EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AMENDMENTS RELATING TO NALOXONE AND TRANSFERS OF FUNCTIONS) REGULATIONS 2024

2024 No. 1125

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care ('DHSC') and is laid before Parliament by Command of His Majesty

2. Declaration

2.1 Andrew Gwynne, Minister for Public Health and Prevention at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

2.2 Natasha Burgon, Director of Health Improvement at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Rosie Conry at the Department of Health and Social Care (email: addictionspolicy@dhsc.gov.uk) can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

Availability of Naloxone

4.1 Medicinal products containing naloxone and its salts, esters or stereoisomers ("naloxone") reverse the effects of an opioid overdose, and so can help to prevent overdose deaths. Although naloxone is a prescription-only medicine, currently the Human Medicines Regulations 2012 ("HMRs") provide an exemption for drug and alcohol treatment services to supply naloxone hydrochloride without a prescription in the course of the provision of those services, where required for the purpose of saving lives in an emergency.

4.2 These Regulations will allow more named services and professionals to obtain stocks of naloxone and supply it to anyone requiring access for use in an emergency involving an opioid overdose. These Regulations will also allow, via the creation of naloxone supply networks, for new registration services that would enable professionals and organisations not named in the legislation to supply naloxone (including homelessness and supported accommodation services), subject to appropriate training and safeguards.

Amendments to the references to Public Health England and the Health and Social Care Board

4.3 These Regulations also update the HMRs to reflect recent changes within the healthcare systems in England and Northern Ireland. Public Health England (PHE)

was dissolved as of 1 October 2021, with its health protection function transferred to the UK Health Security Agency (UKHSA), and health improvement and public health functions to DHSC, and NHS England. Separately, in Northern Ireland the Regional Health and Social Care Board (HSCB) was dissolved on 31 March 2022 and its commissioning functions were transferred to the Department of Health (NI).

Where does the legislation extend to, and apply?

4.4 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is all of the United Kingdom.

4.5 The territorial application of this instrument (that is, where the instrument produces a practical effect) is all of the United Kingdom.

5. Policy Context

What is being done and why?

Availability of Naloxone

5.1 We consider these proposals a matter of public health and safety in the UK. Drug misuse deaths have doubled since 2012 and opioid-related deaths make up the largest proportions of drug-related deaths across the UK. Naloxone is a life-saving medicine that reverses the effects of an opioid overdose and should be made more widely available as a way of reducing deaths from opioid overdoses. An independent review of drugs[1] published in August 2021highlighted increasing access to naloxone as a vital harm reduction measure that will save lives. The Advisory Council on the Misuse of Drugs (ACMD) is an independent expert body that advises Government on drug-related issues in the UK. In 2022, the ACMD published a review of the UK naloxone implementation[2] which further stressed the importance of naloxone and that more work is required to widen the access to, and increase the uptake of, naloxone.

5.2 Since then, there has also been an increase in the presence of new synthetic opioids in the illicit drug supply. These synthetic opioids are more potent, so are more deadly than other opioids traditionally available through illicit drug supply. This has led to increases in overdoses and deaths in some areas. So, it is more important than ever to increase access to naloxone.

5.3 These Regulations will allow a much wider range of services, healthcare professionals, and organisations to supply naloxone on a 'take-home' basis for use in a future emergency involving an opioid overdose. This could include providing naloxone to a family member or friend of a person who is known to be using opiates such as heroin or opioids, or to professionals such as an outreach worker for a homelessness service whose clients may include people who use these drugs. This would potentially support thousands of people across the UK and help reduce the number of deaths from opioid overdoses.

Amendments to references to Public Health England and the Health and Social Care Board

5.4 These changes are consequential. They result from the dissolution of PHE and HSCB, with the transfer of responsibilities and functions described in 4.3 having already taken place.

