Market Consultation

For a UK Stockpile of Naloxone & Potential Alternative Opioid and Synthetic Drugs Antagonists/Antidotes

Project: C260521

Version Number: V1.0

Date: 03 April 2024

# Introduction

This Supplier Questionnaire and accompanying attachments are being made publicly available to any organisations that are interested in the **UK Stockpile of Naloxone & Potential Alternative Opioid Antagonists/Antidotes.**

This exercise is intended to provide potential bidders with the opportunity to view and comment on the requirements for a **UK Stockpile of Naloxone & Potential Alternative Opioid Antagonists/Antidotes** if they wish to do so.

The Department of Health and Social Care is seeking to further understand the capacity of the market to meet potential changes in the demand of naloxone, as well as the availability of alternative opioid antagonists/antidotes. In particular:

1. what implications wider supply chains could have on the manufacturing process, sourcing and supply of the API and drug product (e.g. syringes and nasal sprays)
2. current domestic and foreign production of naloxone, supply points, and potential ability to flex production, supply and onshore storage of the drug product.
3. the nature of the naloxone products produced (e.g., nasal vs injectable), the amount of the active ingredient contained in different products and the bioavailability of the drug after administration.
4. The nature of potential novel or at market alternatives to naloxone

This Supplier Questionnaire is being issued in conjunction with the **UK Stockpile of Naloxone & Potential Alternative Opioid Antagonists/Antidotes Market Engagement Brief**.

# Next steps

The Department will make the decisions on the approach to a **UK Stockpile of Naloxone & Potential Alternative Opioid Antagonists/Antidotes** having considered feedback from this engagement.

If suitable services are available and the Department seeks to proceed with procurement, an ITT will be released to the market after receipt of potential bidder(s) comments, though the procurement timetable has not been finalised at this stage.

Any ITT will include the final specification, pricing schedule, evaluation criteria and terms and conditions.

Regards,

**Corporate and Clinical Services, Commercial Lifecycle**

**Commercial Directorate, Department of Health & Social Care**

**39 Victoria Street, London, SW1H 0EU**

Guidance for completion

* + 1. This Supplier Questionnaire forms part of the market engagement activity to support the procurement of the **UK Stockpile of Naloxone & Potential Alternative Opioid Antagonists/Antidotes.**
		2. The purpose of this questionnaire is to explore the market reaction to the proposed requirement. We hope to identify critical success factors and potential barriers to inform a potential formal procurement process. To maximise the success of any subsequent procurement process we request that suppliers are open and honest in their responses and provide as much detail as possible.
		3. Prior to completing this questionnaire, suppliers are requested to read the accompanying Market Engagement Brief which sets out the background and the proposed service requirements.
		4. Participation in this Market Consultation is voluntary. It is not required to provide an answer to every question if particular questions are not relevant.
		5. The Department wishes to encourage participation at this stage to ensure a wide number of responses. The market engagement processes described above do not form part of the formal procurement process. If and when the formal procurement process commences any supplier may join the competition and all supplier bids will be evaluated on the same basis.
		6. The completed questionnaire should be returned no later than **Friday 19th April 2024 at 12:00 and shall be submitted via email to** **ccsinbox@dhsc.gov.uk****.**
		7. The Freedom of Information Act 2000 (FOIA) applies to the Department. You should be aware of the Department 's obligations and responsibilities under the FOIA to disclose, on written request, recorded information held. Information provided by you in connection with this market engagement exercise, or with any Contract that may be awarded as a result of this exercise, may therefore have to be disclosed in response to such a request, unless the Department decides that one of the statutory exemptions under the FOIA applies. The Department may also include certain information in the publication scheme which it maintains under the FOIA.
		8. In certain circumstances, and in accordance with the Code of Practice issued under section 45 of the FOIA or the Environmental Information Regulations 2004, the Department may consider it appropriate to ask you for your views as to the release of any information before a decision on how to respond to a request is made. In dealing with requests for information under the FOIA, the Department must comply with a strict timetable and the Department would, therefore, expect a timely response to any consultation within two working days.
		9. You may provide information which is confidential in nature and which you may wish to be held in confidence. You must give a clear indication which type of material is to be considered confidential and why it is considered to be so, along with the time period for which it will remain confidential in nature. The use of blanket protective markings such as "commercial in confidence" will no longer be appropriate. In addition, marking any material as confidential or equivalent should not be taken to mean that the Department accepts any duty of confidentiality by virtue of such marking. Please note that even where you have indicated that information is confidential the Department may be required to disclose it under the FOIA if a request is received.
		10. The Department cannot accept that trivial information or information which by its very nature cannot be regarded as confidential should be subject to any obligation of confidence.
		11. In certain circumstances where information has not been provided in confidence, the Department may still wish to consult with you about the application of any other exemption such as that relating to disclosure that will prejudice the commercial interests of any party.
		12. The decision as to which information will be disclosed is reserved to the Department notwithstanding any consultation with you.
		13. Whilst the Department expects to proceed to procurement in due course, there is no obligation to do so as a consequence of this early market engagement activity. The invitation to tender (ITT) process will be published to potential bidders via the DHSC Atamis e-Sourcing Portal, where suppliers will need to register and access the ITT documents - [Welcome (site.com)](https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fatamis-1928.my.site.com%2Fs%2FWelcome&data=05%7C02%7CDarrell.Griffith%40dhsc.gov.uk%7C6cc091353ad3453f498508dc00974009%7C61278c3091a84c318c1fef4de8973a1c%7C1%7C0%7C638385896812423191%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=35OUHewbkWDwU5dqePw%2F71j0VCbe1QeOZYu0RueqVcA%3D&reserved=0)
		14. The publication of any documents at this stage is intended to provide potential bidders with the opportunity to view and comment on a draft specification for the requirement. The Department does not intend to be bound by any information at this stage. The Department makes no commitment to accept recommendations or suggestions. Once published, the Invitation to Tender will contain the final requirements in relation to this service. All previous versions, including any documents published at this stage should be disregarded.

