



Annex 2

Information for Bidders

Tender Reference: [xxxx]



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1. Notice to Bidders

- 1.1. This *Information for Bidders* document, the Selection Questionnaire, the Invitation to Participate in Dialogue (to follow), associated annexures and any ancillary documents (together "the Procurement Documents") are being made available on the condition that the information contained within them is used solely in connection with the competitive tender process to procure the Authority's Requirements (as defined hereinafter) on behalf of NHS England (the Authority) and for no other purpose.
- 1.2. Whilst reasonable care has been taken in preparing the Procurement Documents, neither the Authority nor any of its advisers accepts any liability or responsibility for the adequacy or completeness of any information or opinions stated in this document. No representation or warranty, express or implied, is or will be given by the Authority or any of its representatives, employees, agents or advisers with respect to this document or to any information on which it is based. Any liability for such matters is expressly disclaimed.
- 1.3. In this document, words such as "anticipates", "expects", "intends", "plans", "believes" and "will" (and words and terms of similar substance) indicate the Authority's present expectation of future events, which are subject to a number of factors and uncertainties that could cause actual requirements to differ materially from those described.
- 1.4. Neither the issue of the Procurement Documents nor any of the information presented in them should be regarded as a commitment or representation on the part of the Authority (or any other person) to enter into a contractual arrangement. If a Bidder proposes to enter into an agreement with the Authority, it must rely on its own enquiries and on the terms and conditions set out in the agreement(s) (as and when finally executed), subject to the limitations and restrictions specified in it.
- 1.5. In so far as it is compatible with any relevant laws, the Authority reserves the right, without prior notice, to change the basis of, or the procedures for, the competitive process for the award of the contract or to reject any or all SQ responses or Tenders (as the case may be) and to terminate discussions involving (directly or indirectly) Bidders at any time. In no circumstances will the Authority incur any liability in respect of the foregoing.

Note to Bidders – this document – as the context so requires – refers to (i) an **[existing] [new]** antimicrobial, the subject matter of this procurement process; and (ii) a **[new] [existing]** antimicrobial being the subject of a parallel, but separate, procurement process.

Accordingly, the term '**Project**' in this document refers to background information and the overarching strategy for the procurement of both the new AND existing antimicrobial products.

2. Background to the Authority's Requirements

2.1 AMR Background

- 2.1.1 Antimicrobial resistance (AMR) arises when infectious organisms evolve ways to survive antimicrobial treatment. Once standard treatments are ineffective, it is easier for infections to persist and spread. Although resistance occurs naturally, the inappropriate use of antimicrobials in both human and animal medicine, plants and crops, alongside unintentional exposure, for example, through environmental contamination and food, is rapidly accelerating the pace at which it develops and spreads.
- 2.1.2 Infections resistant to currently available antibiotics are an increasing problem both in the UK and globally. The rapid spread of multidrug resistant organisms means that soon we may not be able to treat everyday infections or diseases effectively. Without effective antibiotics, minor surgery and routine operations will become high risk procedures. The impacts of leaving AMR unchecked are wide-ranging and extremely costly, not only in financial terms but also in terms of global health, food sustainability and security, environmental wellbeing, and socio-economic development.
- 2.1.3 AMR is one of the most pressing global challenges we face. Already, drug resistant infections are estimated to cause 700,000 deaths each year globally. That figure is predicted to rise to 10 million, alongside a cumulative cost of \$100 trillion, by 2050 if no action is taken. The World Bank estimates that an extra 28 million people will be forced into extreme poverty by 2050 unless AMR is contained.
- 2.1.4 In recognition that no country can tackle AMR within the life of a single five-year plan, the UK government set out its vision for a world in which AMR is contained and controlled by 2040 accompanied by a five-year national action plan that will begin to fulfil that vision. Both documents take a comprehensive 'One-Health' approach across humans, animals, agriculture, the environment and food. The UK government will continue to play its part in tackling the global problem of AMR by modelling best practice at home and supporting progress internationally. In the UK we will contribute to the global effort through a lower burden of infection and better treatment of resistant infection; optimised use of antimicrobials with good stewardship across all sectors; and new diagnostics, therapies, vaccines and interventions in use and accessed by all.

