# Provision of [a New][an Existing] Antimicrobial to the NHS in England via a subscription-based payment model

## Invitation to Participate in Dialogue

### Stage 1

Reference: [xx]

**DRAFT FOR MARKET ENGAGEMENT ONLY**

NHS England and NHS Improvement

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## Notice to Bidders

1. This Invitation to Participate in Dialogue (ITPD) document is being made available on the condition that the information contained within it is used solely in connection with the competitive tender process to procure the Requirement (as defined hereinafter) on behalf of NHS England (**Authority**) and for no other purpose.

2. Whilst reasonable care has been taken in preparing the ITPD, 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 ITPD. 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 the ITPD or to any information on which it is based. Any liability for such matters is expressly disclaimed.

3. In this ITPD 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.

4. Neither the issue of this ITPD nor any of the information presented in it 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.

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 Tenders 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.

# Part 1

# Summary of the Procurement

## 1. Introduction

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.

1.2 This ITPD is issued to Bidders on [**DATE**] 2020 and represents the beginning of the first stage of the Competitive Dialogue process. The purpose of the dialogue is to identify the solution(s) and Bidder(s) which can best meet the Authority's needs and objectives for the Requirement.

1.3 In summary, the aim of this ITPD stage 1 is to enable the Authority to glean, inter alia, an understanding of the range of Bidders' potential solutions that may be capable of meeting the Requirement together with Bidders' indicative costs proposals and to initiate dialogue with Bidders in relation to the Initial Solutions proffered. Detailed information of the proposed structure of the Competitive Dialogue process leading up to the award of contract is set out in detail in Part 3 of this ITPD.

## 2. Overview of the Procurement

2.1 This Procurement relates to the selection of [a new] [an existing] 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.

2.2 Subject to receipt of compliant offers, the Authority intends to award a single contract for supply of the [new] [existing] antimicrobial that best satisfies the Authority's Requirements.

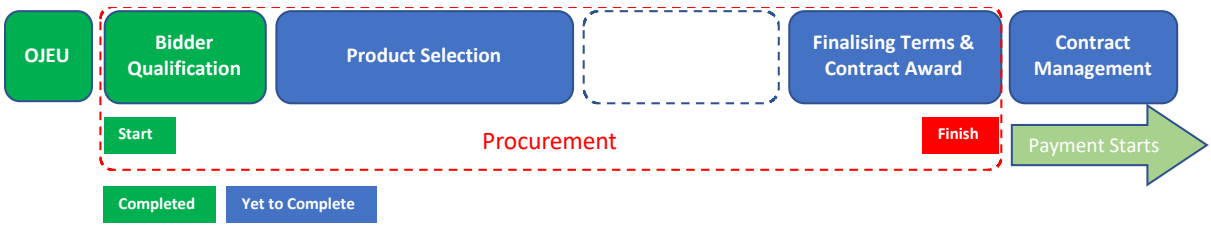
2.3 The process for this Procurement includes the following key steps:

i) Product Selection

ii) Health Technology Assessment

iii) Finalising terms and Contract Award

***Figure 1 Summary Process***




Product Selection

2.3.1 The Authority has specified requirements and an evaluation methodology for determining product selection (*see Part 4 - 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 Requirements in the NHS in England. 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

2.3.2 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

2.3.3 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.

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

2.5 It is anticipated that the Contract will commence on [**1 April 2022]**.

**NOTE** - see Part 3 (*The Competitive Dialogue Process*) of this ITPD for further details

## 3. Timetable

3.1 The indicative timetable for the Competitive Dialogue is set out below. Whilst the Authority does not intend to depart from the timetable, they reserve the right to do so at their sole discretion.

***Table 1* – *Procurement Timetable***

| Activity | Date |
|---|---|
| Stage 1: Issue of ITPD, Invite Bidders to submit Initial Solution | [03/07/2020] |
| Initial Solution submission | [24/07/2020] |
| Stage 2: Commence detailed dialogue | [03/08/2020] |
| Close dialogue | [04/09/2020] |
| Stage 3: (i) draft Invitation to Submit Final Tender (ISFT) ***(Optional at Authority's discretion)***<br>(ii) Invitation to Submit Final Tender (ISFT) | [04/09/2020] |
| Receive ISFT / Final Tender response | [18/09/2020] |

| | |
|---|---|
| Evaluate and select successful / winning Bidder | [30/10/2020] |
| HTA process | [04/01 to 17/12 2021] |
| Contract Finalisation, Contract Award / 10 Day Standstill Period | [04/01 to 31/03 2022] |
| Contract Commencement | [1 April 2022] |

## 4. Clarifications and Submission Date

4.1 Bidders can raise clarifications on the content of this ITPD and the Requirement generally until [**date**] **2020**

4.2 Bidders' Tender submissions in response to this ITPD document must be submitted through the Bravo e-tendering portal no later than [**date**] **2020**

4.3 Please note that Bidder clarifications and / or Tender submissions received after the closing deadlines in paragraphs 4.1 and 4.2 respectively may be rejected.

## 5. Procurement Documents

5.1 Documents and information related to the Procurement are located in the *Attachments* section of the NHS England Bravo Solution E-Tendering Portal [**itt_xxx]**.

5.2 The Procurement Documents and information may be updated from time to time.

5.3 The Bravo portal will notify the Bidder's Authorised Representative when documents are added or updated.

5.4 No documents or information located in the Attachments section of the NHS England Bravo Solution E-Tendering Portal may be deleted and no documents should be marked, altered, modified, varied, defaced, damaged or destroyed in any way.

5.5 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 immediately reported via the Bravo E-Tendering Portal messaging function or by contacting the Bravo Helpdesk.

# Part 2
# Background to the Authority's Requirements

## 1. AMR Background

1.1 Antimicrobial resistance arises when the organisms that cause infection evolve ways to survive treatment. Once standard treatments are ineffective, it is easier for infections to persist and spread. Infections resistant to currently available antibiotics is 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. Inappropriate use of antimicrobial medicines has also added to the problem. 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.

1.2 AMR is one of the most pressing global challenges we face this century. 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.

1.3 The United Kingdom (UK) Government has recognised AMR as a global problem and is committed to taking action at home and supporting progress internationally. The UK's vision, to see AMR contained and controlled by 2040, is supported by a five-year national action plan that reflects both the World Health Organization's (WHO) priorities for tackling AMR and the United Nations framework for action

1.4 The scale of the AMR threat, and the need to contain and control it, is widely acknowledged by governments, international agencies, researchers and private companies alike.

## 2. AMR Burden in the UK

2.1 While the UK has made progress in reducing its use of antibiotics in humans and animals in the last five years, drug-resistant gram-negative blood stream infections in humans have increased by 35% from 2013 to 2017. Resistant infections are estimated to contribute to over 2,000 deaths in this country each year.

2.2 Increasing AMR will cause people to suffer longer infectious illnesses as they become more difficult to treat, 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.

## 3. Rationale for a Change in Approach

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.

3.2 The vision of the UK Government, and that of NHS England and Improvement and NICE, is of a world in which AMR is effectively contained, controlled and mitigated by 2040.

3.3 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, due to high research and development costs and low returns.

3.4 The UK's AMR national action plan 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 is 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 value to the NHS, as opposed to the volumes used. 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 of antimicrobials.

## 4. Progress to Date

4.1 A joint government and industry AMR working group was established in 2015, where the principle of an innovative payment model was agreed. The Economic Evaluation Policy Research Unit (EEPRU) reported in October 2018 that there was scope for a pragmatic HTA framework informed by health economic modelling and expert opinion.

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'.

4.3 The UK was one of the first countries to establish a National Action Plan (NAP) on AMR, with a strategy and action plan in place as early as 2000. In 2013, we reinforced the approach of our action plan by publishing our first fully integrated five-year strategy for tackling AMR across human and animal health. The 2013-2018 AMR strategy committed the UK to action in seven key areas, including infection prevention and control, prescribing practice, professional education and public engagement, development of new and innovative treatment and technologies, surveillance, research and international collaboration.

4.4 The UK AMR national action plan provides that the National Institute for Health and Care Excellence (NICE) and NHS England and NHS Improvement (NHSE&I) "…*will test a new model that will de-link the payments made to companies from the volumes of antibiotics sold, basing the payment on a NICE led assessment of the value of the medicines while supporting good stewardship*".

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

4.5.1 Completed a period of targeted stakeholder engagement:

4.5.2 Developed the adjusted HTA process;

4.5.3 Developed a new payment model;

4.5.4 Defined the maximum amount NHSE&I is prepared to pay per product per annum; and

4.5.5 Defined the process and criteria for NHSE&I to select products to contract with;

4.6 In developing the above, NHSE&I and NICE have concluded:

**A maximum of two antimicrobial products will be selected for the project, one existing and one new.**

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

4.6.2 Selecting one existing and one new product ensures we adequately test the new HTA process and new payment model but with one of the products already in the market (and with some information on usage and emergence of resistance) will enable us to tighten up the modelling and reduce uncertainty associated with this new HTA approach .

