max score against evaluation criteria	achieves between 70%-79% of max score against evaluation criteria	achieves between 60%-69% of max score against evaluation criteria	achieves between 50%-59% of max score against evaluation criteria

48. The subscription contract is for an initial three-year period which is extendable up to 15 years in total to cover the patent exclusivity period of the product. The contract period will not be extended beyond the patent life. The intention is that the contracts will be extended up to the patent expiry date but not beyond. It is possible that the product could change between value bands (in either direction) during the contract term, depending on how the value of the product to the NHS evolves over time. NHS England reserves the right to terminate a contract should NHS England determine that the value of the product to the NHS no longer warrants a subscription contract.

49. Those products that are awarded a contract will receive a fixed agreed fee each year split into four quarterly payments. These payments will have two elements:
    a) sales revenue; and
    b) top up fee.

50. As companies will continue to supply their product through traditional supply chain channels, e.g., wholesalers, the companies will receive sales revenue in the usual way. Companies will need to keep records of the volumes they supply to each NHS body each month and submit it to the authorities for reconciliation. Depending on the NHS list price, companies may be required to agree a different invoice price to be paid at the point of sale. This will not change the overall level of revenue only the balance of revenue they receive from sales revenues and the top up fee.

51. NHS England and the devolved governments will calculate the top up fee once a quarter. This is equal to the annual fee (divided by 4) minus the revenue from sales. The contract includes a mechanism to reconcile payment from one quarter to another and at year end to recognise that initial sales data may be provisional.

4. Public Contract Regulation Compliance

52. Compliance with the Public Contract Regulations is a legal requirement for UK authorities. Use of a PCR compliant approach also provides a mechanism to select a limited number of products from those available, should there be a limited number of subscription style contracts available. NHS England have considered the potential procurement routes available within the Regulations and currently propose to use the Restricted Procedure to award subscription type payment contracts. The principal reasons for proposing the restricted procedure are:

a) it facilitates the proposed two stage approach (eligibility and award);

b) it is a relatively simple, well understood and quick (6-8 month) process from advertising the opportunity, completing the eligibility and award stages and having signed contracts in place;

c) Based upon the learning from the pilot procurement process and management of the two initial contracts:

   i) NHS England currently do not see the need for detailed dialogue with suppliers during the procurement process;

   ii) NHS England have already developed a tried and tested form of subscription style contract ; and

d) The existing contract and proposed award process, will enable suppliers to respond to the NHS requirements.

53. NHS England anticipate updating the procurement approach for subsequent procurements once the new public contract regulations are published, however, NHS England anticipate the process will largely reflect the Restricted Procedure described above.

54. Under the public contract regulations, the authority will publish documentation that includes all the information needed for companies to apply for a tender opportunity. The documentation will include the eligibility and the award criteria. These will be reviewed each year before notice of the tender is given.

Where the material in the documentation is changed, the authority will look to hold a pre-market engagement to inform companies of the details in the tender.

Annex A: Engagement Questions

Section 1: Background and Purpose **Section 2:** Introduction						
	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / NA
To what extent do you agree or disagree with purpose of the Antimicrobial Products Subscription Model?	❑	❑	❑	❑	❑	❑
Comments:	*Please provide any further comments you have here.*					

Section 3: Key features of the Antimicrobial Products Subscription Model						
Route to commissioning						
	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / NA
i. To what extent do you agree or disagree with the overall procurement process outlined in the Guidance on Commercial Arrangements for Antimicrobial Products?	❑	❑	❑	❑	❑	❑
ii. To what extent do you agree or disagree with having an eligibility stage prior to the procurement process?	❑	❑	❑	❑	❑	❑
iii. To what extent do you agree or disagree that the eligibility criteria should be based on WHO priority pathogens?	❑	❑	❑	❑	❑	❑
Comments:	*Please provide any further comments you have here.*					
Opportunities for companies to obtain clarification						

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / NA
To what extent do you agree or disagree with the opportunity for companies to obtain clarification?	❑	❑	❑	❑	❑	❑
Comments:	*Please provide any further comments you have here.*					

Award criteria and scoring mechanism

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / NA
i. To what extent do you agree or disagree that the three main categories describe the main areas of value?	❑	❑	❑	❑	❑	❑
ii. To what extent do you agree or disagree that the criteria in each category will allow for differentiation between products?	❑	❑	❑	❑	❑	❑
iii. To what extent do you agree or disagree with the scoring approach for each criteria?	❑	❑	❑	❑	❑	❑
iv. To what extent do you agree or disagree with the weighting attributed to each criteria?	❑	❑	❑	❑	❑	❑
Comments:	*Please provide any further comments you have here.*					

Model contract

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / NA
i. To what extent do you agree or disagree with the four value bands being proposed for the contract?	❑	❑	❑	❑	❑	❑
ii. To what extent do you agree or disagree with key performance indicators on surety of supply and compliance with good stewardship practice?	❑	❑	❑	❑	❑	❑

iii. To what extent do you agree or disagree with the length of contract being proposed?	❑	❑	❑	❑	❑	❑
Comments:	*Please provide any further comments you have here.*					

Equality	
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?	
Comments:	*Please provide any comments you have here.*

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 ☐ No

If yes, please specify the source of funding and sums involved in each of the last three years:

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This publication can be made available in a number of alternative formats on request.