2.2 AMR Burden in the UK

- 2.2.1 AMR is already threatening modern medicine. Resistant infections are estimated to contribute to over 2,000 deaths in this country each year and cost the NHS in England approximately £95million per annum
- 2.2.2 In 2018, there were over 60,000 antibiotic resistant severe infections in England; equivalent to 165 new antibiotic-resistant infections per day. This represents an increase of 9% on the previous year.

- 2.2.3 Increasing AMR will cause people to suffer more protracted infectious illnesses as they become more difficult to treat as well as leading to more long-term consequences, the number of human deaths and suffering attributable to infectious disease will increase as will the socio-economic costs associated with treating ill health in humans.

2.3 Rationale for a Change in Approach

- 2.3.1 Few new classes of antibiotic have been discovered since the 1980s. This, together with the sub-optimal use of the drugs we already have, means we are heading rapidly towards a world in which our antibiotics no longer work.
- 2.3.2 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. High research and development costs and low returns (due to restrictions in uptake to reduce resistance patterns) have led to market failure, i.e. companies do not see the return on investment seen with other innovator products where uptake is encouraged rather than restricted.
- 2.3.3 In addition, pharmaceutical company revenues depend on volume of sales, undermining antimicrobial stewardship initiatives.
- 2.3.4 The need to explore “practical market incentive options” to address the urgent issue of bringing new antibiotics to market by stimulating the pipeline for antimicrobials was mandated by the G20 leader’s statement in 2017.

2.4 Progress to Date

- 2.4.1 The UK government established a Joint Government/ Industry AMR working group in 2015 to see how the UK could help incentivise industry to continue to invest and secure a sustainable drug pipeline for years to come. The principle of an insurance-based “de-linkage” model was broadly agreed. The Economic Evaluation Policy Research Unit (EEPRU) concluded that estimating all the benefits of a new antimicrobial was complex but there was scope for the development of a more pragmatic HTA framework informed by health economic modelling and expert opinion but recommended that this be tested in a real-world setting.
- 2.4.2 The Secretary of State for Health set out the UK’s vision for tackling AMR in 2040 at the World Economic Forum in January 2019, stating that the *‘NHS can take a global lead in pioneering a new payment system, one that reflects the true value of antibiotics to society’*.
- 2.4.3 The UK national action plan for AMR includes the commitment to lead the way in testing solutions that address the failure of companies to invest in the development of new antimicrobials. The UK became the first country in the world to announce that it will test innovative models that pay companies for antimicrobials based primarily on a health technology assessment of their overall value to the NHS in England, as opposed to the volumes used.

2.4.4 On 9 July 2019, the National Institute for Health and Care Excellence (NICE) and NHS England & NHS Improvement (NHSE&I) formally launched the UK Project for developing and testing an innovative model for the evaluation and purchase of antimicrobials.

2.4.5 Following the launch of the project on 9 July 2019, NHSE&I and NICE have jointly:

- a) Developed an adapted Health Technology Assessment (HTA) framework;
- b) Developed an innovative payment model;
- c) Defined the process and criteria for NHSE&I to select products to contract with;
- d) Developed procurement documents and contract;
- e) Recruited a Project Advisory Group (PAG);
- f) Consulted extensively with stakeholders and industry on the proposed approach and outline model’;
- g) Updated elements of the approach having considered stakeholder feedback; and
- h) Continued to promote the project at international fora and share learning.

3. Rationale for the proposed approach for the Project

3.1 Introduction

3.1.1 Following a period of market engagement on the draft procurement documents, feedback was received from eighteen (18) individuals and organisations and the PAG.

3.1.2 The feedback reflected several key themes. This section provides a brief rationale, by theme, of the approach included by the Authority in the Procurement Documents.

