Release's response to the Department of Health and Social Care's Consultation: Proposals to expand access to take-home naloxone supplies

March 2024

Release
Drugs, The Law & Your Rights

Release is the national centre of expertise on drugs and drugs law in the UK. The organisation, founded in 1967, is an independent and registered charity. Release provides free non-judgmental, specialist advice and information to the public and professionals on issues related to drug use and to drug laws. The organisation campaigns directly on issues that impact on its clients - it is their experiences that drive the policy work that Release does and why Release advocates for evidence-based drug policies that are founded on principles of public health rather than a criminal justice approach. Release believes in a just and fair society where drug policies should reduce the harms associated with drugs, and where those who use drugs are treated based on principles of human rights, dignity and equality. Release is an NGO in Special Consultative Status with the Economic and Social Council of the United Nations.

As an organisation recognised by the Department as having contributed to the urgent need to expand access to take-home naloxone supplies we are pleased to see further progress being made. We consider that reclassifying Naloxone as a Pharmacy medicine, as opposed to Prescription-only Medication, or otherwise exempting it, may be more successful in achieving the expanded access that the current circumstances require. Nonetheless we are broadly supportive of the mechanisms proposed.

Response to substantive questions:
Route 1
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

Release strongly agrees with the services and professionals it is being proposed to name in the Human Medicines Regulations 2012. These services and professionals will be an important part of the approach to widen the availability of Naloxone to those most likely to need access to it.

We note the difficulties in finding consistent definitions across the UK for some services. This is unfortunate, as all statutory homelessness services, and many and voluntary ones, would benefit from being included within Route 1 to ensure greater availability of Naloxone to a population in need of this. Drug-related deaths among people without a home continue to increase. Requiring both Local Authorities and their staff to be named individually, on the proposed ‘Route 2’ register, risks severely hampering the proposed expansion to a group who would clearly benefit from easier access to Naloxone.

While acknowledging a desire to maintain specificity within the amendments, a broad allowance could be considered given the importance of these interventions for those without a home. We note such allowances have been possible in the proposed definition of a "*provider of probation services*", and similarly for drug treatment services, where a common-sense approach is adopted that people employed or engaged in these roles will be obvious to identify. Such an approach could also be taken here, for example specifying that those employed or engaged by a Local Authority to support individuals who are homeless within the ambit of Part VII of the Housing Act 1996 (in England) or under Part II of the Housing (Scotland) Act 1986. The proposed Guidance could then provide clearer detail to Local Authorities, or their equivalents, on what is envisaged. This would be particularly important given the proposal for the Guidance to "*strongly encourage*" the named services to carry out this role, whereas this will not be true under Route 2. This risks a postcode lottery for this expanded support.

We would also strongly welcome a further addition that those employed or engaged in the provision of homelessness services such as day centres could also be included through Route 1. However, we do appreciate the definition here would face even greater difficulties in being sufficiently specific.

We also advocate for the inclusion of Universities, and their Student Unions, within Route 1 and, where possible, other education providers. The significant rise of synthetic opioids necessitates a proactive approach to naloxone distribution to mitigate the increased risk of overdose and death. These synthetic opioids are present not only in the heroin supply, but increasingly also found in illicitly sourced benzodiazepines and other substances purchased in the belief of them being genuine prescription medications. The dangers of unexpected overdose and drug-related deaths among these populations is therefore now much greater than it was at the time of the previous consultations.

Young people who may not recognise these risks are far less likely to be engaging with drug and alcohol services, community pharmacies, or the other proposed services. Granting University staff the authority to distribute Naloxone to others without a prescription, and without a need to be individually registered via Route 2, would fulfil at least two benefits. Firstly, it increases the availability of Naloxone to a cohort who are at risk of overdose and death who may not be engaging with other services where it will be more readily available under Route 1. It also recognises the roles of Universities as not just institutions of learning and development, but as active contributors to improving the health and social good of the local community.

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)

Release agrees that services and professionals should be trained on the appropriate storage of Naloxone. This training should also include the appropriate situations in which Naloxone can be supplied, both under these new routes under consultation, and the life-saving emergency provisions previously in effect.

We would discourage having the training requirement be too onerous. Guidance could be used to good effect here to recognise the varying training needs. The proposed Regulation 237A(2)(e) provides for Local Naloxone Providers to supply Naloxone without a prescription where it is satisfied the person being supplied has underdone appropriate training. Regulation 237A(8) provides that training is appropriate if an appropriate national body is of the opinion it is appropriate, and further it recognises for **specified** appropriate persons that *other training* may objectively also be appropriate training.

The overall intent of not including the Local Naloxone Providers within this provision is not obvious to us. However, we would welcome either in the Regulations or in later Guidance confirmation how the Local Naloxone Providers would demonstrate compliance with the requirement to have had appropriate training.

Route 2 Questions:
Question 1
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)

Release agrees with enabling organisations to supply naloxone without a prescription through the registration route but believes that the regulations need to ensure that volunteers from approved organisations under Route 2 are not dissuaded from providing naloxone under the proposed new regulation 237A(5)(c). This requires that local naloxone providers must keep a record of all persons employed or engaged by them who are able and trained to provide medicinal products that contain naloxone hydrochloride.

Individuals with relevant lived or living experience with drug use may wish to support organisations through supplying naloxone as a peer but may also have reasonable concerns that being registered on the local naloxone provider's list could make their connections to drug using communities public. This risk appears in the proposed new regulations 237A(11) and (12) where a supplier of naloxone might provide an appropriate national body with information about naloxone supply, and it is specified

that such information disclosure would be considered necessary for the performance of a task carried out in the public interest.

Question 2
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)

No further requirements.

Question 3
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)

Release agrees with the above section to remove the license requirement for network coordinators and does not believe that other requirements need to be introduced under route 2 to ensure the safe supply of naloxone.

Question (Re: data collection)
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*

Release agrees that a legislative gateway to support the sharing of data on the supply of naloxone should be provided to individuals and services providing naloxone, so long as the requirements on data collection and sharing are not a barrier to smaller organisations partaking in the distribution of naloxone. Data collection should both be minimally invasive to the recipients of naloxone and to local level distributors of naloxone.

Comments on the full legislation

Question

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

In our experience the previous provisions in Parts 2 and 5 of Schedule 17 caused some uncertainty as to the intended breadth of the definition. Release is aware that some felt able to interpret 'Persons employed or engaged in the provision of drug treatment services provided by, on behalf of or under arrangements made by' the four subsequent bodies as sufficiently clear to allow peer-to-peer naloxone supply to take place, subject to the peers receiving appropriate training beforehand. Peers would complete training and sign volunteer agreements, thereby being engaged in the provision of drug treatment services.

The lack of certainty as to this, however, hampered the development of this model due to reservations as to this interpretation. With the same wording being adopted for the now proposed Regulation 237A(2)(a) we would welcome clarification in Guidance that such volunteer programmes would be considered to fall within its ambit. Ensuring drug treatment services are able to work with their existing networks to expand access to Naloxone will be crucial, and providing assurance that such programmes can be run within Route 1 would be warmly welcomed.

This would avoid such programmes having to comply with the additional requirements proposed under Route 2. While Route 2 offers an excellent route for new services to ensure the availability of Naloxone we hope it will not be at the expense of introducing new complications for existing distribution schemes, such as requiring all volunteers to agree to have their personal information stored on the proposed register.

Question
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)

No comments.