Developing and testing innovative models for the evaluation and purchase of antimicrobials

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This webinar will commence at 13:05

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25 November 2019
Housekeeping

- Duration of webinar is approximately two hours

- Please mute phones, to minimise background noise

- Use the ‘chat function’ to send in your questions. To enable the chat function please click the ‘bubble’ icon located on the toolbar at the bottom of the screen. Click the ‘To Everyone’ option to enter a question.
Introduction & Overview

The story so far

- The UK AMR Action Plan was published in January 2019 and made a commitment to developing a new payment model for antibiotics
- The payment model aims to ensure companies have a financial incentive to invest in an antibiotic development programme and support good stewardship

Purpose of today

1. Share stakeholder feedback from the engagement exercise
2. Share plans for the project
3. Update on continuing role of stakeholders
4. Give details of the procurement approach
Stakeholder Feedback
Feedback

Targeted stakeholder engagement was undertaken from 31 July to 6 September 2019, and responses were received from 12 organisations. Thank you for taking the time to feedback on the following areas:

I. Topic selection criteria and process
II. Evaluation framework
III. Commercial model
Stakeholder feedback from the engagement exercise on: topic selection criteria and process

We heard the following:

- There is a potential risk of reputational damage to companies if their products aren’t selected.
- It is important to have stewardship for the selected antimicrobials. There is a potential for market distortion with products selected for the project being used inappropriately.
- There is a potential risk of tension between WHO priority list and UK priorities and relevance of CDC (Centres for Disease Control and Prevention) pathogen list.
- It is unclear why products with a Marketing Authorisation for more than three years would be unsuitable for the project.
- There is a need to understand the role of narrow and broad spectrum antibiotics in the selection criteria.

- There is a need for transparency around the topic selection criteria, procurement process and communication around the chosen antimicrobials.
- It is important to mitigate against the potential risk of product withdrawals from the project.
- There is a risk of the project failing to identify an implementable model for AMR reimbursement and consequently having the perverse effect of disincentivising AMR research.
- It is important to ensure that the essential criteria avoid any implicit bias against smaller companies and that they are adequately represented amongst the project’s stakeholders.
Stakeholder feedback from the engagement exercise on: the evaluation framework

We heard the following:

- There is a complexity of economic analysis and subsequent uncertainties for committee decision making.
- There is an observation that the potential to consider use beyond the Marketing Authorisation would be unusual.
- There are concerns that the “QALY approach” and current NICE threshold may not be appropriate for antimicrobials.
- It is important to consider additional sources of information.
- There is a proposal that a multi-criteria decision analysis (MCDA) approach may be more appropriate for antimicrobials.

It is important to determine the way the selected antimicrobials will be used within the NHS, particularly which clinical scenarios are included in the modelling.

- There are proposals that societal and productivity benefits should be considered when assessing antibiotics, as well as the impact of failing to develop any new antimicrobials.
- Comment was received that the evaluation framework is high level and should be worked out in as much detail as possible.
- There are concerns around the availability of efficacy and effectiveness data for the selected antimicrobials (particularly for the antimicrobial due to receive its MA rather than already on the market).
Stakeholder feedback from the engagement exercise on: the commercial model

We heard the following:

- There are concerns that outcomes-based arrangements are difficult to operationalise and prone to challenge.
- There was a suggestion that a commercial framework based on the existing supply chain would simplify implementation.
- There is a need to ensure manufacturing capacity irrespective of volumes required (if fully delinked).
- There is a proposal that the commercial arrangement should cover a period which is greater than the project timings, possibly in line with the product patent period or longer.

It is important to:

- Be able to operationalise the final model within the NHS.
- Incentivise a generation of data.
- The commercial models that fully delink volumes supplied from sales revenue were strongly favoured, alongside the importance of learning lessons from similar contractual arrangements in other fields (e.g. defence contracts).
- There was a concern as to whether the NICE assessment will come up with an incremental cost effectiveness ratio to guide the commercial negotiations.
- Balance risks between the NHS and the company appropriately.
We heard the following:

- There is a desire for clear and transparent communication with all stakeholders throughout the project.