3.1.3 Key themes:

- a) The number of antimicrobials included in the Project
- b) Focus on products that are active against pathogens on the WHO Priority List
- c) The need for a procurement process
- d) Product qualification (eligibility) criteria
- e) Type of payment model
- f) How the maximum payment threshold value was derived
- g) Contract Terms
- h) Confidentiality
- i) Impacts on antimicrobials not selected for the project
- j) Company commitment to the project
- k) The role of HTA in determining a final contract value
- l) HTA evaluation methods and timetable
- m) Importance of engaging and influencing international partners and involvement of the UK devolved administrations
- n) Project review and on-going arrangements for the evaluation and purchase of antimicrobials

3.2 The number of antimicrobials included in the Project

3.2.1 A maximum of two (2) antimicrobial products will be selected in the initial development and test Project, one (1) [existing] [new] antimicrobial product (this procurement exercise) and one (1) [new] [existing] antimicrobial product (which is being procured separately)

3.2.2 The maximum is determined by the UK capacity to undertake this type of HTA concurrently.

3.2.3 Selecting one (1) existing and one (1) new product ensures that the new HTA process and new payment model are tested adequately. Including a new product simulates undertaking the new HTA close to the date the products achieves its license. Including an existing product already in the market (and with some information on usage and emergence of resistance) will enable uncertainty associated with this new HTA approach to be reduced.

3.2.4 An unavoidable consequence of selecting one (1) existing and one (1) new antimicrobial is that the selected antimicrobials may not address different clinical needs.

3.3 The products to be selected

- 3.3.1 The Project will focus on products that address a high-unmet need both in the UK and internationally. The WHO 2020 publication on the antimicrobial development pipeline comments on its modest size and a distinct deficit in novelty, with specific comments on a gap in novel products active against resistant Gram-negative pathogens, and particularly commented on a relative lack of new agents against metalloβ-lactamase (MBL)-producing pathogens. In addition, UK data shows reductions in MRSA and *Clostridoides difficile* infections but an increase in antibiotic-resistant Gram-negative blood stream infections. This issue is particularly concerning in high risk settings such as ICU, Haematology/Oncology, organ transplantation.
- 3.3.2 The product selection criteria therefore give particular weight to antimicrobial products which address resistant Gram-negative pathogens in high-risk settings. The academic work at the University of York, which prefaced the Project, looked at new methodology to better assess the added value that a new antimicrobial brings to market. York concluded that an enhanced HTA was possible but that one challenge is the uncertainty around level of usage and emergence of resistance to the new antimicrobial. One of the recommendations from EEPUR was to apply this new methodology in the real world, and that one of the products should already be in usage so that there would be more information on level of usage and emergence of resistance. This would then help to tighten up the economic modelling and allow more robust assessment of a new antimicrobial product. Therefore, one of the products selected will be a relatively recent entry to the UK market with at least 12 months usage and resistance data, and the second product selected will be required to achieve a licence and launch in the UK by the 31st December 2020.
- 3.3.3 Therefore, product selection will focus on those products that are (i) active against pathogens on the WHO Priority List and (ii) address a high unmet need within the NHS in England;

3.4 The need to undertake a PCR 2015 compliant procurement process

- 3.4.1 The Project seeks to, inter alia; develop a new payment model for antibiotics that fully delinks payments from the volumes of medicines used by the NHS in England. In order to do this NHS England will need to enter into contract (Contracts) with organisations that produce / supply the antibiotic in accordance with the Authority's Requirements.
- 3.4.2 The scope and nature of the Contracts are such that they must, as a matter of law, be competitively tendered in accordance with the provisions of the Public Contract Regulations 2015 (as amended) (PCR 2015).
- 3.4.3 The Project will, by way of separate procurement exercises, select only two (2) available product to progress to HTA and subsequently to the award of contract with NHS England, each with a potential value of £10m per year. This situation is markedly different to most '*standard*' NICE HTA processes where topic selection does not directly result in the award of a contract.
- 3.4.4 The limit of two (2) HTAs (1 for the existing antimicrobial and 1 for the new antimicrobial) and the PCR 2015 requirements has a number of implications for the Project including:

- a) The product selection (topic selection) process determines not only the products to proceed to HTA but also the products to be awarded contracts;
 - b) The criteria used for product selection must be specified in advance and must include cost;
- 3.4.5 The Authority is satisfied that the proposed process for the selection of two (2) products (one for the existing antimicrobial and one for the new antimicrobial) to deliver the Project objectives in accordance with the Authority's Requirements is compliant with the PCR2015.

