NICE National Institute for Health and Care Excellence

NHS

Frequently Asked Questions: developing and testing innovative models for the evaluation and purchase of antimicrobials

Below are the questions that were received during the webinars which were held by the project team on Wednesday 25th March 2020.

We have provided answers to clarify the intentions of the project. Please note that the final procurement documents and contract terms are subject to change once we have received all feedback from stakeholders.

1. **What is the basis or rationale for setting the max payments at £10m per year?**
   The UK Government recognises the importance of pull incentives in order to help stimulate the antimicrobial development pipeline. The principle of the project is to test a model that pays companies for antimicrobials based on a health technology assessment of their value to the NHS, as opposed to the volumes used. It is critical that we make sure that the NHS gets the best value from its drug and the maximum contract value has been derived under the assumption that the UK pays its fair share. The UK accounts for about 2.4% of global sales of antibiotics and 4.2% of GDP of the G20. The antibiotic reimbursement contract proposed covers just the NHS in England which represents 84% of the UK. We believe that if the £10m, on offer from this contract, was scaled up from 3% - 3.5% (England's share) then global revenues would be between $3.5bn to $4bn over 10 years.

2. **Is the maximal fee of <£10m able to achieve the aim of being an attractive pull incentive for industry?**
   Yes. The contact value of £10m covers the NHS in England. Given that England represents approximately 2% of global pharmaceutical sales and 3.5% of G20 GDP, scaling £10m contract value would deliver $3.5bn to $4bn in global sales over 10 years. This is in the $2bn - $4bn range for global sales suggested by independent commentators. While the UK is taking an important step, this project cannot solve the global antimicrobial pipeline on its own. For our work to have the full effect, we need other

countries to offer similar incentives in their own domestic markets, alongside regional or global market incentives solutions.

3. **What will happen if the Health Technology Assessment (HTA) results in a valuation higher than £10m?**
   The contract value is capped at £10m per year or the value offered by the winning bidder. If the HTA suggests the value of the antibiotic is greater than £10m then the lesser of (i) the cap of £10m or (ii) the value offered by the winning bidder will apply. Under UK Public Contract Regulations 2015 it is not possible to increase the £10m cap or the tendered contract value (whichever would apply) at this juncture – i.e. once the final tenders have been submitted and the 'winning' supplier has been selected (to progress to HTA) without undermining the basis of that selection. Doing so would materially expose the procurement process to the risk of challenge - including the process having to be stopped and restarted - and potentially an award of damages / costs in favour of the aggrieved bidder/s who bring the challenge. Once the HTA has been completed, the contract will be finalised with the supplier and will (subject to Freedom of Information Act (FoIA)) be commercially confidential.

4. **After three years would you consider increasing the total contract value above £10m if the HTA assessment process shows it is undervaluing the two products in the test?**
   No. Under UK Public Contract Regulations 2015 it is not possible to increase the contract value once the supplier has been selected (to progress to HTA) without undermining the basis of that selection. This would risk the process having to be stopped and restarted.

5. **What happens if use is very low/negligible throughout the contract?**
   The reimbursement model seeks to delink payment for the antibiotic from the volume of packs of the product used. So, if in some years the use of the antibiotic is low the supplier will still receive the agreed annual payments. If in some years the volumes of the antibiotic used are higher than anticipated, the same agreed contract payments will still be made.

6. **Will there be additional levels of R&D incentives to stimulate future development?**
   The UK is the first country in the world to announce that it will test new models that pay companies for antibiotics based primarily on a health

technology assessment of their value to the NHS, as opposed to the volumes used. The UK AMR national action plan also includes the commitment to continue to invest in research to support the development of new and alternative treatments, vaccines and diagnostics. The UK has been working with the Access to Medicines Foundation, the FAIRR initiative, the UN Principles for Responsible Investment office and investors to establish an '**Investor Year of Action on AMR**', launched at the World Economic Forum in January this year.

7. **As the agreed payment can be flexed up or down (in the scenario of extension to 10 years) but the payment cannot exceed the £10m max this would suggest that the payment cannot be flexed up if the agreed fee with a supplier was £10m? / Can a payment agreement below £10m be 'flexed up' after NICE guidance?**
   The contract design has the flexibility to adjust the contract value but only within the parameters of the maximum contract value. Therefore, if the initially agreed value is £10m, then it will not be possible to pay above £10m for that product without terminating the contract and starting a new procurement process.

8. **Was any consideration given to whether the 'existing' and 'yet to be launched' products should NOT have equivalent maximum contract values?**
   The aim of this project is to demonstrate the feasibility of innovative models that pay companies for antimicrobials based primarily on a health technology assessment of their value to the National Health Service (NHS) as opposed to the volumes used. We do not see any benefit in offering different contract values to 'existing' products or 'yet to be launched' products.