To be eligible for consideration, an existing antimicrobial product must:

4.6.3 have an EU licence; and

4.6.4 have a UK launch, dated between 1 January 2017 and 31 December 2018; and

4.6.5 be active against pathogen(s) on the WHO priority pathogen list and which are covered by the Licensed Indication(s).

Similarly, to be eligible for consideration, a new antimicrobial product must:

4.6.6 be timetabled to be licensed for use and launched in the UK prior to 1 January 2021; and

4.6.7 be active against pathogen(s) on the WHO priority pathogen list and which are to be covered by the Licensed Indication(s).

**Product selection should focus on those products that are active against pathogens on the WHO Priority List and address a high unmet need within the NHS in England;**

4.6.8 This test 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 focus on a relative lack of new agents against metallobetalactamase (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.

4.6.9 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 this 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, and one of the recommendations from EEPRU was to test this new methodology in the real world, but 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 we select will be a relatively recent entry to the UK market with at least 12 months usage and resistance data, and the second product we select will be required to achieve a licence and launch in the UK by the end of 2020.

**The product selection process must be undertaken in accordance with the Public Contract Regulations 2015 (as amended);**

**The payment model should provide a pull incentive**

4.6.10 Selected suppliers will receive a higher income than would otherwise be the case under a 'normal' payment model, that reflects the product's value to the NHS in England, once the product has been successfully launched.

4.7 Following the initial targeted engagement, NHSE&I and NICE developed draft procurement documents which were shared with stakeholders on [20 March] 2020. A period of market engagement was held from [20 March 2020 to 17 April] 2020.

4.8 Stakeholders were invited to comment on the draft procurement documents and, where considered appropriate by the Authority, the comments received have been incorporated into these Procurement Documents.

# Part 3
# The Competitive Dialogue Process

The Requirement is being procured under the Competitive Dialogue process. The Dialogue is essentially a competitive process during which the Bidders discuss with the Authority their solution and the contractual documents, with a view to reaching a solution and a set of contract documentation which can form the basis of a final tender. Post tender, further negotiation is not permitted by law, and so any changes which take place may only be of a clarificatory nature, and may not affect the key commercial aspects of the final tender.

It is therefore important for Bidders to note that this is a competition, not a negotiation, and that they **must** raise all significant points which they wish to raise during the Dialogue phase.

The Authority will consider incorporating proposals for change which are based on, for example, improving workability or value for money, but does not guarantee to do so. The intention is to work towards a single common set of contract documents (so far as possible) upon which the Final Tenders are to be based.

The extent to which Bidders propose significant changes to the final contract documentation will be taken into account in the evaluation of the Final Tenders. Therefore, the more significant the amendments proposed, the greater will be the potential adverse effect on the scores.

The aim of this structure is to enable consistency and fairness in scoring the Bidders' Final Tenders, and also to achieve efficiency in the Dialogue process and save both the Authority and the Bidders from incurring excessive costs.

## 1. ITPD Stage 1 – Initial Solutions

1.1 This ITPD represents the first stage in the Competitive Dialogue process.

1.2 The objective of ITPD Stage 1 is to (i) enable the Authority to gain a better understanding as to the range, nature and scope of Bidders' potential solutions to meet the Authority's Requirements including (but not limited to) the key clinical, technical, commercial, legal and financial issues that arise in relation to the Requirement; and (ii) initiate dialogue with Bidders on their proposed Initial Solutions.

1.3 Initial Solutions will form the basis of detailed dialogue with each Bidder – see ITPD Stage 2 below.

1.4 Bidders will have the opportunity to engage with the Authority in April – date to be confirmed) by way of video conference (on a one to one basis) to raise any clarifications in advance of submitting their Initial Solutions

1.5 **NOTE** –Bidders' Initial Solutions will not be scored, and there will not be any down selection (short listing) at this ITPD stage 1. However, any Initial Solution which does not meet the

Authority's minimum requirements (set out in Annex 1 (*Authority's Requirements*) may be disqualified.

1.6 **NOTE FURTHER** – Although there will be no down-selection / shortlisting at this stage, the Authority may give feedback to Bidders in respect of their Initial Solutions. Where any Bidder appears to have significant deficiencies in their solution which might make their solution unacceptable at Final Tender stage unless addressed, the Authority reserves the right to inform that Bidder of the deficiency / gap and offer that Bidder the option of withdrawing. The Bidder is not bound to do so and there will be no prejudice to the Bidder if it decides to continue – this is intended purely as an honest indication of the position at an early stage so that Bidders who are trailing may take the option of saving costs and withdrawing.

## 2. ITPD Stage 2 – Detailed Dialogue

2.1 The Authority will conduct detailed dialogue meetings with each of the participating Bidders who have responded to ITPD Stage 1 for the purpose of discussing their respective proposals, narrowing down potential issues and refining the Authority Requirements with the aim of (i) identifying and defining the means of achieving the best solution to meet the Authority's Requirements and (ii) developing the Contract.

2.2 Bidders need to ensure they have appropriate legal, technical and financial support personnel available during this stage of the procurement and maintain continuity of these personnel throughout the process.

2.3 The dialogue process will include a series of meetings with each Bidder to discuss particular aspects of the Requirement / ITPD documentation to address, inter alia, the following:

2.3.1 the characteristics of the Bidders offered product;

2.3.2 the payment mechanism and performance criteria;

2.3.3 the commercial terms;

2.3.4 the antimicrobial access, stewardship and surveillance requirements; and

2.3.5 contract monitoring and reporting

2.4 The process may also include the submission of further written proposals, presentations, interviews and further site visits.

2.5 A detailed dialogue plan and Rules of Engagement will be provided to each Bidder in due course

2.6 The Authority reserves the right at any time not to continue the detailed dialogue Stage with any of the Bidders, to extend or shorten the detailed dialogue Stage including the number of meetings / rounds of dialogue to be held.

2.7 At this juncture it is anticipated that there will be a minimum of [4] rounds of dialogue meetings with each Bidder. The duration of each dialogue meeting will be [1] day.

2.8 The dialogue process may also include the submission of further written proposals, presentations, meetings and interviews.

2.9 The Authority may, at its sole discretion, extend the dialogue process or introduce subsequent dialogue stages.

2.10 The detailed dialogue Stage will continue until the Authority is, as satisfied as is feasible, that the solutions(s) proposed by Bidders substantially meet all of the Authority's Requirements. At this point, the Authority will declare Dialogue to be concluded.

2.11 The Authority will issue a revised Contract. Changes incorporated into the revised Contract from the detailed dialogue Stage will be implemented across the board for all Bidders; in other words there will be a standard Contract so far as possible.

2.12 Bidders will get one further opportunity to respond to the Authority, with points which must be either related to points they have raised before, or arise from drafting changes, or are minor typos/gap filling. Entirely new points (unless they result from the revised drafting) will **not** be discussed at this stage.

2.13 The Authority will consider any points raised and may (at its discretion) elect to have further meetings to discuss these with the Bidders.

## 3. Draft Invitation to Submit Final Tender ("Draft ISFT") - Stage 3(a) (optional)

3.1 The Authority may, at its discretion, undertake a Draft ISFT stage. This stage, if undertaken, is intended to enable Bidders to prepare and submit a draft final tender response setting out, inter alia, the solutions which have developed through the dialogue process to date. It is also intended to provide an indication of the Authority's expected position regarding the evaluation criteria and scoring methodology at the invitation to submit final tender (ISFT) stage (although the Authority reserves the right to change its position at the ISFT stage).

## 4. Invitation to Submit Final Tender ("ISFT") - Stage 3(b)

4.1 The Authority will prepare the near-final draft contractual agreements (the "ISFT Agreement") which will be sent out to all Bidders with the final tender documentation.

4.2 In response Bidders will submit their Final Tenders. The Final Tenders must be based on the solution(s) identified at the conclusion of the Dialogue and should meet all the Authority Requirements.

4.3 Bidders will have one (1) opportunity only to respond to the Authority with Final Tenders, to include both price and non-price factors and must complete and submit:

4.3.1 Clinical Response Template (Annex 5);

4.3.2 Non-Clinical Response Template (Annex 6);

4.3.3 Financial Response Template (Annex 7)

4.3.4 Confidentiality Undertaking (Annex 14); and

4.3.5 FOI Declaration (Annex 15).

4.4 Bidders will be expected to confirm their acceptance of the form of the ISFT Agreement.

4.5 The Authority may at its discretion seek to "*clarify, specify and optimise*" elements of any Bidders' Final Tender, provided this does not involve changes to the basic features of the Final Tender. **It must be stressed that the Authority's may not, and will not, enter into any negotiation of any material feature or key contract term of the Final Tenders post-tender.** Any activity which leads to changes to a Final Tender will not be allowed to change a material feature of a Tender, key contract term or distort competition.