3.5 Bidder Selection (eligibility) criteria

- 3.5.1 The Authority considers that the time window for the **new antimicrobial** to be licensed and launched should remain between **01/01/20** and **31/12/2020**.
- 3.5.2 The Authority considers that the time window for the **existing antimicrobial** to be licensed and launched should be extended from 01/01/2017 - 31/12/2018 to **01/01/2017 - 31/12/2019**. This modified time window is reflected in the updated Procurement Documents.
- 3.5.3 With only two (2) slots (one for each procurement) and the need to focus on UK highest unmet need i.e. resistant gram-negative infection, this area is served well by using the WHO priority pathogen list to inform candidate selection, and the Authority's focus in the Project is supported by the January 2020 WHO publication on the antimicrobial pipeline and its deficiencies. When the Project is complete, the criteria for selection and prioritisation can of course be revisited for any future, similar projects.

3.6 Type of payment model

- 3.6.1 The Authority, in an earlier targeted stakeholder engagement exercise in summer 2019, received clear stakeholder feedback that a fully *delinked* model was preferred where the intention was to pay for the value to the NHS in England, as determined through the HTA, irrespective of the volumes used. Industry stakeholders during the current market and stakeholder engagement seemed less concerned than other stakeholders around a stop-loss mechanism, consistent with the earlier feedback. A fully delinked model is still considered appropriate by the Authority; however, the Authority does consider that the contract should include a mechanism to limit supplier risk in the event of truly exceptional increases in demand that could not reasonably have been foreseen. However, such a mechanism must not materially dilute the *delinked* nature of the contract. The Authority proposes to include a 'commercial principle' placeholder in the contract and further discuss this topic during dialogue.

3.7 How the maximum payment threshold was derived

- 3.7.1 In deriving the maximum payment threshold, the Authority took account of the available literature on the level of global sales that would be needed for antimicrobials to become attractive investment propositions and considers that £10,000,000 per annum per antimicrobial to be a reasonable "fair share" for England. Based on the current NHS England spend data on antimicrobials, the Authority is confident that £10,000,000 pa per antimicrobial represents a significantly higher level of reimbursement than companies would receive from NHS England under the current arrangements.

3.7.2 It is also important to note that the maximum payment threshold (and all other terms in the procurement documents) apply specifically to the current project. Learning from the Project, including the value estimates from the HTA, will inform future arrangements for the valuation and purchase of antimicrobials.

3.8 Contract Terms

3.8.1 The Authority recognises the need for clarity regarding contract terms where possible and has revised the procurement documents accordingly. In addition, the dialogue stage of the procurement process provides potential suppliers with an opportunity to clarify contractual terms in advance of final tender proposals being submitted.

3.8.2 The contract duration will be an initial term of three (3) years, with a potential extension of up to an additional seven (7) years or patent expiry (whichever is the earlier) i.e. the maximum term is ten (10) years. Such extension will be by mutual agreement in accordance with the operative terms and conditions.

3.8.3 Reimbursement revenues for the contract will **not** be exempt from the Voluntary Scheme for Branded Medicines Pricing and Access 2019.

3.9 Freedom of Information and Confidentiality

3.9.1 Confidential information means all information which is supplied by the Authority to a Bidder, whether in writing, orally or in any other form, directly or indirectly from or pursuant to discussions with such Bidder or which is obtained through observations made by such Bidder which is designated by the Authority as confidential or which is otherwise of a confidential nature. Each Bidder shall hold in confidence any confidential information, provided that such Bidder shall not be restricted from passing such information to its professional advisers, or its proposed sub-providers (subject to obtaining appropriate confidentiality undertakings) but only to the extent necessary to enable it to prepare its SQ or tender response and participate in this procurement

3.9.2 Bidders are reminded that the Authority is subject to the requirements of the Freedom of Information Act 2000 ("FoIA") and the Environmental Information Regulations 2004 ("EIR"). Accordingly, the Authority may be required to disclose, on request, information submitted to it by Bidders in connection with this SQ. Information may be exempt from disclosure under FoIA where its disclosure would breach confidentiality or be likely to prejudice the commercial interests of any person, but the Authority can give no assurances as to whether or not information received from Bidders in connection with this SQ would be disclosed in response to a request made under FoIA. In the event that such a request is received by the Authority, the Authority shall, in accordance with its obligations under the Code of Practice made under section 45 FOIA, consult with any party whose interests are likely to be affected by disclosure and take their views into account. However, the Authority shall be responsible for determining at its absolute discretion whether any such information is exempt from disclosure in accordance with the provisions of the FoIA or the EIR and whether any such information is to be disclosed

in response to an information request. Even if the Authority initially refuses to disclose requested information, Bidders should be aware that disclosure may be enforced by the Information Commissioner or the Courts.

