Part A 1. International Non-proprietary Name of the medicine.

Naloxone

2. Proprietary name(s).

These formulations of naloxone hydrochloride, used to reverse opioid overdose, are currently available in New Zealand.

Ampoules, funded by Pharmac, but on PSO only:

> DBL™ Naloxone Hydrochloride Solution for injection, 400 mcg/mL (Prescription) – Pfizer (1 October 1992). Packaging: Ampoule, glass, 1 mL, in 5 dose units.

Ampoules, not funded by Pharmac

> Naloxone Hydrochloride Solution for injection, 400 mcg/mL (Prescription) - Max Health Limited (29 June 2017). Ampoule, glass, 1 mL, in 5 and 10 dose units.
>
> Naloxone Juno Solution for injection, 400 mcg/mL (Prescription) Juno Pharmaceuticals NZ Limited (23 August 2018). Ampoule, glass, 1 mL, in 1, 5 and 10 dose units.

Nasal spray in an emergency kit, not funded by Pharmac

> Nyxoid Nasal spray solution, 1.8 mg, Emergency kit (General sale) Mundipharma New Zealand Ltd (28 August 2020).

Difficulties with availability

In 2017, the Medicines Classification Committee reclassified naloxone to be available without a prescription if distributed as part of an approved emergency kit. However, it took several years - and huge effort - to find a company willing to repackage a naloxone product into an emergency kit. A Nyxoid nasal spray kit finally became available in 2020, produced by Mundipharama and distributed by Pharmaco.

However, the Nyxoid kit it is still not widely used because:

- It is so expensive, at $92 incl. GST, per kit. This puts it out of reach of many individuals, especially with a shelf life of only two years. This is a barrier to access and disadvantages a vulnerable population.
- It is not widely stocked by pharmacies, and is difficult for people who use drugs to get hold of.
- It is not funded by Pharmac, so DHBs are not allowed to purchase it.

The company does only two import-orders of Nyxoid per year. It does not hold much stock in the country and as such would not be in a position to respond quickly should we have a sudden opioid overdose crisis here.

Despite strenuous efforts from various parties (including the Ministry of Health) to find a company prepared to produce and supply an “approved emergency kit” containing ampoules, this has not been possible, so these remain prescription-only. This severely limits opportunities for wide distribution. Organisations such as needle exchanges cannot legally buy or hold naloxone onsite for

distribution to clients and doctors can only prescribe to named individuals. The need to visit a doctor means increased cost and effort for those who might benefit from holding naloxone – particularly friends and family member of those at risk of overdose.

Ampoules are funded only on Practitioner Supply Order, in packs of five. This allows distribution for "emergency use, teaching and demonstration purposes, and for provision to certain patient groups where an individual prescription is not practicable". There are very limited distribution options via this route. Some service providers and DHBs have found workarounds to get the ampoules distributed to named individuals and made up into emergency packs by pharmacies, but coverage has been patchy across the country.

Ampoules are low cost compared to the nasal spray option, and are preferred by some clients over the spray - but the current legal classification makes use of ampoules problematic.

The intention of the MCC in reclassifying naloxone in 2017 was presumably to bring it into line with best practice overseas, in places such as Australia, and make it easier to provide naloxone widely to individuals and in communities that are, or may become, at risk of overdose.

Unfortunately, the wording chosen has not worked for us in New Zealand, because it has been so hard to find companies willing to produce an "approved emergency kit".

3. Name and contact details of the company / organisation / individual requesting a reclassification.

New Zealand Drug Foundation
265 Wakefield Street
Te Aro
Wellington 6012
[redacted]

4. Dose form(s) and strength(s) for which a change is sought.

We would like the reclassification to cover all forms of naloxone - both current and future preparations - that are indicated for the reversal of opioid overdose. This would exclude products where naloxone is combined with another active ingredient (i.e., buprenorphine) for the *prevention* of opioid overdose (prophylactic).

Naloxone is currently available in New Zealand in 400 microgram/mL preparations as 1 mL ampoules, and as a 1.8 mg nasal spray. We seek changes for these products as well as any future dosage preparations indicated for the reversal of opioid overdose. Some countries have a prefilled syringe available, for example. The more options for products that are available - and the least restrictive the medicines classification - the better coverage we will be able to achieve for this life-saving medication.

5. Pack size, storage conditions and other qualifications.

We do not seek to repackage naloxone. For example, we propose that naloxone ampoules would only be distributed in their original packaging, so meeting legislative labelling requirements and protecting the naloxone from light.

