

ROYAL PHARMACEUTICAL SOCIETY

Proposals to expand access to take-home naloxone supplies

RPS response

Route 1: Named services and professionals

Proposed list of named services and professionals that can supply naloxone without a prescription

Question 1: To what extent do you agree or disagree with the proposed list of named services and professionals that can supply naloxone without a prescription?

- **Strongly agree**
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Outreach services or carer-led/ peer-led initiatives also need to be considered.

Proposed training requirements for named services and professionals

Question 2: To what extent do you agree or disagree that the training requirements for named services and professionals should include the storage and supply of naloxone, as well as how to support those supplied with naloxone with its storage and administration?

- **Strongly agree**
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Please explain your answer. (Maximum 500 words)

It is important that naloxone is always supplied with the appropriate training on its use, its limitations and the importance of calling emergency services, as well as storage, supply and administration advice. Named services and professionals must be equipped with the knowledge and skills to handle it effectively. They should be educated on best practices for storage, including temperature control, protection from light, and ensuring accessibility in emergency situations. They should be trained on administering naloxone safely and effectively, including understanding dosages, routes of administration (such as intramuscular or intranasal), and recognising signs of opioid overdose. Information on how to support individuals (e.g. opioid users) supplied with naloxone in its storage and administration must also be included. Training programmes must be tailored to different professionals and services adapted to the needs of healthcare professionals or others such as police officers/ community outreach workers.

However, to ensure this training is delivered consistently it needs to be clear and concise both for those being trained to supply and those being trained to use. The medication is straight forward to administer and well packaged and the training should reflect that.

Training on the safe and secure handling of medicines, with particular reference to naloxone is important, including the importance of medicines storage out of reach and sight of children. However, pharmacists are already trained in this area so should be exempt from this requirement.

In the case of pharmacists, and potentially others accessing this training, this training would also need to be accessible e.g. a short online module which could be completed at a time that suited them. Consideration should be given to advising on appropriate training intervals in the guidance rather than in law.

Route 2: registration with a naloxone supply network co-ordinator

Supplying naloxone by registering with a network co-ordinator

Question 3: To what extent do you agree or disagree with enabling services and organisations to supply naloxone without a prescription, through the registration route?

- **Strongly agree**
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Please explain your answer. (Maximum 500 words)

People who are experiencing homelessness can struggle with access to medication in general. Some are not in touch with any treatment services which would allow them to receive prescriptions for naloxone. Allowing settings or individuals who are in contact with these people the ability to supply naloxone would increase the availability and the chance of it being used to save a life.

For individuals who use opioids, obtaining a prescription for naloxone may pose numerous barriers including practical or psychological barriers (e.g. stigma). Enabling services to supply naloxone without a prescription can significantly increase access to this life-saving medication. In addition, allowing named services and professionals, such as probation or police officers, to supply naloxone empowers these frontline workers to take proactive steps in addressing opioid overdoses within their settings and communities. They are often the first point of contact for individuals at risk and can intervene effectively with timely access to naloxone.

Naloxone is very safe and supply carries very low risk, and we have precedent for this model already.

Conditions for supplying naloxone under route 2

Question 4: If you think there are any other requirements that services under route 2 should meet to ensure safe supply of naloxone, please outline them. (Maximum 500 words)

- Services should adhere to standardised evidence-based protocols and policies related to the storage, handling, supply and administration of naloxone.
- Collaborations/ communication among services will potentially ensure continuity of care of individuals who might require or have a history of using naloxone.
- Services should engage with communities to raise awareness about the availability of naloxone among their communities.
- Professionals and named services should ensure continuing education and professional development related to the storage, handling, supply and administration of naloxone.
- There should be a robust audit trail to demonstrate who has accessed and supplied the naloxone

Wholesaler dealer's licence under route 2

Question 5: If you think there are other requirements that non-public or statutory services and organisations under route 2 should meet to ensure safe supply of naloxone, please outline them. (Maximum 500 words)

Perhaps a modified Wholesale Dealers License (WDL) only for naloxone could be established to ensure quality control processes from factory to distributor are auditable and to standard rather than complete abolishment of the license. The need for a licence may pose additional legislative and financial barriers for access to naloxone and we would want to prevent this if possible.

Professionals who offer to provide the supply of take-home naloxone service should not be subsequently burdened or hampered in accessing naloxone through whichever route that may be. The robustness of any supply chain and wholesaler arrangements for access to naloxone must be assured to ensure continuity of supply and patient/ client access.

