

Market Engagement Brief

UK Stockpile of Naloxone & Potential Alternative Opioid and Synthetic Drug Antagonists/Antidotes

1. Purpose

DHSC is conducting a market engagement exercise to understand more about the companies and services in the UK that can, or that are seeking to produce, distribute, supply and store different formulations of naloxone and of other drugs that can reverse the effect of an opioid overdose or of drugs taken with opioids.

The outcome of the market engagement will inform decisions around potential future procurement and storage of buffer stock as well as providing information on how the market could meet a potential increase in demand across the UK.

2. Summary

Naloxone is a lifesaving medicine that reverses the effects of an opioid overdose. The 10-year Drug Strategy sets out the specific commitment that the UK Government would review the potential of making naloxone more accessible.

Since 2019, DHSC has maintained a buffer stock of naloxone to enable a rapid deployment in response to an opioid crisis including adulteration of other drugs with synthetic opioids. The department is considering plans to review this arrangement and needs to understand how the market might meet its future needs.

DHSC is seeking to further understand the capacity of the market to meet potential changes in the demand for naloxone. In particular:

- what implications wider supply chains could have on the manufacturing process, sourcing and supply of the API and delivery devices (e.g. syringes and nasal sprays)
- current domestic and foreign production of naloxone, supply points, and potential ability to flex production and supply.
- 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.

Naloxone is a prescription-only medicine regulated by the Human Medicine Regulations 2012. This means that there are controls on who can legally administer, sell, and supply naloxone. DHSC is currently undertaking a public consultation on expanding access to naloxone without a prescription, the impact that this may have on demand is unknown, but we anticipate that this, combined with the increased prevalence of synthetic opioids, will increase demand for naloxone.

3. Background

In December 2021, the UK Government published its 10-year drug strategy which committed to preventing 1,000 drug-related deaths by 2024/25. Naloxone is a prescription only medicine, but the Human Medicines Regulations (HMR) allow drug and alcohol treatment services to supply naloxone to an individual without a prescription. The regulations also allow anyone to administer naloxone in an emergency situation.

Widening access to naloxone is a critical component of achieving this ambition. The UK Government committed to amending the [Human Medicines Regulations 2012](#) to widen the number of services and professionals who can distribute naloxone to people who might encounter an opioid overdose, including at-risk people who use drugs.

Opioid-related deaths make up the largest proportions of drug-related deaths across the UK. In 2022, opioids were involved in:

- 73% of drug misuse deaths in England
- 60% of drug misuse deaths in Wales
- 82% of drug misuse deaths in Scotland
- 60% of drug misuse deaths in Northern Ireland

Naloxone forms a key part of the strategy to reduce the number of deaths, which is becoming particularly important as the prevalence of synthetic opioids in the illicit drug market increases. These synthetic opioids are more potent, and potentially can be more deadly than other opioids currently and previously available through illicit drug supply.

While the exact impact of synthetic opioids on opioid related deaths is yet to be fully understood, work is ongoing to assess the impact of the rise of synthetic opioids and the necessary steps to reduce harm including increased use of naloxone.

4. Manufacturing and Supply

Naloxone has been in production for many years and comes in a variety of different forms and drug delivery mechanisms. Naloxone for use in the community currently comes in 3 forms:

- one pre-filled syringe (injectable)
- nasal sprays (nasal)
- ampoules for injection

Although ampoules could be (and previously have been) used in the community, their use is very rare now that there are 3 formulations with a specific community indication (injectable and 2 x nasal).

All currently licenced products have a shelf-life of around 3 years after which they should be replaced, which in addition to rates of usage, dictate rate of production needed. This provides a cycle for modelling purposes that can help inform management of stock maintenance.

5. Active Pharmaceutical Ingredient and delivery devices

There is also recognition that procurement of the active pharmaceutical ingredient (API), usually as a salt of naloxone (such as naloxone hydrochloride) is a major deciding factor in how rapidly and in what quantity batches of naloxone products can be produced. This is also applicable to the delivery devices: syringes and nasal sprays. These supply chains are reliant on existing international supply chains which, if impacted by manufacturing problems or multi geography demand, could be unable to supply the UK at a time of need.

6. Buffer Stock

DHSC has historically maintained a buffer stock of naloxone as a precautionary measure to help support a response to a potential crisis. Stock can be released from the buffer into business-as-usual stock to meet increased demand arising from localised or widespread increases in opioid overdoses.

DHSC is in the process of reviewing the potential options for a new contract. This market engagement exercise will help to inform any future requirement.

7. Public Consultation on Legislative Changes

Building on an initial consultation in July 2021, the potential legislative changes propose to expand the current exemption from the need for a prescription for naloxone under the Human Medicines Regulations, which currently enables drug and alcohol treatment services to supply naloxone (injectable since 2015, nasal since 2019) without a prescription.

The expansion would operate through two routes:

- Proposed list of named professionals and services that can supply take-home naloxone.
- A new registration service that would enable individuals and organisations not specifically named in the legislation to supply naloxone, subject to appropriate training and safeguarding.

The consultation was published at the end of January 2024, and closed on 6 March 2024. The legislative change is expected to lead to some increased demand for naloxone from non-drug services but the exact impact of this is currently not yet known. Work will commence with the wider market to understand how it could respond to increase in demand.

8. Overview of Requirements

Legal and other requirements for the licencing (marketing authorisation) of naloxone products in the UK sits with the Medicines and Healthcare products Regulatory Agency and are summarised in Public Assessment Reports.

DHSC is interested in learning more about products that are appropriate for community use, not a clinical setting (not ampoules or similar presentations), including the provision of appropriate packaging and instructions such that a lay person with adequate training is able to administer it in an emergency situation. We would also require an appropriate level of training to be available to meet the safety standards set out in any previous or future iterations of the Human Medicines Regulations.