9. **Have you considered the ability (or lack of ability) of other European countries to pay when deciding on the contract maximum value? This impacts the EU market attractiveness and the attractiveness of the AMR sector to pharmaceutical companies and investors.**
   The contract value has been derived under the assumption that the UK pays its fair share. We recognise that for this type of payment model to deliver a pull incentive, other countries will need to offer similar incentives in their domestic markets. The UK continues to work with partners

through the G20 and other fora to promote AMR issues and share learning from the project.

10. **What is the administrative cost associated with the programme?**
    The largest proportion of costs will be the contract value for the selected antibiotic products; the contract value will be informed by the outcome of the adapted HTA but will not exceed the maximum contract value of £10m per year per product. In addition, there is a cost to run the HTA for each product, which we anticipate will be in the range of doing a normal multiple technology appraisal. Additional administration costs for the Department of Health and Social Care, NICE and NHS England and Improvement are absorbed within normal administrative budgets.

11. **What will be the cost for hospitals?**
    We will agree with each company an invoice price that will be paid by hospitals direct to the manufacturer. This amount will then be deducted from the contract value.

12. **If hospitals are invoiced at point of purchase, how will they recover this money?**
    During contract finalisation, the intention is that we will set an invoice price to allow the normal distribution system to function. The revenues from this invoice price will be netted against the contract value so that it remains at the agreed level. Hospitals in England are reimbursed for medicines through their overall budgets. Only high cost medicines attract specific funding. We anticipate the same arrangements will apply.

13. **Will the fixed-fee completely replace sales of the selected products in England, including private hospital sales?**
    The proposed contract will cover the use of the selected antibiotic for the NHS. It does not cover the use of the products in private hospitals. Note, these arrangements are for England only and do not cover the other nations of the UK.

14. **Will the price charged to hospitals have an impact on international referencing prices?**
    The UK does not operate an international referencing price system. The final contract value for this project and the price to hospitals will remain

(subject to FOIA) commercially confidential and so we do not anticipate the price charged to hospitals will influence international reference prices.

15. **Will the annual agreed payment amount per antibiotic be publicly available?**
    The final contract value for the project will remain commercially confidential, subject to FOIA. However, the NHSE&I maximum contract value (£10m) will not be confidential.

16. **What will happen if usage exceeds the annual fee?**
    This project will deliver a payment model that is delinked from volumes used. Therefore, in some years we would expect volumes to be low, and in other years we would expect volumes to be higher. However, the contract value paid each year is the agreed amount.

17. **Is the HTA process date fixed? Is there any flexibility around this? How do you guarantee that the selected product is really useful, or even better, the most useful for the NHS if the HTA phase comes only after product selection?**
    The timeline for the HTA process is based on NICE's Multiple Technology Appraisal process and refined to balance the requirements of an evidence-based evaluation of a new antimicrobial, while delivering in as short a timeframe as possible. The procurement process has been designed to identify the most clinically useful antimicrobials (based on the qualification criteria outlined in Document "AMR - QQ - Annex 1 - Qualification Questions & Criteria vME-Final" and product selection criteria outlined in Document "AMR - ITPD - Annex 04 - Award Questions & Criteria vME-Final").
    The procurement includes a process similar to topic selection and where the selection criteria have been developed to try and identify those products most likely to be most useful to the NHS.

18. **Is the HTA value transparently communicated to the company?**
    The company will be fully informed of all of the outputs from the HTA evaluation. Commercial and academic in confidence information from other sources will need to be considered on a case-by-case basis.

NICE National Institute for Health and Care Excellence

NHS

19. **Is there a possibility that a company may withdraw before execution of contract?**
    This is possible and we will be liaising closely with selected companies about expectations.

20. **If the HTA suggests that a selected product has a very low value, would you de-select it, and choose one that had previously been rejected?**
    The procurement process has been designed to identify the most clinically useful antimicrobials based on the qualification criteria outlined in Document "AMR - QQ - Annex 1 - Qualification Questions & Criteria vME-Final" and product selection criteria outlined in Document "AMR - ITPD - Annex 04 - Award Questions & Criteria vME-Final". There is no ability to de-select one product and replace it with another product once the initial product has been selected through the procurement process.

21. **Have you undertaken an assessment of the number of products which meet the date criteria for launch?**
    Choosing an antimicrobial that has been available and used in the NHS provides some resistance and usage data to support the NICE evaluation and reduces the uncertainty associated with the economic modelling. New antimicrobials will not have evidence from the NHS to support their adoption, which is why we have chosen to include in the test one antimicrobial which will enter the market during or after the HTA evaluation. The number of products satisfying each date criterion has not been formally established but we will review before the criteria are finalised.