4.6 The Authority reserves the right at any time not to commence or continue the ISFT Stage with Bidders.

4.7 Following the submission of Final Tenders, the Authority will undertake an evaluation and selection process to identify the Bidder (the "Winning Bidder") who provides the most economically advantageous tender, to whom the Authority's is minded to award the contract.

4.8 The Authority will notify the Winning Bidder and the other Bidders of the outcome. This does not yet constitute the award of a contract or a promise or decision to award a contract. The Winning Bidder will then proceed to HTA.

## 5. Health Technology Assessment (HTA) Process

5.1 The purpose of the HTA process is to estimate the value of the product to the NHS in England.

5.2 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.

5.3 The HTA process will be run by the National Institute for Health and Care Excellence (NICE).

5.4 Further details of the HTA process are provided in Annex 8.

5.5 It is anticipated that the HTA recommendations will be available to both NHSE&I and the Winning Bidder.

## 6. Finalising Terms & Contract Documents

6.1 Following selection of the Winning Bidder and post the HTA process there may be further activity between the Authority and the Winning Bidder to (i) "*confirm financial commitments or other terms contained in the Final Tende*r" and (ii) to take account of the outcome of the HTA; provided, again, that there are no substantial changes to the Final Tender and that this does not risk distorting competition or causing discrimination.

6.2 It is anticipated that this stage will encompass and conclude:

6.2.1 the annual fee to be paid to the supplier (contract value);

6.2.2 finalising the service, stewardship and/or surveillance requirements to reflect the product specific HTA recommendations;

6.2.3 finalising the contract performance criteria (KPIs) to reflect the product specific HTA recommendations.

6.2.4 agreement, informed by the outcome of the HTA, of the annual Contract Value to be paid to the winning Bidder, *Provided That* the annual Contract Value is equal to or less than the lessor of the NHSE&I Maximum Contract Value or the Bidder Maximum Contract Value

6.3 During this period some or all aspects of the financial information provided at PQQ stage may also be confirmed or re-checked at this stage. This will not be re-scored, and the process is purely to ascertain that the information given at PQQ stage is still correct and that there have been no significant adverse changes.

6.4 Once all matters are satisfactorily completed, the Authority will make its decision whether to award the contract to the Winning Bidder.

## 7. Standstill Period

7.1 Once the Authority has reached a decision in respect of contract award it will notify all Bidders of that decision and provide a standstill period of 10 calendar days before entering into a contract (the “Contract”) with the Winning Bidder.

7.2 Certain information regarding the scores achieved by Bidders and the score of the winning Bidder will be made available to individual Bidders as required by law. Further debrief information may be requested and this procedure will be clarified to Bidders later in the process.

## 8. Approvals

8.1 The award of contract is subject to the formal approval processes of the Authority. Until all necessary approvals are obtained and the standstill period (referred to above) has elapsed, the Contract will not be entered into and will not become contractually binding.

# Part 4

# Award Methodology & Criteria

## 1. Introduction

1.1 Any contract awarded as a result of this procurement will be on the basis of the offer which is most economically advantageous to the Authority.

1.2 Bidders' Tender submissions will be evaluated by the Authority applying the evaluation criteria set out in this Part 4 and Annex 4.

1.3 **NOTE** - although the high level criteria will remain consistent throughout the procurement process, the relative weightings of the underlying sub-criteria assigned to each of the evaluation criteria may, at the Authority's sole discretion, be varied during the course of the procurement process.

1.4 Bidders will be notified, sufficiently in advance of any Tender submission that is to be scored or evaluated, of the relative weightings of the underlying sub-criteria, so that Bidders can take the same into account when preparing their Tender responses.

1.5 **IMPORTANT** - Bidders' Initial Solutions submitted in response to this ITPD will **NOT** be scored or evaluated for the purposes of down selection (or otherwise) at this ITPD stage (*see Part 3 of this ITPD for further details*).

## 2. Award Methodology

2.1 The award criteria are grouped into three themes:

2.1.1 Clinical (quality);

2.1.2 Non-clinical (quality); and

2.1.3 Financial (cost).

2.2 The award methodology selects the product to progress to HTA and contract award, primarily based upon the quality (clinical and non-clinical) criteria.

2.3 Key steps in the award methodology include:

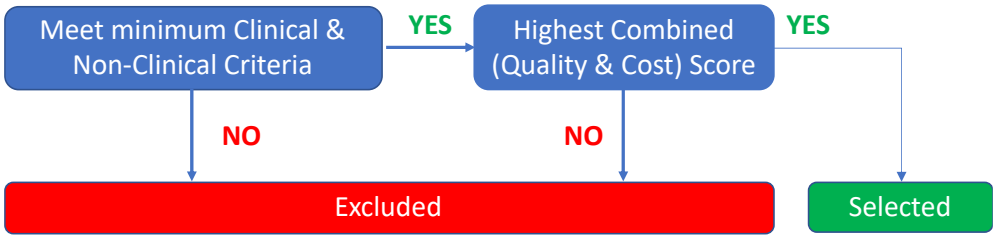
2.3.1 Bidders must achieve a threshold score for the clinical and non-clinical criteria, otherwise they are excluded.

2.3.2 Bidders that achieve the threshold score for the clinical and non-clinical criteria are ranked based upon their overall scores i.e. their combined clinical, non-clinical and cost criteria scores (highest score = ranked #1).

2.3.3 The Bidder ranked #1 i.e. that satisfies the threshold clinical and non-clinical criteria and that achieves the highest overall score, wins.

2.3.4 If no Bidder achieves the threshold score for the clinical and non-clinical criteria, then the Authority may reduce the thresholds in accordance with paragraph 4 until one or more Bidders satisfy the revised threshold.

***Figure 2 Award Methodology***




2.3.5 NHSE&I have established a maximum contract value, (the **NHSE&I Maximum Contract Value**) of £10m (Ten Million Pounds) excluding VAT. This is the maximum annual fee that NHSE&I is prepared to pay per annum for supply of an antimicrobial via a fixed fee payment model.

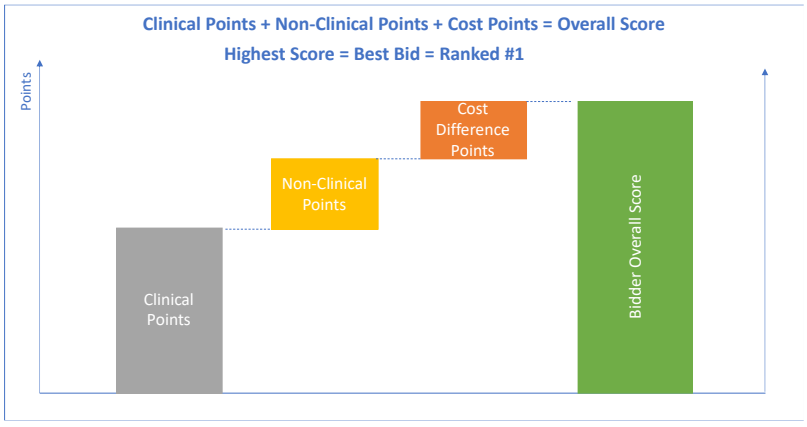
2.3.6 As part of their submission, Bidders are invited to offer a maximum contract value lower than the NHSE&I Maximum Contract Value (the **Bidder Maximum Contract Value**).

2.3.7 In the award methodology, the contract value used for each Bidder is the lesser of the NHSE&I Maximum Contract Value and the Bidder Maximum Contract Value.

## 2.4 Combining Clinical, Non-Clinical & Cost Criteria

2.4.1 The methodology to combine the clinical and non-clinical elements of the assessment with cost is illustrated in Figure 3 below.

***Figure 3 Overall Score***



2.4.2 In order to combine the three elements, any difference between the NHSE&I Maximum Contract Value and the Bidder Maximum Contract Value is converted into points.

2.4.3 The cost difference is converted to points using a conversion rate of £1m = 2,000 points.

2.4.4 The points awarded for any cost difference are then added to the clinical and non-clinical points to derive the Bidders Overall Score.

2.4.5 In the circumstances where cost is considered, the supplier with the highest Overall Score is selected to proceed to HTA, finalising terms, and contract award and implementation.

## 3. Award Criteria

3.1 The award criteria are set out in Annex 4.

3.2 The award criteria are primarily scored criteria where the Bidder provides a written response to a set of questions which are evaluated by a panel of experts in accordance with the scoring methodology and criteria.

3.3 The award criteria are grouped in to three themes:

3.3.1 Clinical;

3.3.2 Non-clinical; and

3.3.3 Financial.

3.4 The clinical themed criteria seek to assess:

3.4.1 The number of WHO priority pathogens included in the licensed indications;

3.4.2 The degree to which the proposed antimicrobial satisfies a high unmet need in the UK;

3.4.3 Performance of the antimicrobial against key resistance determinants in the UK

3.4.4 The clinical severity of the disease area(s) covered by the antimicrobial; and

3.4.5 The degree to which the proposed antimicrobial is novel;

3.5 The non-clinical themed criteria seek to assess:

3.5.1 Surety of supply;

3.5.2 Antimicrobial (including environmental) stewardship; and

3.5.3 Antimicrobial surveillance.

3.6 The financial criteria seek to confirm that the supplier will supply their antimicrobial in accordance with the contract at an annual fee which is the lower of:

3.6.1 NHSE&I Maximum Contract Value; or

3.6.2 The Bidder Maximum Contract Value; or

3.6.3 The value fee agreed between the parties following completion of the HTA process.

3.6.4 **NOTE** - The contract value agreed following the HTA cannot exceed the lower of the NHSE&I Maximum Contract Value and the Bidder Maximum Contract Value.