[1] https://www.gov.uk/government/collections/independent-review-of-drugs-by-professor-dame-carol-black
[2] https://www.gov.uk/government/publications/acmd-naloxone-review/government-reponse-to-uk-naloxone-implementation-report

5.5 These changes will allow the HMRs to remain current and accurate.

What was the previous policy, how is this different?

Availability of Naloxone

5.6 Naloxone is a prescription-only medicine, meaning that it has to be supplied in accordance with a prescription of an authorised prescriber, and by or under the supervision of a pharmacist at a registered pharmacy, subject to the extensive exceptions in Part 12 of the HMRs. The previous policy was to ensure that it could be supplied in the course of drug treatment services commissioned by specified entities (NHS bodies, local authorities, PHE (now dissolved) and the Public Health Agency in Northern Ireland. This was an important but relatively narrow gateway for making naloxone available to individuals who may be at risk of, or may come into contact with people who may be at risk of, an opioid overdose.

5.7 These Regulations allow more named services and professionals to obtain stocks of naloxone and supply it on a 'take-home' basis to anyone requiring access for use in a future emergency involving an opioid overdose. However, we also wish to build on the success of a temporary measure introduced in Scotland, on the basis of a statement of prosecution policy by the Lord Advocate, that enabled a broad range of services, outside the normal commissioning frameworks, to sign up with the Scottish Government to supply naloxone without a prescription. This includes a 'click and deliver' service run by Scottish Families Affected by Alcohol and Drugs[3], which enables people to have naloxone delivered anonymously to their door. These Regulations will allow this approach to be rolled out across the UK, and so, for example, for homelessness and supported accommodation services to sign up for supplying naloxone, subject to appropriate training and safeguards, as well as charities and voluntary organisations such as Scottish Families Affected by Alcohol and Drugs.

Amendments to references to Public Health England and the Health and Social Care Board

5.8 In summer 2020, the Secretary of State for Health and Social Care announced that PHE would be replaced essentially by UKHSA and DHSC. There are a small number of references to PHE remaining in the HMRs that need to be amended to reflect the transfer of functions.

5.9 In Northern Ireland, as part of a major programme of work to transform their health and social care system, as set out in Health and Wellbeing 2026: Delivering Together, the HSCB closed on 31 March 2022 and its commissioning functions were transferred to the Department of Health (NI). The Department of Health (NI) is seeking an amendment to the HMRs in order to be expressly designated as a 'health authority' to fulfil the legal requirements as set out in the HMRs that were formerly attributed to the HSCB. Up until now, they have relied on a transitional provision that has achieved the same outcome.

6. Legislative and Legal Context

How has the law changed?

Availability of Naloxone

6.1 As noted above, naloxone is a prescription only medicine, meaning that it has to be supplied in accordance with a prescription of an authorised prescriber, and by or under

[3] https://www.sfad.org.uk/

the supervision of a pharmacist at a registered pharmacy, subject to the extensive exceptions in Part 12 of the HMRs. Those exceptions include a number of exceptions in Schedule 17 to the HMRs, and these include the current exceptions for the supply of naloxone by drug treatment services. These drug treatment services exceptions have been revoked and consolidated into a new provision, regulation 237A, which sets out the features of the new arrangements. As well as for the existing suppliers (paragraph (2)(a)), individuals who may supply naloxone will now include those employed or engaged by the medical services of His Majesty's forces (paragraph (2)(b)), by various service providers that are part of the criminal justice system (paragraph (2)(c)), an list of registered health care professionals who may not have prescribing rights (paragraph (2)(d)) and a new type of organisation known as a local naloxone provider – which will be the mechanism for allowing organisations such as Scottish Families Affected by Alcohol and Drugs to sign up to be providers of naloxone (paragraph (2)(e)).

6.2 Most of the detail in regulation 237A is about the setting up of the naloxone supply networks of which the local naloxone providers will be a part. Critically, there will need to be a naloxone supply network co-ordinator, commissioned to perform that role by the relevant national authorities in each country, and they will make the necessary arrangements with the local bodies that want to sign up to be local providers. The outcomes to be achieved by both the arrangements that the national authorities have with the supply network co-ordinators, and arrangements that the supply network co-ordinators have with the local naloxone providers, are specified on the face of the legislation, and there are also provisions to deal with transfers of data so that all the arrangements can be appropriately monitored.