3.10 Impacts on antimicrobials not selected for the Project

- 3.10.1 The aim of the Project is to demonstrate the feasibility of an innovative model that pays companies for antimicrobials based primarily on an HTA of their value to the NHS in England as opposed to the volumes used. Given the scientific and commercial complexity, this innovative model will be tested through two (2) exemplar products prior to considering any wider change to purchasing policy.
- 3.10.2 New antimicrobial products not being tested through the applicable procurement will be available to NHS England, prescribed and reimbursed in line with normal practice. The Authority understands the concerns raised by companies about not being selected for that procurement. NHS England will endeavour to collaborate with the industry trade associations and the project advisory group with a view to ensuring clear and effective communications.
- 3.10.3 Suppliers that participate in this project and are unsuccessful, would not be precluded from participation in future projects or commissioning arrangements.

3.11 Bidder / Supplier commitment to the Project

- 3.11.1 The Authority recognises the need for clarity regarding the expectations and obligations placed on organisations who seek to participate in the Project and has updated the Procurement Documents to reduce ambiguity to the extent possible. If required, further clarification can be sought via the clarification process and/or during the dialogue stage of the procurement.

3.12 The role of HTA in determining a final contract value

- 3.12.1 The principle of the Project is to test a model that pays supplier organisations for antimicrobials based on an HTA of their value to the NHS in England. The trialling of the HTA methodology for antimicrobials will also be key to understanding the extent to which the various attributes of value can be captured through HTA – informing future policy on the evaluation of antimicrobials.
- 3.12.2 Given that there may well be high levels of uncertainty associated with value estimates from the HTA, a maximum payment threshold is considered important both in setting expectations for companies considering participating in the procurement and in managing financial risk to NHS England.
- 3.12.3 The scoring system has been designed such that the price offered by Bidders – which will be set against a disclosed maximum contract value - will only be considered if the products offered achieve a minimum quality (clinical & non-clinical) score threshold. This ensures that only a product that scores highly against the quality (clinical & non-clinical) criteria will be selected.
- 3.12.4 Undertaking the Project, including the value estimates from the HTA, will inform future arrangements for the valuation and purchase of antimicrobials.

3.13 HTA evaluation methods and timetable

- 3.13.1 The Authority consider that the HTA methods presented as part of the market and stakeholder engagement are appropriate and that, given the diversity of stakeholder comments, specific changes would not be appropriate. This builds on the report published in Autumn 2018 by EEPRU.
- 3.13.2 The process is broadly based on a NICE Multiple Technology Appraisal (MTA) which typically takes 49 - 60 weeks and the Project requires a bespoke process to deal with the complexity of considering the full dimensions of value for antimicrobials. Two HTAs will be conducted, with each constituting a significant call on resource and expertise available to the project. Given the high scientific complexity of undertaking HTA on antimicrobials, the Authority consider that the timelines presented are as short as feasible for the Project. It is important to note, however, that the Project will inform both the methods and timelines for the future evaluation of antimicrobials and opportunities for timely guidance could be identified.

3.14 Importance of engaging and influencing international partners and involvement of the UK devolved administrations

- 3.14.1 The UK's project supports the need to explore "practical market incentive options" as mandated by the G20 leader's statement in 2017 to address the urgent issue of bringing new antibiotics to market by stimulating the pipeline for antimicrobials.
- 3.14.2 Colleagues in Scotland, Wales and Northern Ireland remain important stakeholders to the project and we will continue to work with them.
- 3.14.3 While the UK is taking an important step, the Authority recognises that the successful implementation of subscription payment models for antimicrobials in England would not alone represent a major improvement in the attractiveness of investing in antimicrobials. For our work to have the full effect, we need other countries to offer similar incentives in their own domestic markets, which, collectively, achieve a meaningful incentive for global investment.
- 3.14.4 To maximise the project's chances of success, the UK is drawing on the breadth of national and international clinical, technical and industrial expertise. Sharing progress and learning from the project is an important part of the UK's approach.
- 3.14.5 In addition, the UK has taken the lead in lobbying for tangible commitments on market incentives in the 2019 G20 Leaders' declaration and is working with a number of like-minded countries to advocate for clear, next steps from all G20 members.