3.6.5 *Table 2* below summarises the recommended points per clinical (AMR1 & AMR2) and non-clinical (AMR3 to AMR5) criteria

***Table 2 – Points per Criterion***

| Question | Key Component | Criteria | Points |
|---|---|---|---|
| AMR1 | KC1<br>WHO Priority Pathogens | 1st Priority 1<br>2nd Priority 1<br>3rd Priority 1<br>Any / All Priority 2<br>Any / All Priority 3 | 6,000<br>2,500<br>1,250<br>1,000<br>500 |
| | KC2<br>Unmet Need | High<br>Medium<br>Low | 6,000<br>4,000<br>1,000 |
| | KC3<br>Key Resistance Determinants | High<br>Medium<br>Low<br>None | 6,000<br>4,000<br>1,000<br>0 |
| | KC4<br>Disease Setting | High<br>Low<br>PC | 6,000<br>4,000<br>1,000 |
| AMR2 | KC1 | New Class | 2,000 |
| | KC2 | New Pathogen Target | 1,500 |
| | KC3 | New Mode of Action | 1,500 |
| | KC4.a<br>KC4.b | Reduced susceptibility<br>No cross resistance | 1,500<br>1,000 |
| | KC5 | Additional Benefits | 500 |
| AMR3 | | Surety of Supply | 5,000 |
| AMR4 | | Antimicrobial Stewardship | 5,000 |
| AMR5 | | Antimicrobial Surveillance | 5,000 |

## 4. Clinical & Non-Clinical Threshold Scores

4.1 Bidders must achieve a threshold score for the clinical and non-clinical criteria, otherwise they are excluded.

4.2 The initial threshold scores required to pass the clinical and non-clinical criteria are included in *Table 3*

4.3 If no Bidder achieves the threshold score for the clinical and non-clinical criteria at the Final Tender stage, then the Authority may reduce the thresholds in accordance with *Table 3* until one or more Bidders satisfy the revised threshold.

***Table 3 – Clinical & Non-Clinical Threshold Scores***

| | Clinical Score Threshold | Non-Clinical Score Threshold |
|---|---|---|
| Initial Threshold | Greater than or equal to 24,200 points (c67% of the Maximum Score) | Greater than or equal to 3,500 points for each of AMR3, AMR4 & AMR5 |
| Revised Threshold 1 | Greater than or equal to 21,800 points (c60%) | Average of AMR3, AMR4 & AMR5 is greater than or equal to 3,500 points |
| Revised Threshold 2 | Greater than or equal to 19,600 points (c54%) | |
| Revised Threshold 3 | Greater than or equal to 18,100 points (c50%) | |
| Revised Threshold 4 | Less than 18,100 points | |

4.4 The Authority may abandon the procurement if it considers that the offered products provide insufficient value to the NHS in England.

## 5. Contractual Compliance

5.1 Bidders should note that at **Final Tender** stage (at the Authority's discretion) contractual compliance will be evaluated on a Pass/Fail basis; save where the Authority considers at its sole discretion that certain terms are inconsistent or redundant, the Contract will be non-negotiable. Accordingly, Bidders will be required to confirm their acceptance of the Contract to register a Pass.

5.2 Therefore it is important to raise all issues with the Contract at this stage so that they can be dealt with in the Dialogue process.

# Part 5
# Financial

## 1. Payment model

1.1 The payment model describes how the NHS will reimburse the Bidder for supply of the antimicrobial in accordance with the Contract via a fixed fee payment model. The payment model includes:

1.1.1 The fixed fee to be paid for supply of the selected antimicrobial in accordance with the terms of the supply contract. (The fixed fee will be determined by the procurement process, informed by the valuation provided by the NICE HTA);

1.1.2 How and when the fixed fee will be paid;

1.1.3 How payment for the antimicrobial by provider organisations (e.g. NHS Hospitals) will be handled to maintain separation between the fee paid and quantity supplied;

1.1.4 The performance requirements that determine the proportion of the fixed fee actually paid;

1.2 The payment model incorporates a subscription-type contract value (fixed fee) with a performance component, whereby payment of the contract value is not linked to the volume of antimicrobials supplied, however payment of the contract value is contingent upon the Bidder satisfying specified performance (e.g. surety of supply, stewardship and surveillance) requirements.

1.3 The annual contract value paid to the supplier will be agreed between NHSE&I and the Bidder during the Final Negotiation stage and will be informed by the outcome of the NICE HTA.

1.4 However, to ensure affordability for the NHS, irrespective of the HTA valuation, the maximum contract value will be no more than the NHSE&I Maximum Contract Value, or the Bidder Maximum Contract Value offered during the procurement, if lower.

**The NHSE&I Maximum Contract Value is £10m excluding VAT**

1.5 The maximum contract value will be the maximum income a Bidder will receive in any contract year.

1.6 The performance requirements include:

1.6.1 Antimicrobial stewardship;

1.6.2 Surety of supply;

1.6.3 Compliance with good manufacturing practice;

1.6.4 Compliance with good antimicrobial environmental practice;

1.6.5 Compliance with monitoring & reporting requirements; and

1.6.6 Provision of information to support antimicrobial surveillance.

1.7 The supplier's performance against the performance requirements will determine what proportion of the maximum contract value is actually paid (the Adjusted Contract Value).

1.8 There will be no minimum Adjusted Contract Value and the payment will be zero if the performance falls below a minimum threshold of [80]%.

1.9 In addition, in order to ensure the income received is delinked from the amount of product supplied, the adjusted contract value will be reduced by a sum equal to the value of product purchased by care providers.

1.10 Care providers will purchase the antimicrobial via normal distribution routes at a nationally agreed nominal Invoice Price, with the price being set to encourage appropriate use of the antimicrobial (i.e. the Invoice Price should not so high as to discourage appropriate use but also not so low as to encourage inappropriate use).

1.11 During the term of the contract, NHSE&I may initiate a review of the contract:

1.11.1 in the event of the supplier significantly or repeatedly underperforms against the service or stewardship requirements; or

1.11.2 if, in the opinion of NHSE&I, there has been a material change to the assumptions used within the HTA; or

1.11.3 if, in the opinion of NHSE&I, there has been a material reduction to the unmet need addressed by the product.

1.12 NHSE&I may initiate the contract review at any time and the review may result in:

1.12.1 reduction of the Maximum Contract Value (subject to the agreement of the supplier);

1.12.2 adjustment of the performance requirements;

1.12.3 adjustment of the performance criteria;

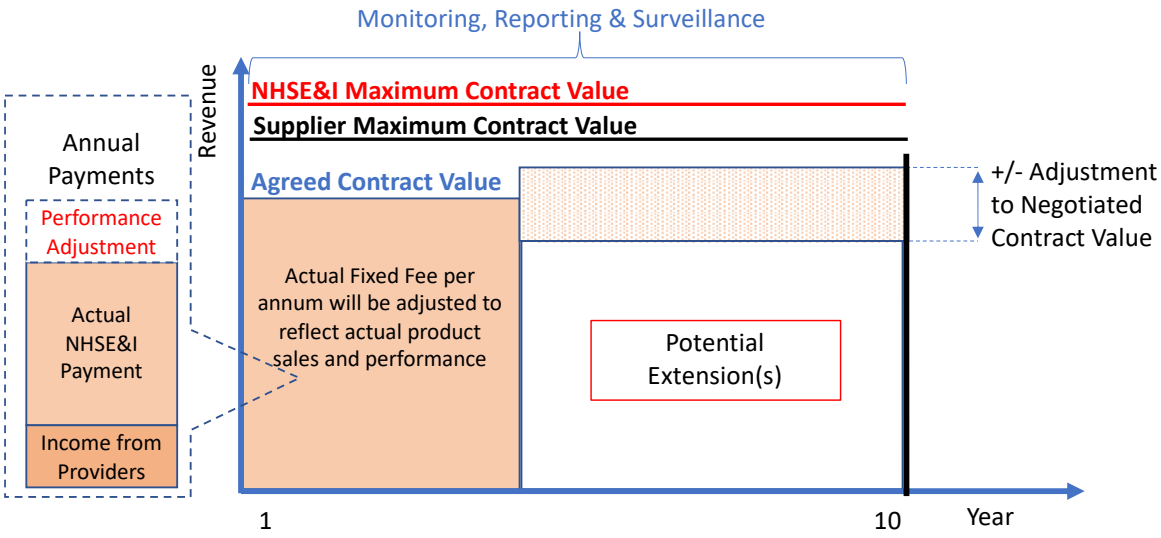
1.12.4 adjustment of the data capture and reporting requirements;

1.12.5 termination of the contract.