We would also recommend that:

- Services should ensure that naloxone supplies meet quality standards and regulatory requirements as it is the case with any prescription only medicine (POM).
- Services must ensure robust supply chain management practices to track the movement of naloxone from procurement to supply as it is the case with any prescription only medicine (POM) (specially where the FMD (Falsified Medicines Directive) is no longer active following Brexit).

Data collection on naloxone supply for routes 1 and 2

Question 6: To what extent do you agree or disagree that the named services and professionals that supply naloxone to individuals should be provided with a legislative gateway to support the sharing of data on the supply of naloxone?

- **Strongly agree**
- **Agree**
- **Neither agree nor disagree**
- **Disagree**
- **Strongly disagree**

Providing a legislative gateway could enhance data collection efforts, information sharing between services, enabling more accurate and comprehensive evaluative reporting and better understanding of naloxone supply, effectiveness of interventions, and their impact on reducing opioid-related deaths. Access to timely and relevant data can inform evidence-based policy-making and informed decision-making to address opioid overdose cases effectively. It's essential to ensure that any data sharing mechanisms uphold patient confidentiality and privacy rights and adhere to GDPR regulations.

If the collection of data is for epidemiological analysis of factors that impact on drug related deaths (DRD) then the better route is through the ongoing work Anne Lingford-Huges is heading to bring drug and alcohol service data into data linkage projects (which by default would include their National Drug Treatment Monitoring System ((NDTMS) data inc naloxone).

Amending the legislation

Question 7: If you have any further comments on the detail of the draft legislation, please outline them. (Maximum 500 words)

- Clear and unambiguous language and provisions of the legislation
- Clear definition of the scope of services authorised to supply naloxone without a prescription.
- Clear definitions and criteria for eligibility to access naloxone without a prescription would ensure consistent implementation across all jurisdictions within the UK.
- Robust safeguards including requirements for training, record-keeping, reporting, and adherence to quality standards, auditing, etc.

- Mechanisms to enhance flexibility and accessibility in naloxone supply, taking into account the diverse needs of individuals at risk of opioid overdose. These might include mobile outreach services or carer-led/ peer-led initiatives.

An additional comment is around how 'lawfully engaged in drug treatment' has been represented in this consultation. The legislative framework which allowed naloxone to be supplied without prescription uses the phrase 'those lawfully engaged in drug treatment'. This applies to pharmacies that provide opiate substitution therapy and needle and syringe provision as part of a commissioned service. At the individual pharmacy level, the pharmacist or pharmacy technician (pharmacy professionals) are not stated. By doing so, we are concerned that the unintended consequence of preventing medicines counter assistants (MCAs) from supplying naloxone may occur. Currently MCAs make supplies, under pharmacist supervision, in many pharmacies. This is important as MCAs undertake 90% of needle and syringe transactions in community pharmacy (Scott & Mackridge, 2008).

Question 8: If you think the proposals risk impacting people differently, or could impact adversely on any of the protected characteristics covered by the public sector equality duty set out in section 149 of the Equality Act 2010 or by section 75 of the Northern Ireland Act 1998, please outline them. (Maximum 500 words)

The legislation needs to address considerations of inclusivity and equity in naloxone access, recognising the disproportionate impact of opioid overdose on marginalised and vulnerable at risk populations. Individuals from lower socioeconomic backgrounds may face barriers to accessing naloxone due to lack of awareness, transportation issues, or limited financial resources (e.g. new prison leavers, homeless individuals). Certain ethnic groups may experience disparities in access to naloxone due to language barriers and cultural stigmas. Individuals with disabilities may face challenges in accessing naloxone if services offering naloxone distribution are not accessible. Gender-based differences must be considered e.g. women may be more likely to experience opioid overdoses in private settings, such as homes, where naloxone availability is critical. Adolescents and young adults may be at increased risk of opioid overdose due to experimentation or peer pressures, while older adults may face challenges related to polypharmacy and comorbidities. Naloxone supply efforts should consider age-specific and gender-specific risk factors, highlighting the need equitable access to naloxone across urban and rural areas (e.g. through targeted outreach, mobile distribution services, and collaboration between services), as well as the need for culturally sensitive outreach interventions.

Community pharmacies are in the heart of local communities and have a significant role to play in supporting people with take home naloxone. In Greater Glasgow and Clyde, community pharmacists have been trained and supplied with naloxone kits and to date, they have saved over 20 lives and an example can be found at <https://www.rpharms.com/scotland/best-practice-scotland/your-best-practice/saving-life-with-naloxone>