- Companies directly and indirectly engaged in the project should be actively consulted throughout the project.
Feedback

Thank you for your helpful feedback

The feedback received was:

- Constructive and insightful
- Largely supportive of the proposals outlined in the three draft documents
Our Project Plans
The core elements from the targeted engagement remain

As set out in the engagement exercise, we can confirm that the process will include the following:

Step 1: Topic/ Product Selection
Step 2: Health Technology Assessment
Step 3: Commercial Negotiation

These three elements will take place within a procurement exercise

A multi-year contract with an annual fee

The annual fee may consist of a base payment and a supplementary payment conditional on contract elements being met

Contract elements might include compliance with good stewardship and availability of supply

The company will be expected to hold regular contract meetings with NHS England to monitor the delivery of the service

As this will be a public sector contract, we will give notification of the contract offer through the Official Journal of the European Union (OJEU)
What will the process look like?

- **Step 0:** Time is needed upfront to design the process and test this with stakeholders – as only limited changes can be made during the procurement itself.
- **We will seek comments on draft documents in the New Year. These documents will be as detailed as possible.**
The procurement will follow three steps:

**Step 1:**
Product selection

All companies with a product that they consider meets the published criteria can put themselves forward.

During the product selection phase, the project team will hold dialogue meetings with each qualifying company as part of the process to identify the two providers/products to proceed to HTA. Dialogue is likely to focus on product characteristics, the service requirements, commercial terms and the payment mechanism.

**Step 2:**
Health technology assessment

Following dialogue, the selected products will move forward to the NICE HTA phase in order to estimate their value.

**Step 3:**
Final commercial negotiation

NHS England will hold final commercial negotiations with the selected suppliers once the NICE guidance is available.

Draft for engagement: subject to change
Step 1: Product selection

Step 1 will include a competitive dialogue with each company that applies and satisfies the qualification criteria:

- This will help us decide which companies have the products we think are best placed to be taken forward to the HTA part of the process
- Qualification criteria and product selection criteria will be published as part of the procurement documentation so companies will know what we are looking for
- A panel of experts will help us assess which products best satisfy the selection criteria and should be selected
- The process will be used to select one existing and one new antimicrobial (via separate procurements or different ‘lots’ within a single procurement)
Step 1: Product selection

**Qualification Criteria**
- Acceptance of and commitment to:
  - Draft contract / commercial terms
  - Stewardship requirements
  - Service requirements
  - Monitoring / reporting requirements
  - EU license / UK launch requirements
- Minimum information for the product offered for consideration
- Actual usage data requirements (where applicable)

**Product Selection Criteria**
- Requested information
- Unmet need
- Degree of novelty
- Severity or relevant disease area
- Anticipated health benefits / added value
- Antimicrobial stewardship
- Patient access
- Monitoring and reporting
- Operational delivery (e.g. IG, Risk)
- Cost

Draft for engagement: subject to change
Step 2: Health technology assessment

• The health technology assessment is largely unchanged from the process set out in the engagement exercise earlier this year:
  o NICE and EEPRU will issue a scoping document;
  o EEPRU will produce a technical HTA report; and
  o A NICE committee will consider the evidence leading to NICE issuing guidance to inform subsequent commercial negotiations
Step 3: Final commercial negotiations

- NHS England will negotiate with each of the selected suppliers to agree a value for their antibiotic based on the NICE guidance and the commercial dialogue in Step 1.
- The other terms of the contract (discussed between NHS England and the supplier at step 1) will be confirmed.
- Data requirements and monitoring requirements will be confirmed.
- Start date and length of contract and review periods will also be confirmed.
- Once agreed the contract can be awarded.
Contract award

- Once the contract has been awarded, we will hold regular contract review meetings (anticipate quarterly) with the suppliers
- Contract management will be in place to monitor the delivery of the agreed contract terms
- We anticipate supplier to provide monthly:
  - Ongoing stewardship monitoring and reporting; and
  - Ongoing data / evidence collection and reporting
Next Steps

- We will consider the feedback from stakeholders during the targeted engagement as we prepare the procurement documents;
- The draft procurement documents will include more information on the selection criteria, payment mechanism, stewardship requirements, HTA process and commercial terms;
- We are preparing to share these key documents with stakeholders early in the New Year and will be asking for feedback;
- We aim to launch the procurement from Q2 2020.
Role of stakeholders
How we will engage with stakeholders?