A range of health and social service providers would like to be able to distribute existing naloxone products along with appropriate equipment and instructions, for the reversal of opioid overdose.

We anticipate no need to change storage conditions and other dispensing protocols – these would remain the same as those applying to the existing, approved, medicines in New Zealand.

6. Indications for which change is sought.

Naloxone is an emergency medicine for the reversal of opioid overdoses. It was classified as an essential medicine by the World Health Organization in 2013,[1] and it is considered best practice in many countries to distribute it proactively to communities who are at risk of overdose.[2]

Opioid use can result in respiratory depression and respiratory arrest. Naloxone reverses these effects and increases respiration rate.

The effects of naloxone administration begin within two minutes when given intravenously, and within five minutes when injected into a muscle. The medicine can also be administered by spraying it into a person's nose. Naloxone blocks the effects of opioids from 30 to 90 minutes. Multiple doses may be required, as the duration of action of some opioids is greater than that of naloxone.[3]

7. Present classification of the medicine.

After a classification change in 2017, naloxone became prescription-only, "except when provided as part of an approved emergency kit for the treatment of opioid overdose".[4]

The naloxone nasal spray Nyxoid has been available as an approved emergency kit since 2020 and is thus available as general sales (but see the barriers noted above as to cost and availability).

Naloxone ampoules remain prescription-only, as no approved emergency kit has been produced.

8. Classification sought.

We provide two options here and set out some relevant considerations.

Preferred option

Reclassify naloxone as general sales, with no qualifications.

With this classification, needle exchanges, opioid substitution treatment providers and organisations such as NZ Drug Foundation could purchase and hold the medicine onsite and give it out to people who use drugs, their families and friends, without the need for a prescription. This was presumably

[1] https://www.who.int/medicines/publications/essentialmedicines/18th_EML.pdf
[2] https://pubmed.ncbi.nlm.nih.gov/31058922/
[3] https://nida.nih.gov/publications/drugfacts/naloxone
[4] New Zealand Gazette, No. 77 — 3 August 2017

the intention of the reclassification in 2017, but it has not been possible to get any 'emergency kits' approved for distribution other than Nyxoid - which is expensive, not accessible to DHBs because unfunded, and has limited stocks.

Under this classification, we understand that emergency departments would also find it easier to distribute naloxone (under Schedule H).

We prefer this option because it is straight forward, future-proof, and least likely to mean unforeseen bureaucratic hurdles.

Second best option

Keep naloxone as a prescription medicine, "except when provided, or intended to be provided, for the reversal of opioid overdose, along with equipment and instructions".

This option is similar to the current classification, but the need for an 'approved emergency kit', which has proven so problematic, has been removed.

The wording is less precise and more open to interpretation than our preferred option, above, which gives space for unforeseen bureaucratic barriers to arise. However, it has the advantage of requiring that equipment and instructions be provided alongside the medicine.

Note that Health Navigator already provides peer-reviewed instructions online for use of naloxone in an overdose emergency.[5] These could be used or adapted by those wishing to distribute naloxone.

Other considerations

- It is important that the current ability of community based prescribers to use the PSO function to get funded naloxone to some clients is not compromised by any classification change. Similarly, DHBs must be able to continue to prescribe naloxone to named clients.
- The nasal spray Nyxoid is currently available as general sales because it comes as an approved emergency kit. We want Nyxoid to remain available under general sales.

9. Classification status in other countries (especially Australia, UK, USA, Canada).

Australia

In Australia, naloxone is a prescription medicine "except when provided as part of an emergency kit which includes information on how to identify opioid overdose, how to draw up and administer an intramuscular injection, and advice on other steps to take to mitigate risk such as putting the patient in the recovery position and calling an ambulance for further medical support with the finer details to be determined by the appropriate organisation."

Australia has three different formulations of naloxone available (nasal spray, pre-filled syringe and ampoules), each of which can be given out with or without a prescription.

[5] https://www.healthnavigator.org.nz/medicines/n/naloxone-for-opioid-overdose

We have a very similar medicines classification in New Zealand yet (despite best efforts) have not been able to attract a sponsor to apply for approval of a parenteral emergency kit. It also seems very unlikely that we will be able to do so given the small size of our market here - thus this application.