1.13 The initial contract term will be **three (3) years** with an option (at the sole discretion of NHSE&I) to extend the contract for a period or periods up to a maximum of **ten (10) years**.

1.14 NHSE&I may terminate the contract at any time (for convenience) subject to the provisions set out in the Contract.

***Figure 4 Payment Model***




## 2. Payments

2.1 The Agreed Contract Value, adjusted for performance and care provider purchases, will be paid in quarterly instalments.

2.2 Each quarter:

*Payment = Adjusted Contract Value (for the previous quarter), less Care Provider Purchases (for the previous quarter)*

*Where: Adjusted Contract Value = Agreed Contract Value x Supplier Performance % (for the previous quarter)*

2.3 *Table 4* below provides the anticipated timing of performance reviews and payments for each contract quarter.

*Table 4 – Timing of Performance Reviews & Payments*

| **Quarter** | **A** | | | **B** | | |
|---|---|---|---|---|---|---|
| **Month** | **1** | **2** | **3** | **1** | **2** | **3** |
| Contract Quarter | X | X | X | | | |
| Performance Reporting | | | | X | | |
| Performance Review | | | | | X | |
| Payment | | | | | | X |

2.4 Performance components that are measured less than once per quarter (e.g. if they are based upon annual audit reports), will be included in the first review after the performance information is available. If necessary, previous Supplier Performance %'s may be adjusted to reflect the latest performance information.

2.5 Similarly, the next and subsequent quarterly payments may be adjusted such that the payments made to the supplier equals the sum that should have been paid to the supplier if the performance information referred to in 2.4 above had been available at the end of each quarter.

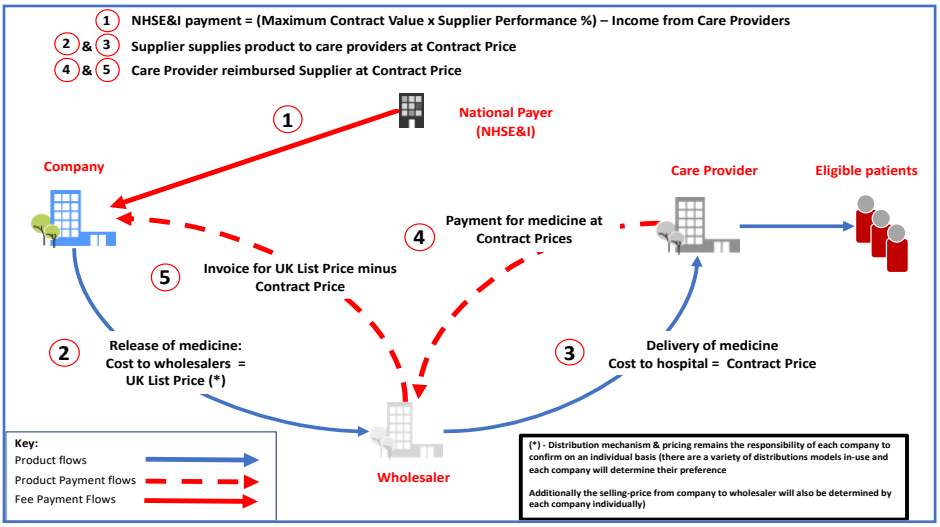
## 3. Payment & Supply Flows

3.1 NHSE&I pays the supplier the agreed fee in quarterly instalments, adjusted for performance and minus any adjustments for product supplied to care providers;

3.2 The supplier provides the product to the care provider at the Invoice Price (via a wholesaler if that is their current / preferred delivery model);

3.3 The care provider reimburses the supplier (if needed via a wholesaler) at the Invoice Price;

*Figure 5 Product and Payment Flows*




## 4. Invoice Price

4.1 A national list price will be maintained for the purposes of international reference pricing.

4.2 An Invoice Price will be agreed with each Bidder as part of the procurement process. All NHS care providers will purchase the product at the agreed Invoice Price.

4.3 The Invoice Price agreed should be:

4.3.1 accessible for NHS care providers;

4.3.2 set to encourage appropriate usage (i.e. not be too high so it deters appropriate usage and not too low so it encourages inappropriate usage);

4.3.3 reflect the price of an appropriate comparator or range of comparators.

4.4 This mechanism accommodates different prices for the selected products whilst ensuring the system only pays the Agreed Contract Value.

4.5 Suppliers can utilise their existing supply chain capabilities to supply to care providers at the agreed Invoice Price.

## 5. Determining the Agreed Contract Value

5.1 The Agreed Contract Value will be finalised with the winning Bidder following completion of the HTA.

5.2 The structure & finalisation of pricing terms will be informed by the outcome of the HTA.

5.3 The Agreed Contract Value will not exceed the lower of the NHSE&I Maximum Contract Value and the Bidder Maximum Contract Value.

## 6. Determining the Adjusted Contract Value

6.1 The Adjusted Contract Value is equal to the Agreed Contract Value multiplied by the Supplier Performance %.

6.2 The Supplier Performance % reflects the Suppliers performance against the Performance Criteria.

## 7. Performance Framework

7.1 Details of the required standards of performance are included in the:

7.1.1 Stewardship Specification;

7.1.2 Supply Specification;

7.1.3 Monitoring & Reporting Specification;

7.1.4 AMR Industry Alliance – Making Antibiotics Responsibly; and

7.1.5 Antimicrobial Surveillance Specification.

7.2 The Performance Framework provides the mechanism to calculate the Supplier Performance %.

7.3 The Supplier Performance % = (1000 – Performance Deductions) / 1000

7.4 Table 6 provides detail of the performance criteria and associated deductions if the performance criteria are not met.

***Table 5 – Performance Criteria (DRAFT)***

| Performance Criteria | Deduction |
|---|---|
| Antimicrobial Stewardship | |
| [Promotion of the product in England] | [150] |
| Surety of Supply | |
| [Per failure to supply (the product is not available at the time and Care Provider location required)] | [100] |
| Good antimicrobial manufacturing and environmental practice* | |
| [AMR Industry Alliance – Making Antibiotics Responsibly audit report indicates the supplier / their supply chain has not satisfied the minimum expectations] | [150] |
| Monitoring & Reporting | |
| [Per incomplete, late or omitted reporting submission per Quarter] | [100] |
| Antimicrobial Surveillance | |
| [Per incomplete, late or omitted reporting submission per Quarter] | [100] |

***Suppliers are required to provide a copy of their Making Antibiotics Responsibly Audit Report within the first Contract Year.***

7.5 If the sum of Performance Deductions is greater than [200], then the Supplier Performance % = 0%

# Part 6
# Legal and Contractual

## 1. Contract Structure

1.1 The Contract structure between NHS England and the Supplier is illustrated in fig. 7 below.

1.2 NHS England will enter into an NHS Standard Contract with the appointed Supplier for provision of the antimicrobial Requirement

1.3 The Contract will contain (amongst other 'local' terms):

1.3.1 bespoke payment provisions;

1.3.2 obligations on the Supplier to deliver the antimicrobial included in their Final Offer;

1.3.3 obligations on the Supplier to comply with the performance requirements;

1.3.4 obligations on the Supplier to comply with the specifications; and

1.3.5 the standard Commercial Medicines Unit (CMU) provisions regarding the supply of pharmaceuticals;

## 2. Form of Contract

2.1 The Contract will be signed by the Supplier and NHS England.

2.2 The draft Contract (subject to inclusion of schedules that are subject to the outcome of dialogue) is included within the Procurement Documents at Annex 9.

2.3 The draft Contract is the NHS Standard Contract for the Supply of Goods and the Provision of Services (Contract version).

2.4 The Contract shall also encompass those terms and conditions included in Annex 10, 11, 12 & 13 - Contract technical specification as the Authority considers necessary.

2.5 Bidders should note that the terms of the Contract will be updated in line with any newly updated and published version of the NHS Standard Contract prior to contract award. NHS England may vary the terms of the Contract annually in line with updates to the relevant NHS Standard Contract for the relevant year.

2.6 The core Contract terms and conditions are not negotiable at any time. Bidders may seek clarification only in respect of any points of ambiguity or apparent error in the Contract terms and conditions.

2.7 Where the Supplier intends to subcontract clinical services then the Authority requires the Supplier to enter into a sub-contract with such sub-contractors on the basis of the NHS Standard Contract sub-contract, published at:
https://www.england.nhs.uk/nhs-standard-contract/17-18/
(updated from time to time and in line with the version of the NHS Standard Contract which is entered into with the Supplier). In accordance with General Condition 12.1 of the Contract, the Authority's approval of such sub-contracting arrangements will be subject to the Authority's approval of the form of sub-contract for such sub-contracted clinical services.