3.15 Project review and on-going arrangements for the evaluation and purchase of antimicrobials

- 3.15.1 Evaluation will be ongoing throughout the project and will be critical in shaping UK policy on the wider application of the model. The Authority agrees that the review stage is critical and that where learning from the project highlights opportunities for optimisation, these should, where

appropriate to do so, be exploited in other on-going arrangements for the evaluation and purchase of antimicrobials.

4. The Authority's Requirements

4.1 Objectives

- 4.1.1 The Authority has designed the procurement with the following key objectives in mind:
- 4.1.1.1 To provide an example payment mechanism that, if adopted internationally, could provide a pull incentive to contribute to renewed research and development into new antimicrobials.
 - 4.1.1.2 To test a new NICE Health Technology Assessment (HTA) for antimicrobials;
 - 4.1.1.3 To test a subscription-type payment model for antimicrobials;
 - 4.1.1.4 To contract for an [existing] [new] antimicrobial via an affordable subscription-type payment model; and
 - 4.1.1.5 To comply with the Public Contract Regulations 2015 (PCR 2015);

4.2 Key Requirements

- 4.2.1 Therefore, the Authority's key requirements are:
- 4.2.1.1 To contract with the Supplier of the antimicrobial that can best satisfy the Authority's award criteria;
 - 4.2.1.2 To contain total expenditure, for the [existing] [new] antimicrobial within £10m per annum, excluding fees and taxes;
 - 4.2.1.3 To maximise value for money for the Authority;
 - 4.2.1.4 Supplier acceptance of and compliance with the Authority's terms and conditions of contract (the Contract);
 - 4.2.1.5 For industry to proactively support antimicrobial stewardship;
 - 4.2.1.6 Supplier compliance with relevant legislation and guidance including (but not limited to) the PCR 2015 and Association of the British Pharmaceutical Industry (APBI) guidelines.

5. Overview of the Procurement

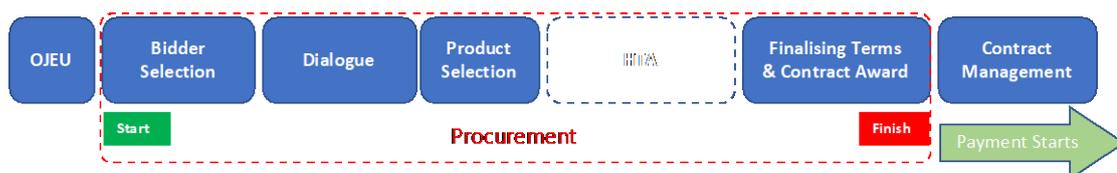
5.1 Introduction

- 5.1.1 The Authority is undertaking this Procurement in accordance with the Public Contracts Regulations 2015 (as amended) and will use the Competitive Dialogue (CD) award procedure.
- 5.1.2 This Procurement relates to the selection of an [existing] [new] antimicrobial that can best satisfy the Authority's Requirements in the NHS in England and where remuneration for its supply will be via a fixed fee, unrelated to the volume supplied.
- 5.1.3 Subject to receipt of compliant offers, the Authority intends to award a single contract for supply of the [existing] [new] antimicrobial that best satisfies the Authority's Requirements.
- 5.1.4 This document and the Selection Questionnaire issued to Bidders represents the beginning of the procurement process.

5.2 Overview of this Procurement ([Existing] [New] Antimicrobial)

- 5.2.1 The process for this Procurement includes the following key steps:
1. SQ Stage (all Bidders who express an interest)
 - i. Bidder Selection
 2. Tender / ITPD Stage (only Bidders who pass SQ stage)
 - i. Product Selection
 - ii. Health Technology Assessment
 - iii. Finalising terms and Contract Award

Figure 1 Summary Process



Bidder Selection

- 5.2.2 The Authority has specified minimum requirements for Bidders' economic and financial standing and technical and professional ability (the **Selection Criteria**). The Selection Criteria are designed to assess Bidders' capacity and capability in principle to satisfy the requirements, which are the subject of the Procurement. Only Bidders that satisfy the Selection Criteria, will be invited to participate in the Product Selection (dialogue) process.
- 5.2.3 Bidders are required to complete and submit the Selection Questionnaire included on the NHS England Bravo Solution E-Tendering Portal by the specified deadline.