Supplier Response Template

***(This should be completed by the Supplier or a partner or an authorised representative in his / her own name and on behalf of the company / organisation completing this questionnaire)***

|  |  |
| --- | --- |
| **Organisation:** |  |
| **Name of authorised representative:** |  |
| **Position:** |  |
| **Date:** |  |

Market Insights

|  |
| --- |
| ***Does your company have a marketing authorisation to supply a naloxone formulation in the UK? If so, please specify the drug product presentation below:*** |
| **Finished Dosage Form** | **Please Specify Concentration** |
| Ampoules | *e.g. Naloxone 400micrograms/1ml solution for injection ampoules* |
| Pre-filled Syringes |  |
| Nasal Spray |  |
| Other |  |

|  |
| --- |
| **Are you intending to seek a marketing authorisation to supply a new or additional presentation of naloxone into the UK?**  |
| **Finished Dosage Form** | **Please Specify Timescales for MA Approval** |
| Ampoules |  |
| Pre-filled Syringes |  |
| Nasal Spray | *e.g. Yes, 2.0mg single dose spray (12-18 months)* |
| Other |  |

|  |
| --- |
| **What are your current annual sales volumes of naloxone drug product into the UK (in patient courses)?** |
| **Finished Dosage Form** | **No. Patient Courses** |
| Ampoules | *e.g. 100,000 patient courses* |
| Pre-filled Syringes |  |
| Nasal Spray |  |
| Other |  |

|  |
| --- |
| **To which organisations are you supplying your naloxone drug product in the UK?**  |
| **Please provide details below:** |

|  |
| --- |
| **What is your current annual sales volume of naloxone drug product globally (No. patient courses)?** |
| **Finished Dosage Form** | **No. Patient Courses** |
| Ampoules |  |
| Pre-filled Syringes |  |
| Nasal Spray |  |
| Other |  |

|  |
| --- |
| **Typically, how much finished product would you hold in storage in the UK, for the UK market, at any one time?** |
| **Finished Dosage Form** | **No. Patient Courses** |
| Ampoules | *e.g. 20000-30000 ampoules* |
| Pre-filled Syringes |  |
| Nasal Spray |  |
| Other |  |

|  |
| --- |
| **Typically, how much finished product would you hold in storage outside of the UK, for the UK market, at any one time?** |
| **Finished Dosage Form** | **No. Patient Courses** |
| Ampoules |  |
| Pre-filled Syringes |  |
| Nasal Spray |  |
| Other |  |

|  |
| --- |
| **Approximately how much time would you need to increase your current stockholding in the UK, for the UK market, by the amounts below?** |
| **Percentage Increase** | **Time** |
| Up to 10% | *e.g. 1-2 months* |
| 10 – 25% |  |
| 25 – 50% |  |
| 100% |  |
| **Please detail the potential constraints to scaling up sooner than detailed above:** |

|  |
| --- |
| **By what volume (patient courses) would you consider increasing your stockholding in the UK market were patient access to be increased?****Please provide details below:** |
|  |

Supply Chain Insights

|  |
| --- |
| **In a typical year how much of the active pharmaceutical ingredient (in kgs) would you purchase for UK supply, and from which locations?** |
| **Location** | **Mass (kgs)** |
| UK | *e.g. 40kgs, +99% naloxone HCl* |
| Europe |  |
| Other (please specify) |  |

|  |
| --- |
| **In a typical year how much of the active pharmaceutical ingredient (in kgs) would you purchase for global supply, and from which locations?** |
| **Location** | **Mass (kgs)** |
| UK |  |
| Europe |  |
| Other (please specify) |  |

|  |
| --- |
| **What are the locations of manufacture of the drug product for the UK market?** |
| **Location** | **% of Total UK Demand** |
| UK |  |
| Europe | *e.g. 100%* |
| Other (please specify) |  |

|  |
| --- |
| **Where different from above, what are the locations of manufacture of the final packaged product for supply to the UK market?** |
| **Location** | **% of Total UK Demand** |
| UK |  |
| Europe |  |
| Other (please specify) |  |

|  |
| --- |
| **Are there any elements of the naloxone finished product supply chain that have suffered a significant disruption over the past 36 months, resulting in a shortage in supply to either the UK or European markets?**  |
| **Please provide details below:** *e.g. excipients, device parts etc.* |

|  |
| --- |
| **Are there any other products that you are developing or producing that could act as an alternative opioid antagonist to naloxone?**  |
| **Please provide details below:** |

|  |
| --- |
| **Are there any products in development that combine antagonists to other known illicit drugs (for example xylazine) that are often used in combination with, or found in adulterated supplies of, opioid products with opioid antagonist such as naloxone?**  |
| **Please provide details below:** |

|  |
| --- |
| **Are there any additional risks or challenges that should be considered in the delivery of this service?** |
|  |

|  |
| --- |
| **Would you intend to bid for this opportunity? If yes, would you need to partner/collaborate with other parties?** |
|  |

**thank you for taking the time to** **complete this questionnaire**