5th June 2020

1. **Introduction**

The Medicines and Healthcare products Regulatory Agency (the Agency) are running a Pre-Market Engagement Exercise in order to soft test the market for interest and ability to respond to a future tender.

This is Pre-Market testing and in no way will any information gained during this exercise be used in the evaluation of any future tender run by the Agency. Suppliers who take part in this exercise will not be benefited by this or discriminated against in any future tender for this requirement.

The future tender is for Physico Chemical Laboratory Services including analytical expertise and laboratory facilities

* Analytical
  + Testing of pharmaceutical materials and products to established methods and specifications
    - Turnaround time will be dependent on urgency
    - Provide data to support regulatory/legal enforcement
  + Development/verification of methods
    - 40+ British Pharmacopeia (BP) monographs per year [Assay, related substances, identification and performance (e.g. dissolution) tests]
    - Ad-hoc methods (e.g. screening; investigations)
  + Characterisation and regular stability monitoring of chemical reference material
    - A catalogue of 800+ materials

* + Investigation/troubleshooting of potential defective/sub-standard medicinal products
    - Design/agree suitable testing strategies
    - Provide data to support regulatory decision making/action
* Procurement and stock management
  + of materials (Active Pharmaceutical Ingredients and impurities) to create and replace chemical reference material
  + Ensuring availability of catalogue for customers
* Production
  + of chemical reference material products, including vialling, and accompanying leaflets, labels, safety data sheets
* Storage and Dispatch
  + of chemical reference material products to end users
    - approx. 3700 orders each year
    - approx. 31000 units each year
    - appropriate storage conditions (ambient, fridge, freezer)
* Quality Standard
  + all work to be to an appropriate recognised standard (ISO 17025 or other appropriate standard)

1. **Purpose**

The purpose of this exercise is to;

* Share information about the Agency and this requirement with the market
* Explore the potential in the market
* Discover if the current situation has an impact of the market and for how long this impact will continue.
* Find out if the market has the capacity to complete a tender during the current lockdown restrictions.
* Seek supplier views to help form our approach to market. For example, can the market respond better to a tender that is split into multiple Lots for the above requirement.
* Understand potential timescales involved during implementation of the contract(s)

1. **Actions**

If you are interested in finding out more about this Pre-Market Engagement, please email to register your interest as soon as possible and by 12 noon on Wednesday 24th June at the very latest.

We will then send you a brief presentation and a short list of questions. You will also be invited to a remote meeting. Please review the presentation and prepare answers to the questions. You may decline the meeting at any point. Once you have reviewed the specification please send your answers prior to the remote meeting to [Catherine.norris@nibsc.org](mailto:Catherine.norris@nibsc.org)

The meeting will run as follows

* Short presentation by MHRA team
* Suppliers to give their responses to the questions they have been sent.
* Q and A session for both parties.

The meeting will be hosted on Microsoft Teams and may be recorded for information purposes only. The recording will be deleted after 2 weeks.

We will endeavour to hold all meetings between 15th and 26th June. The Agency reserves the right to limit the number of suppliers who are invited to meet with us.

1. **Contact information**

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