2.8 For the avoidance of doubt, the Authority will not mandate terms and conditions for sub-contracts for the supply of goods or non-clinical services. However, unless otherwise agreed with the Authority in writing, the terms and conditions for such sub-contracts shall be subject to the approval of the Authority as it sees fit, in line with General Condition 12.1 of the Contract.

## 3. Contract Duration

3.1 As a result of this procurement exercise the Contract will be entered into with the successful bidder for an initial period of 3 years with the Authority having the option to extend for a period, or periods up to a total of 10 years.

## 4. Contract Award and Signature

4.1 Within one month of the Authority notifying the Supplier of the Authority's decision to proceed to award of contract, the Supplier must:

4.1.1 enter into the Contract with the Authority;

4.1.2 enter into all necessary contractual arrangements to put in place the sub-contracting arrangements and/or consortium arrangements which formed part of the Bidder's qualification stage / Final Tender submission, including forming any legal entity and provide evidence of this to the satisfaction of the Authority.

4.2 The Authority may abandon the procurement or award the Contract to the next highest ranked Bidder if the Bidder does not meet the requirements of paragraph 4.1 above or where the Authority enters into the Contract with the Supplier but terminates this Contract due to failure by the Supplier to meet the mobilisation requirements and /or conditions precedent set out in the Contract.

4.3 No offer or bid is deemed accepted until the relevant contractual documents have been duly signed on behalf of the Authority, the Supplier and all other relevant parties and declared unconditional. No dialogue or communication with the Authority whether prior to, during or subsequent to the submission of any bid implies acceptance of any offer or constitutes an indication that the Bidder will be awarded the contract. Only the express terms of any written

contract(s) which is finally agreed and signed for and on behalf of the relevant parties and which is duly declared unconditional shall have any contractual effect.

## 5. Mobilisation

5.1 Mobilisation will commence, subject to agreement, following execution of the Contract and will end at Service Commencement. The Supplier(s) may commence mobilisation prior to the contract execution date but this will be at their risk and cost.

## 6. Service Commencement

6.1 The Supplier is required to commence delivery of services on or before **1 April 2022** or such other date as agreed between NHS England and the Supplier.

## 7. Conditions of Offer

7.1 A response to an Invitation to Submit Final Tender is an irrevocable offer by the Bidder and the Bidder separately undertakes with the Authority that the Submission will remain open for acceptance by the Authority for up to 18 months from the ISFT submission deadline.

7.2 In submitting its ISFT Submission, the Bidder warrants, represents and undertakes to the Authority that:

7.2.1 All information and representations made to the Authority by the Bidder, its staff or agents in connection with or arising out of the qualification questionnaire (QQ), ITPD, ISFT and/or associated documents, are true, complete and accurate;

7.2.2 It has made its own investigations and undertaken its own research and due diligence and has satisfied itself in respect of all matters (whether actual or contingent) relating to the QQ, ITPD, ISFT and associated documents and that it has not submitted its Bid Submission in reliance upon any information, representation or assumption which may have been made by or on behalf of the Authority (save in respect of any information which is expressly warranted by the Authority); and

7.2.3 Where there is a change to the information provided to the Authority at any time the Bidder must advise the Authority as soon as practicable, even if this is prior to the date of submitting the Bid Submission and disclose such changes in full.

7.3 The Authority reserves the right to retain all and any of the information supplied to it by the Bidder(s).

## 8. Transition from Current Arrangements

8.1 In the event that contracts are awarded as a result of this procurement, then any existing framework agreements for the supply of the antimicrobial will be terminated.

## 9. Contract Monitoring and Management

9.1 Monitoring & Reporting:

Supplier Monthly Reporting

9.1.1 The Supplier will provide a monthly report detailing the total number of packs supplied in the previous month. As a minimum, the report will specify the number of packs delivered, the delivery date and delivery address.

Supplier Quarterly Reporting

9.1.2 The Supplier will provide a quarterly report detailing its performance, together with supporting evidence, against each of the performance criteria.

9.2 Contract Management

9.2.1 The Authority anticipates undertaking contract review meetings with Suppliers at least quarterly, with monthly meetings during the initial six (6) month period of the Contract.

9.2.2 The contract management arrangements will be discussed during dialogue; however the quarterly review meetings will include validating the Suppliers performance against the performance criteria in the previous quarter.

# Part 7
# Governance & Administration

## 1. Definitions

1.1 For the purposes of this ITPD the capitalised words and expressions that follow have the meanings hereby assigned to them unless the context specifically requires otherwise.

| | |
|---|---|
| **Agreement** | the agreement to be entered into between the Authority and the winning Bidder in respect of the Requirement |
| **Authorised Representative** | the nominated person authorised on behalf of the Bidder |
| **Authority and / or Contracting Authority** | the NHS Commissioning Board, referred to as "*NHS England*" |
| **Bidder** | the person, firm, company or consortium that has been invited to respond to this ITPD |
| **Competitive Dialogue** | a procedure, pursuant to the Public Contracts Regulations 2015 as amended (the "Regulations") by which the Authority will, with the aim of meeting its Requirements, conduct the procurement of the Requirement |
| **Contract or Draft Contract** | the draft terms and conditions of contract and associated schedules set out in Annex 9 (Draft Contract) to this ITPD |
| **Deliverables** | the deliverables set out in Annex 2 of this ITPD which Bidders are required to respond to in their Initial Solution |
| **Existing Antimicrobial** | an antimicrobial with an EU license and a UK launch dated on or between 1 January 2017 and 31 December 2018 and the Licensed Indication(s) include one or more pathogens on the WHO priority pathogen list against which the antimicrobial is active |
| **Final Tender** | the "best and final offer" to be submitted by Bidders in their final tender submission |
| **Invitation to Participate in Dialogue** or **ITPD** | this invitation to participate in dialogue, which is a part of the Competitive Dialogue process for the procuring the Requirement |
| **Invitation to Submit Final Tender** or **ISFT** | the final tender document to be issued in this process, which will invite Bidders to submit their Final Tenders |
| **Initial Solution** | a Bidder's initial proposals for meeting the Authority's Requirements in accordance with the terms of this ITPD |

| | |
|---|---|
| **Material Sub-Contractor** | any sub - contractor, whether of the Supplier itself or at any further level of sub - contracting, under any Sub – Contract where the subcontractor is providing clinical services or where the value of the Sub – Contract is valued at more than 10% of the total value sub-contracted by the Supplier |
| **New Antimicrobial** | an antimicrobial that is timetabled to be licensed for use and launched in the UK prior to the 1st January 2021 and the Licensed Indication(s) include one or more pathogen on the WHO priority pathogen list against which the antimicrobial is active |
| **Procurement** | this procurement process relating to the supply and delivery of antimicrobials |
| **Procurement Documents"** | the documents referred to in this ITPD and all associated Appendices, Annexes or other documents referred to therein |
| **Relevant Organisation** | any organisation(s) or person that the Bidder is relying on when making their ITPD submission and/or for the purpose of the performance of any obligation on the part of the Supplier under any ensuing Agreement, including without limitation: the Bidder; the Supplier; each Material Sub-Contractor |
| **Regulations** | the Public Contracts Regulations 2015 (as amended) |
| **Requirement** | the antimicrobial medicine which the Authority wishes to procure, information and details of which are set out in Annex 1 of this ITPD document and "Requirements" shall be construed accordingly |
| **Rules of Engagement** | the Authority's rules of engagement concerning the conduct of the dialogue phase of this procurement |
| **Sub – Contract** | any sub - contract entered into by the Supplier or by any Sub - Contractor of any level for the purpose of the performance of any obligation on the part of the Supplier under this Contract |
| **Sub – Contractor** | any sub - contractor, whether of the Supplier itself or at any further level of sub - contracting, under any Sub – Contract |
| **Supplier(s)** | he Bidder who has entered into a Contract with the Authority to supply and delivery antimicrobials |

| | |
|---|---|
| **Tender** | the responses (including Initial Solution) submitted by Bidders in accordance with the terms of this ITPD and ISFT issued by the Authority during the course of this Competitive Dialogue process |
| **TUPE** | Transfer of Undertakings (Protection of Employment) Regulations 2006 (SI 2006/246) |
| **Update** | a written notification by the Authority to the Bidders. Updates may be issued during the tender period to amend or to provide further clarification to any part of the ITPD |

## 2. General

2.1 By signing/submitting a Tender, the Bidder and each Relevant Organisations warrants that, save as disclosed in writing to the Authority with the Tender, any information supplied by it remains true and that it has:

a) Not passed a resolution, nor is it the subject of an order by the court, for the company's winding-up otherwise than for the purposes of bona fide reconstruction or amalgamation, nor has it had a receiver, manager or administrator on behalf of a creditor appointed in respect of its business or any part thereof, nor is it the subject of proceedings for any of the above procedures, nor is it the subject of similar procedures under the law of any other states;

b) Not been convicted of a criminal offence relating to the conduct of its business or profession;

c) Not been convicted of any of the offences listed in Regulation 57 "Mandatory exclusions" of the Public Contracts Regulations 2015;

d) Not been in in any of situations listed in Regulation 57 "Mandatory and discretionary exclusions for non-payment of taxes etc" or "Discretionary exclusions" of the Public Contracts Regulations 2015, subject to the exercise of Discretion, or acceptance of evidence of Self-Cleaning, on behalf of the Authority, as provided for under Regulation 57.

e) Not made any material misrepresentation in providing any of the information required in relation to the or ITPD or ISFT; and

f) Not disclosed, copied, reproduced or distributed and will not disclose, copy, reproduce or distribute any information contained in the Procurement Documents or supplied by the Authority to any third party at any time except for the purpose of enabling a response to the ITPD or ISFT to be prepared.