22. **How will the HTA ensure that the two products cover different pathogens when they could score similar points?**
    It is possible that the antimicrobials selected for the test could have similar or overlapping indications, if they have the highest scores.

23. **How is the programme ensuring good stewardship?**
    Through existing payment arrangements, pharmaceutical company revenues depend on volume of sales, giving companies an incentive to market products. A model that delinks payments made to companies from volumes used will support good antimicrobial stewardship. Further, the

commercial arrangements for selected products will include requirements for suppliers to ensure that optimal stewardship arrangements are maintained through the introduction of the product and that they are making efforts to keep environmental contamination of antimicrobials to a minimum.

24. **How does NHSE define promotional activity and how would NHSE envisage appropriate use of the products being achieved?**
Appropriate use of products is set out by NICE guidance NG15 published in August 2015. Under the contract for supplying the antibiotic companies will be asked to agree not to use drug representatives to promote higher levels of uptake and sales of the product. Additional requirements may be added once we have reviewed feedback received during market engagement.

25. **When will be the right time to submit an application to participate in the procurement process?**
Suppliers should register their interest in the procurement process once the Official Journal of the European Union (OJEU) notice has been published. We anticipate the OJEU will be published in May and will include instructions on how to register.

26. **Why revise the thresholds (during scoring and topic selection), instead of selecting the product with the highest score?**
Minimum clinical and non-clinical scores have been specified before the overall score (combined clinical, non-clinical & cost score) is considered to ensure the selected products mostly address the NHS clinical and non-clinical requirements before considering cost. Selection based upon the highest overall score alone does not do this. To mitigate the risk that the thresholds have been set too high, we have introduced a number of thresholds that can be applied if needed. This should avoid the need to stop and restart the procurements with new thresholds and wasting the time invested to that point.

27. **Is the process contingent on more than one product participating (in each category?)**

Ideally, we will receive multiple applicants for both the existing and new antimicrobial procurements, however the process can continue if only one supplier submits a response or qualifies.

28. **Will the principle be extended across the other countries of the UK, where a product would be licenced?**
The contract will apply to the NHS in England. We are in discussions with the administrations of the other nations of the UK about the project. Colleagues in Scotland, Wales and Northern Ireland are important stakeholders to the project.

29. **How would NHSE ensure that products purchased under the scheme are used only in England and not 'traded' to other countries?**
Suppliers control the supply chain up to the point of delivery at the hospital and so we would expect suppliers to apply their normal controls to prevent this. In addition, NHSE&I will monitor the quantity delivered to hospitals and the actual usage. Furthermore, the performance requirements in the contract will strongly incentivise product to be available when needed.

30. **If the project is successful, when will you make a decision on expanding the scheme? When would you initiate a second call for applicants?**

Full roll out will depend on the outcome of this project, and it will be important to evaluate the model thoroughly before considering changes to routine commissioning.

We anticipate that the contracts will start in April 2022, and we expect that they will need to run for at least 12 months before we can evaluate how they are operating.

31. **What are the possibilities for products that are not selected in this process?**
The aim of the project is to demonstrate the feasibility of an innovative model that pays companies for antimicrobials based on a health technology assessment of their value to the NHS, as opposed to the volumes used.

New antimicrobial products not selected for this project should be brought to market in the usual way and will be prescribed in the NHS in line with established practice.

Any decision about making a subscription style model part of routine commissioning will depend on the evaluation of this project.

32. **What activities will you undertake to support appropriate uptake within the NHS?**
Guidance on good stewardship and the use of antibiotics is set out in NICE guidelines (NG15), which was published in August 2015. This will form the basis for usage of the antibiotics selected for this contract.

33. **After three years, is the option to continue with the contract at the discretion of the NHS and the supplier?**
The agreement will be for an initial period of three years, with the Authority having the option to extend for a period, or periods up to a total of 10 years.

34. **What is the impact of COVID-19 on the project going forward?**
We recognise the importance of this project. While NICE and NHS England and NHS Improvement have had to re-prioritise much of its work programme since the start of March, the work on antibiotic payment model will continue as planned to the extent that resources allow.

35. **How many antimicrobial products will be accepted for this project?**
The procurement project is for two products which will be used to test that the HTA process and the payment model achieves the project aims.

36. **Will there be any monitoring of source of supply?**
Availability and supply of the products will be monitored. This will be discussed and agreed with companies as part of the tender process.

37. **Will the contract shift automatically if there is a change of ownership of the antibiotic?**
The contract includes provisions relating to a change of control, assignment, subcontracting etc. These provisions typically require the

Authority's prior written consent, otherwise the Authority may terminate the contract.