6.3 Training in the storage and supply of the naloxone will also be key to the success of the new arrangements. All the new providers of naloxone, with the exception of those working in His Majesty's forces (who will make their own arrangements) will be subject to a new training obligation, and the outcomes to be achieved by that training are specified on the face of the legislation. The appropriate national authorities are given powers to approve training – and will also give the guidance to commissioners noted below in paragraph 8.1.

6.4 It is also important that the purposes for which naloxone may be supplied have been expanded beyond "*only where required for the purpose of saving life in an emergency*" in the scheme in Schedule 17 to the HMRs to a broader set of purposes that make it clear that it can be supplied on a "take home" basis, and for people to or for whom it is supplied to carry it around in case they may need it to administer it to themselves or someone else.

Amendments to references to Public Health England and the Health and Social Care Board

6.5 The HSCB change simply makes clear on the face of the HMRs, in the interests of transparency, a change that had already taken effect as the result of a transitional provision. In the case of the PHE changes, there has been a theoretical gap during which UKHSA has not been able to perform the role that PHE was performing, but in practice, DHSC understands that there has been no practical impact. The provisions relate predominantly to supply of medicines under patient group directions and other authorising options have been available.

Why was this approach taken to change the law?

Availability of Naloxone

6.6 The legislative provision made for local naloxone providers was made more complicated by the fact that the identities of both the supply network co-ordinators and of the local providers themselves are unknown at the time of the making of the legislation, and so consideration had to be given as to how much detail could be provided on the face of the legislation and how much could be left to the commissioning arrangements. In the event, an approach has been taken that both ensures that the national authorities are able to make an effective public health response and also ensures that we have reached the practical position that we could not have said significantly more on the face of the legislation to describe the scheme. This has meant that regulation 237A is quite long, but it is with these purposes in mind.

Amendments to references to Public Health England and the Health and Social Care Board

6.7 This is the only possible approach to make the necessary changes.

7. Consultation

Summary of consultation outcome and methodology - Availability of Naloxone -

7.1 A public consultation was required under the Medicines and Medical Devices Act 2021 (MMDA). This policy is reserved rather than devolved in Scotland and Wales, which means this was a statutory consultation by the DHSC, and the Department of Health (NI). This is because it is the DHSC and NI DOH ministers who have the power to make the legislative changes using the MMDA. Since the changes to legislation apply throughout the UK, the consultation was developed closely with the devolved administrations and was published in the joint names of all 4 Governments, being made available in England, Wales, Scotland and Northern Ireland.

7.2 The consultation ran for 6 weeks and closed on 6 March 2024. In total, we received 325 responses, including responses from all four nations. Of these 325 responses, almost a third (101) were on behalf of organisations, with the rest (224) coming from individuals sharing either their personal or professional views and experiences. Overall, the responses showed there is strong support for the proposals outlined in the consultation. The main findings were:

7.2.1 95% of respondents either agreed or strongly agreed with Route 1 (the supply arrangements other than those made with supply network co-ordinators) in which we are expanding the named list of services and professionals able to supply naloxone without a prescription.

7.2.2 92% respondents agreed or strongly agreed that Route 2 (supply arrangements with supply network co-ordinators) was a suitable way to enable take home naloxone provision to a wider audience.

7.2.3 95% of respondents either agreed or strongly agreed that training requirements should include the storage and supply of naloxone, as well as how to support those supplied with naloxone.

7.2.4 84% of respondents either agreed or strongly agreed that 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.

7.3 The consultation response was published in May 2024 Proposals to expand access to take-home naloxone supplies - GOV.UK (www.gov.uk)[4]

Summary of consultation outcome and methodology -Amendments to the references to Public Health England and the Regional Health and Social Care Board

7.4 A public consultation was required under the MMDA. A joint consultation was run with the Department of Health (NI) and was published on GOV.uk. The consultation received less than five responses. The responses came from across the United Kingdom and included individuals sharing personal views and responses received on behalf of organisations.