United States

Naloxone is a prescription only medication under FDA rules. As of mid-2019, officials in 29 states had issued standing orders to enable licensed pharmacists to provide naloxone to patients without the individual first visiting a prescriber.[6]

Canada

In March 2016, Health Canada changed the prescription status of naloxone. Pharmacies and emergency responders are now able to proactively give out naloxone to those who might experience or witness an opioid overdose.[7]

United Kingdom

Naloxone is a prescription-only medicine in the United Kingdom, unless supplied by a drug service to save a life in an emergency.[8, 9] A worker in a recognised drug treatment service can supply naloxone for use in an emergency to a family member or friend of a person using opioids, or to an outreach worker for a homelessness service whose clients include people who use opioids. The United Kingdom regulations do not require the naloxone to be supplied as an 'emergency kit'.

10. Extent of usage in New Zealand and elsewhere (eg, sales volumes) and dates of original consent to distribute.

Exact sales volumes are not available. Data on the extent of use of naloxone in the community is not available. Naloxone access for those at highest risk of opioid overdose (i.e. intravenous opioid users) is minimal at present.

11. Local data or special considerations relating to New Zealand (if applicable).

The current classification of naloxone products is making it harder to distribute take home naloxone, particularly to the highest risk patients.

The available naloxone emergency kit (Nyxoid nasal spray) presents significant cost and access barriers. These kits cost $92 to purchase which is too expensive for most patients. Accessing general sales products like Nyxoid is difficult, given both the cost, the limited availability at pharmacies and the limited production cycles of the product itself.

Naloxone available as prescription-only is unlikely to reach individuals at the highest risk of opioid overdose, particularly from illicit opioid use. Research indicates that many people who use opioids

[6] The Network for Public Health Law (2019). Addressing Opioid Overdose through Statewide Standing Orders for Naloxone Distribution.
[7] Government of Canada (2017). Questions and Answers – Naloxone.
[8] Guidance. Widening the availability of naloxone. Updated 18 February 2019. United Kingdom Government.
[9] The Human Medicine (Amendment) (No.3) Regulations 2015

are unwilling to disclose their use to a health professional or may not be engaged with the healthcare system at all.[10]

Whilst New Zealand does not currently have an opioid epidemic and may not have the predisposing factors to develop an epidemic in ways comparable to places like North America, we are still woefully underprepared to respond to any level of increased overdose from opioids, nationwide.[11]

12. Labelling or draft labelling for the proposed new presentation(s).

We propose that naloxone would only be distributed in the product's original packaging, so meeting legislative labelling requirements and protecting the naloxone from light.

13. Proposed warning statements (if applicable).

We propose that naloxone would only be distributed in the products original packaging, so meeting legislative labelling requirements and protecting the naloxone from light. In addition, any organisation or individual dispensing naloxone for the purpose of reversing opioid overdose would provide both appropriate equipment and instructions for use. We propose these instructions be aligned with information provided on a public health resource, such as Health Navigator.

14. Other products containing the same active ingredient(s) and which would be affected by the proposed change.

We are only proposing changes be made to the classification of naloxone products where the purpose of the product is to reverse an opioid overdose. Thus, this would not impact the provision of products containing naloxone with the indication of preventing opioid overdose (such as Buprenorphine Naloxone BNM sublingual tablets).

Part B

1. Indications and dose

− What is the medicine indicated for, and for which indication(s) is the reclassification application for?
− What is the evidence that the proposed indication is an OTC indication ie, that the diagnosis and treatment can be understood by the consumer; that the risks of inappropriate treatment can be minimised? − What is the treatment population for the indication (age; gender etc.)?
− What is the dose and dose frequency of the medicine for this indication?

Naloxone preparations are indicated for both the prevention of opioid overdose (generally as an active ingredient in an opioid product, for example, buprenorphine) and for the reversal of opioid overdose (as naloxone hydrochloride). The proposed reclassification only applies to products indicated for the reversal of opioid overdose.

[10] https://journals.sagepub.com/doi/abs/10.1177/1363459320925863
[11] https://pubmed.ncbi.nlm.nih.gov/33607479/

Opioid overdose is a straightforward diagnosis for laypersons; this is backed up solidly by the international literature.[12] The risk of administering naloxone to a person not experiencing opioid overdose is negligible. Clinical guidance states that if a layperson is unsure whether a patient is experiencing an opioid overdose that they administer naloxone anyway as associated risks are extremely minimal. Training in association with distribution is proven to increase confidence and minimize administration error.[13] Due to the low risk from administering naloxone, it is also used as a diagnostic tool.[14]

A primary treatment population for naloxone preparations is any person who uses opioids (whether on prescription or illicit). A secondary treatment population is any person who uses non-opioid illicit drugs (such as MDMA or methamphetamine) that may become contaminated with opioids, such as fentanyl or carfentanyl. Around two thirds of those who overdose on opioids in New Zealand currently, and are hospitalised as a result, are women.[15]

The initial dose of naloxone 400 microgram/mL is a 1 mL preparation for injection or the intranasal administration of 1.8 mg preparation. The frequency of administration is based on the clinical presentation of the patient; if respiration doesn't improve upon the initial dose of naloxone, repeated administrations are recommended until the patient is conscious and breathing normally, or until medical intervention arrives.