2.2 The Authority may its own absolute discretion extend the closing date and time for receipt of ITPD and/or ISFT responses. Any extension granted will apply to all Bidders.

## 3. Guidance and Compliance

3.1 Bidders should read these instructions carefully before submitting a response to this the ITPD. Failure to comply with these requirements for completion and submission of the Tender response may result in the rejection of the Tender response. Bidders are therefore advised to acquaint themselves fully with the instructions and conditions set out in this ITPD.

3.2 All Tenders received by the Authority will be checked for compliance with the submission requirements set out in this ITPD. If a Tender is not considered compliant, the Authority will not be obliged to carry out any further evaluation and the Bidder may be eliminated from the procurement. During this period, clarification on any aspect of the Tender may be sought.

3.3 A compliant Tender is defined as one that meets the following criteria (as defined in this ITPD) (i) it is delivered before the Tender submission deadline and (ii) it meets the Tender response requirements;

3.4 The Authority requires adherence to all instructions and conditions within this ITPD from each of the Bidders and the participation in the tender process by each Bidder shall be construed as unqualified acceptance of such obligations by and on behalf of that Bidder.

## 4. Enquiries

4.1 Any enquiries must be submitted in writing via the Bravo e-tendering portal.

4.2 Except where the response to an enquiry relates to commercially confidential matters, the Authority's will copy their responses to all Bidders in accordance with paragraph 6 below in the form of a clarification via the Bravo e-tendering portal.

## 5. Tender Validity

5.1 All Tenders submitted by Bidders must remain open for acceptance up to ***18 months*** from the ISFT submission deadline. Offer Prices must be firm (i.e. not subject to variation) for the period of the contract subject only to any variation provisions contained in the contract documents.

## 6. Language

6.1 All documentation and communication shall be in English.

## 7. Tender Preparation Costs

7.1 Each Bidder shall be solely responsible for all the costs it incurs in the preparation and submission of its Tender up to and including the award of any contract by the Authority. This shall also be deemed to cover the cost of attending any pre or post Tender meetings and dialogue and, should a Bidder be successful, the preparation of contract documents. The Authority shall in no event be responsible or liable for any such costs regardless of the conduct or outcome of the bidding process, and in this respect, the Bidder shall have no recourse to the Authority.

## 3. Variant Bids

3.1 Variant bids are **NOT** permitted.

## 4. ITPD Updates

4.1 Throughout the Competitive Dialogue process, the Authority may issue Updates, which will be identified by a number and the date. These will be issued via the Bravo e-tendering portal.

4.2 Such Updates will contain details of any amendments, additions or variation to the information contained in this ITPD document or documents previously provided, together with any further information, which may assist the Bidders in the preparation of their submissions. No

statements issued by the Authority in relation to this or any other documents shall be relied upon unless ratified by an Update.

## 5. Bidder's Authorised Representative

5.1 All communication relating to this Procurement will be sent via the NHS England Bravo Solution E-Tendering Portal for the attention of the Bidder's Authorised Representative. The Authorised Representative must have full authority to represent the Bidder and attend any meetings on the Bidder's behalf. The Authority may, at any time, request documentary proof of such authority. Bidders shall notify the Authority of any changes to the Authorised Representative's contact details as soon as practicable.

## 6. Confidential Information

6.1 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-contractors (subject to obtaining appropriate confidentiality undertakings) but only to the extent necessary to enable it to prepare its Tender and participate in this procurement.

6.2 The Authority may disclose detailed information relating to Bidders' Tender responses to the Authority's officers, employees, agents or advisers and they may make Bidders' Tender responses available for private inspection by the Authority's officers, employees, agents or advisers.

6.3 The Authority also reserve the right to disseminate information that is materially relevant to all Bidders, even if the information has only been requested by one Bidder, subject to the duty to protect any Bidder's commercial confidence in its responses.

6.4 Should Bidders wish to avoid such disclosure (for example, on the basis that the request or response contains commercially confidential information or may give another Bidder a commercial advantage) the request must be clearly marked "**In Confidence - not to be circulated to other Bidders**" and the Bidder must set out the reason(s) for the request for non-disclosure to other Bidders.

6.5 If the Authority considers that, in the interests of open and fair competition, it is unable to respond to the question or request for clarification or further information on a confidential basis, it will inform the Bidder who has submitted it. The Bidder must as soon as practicable thereafter respond in writing requesting that either the query be withdrawn or treated as not confidential. The Authority will deem that the question or request for clarification or further information has been withdrawn if the Authority is not contacted in writing via the Bravo e-tendering portal within 2 working days following the Bidder being so informed.

6.6 The Authority will act reasonably as regards the protection of commercially sensitive information relating to the Bidder, subject always to the Authority's duties under the Freedom of Information Act 2000.

## 7. Staff Transfers - Transfer of Undertakings Protection of Employment (TUPE)

7.1 Where staff are directly employed under a current contract, the obligations of the Transfer of Undertakings (Protection of Employment) Regulations 2006 (TUPE) or the Cabinet Office Statement of Practice (COSOP) may apply. The Authority have a facilitating role only and are not in a position to make any statement regarding any potential obligations the tender may give rise to under TUPE.

7.2 Bidders are required to take their own advice on whether TUPE or COSOP will apply to the tender and their specific bid. Agreement on staff to be transferred is the responsibility of the successful bidder and the existing provider(s). The Authority makes no warranty that the information provided is correct and accepts no liability or indemnity for any errors or omissions or inaccuracies in the information provided.

7.3 The successful bidder will be required to indemnify the Authority against all possible claims under TUPE (including in respect of any early retirement pension rights). Also it is a further requirement that the successful bidder will pass on all details of their own workforce towards the end of the Contract period so that this information can be passed to other bona fide bidders to enable them to assess their obligations under TUPE in the event of a subsequent transfer occasioned by a future tender process. These terms will be detailed in the Contract entered into by the successful bidder.

7.4 If there are any affected employees, Bidders should expect that some or all affected employees are either currently in the NHS Pension Scheme (NHSPS) or will have a right to return to the NHSPS when their employment next transfers, in line with New Fair Deal. HM Treasury's New Fair Deal policy (available via the link below ) sets out how pensions matters are to be dealt with when staff are compulsorily transferred from the public sector to independent contractors delivering public services or between contractors on re-tendering of such services. Bidders should expect that they will be required to meet all contributions/costs associated with participating in the NHSPS.

7.5 Bidders should expect the contract to be conducted in a manner which reflects Department of Health guidance on the application of New Fair Deal in the NHS, which can be accessed through the links below:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/294850/New_Fair_Deal_-_DH_Guidance_for_NHS_Pension_Scheme.pdf

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/435663/Staff_returning_to_the_NHS_pensions_scheme__1_.pdf

Fair Deal for staff pensions: staff transfer from central government (October 2013) is available through the following link

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/262490/PU1571_Fair_Deal_for_staf_pensions.pdf

7.6 Bidders are advised to conduct due diligence and to take independent advice in relation to pensions matters. Bidders will be required to procure that sub-contractors to whom staff may transfer comply with the same pension requirements and to indemnify the Authority against all possible claims in respect of any sub-contractor non-compliance.

## 8. No Inducement Or Incentive

8.1 The Procurement Documents are issued on the basis that nothing contained in them shall constitute an inducement or incentive nor shall have in any other way persuaded a Bidder or Relevant Organisation to submit a Bid or enter into any contractual agreement.

## 9. Freedom of Information

9.1 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 tender. Information may be exempt from disclosure under FOIA where its disclosure would 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 tender would be disclosed in response to a request made under FOIA. In the event that such a request is received by the Authority it 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. 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.

## 10. Copyright

10.1 Bidders are reminded that the copyright to this ITPD rests with the Authority and its appointed advisors. This ITPD may not either in whole or in part be copied, reproduced, distributed or otherwise made available to any other third party without the prior written consent of the Authority except in relation to the preparation of a Tender. All documentation supplied by the Authority in relation to this ITPD is, and shall remain the property of the Authority and must be returned on demand, without any copies being retained.

## 11. Canvassing

11.1 Any Bidder who directly or indirectly canvasses any member of the Authority or any of its officials or representatives concerning the contract award process for Requirement may be disqualified.