7.5 There were no disagreements with any of the proposals consulted on, and comments were strongly in support of the changes to update legislation to reflect the change in governance and of organisational roles in England and Northern Ireland.

7.6 The consultation response[5] was published in April 2024.

8. Applicable Guidance

8.1 In February 2015, DHSC published advice for commissioners and providers of drug and alcohol treatment services on the provision of naloxone to enable them to take action both in advance and following amendments to the 2012 Regulations. The guidance is available at Widening the availability of naloxone - GOV.UK (www.gov.uk)[6] and will be updated in line with these amendments after the regulations have come into force. DHSC is considering whether it will need to publish any supplementary advice.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

Availability of Naloxone

9.1 A full Impact Assessment has not been prepared for this instrument because there is a low level of impact per business and the measure is below the threshold for making such an assessment. The legislative amendments relating to naloxone are enabling and provide a power for a wider range of professionals, services and family members to be able to give out take-home naloxone supplies if they choose to.

9.2 The primary objective of the proposed policy is to widen access to naloxone so that it can be used to save lives in the event of an opiate overdose. It is expected that the amendments will increase the chance of naloxone being available to be administered when an overdose occurs. This should lead to a reduction in the number of lives lost due to drug misuse. It is beyond the scope of an impact assessment to quantify or monetise this health impact, but it is hoped that it will be significant.

Amendments to references to Public Health England and the Health and Social Care Board

9.3 We have actively considered whether the changes will impact business, charities or voluntary bodies and have determined there will be no impact due to the material

[4] https://www.gov.uk/government/consultations/proposals-to-expand-access-to-take-home-naloxone-supplies
[5] https://www.gov.uk/government/consultations/amending-references-to-phe-and-hscb-in-the-human-medicines-regulations
[6] https://www.gov.uk/government/publications/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone#responsibility

changes having already occurred, with these Regulations providing purely technical name changes to keep the legislation up to date with organisational structures and maintain continuity.

Impact on businesses, charities and voluntary bodies

9.4 There is no significant, impact on business, charities or voluntary bodies because these changes provide an enabling power and do not mandate the supply or carriage of naloxone. The anticipated impact on business is an increase in profits, as a result of the increase in sales that will occur due to more individuals and organisations having access to naloxone. The anticipated impact on charities and voluntary bodies is easier to provide access to take-home naloxone supplies.

9.5 The legislation does not impact small or micro businesses.

9.6 There is no, or no significant, impact on the public sector because these changes provide an enabling power and do not mandate the supply or carriage of naloxone.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 This instrument does not amend the review provision in the HMRs to include in that provision the new arrangements for the supply of naloxone. In line with the requirements of the Small Business, Enterprise and Employment Act 2015, Andrew Gwynne, Minister for Public Health and Prevention has made the following statement:

"It is not appropriate in the circumstances to make provision for review of the naloxone changes in this instrument. This is because there is already a requirement in section 46 of the Medicines and Medical Devices Act 2021 to review the operation of these Regulations every 24 months.".

10.2 This instrument does however update the review provision in the HMRs to take account of the revocation of provisions in Schedule 17 to the HMRs and the PHE changes. In line with the requirements of the Small Business, Enterprise and Employment Act 2015, Andrew Gwynne, Minister for Public Health and Prevention has made the following statement:

"The Human Medicines Regulations 2012 are subject to a regular review by the Secretary of State."

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 Andrew Gwynne, Minister for Public Health and Prevention has made the following statement regarding Human Rights:

"In my view the provisions of the Human Medicines (Amendments Relating to Naloxone and Transfer of Functions) Regulations 2024 are compatible with the Convention."

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts"). It does not relate to the withdrawal of the United Kingdom from the European Union.