Product Selection

5.2.4 The Authority has specified requirements and an evaluation methodology for determining product selection (*see ITPD - Award Methodology & Criteria*). The Award Criteria are designed to allow the Authority to identify, in advance of the HTA, the product most likely to address the Authority's Requirements. The product selection process incorporates discussion (dialogue) between the Authority and individual Bidders. The Bidder whose product is selected via this process will be the sole Bidder invited to proceed to the HTA, finalise terms / confirm financial commitments.

Health Technology Assessment

5.2.5 The Health Technology Assessment (HTA) will attempt to estimate the value of the product to the NHS in England. The process will test an experimental, adapted HTA that goes beyond the normal assessment of the health benefit for individual patients by also capturing the additional elements of value to the health system and wider population which are unique to antibiotics. The HTA process will be led by the National Institute for Health and Care Excellence (NICE).

Finalising Terms & Contract Award

5.2.6 Following completion of the HTA and informed by its outcome, the Authority will finalise contractual terms with the winning Bidder and (subject to necessary approvals) proceed to contract Award.

5.2.7 Supply of the selected antimicrobial(s) shall be in accordance with the Contract.

5.2.8 It is anticipated that the Contract will commence on 1 April 2022.

5.3 Timetable

5.3.1 Set out below is the indicative procurement timetable. This is intended as a guide. Whilst the Authority does not intend to depart from the timetable, they reserve the right to do so at their sole discretion. Nothing in this timetable should be understood to be a representation that any specific thing will be done at or within any specific time or at all.

Activity	Target Date
OJEU advert sent for publication	15/06/2020

Bidder selection

Activity	Target Date
Publication (via Bravo) of Selection Questionnaire (SQ) (DRAFT Invitation to Participate in Dialogue (ITPD) made available following publication of the SQ)	15/06/2020
SQ Clarification Deadline	15/07/2020
SQ Submission Deadline	22/07/2020
SQ evaluation / Bidders selected	07/08/2020

Product selection

Activity	Target Date
Stage 1 - ITPD issued to selected Bidders (via Bravo)	10/08/2020
Bidder Briefing	w/c 17/08/2020
Initial Solution submission	31/08/2020
Stage 2 – Commence Competitive Dialogue	14/09/2020
Competitive Dialogue Closed	23/10/2020
Stage 3 - Invitation to Submit Final Tender (ISFT)	30/10/2020

Draft ISFT (Optional at Authority's discretion)

Activity	Target Date
Final Tender response deadline	13/11/2020
Final Tender Evaluation	11/12/2020
Notify Bidders of the product selected for HTA	Dec 2020

Health Technology Assessment (HTA)

Activity	Target Date
HTA	Jan-Dec 2021

Finalising Terms and Contract Award

Activity	Target Date
Contract Finalisation, Approvals, Contract Award and Standstill Period	Jan-Mar 2022
Contract Mobilisation / Commencement	April 2022

- 5.3.2 The Stage 1 Bidder Briefing is intended to assist Bidders to understand the requirements of the procurement.

5.4 Clarifications and Submission Dates

- 5.4.1 Bidders can raise clarifications on the content of the Selection Questionnaire (SQ) or the Invitation to Participate in Dialogue (ITPD) up until the relevant deadline specified in the SQ or ITPD.
- 5.4.2 Bidders' submissions in response to the SQ and ITPD must be submitted via the Bravo e-tendering portal no later than relevant deadline specified in the SQ or ITPD.
- 5.4.3 Please note that Bidder clarifications and / or Tender submissions received after the deadlines may be rejected.

5.5 Procurement Documents

- 5.5.1 Documents and information related to the Procurement are located in the *Attachments* section of the SQ or ITPD on the NHS England Bravo Solution E-Tendering Portal.
- 5.5.2 The Procurement Documents and information may be updated from time to time.
- 5.5.3 The Bidder's Authorised Representative will be notified via the Bravo portal if documents are added or updated.

5.5.4 Any difficulties or problems with access to the NHS England Bravo Solution E-Tendering Portal or any of the documents or information contained therein should be reported by contacting the Bravo Helpdesk.