## 12. Collusive Submissions

12.1 Any Bidder who:

a) Fixes or adjusts the Tender rates and prices quoted by it under or in accordance with any agreement or arrangement with any other person; or

b) Communicates to any person other than the Authority the amount or approximate amount of its proposed Tender (except where such disclosure is made in confidence in order to obtain quotations necessary for the preparation of the Tender for insurance or similar activity); or

c) Offers or agrees to pay or give, or does pay or give any sum of money inducement or valuable consideration directly or indirectly to any person for doing or having done or causing or having caused to be done in relation to this or any other Tender or proposed Tender, any act or omission; will be (without prejudice to any other civil remedies available to the Authority and without prejudice to any criminal liability which such conduct by a Bidder may attract) disqualified. The Bidder warrants that its Tender shall be bona fide and shall be intended to be competitive and that it has not done and will not do at any time any of the acts set out in paragraph 11.1 above.

## 13. Bidder Membership and Eligibility

13.1 The Authority must be notified in writing of any change in the control, composition or membership of a Bidder that has taken place subsequent to the Bidder's selection to participate in the Competitive Dialogue and of any other material change to the Bidder's response to the PQQ, particularly any material change in the financial position of a Bidder. The Authority reserves the absolute right to withhold approval to any such changes and to disqualify the Bidder concerned from any further participation in the procurement process.

13.2 Bidders are reminded of the eligibility requirements that apply to the procurement process at all times. In particular, these include the provisions set out in Regulation 57 of the Public Contracts Regulations 2016. Any change in the eligibility of a Bidder must be notified immediately to the Authority in writing and may result in such Bidder being disqualified from any further participation in the procurement process.

## 14. Consortia and Subcontracts

14.1 For expressions of interest, Tenders and Final Tenders, the Authority has drawn a distinction between prime and subcontracting arrangements and consortium arrangements. The Authority recognises these terms are often used interchangeably by some Bidders and wishes Bidders to apply the following common terminology to company groupings in the future.

14.2 Where groups of companies come together specifically for the purpose of bidding for appointment as the winning service provider and envisage they will establish a special purpose vehicle as the prime contracting party with the Authority, the Authority will characterise these arrangements as consortium arrangements.

14.3 Where groups of companies come together specifically for the purpose of bidding for appointment as the service provider, but envisage that one of their number will be the service provider, the remaining members of that group will be subcontractors to the service provider.

14.4 The Authority requires all Bidders (if they have not done so already) to identify which of these two arrangements apply in the case of their proposal and precisely which entity they propose to be the service provider.

14.5 The Authority also recognises that Bidders may wish to extend or modify their groupings of subcontractors or consortium members to meet the existing and future requirements of the Authority. To ensure all Bidders are treated in a transparent and non-discriminatory manner, the Authority would like to give the guidance set out below.

14.6 Bidders should note that the principles set out below are provided only for guidance and do not constitute a definitive or exhaustive view of the approach the Authority will take in any individual circumstances. Bidders should notify the Authority of any proposed changes to the identity of consortia or subcontractors.

14.7 The guidance is as follows:

a) where an organisation has identified itself as a Bidder, the withdrawal of that organisation in favour of another member of that organisation's group of subcontractors or otherwise will be treated as the withdrawal of the Bidder itself and will result in the disqualification of the Bidder (and so its subcontractors);
b) where an organisation has identified itself as a Bidder, it is at liberty, until the submission of its Tender, to revise the identity of its subcontractor grouping, provided this does not cause the Authority to reconsider the basis on which the Bidder qualified and was selected;
c) where two or more Bidders wish to consolidate their bids into one bid, specific guidance from the Authority should be sought;
d) if a Tender is submitted by a consortium, the Authority will require any agreement(s) to be entered into by all consortium members on a joint and several basis, or by a lead single entity on behalf of the consortium. In the latter case, other consortium members may be required to enter into direct agreements with or guarantees to the Authority in connection with their sub-contracts and the Authority will require a right of approval over sub-contracts. In the case of a lead entity which is specially created for this contract, the Authority will also require confirmation that the consortium will provide a sufficient level of security, whether by way of guarantees from consortium members or their parents, or otherwise.
e) where a group of organisations has identified itself as a consortium, the grouping may change (by addition or removal of consortium members), provided this does not change the fundamental character of the consortium or cause the Authority to reconsider the basis on which that consortium qualified and was selected;
f) generally, the Authority will be more concerned with the loss of subcontractors or consortium members than with the addition of subcontractors or consortia members;

g) once this ITPD has been issued and the Final Tender received, Bidders will be at liberty to continue to finalise their consortium or subcontracting arrangements until the contract award, unless changes to the constitution of those consortia or subcontracting arrangements would cause the Authority to reconsider the basis on which the Bidder was allowed to continue in the procurement process; and

h) once a contract has been awarded to a Bidder, the Authority would not expect any changes in this group of subcontractors to occur without its consent and the final form Contract will contain appropriate provisions.

## 15. Authority's Advisors

15.1 Bidders should note that the advisers currently appointed on behalf of the Authority in relation to this procurement are:

- **Legal - Blake Morgan LLP**

15.2 The Authority may, at their sole discretion, appoint additional advisors.

15.3 Each Bidder acknowledges that by virtue of submitting a Tender in response to the ITPD it waives any right of objection which it has or may have in relation to the Authority's appointment of professional advisers. The Authority reserves the right to disqualify any Bidder which refuses to provide such a waiver.

## 16. Publicity

16.1 No publicity regarding the procurement of the Requirement or the award of any contract will be permitted unless and until the Authority has given express written consent to the relevant communication.

## 17. Conflict of Interest

17.1 Bidders are instructed to ensure that their potential appointment as the service provider to the Authority for the provision of the Requirement has not and will not create any conflict of interest or any situation that might compromise or prejudice the Authority's duty to manage an open, fair, non-discriminatory and competitive procurement process. In the event of a conflict (or potential conflict) arising at any time during the procurement process, the affected Bidder must report the occurrence of an actual or potential conflict and the means for resolving it to the Authority as soon as reasonably practicable.

17.2 Failure to declare any actual or potential conflict and/or failure to address such conflict to the reasonable satisfaction of the Authority may result in a Bidder being disqualified from this procurement.

## 18. Right to Reject Bidder Responses

18.1 The Authority reserves the right to reject or disqualify a Bidder where:

i) A Tender response is submitted late, is completed incorrectly, is materially incomplete or fails to meet the Authority's Requirements which have been notified to Bidders;

j) the Bidder and/or a member(s) of its supply chain are unable to satisfy the terms of Regulation 57 of the Public Contracts Regulations 2015 (as amended) at any stage during the tender process;

k) the Bidder and/or a member(s) of its supply chain are guilty of material misrepresentation in relation to information provided by the Bidder during the pre-qualification stage and/or in connection with any Tender response;

l) the Bidder and/or a member(s) of its supply chain contravene any of the terms and conditions of this ITPD or other document issued by the Authority or

m) there is a change in identity, control, financial standing or other factor impacting on the selection and/or evaluation process affecting the Bidder and/or a member(s) of its supply chain.

## 19. The Authority's Rights

19.1 Although it is intended that the remainder of this procurement will take place in accordance with this ITPD the Authority reserves the right to:

n) waive the requirements of this ITPD;

o) disqualify any Bidder that does not submit a compliant Tender response in accordance with the instructions in this ITPD;

p) annul the Tender process in its entirety;

q) withdraw this ITPD at any time, or to re-invite Tender responses on the same or any alternative basis;

r) choose not to award any contract as a result of the current procurement process; and

s) make whatever changes it sees fit to the timetable, structure or content of the procurement process and this ITPD from time to time without prior (or any) notice being given by the Authority.

## 20. Interpretation

20.1 In the Procurement Documents, except where the context otherwise requires:

a) Words importing one gender include all other genders and words importing the singular include the plural and vice versa.

b) Enactment means any statute or statutory provision (whether of the United Kingdom or elsewhere), subordinate legislation (as defined by s.21 (1) Interpretation Act 1978) and any other subordinate legislation made under any such statute or statutory provision.

c) A reference to any enactment shall be construed as including a reference to:

   i. any enactment which that enactment has directly or indirectly replaced (whether with or without modification); and

   ii. that enactment as re-enacted, replaced or modified from time to time, whether before, on or after the date of the Procurement Documents.

d) the Glossary of Terms, any abbreviations, the headings to the sections of the Procurement Documents and the Annexes thereto are for ease of reference only and shall not affect the construction of the Procurement Documents;

e) any Appendices or Annexes to the Procurement Documents form part of the Procurement Documents and will have the same force and effect as if expressly set out in the body of the Procurement Documents;

f) in the event of any inconsistency between the provisions of the Procurement Documents and any previously issued documents, the provisions of the Procurement Documents shall prevail

## 21. Governing Law

21.1 The laws of England and Wales and the exclusive jurisdiction of the Courts of England and Wales; shall apply to this Procurement, ITPD, ISFT, the Competitive Dialogue, the Requirement and, subject to applicable law, any dispute, including any non-contractual dispute arising therefrom.

## Annexures

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