• This is a complex project with both national and international implications for AMR
• To maximise the chances of success for the project, we want to be able to draw on the breadth of national and international clinical, technical and industrial expertise as we develop and test the approach
• We want to share progress and learning from the project in an informative and timely way so that others are encouraged to develop their own approach to purchasing and evaluating antimicrobials
• We will be mindful of confidentiality obligations during the procurement process
• Three groups will be brought together to meet these objectives;
  • A Stakeholder Forum;
  • A Project Advisory Group; and
  • An Expert Panel to support the procurement process
Stakeholder Forum and Project Advisory Group

**Stakeholder Forum**
Informal group that will receive regular updates on the project through webinars, newsletters and other communications;
Provide feedback on an ad-hoc basis through participation in webinars, in response to consultation documents or by contacting the Project Team;
Individual members or groups of stakeholders from the Forum (e.g. Academics, Inter-governmental groups) may be invited to provide expert input to the project on an ad-hoc basis;
Requests to join will be permitted at the discretion of the Project Board

**Project Advisory Group**
Advisory Group to the Project Board;
Chaired by Jonathan Van Tam;
Members invited to join by the Project Board;
Provide independent advice/expertise on all aspects of the project;
Contribute constructive challenge;
Act as advocates for the project in the UK and internationally, including disseminating materials to respective memberships;
Meet twice a year through webinars / teleconferences;
Will need to complete Declaration of Interest and sign confidentiality agreements

Draft for engagement: subject to change
Panel of clinical and technical experts to advise and assist in the selection of the two antimicrobials for inclusion in the project; Members of the panel will apply and consider how candidate products meet the selection criteria; Members of the panel will be appointed by the Project Board within a PCR2015 compliant procurement process; Members will need to complete Declaration of Interest and sign confidentiality agreements.
There will be three phases of engagement for the project:

**Pre-procurement**
- Project Advisory Group convened to support pre-tender briefing/ Prior Information Notification;
- Test procurement documents with stakeholders;
- Ongoing updates to Stakeholder Forum including pre-tender brief/ PIN

**During procurement and evaluation**
- Biannual meetings of PAG;
- Quarterly updates to Stakeholder Forum and webinars at key milestones;
- All engagement will need to comply with procurement confidentiality obligations

**Post-procurement**
- PAG convened to consider evaluation of project success;
- Webinar(s) held with Stakeholder Forum to share key learnings and next steps
Indicative stakeholder engagement timeline

**Procurement process**
- Payment Model & Competition Design
- Topic Selection & Valuation Design
- OJEU
- Contract
- Supplier Selection
- Step 1 Product Selection
- Step 2 Single Product Valuation
- Step 3 Commercial
- Award Decision
- Contract management and monitoring

**Procurement milestones**
- Start of procurement
- Suppliers selected and start of evaluation
- Evaluation completed and start of commercial negotiation
- Contract award and start of payments

**Stakeholder milestones**
- Pre-procurement
  - Advisory Group webinar
  - Stakeholder Forum webinar
  - Pre-OJEU Market Engagement
- During procurement and evaluation
  - Advisory Group webinar
  - Stakeholder Forum update
  - Expert panel
  - Ongoing ad-hoc engagement
- Quarterly updates
- Advisory Group webinar
- Advisory Group webinar
- Advisory Group webinar
- Advisory Group webinar
- Advisory Group webinar
- Stakeholder Forum update
- Stakeholder Forum update
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- Stakeholder Forum update

**Draft for engagement: subject to change**
Next steps

• The Project Board will shortly be in touch to invite members to join the Project Advisory Board;

• Further Stakeholder Forum webinars and updates will be scheduled for 2019/20;

• The first meeting of the Project Advisory Board to be held in early 2019.
Procurement considerations
Procurement approach

- We will be as open and transparent as possible about:
  - the process we will go through,
  - the criteria we will use to make our decisions,
  - the contract terms we intend to implement; for the products, and to whom it has been awarded
- NHSE&I is required to comply with the Public Contracts Regulations 2015 ("PCR2015")
- These regulations include a limited number of processes by which the procurement can be conducted
- We have considered all the process options available and concluded that the competitive dialogue procedure will best support the project objectives
Why the Competitive Dialogue Route

- It allows us a degree of flexibility to discuss the commercial arrangements with suppliers.
- For example, it permits discussion (dialogue) between NHSE&I and suppliers during the process (e.g. to discuss: individual product characteristics; product value; contract terms; access arrangements; stewardship; or the payment mechanism.)
- It permits limited changes to NHSE&I’s published requirements following these discussions.
- It is the only procedure that permits some (albeit limited) negotiation following supplier selection – this will enable negotiation of the payment model with the selected supplier after completion of the HTA.
- It enables minimum qualifying criteria to be specified that any supplier must meet in order to be considered further.
- We have considered other options. But the open & restricted procedure is very prescriptive and does not permit dialogue. The innovation partnership is primarily used for joint research and development projects. These were therefore considered unsuitable for this project.
Questions