2. Presentation

− What is the proposed dose form and strength of the medicine to be reclassified? Is this the same for all indications?

− What disposal considerations need to be made for the medicine?

− How practical and easy to use is the proposed presentation?

We are proposing this change applies to the current 400 microgram/mL dose in a 1 mL preparation for injection as well as the 1.8 mg intranasal preparation, indicated for the reversal of opioid overdose. We would also like this to be applied more generally to all future approved forms of naloxone intended for reversal of overdose.

Disposal considerations are the same as under the current pharmaceutical guidelines. No specific changes to be made.

International literature indicates that people find application of naloxone to be straightforward, particularly where it is provided with clear instructions.[16] Ideally, there will be a range of products available (as in Australia, for example) – including injectable ampoules, nasal spray, and pre-filled syringes. This is suggested as preferences can differ depending upon who is administering the naloxone. People who inject drugs as well as healthcare professionals may prefer intravenous naloxone, whereas peers and whānau of people who use opioids may prefer intranasal spray as they will find it less daunting to administer.[17]

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[12] https://www.sciencedirect.com/science/article/pii/S2589537020302182
[13] https://onlinelibrary.wiley.com/doi/abs/10.1111/add.12360
[14] https://link.springer.com/article/10.1007/s13181-015-0525-5
[15] Ministry of Health (2021). Obtained 30 August 2021 under the Official Information Act 1982.
[16] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5005759/#:~:text=Our%20findings%20imply%20that%20lay,to%20respond%20to%20overdose%20events.
[17] https://www.tandfonline.com/doi/abs/10.1080/09687637.2021.1872499

3. Consumer benefits

− What is the history of this medicine's use for the proposed indication(s) ie, number of users; number of countries used in?
− To what extent is this medicine used for the proposed indication(s) ie, duration of use, frequency of use?
− What is the evidence that improved access is beneficial for the individual? − What is the evidence of improved consumer involvement in their health?
− What are the benefits from a consumer viewpoint?

Naloxone is listed as a World Health Organization essential medicine (2013)[18] and is likely available in some way in most countries in the world. Data on the availability internationally, including the global number of users, is not available.

The Global state of harm reduction report (2018) stated that peer take home programmes were in operation in Afghanistan, India, Estonia, Ukraine, Denmark, Italy, Norway, United Kingdom, Mexico, Canada, United States and Australia.[19] In addition, as of 2020, national, regional, or local take home naloxone programmes were implemented in 10 European Union countries, Norway, and the UK.[20] Again data on the international number of users of naloxone through take home programmes is unavailable. However, literature suggests that in countries with opioid crises, distribution is widespread. The BC Centre for Disease Control stated that an estimated 590,000 naloxone kits were distributed across Canada between 2012 and 2018.[21]

Naloxone is available as a take home medicine (and not prescribed to an individual) through different scheduling requirements worldwide.

There is substantial evidence suggesting that improved access to naloxone saves lives.[22] Access to take home naloxone and training has been shown to improve self-efficacy, awareness, and health literacy.[23] It can also promote greater engagement with overdose prevention services and peer networks and in some cases, promote recovery from opioid addiction.[24]

4. Contraindications and precautions

− What are the contraindications for the medicine and how easy are they to identify and prevent? − What are the precautions for this medicine and how easy are these to understand?

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[18] https://www.who.int/medicines/publications/essentialmedicines/18th_EML.pdf
[19] Global state of harm reduction 2018
[20] https://www.emcdda.europa.eu/publications/topic-overviews/take-home-naloxone_en
[21] http://www.bccdc.ca/about/news-stories/stories/report-estimates-more-than-590000-naloxone-kits-distributed-across-canada
[22] https://www.bmj.com/content/322/7291/895.short
[23] https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-017-0160-3
[24] Carley Marshal et al., (2017). Experiences of peer-trainers in a take-home naloxone program: Results from a qualitative study. International Journal of Drug Policy vol 41, pp19-28.

-Does the medicine have a low therapeutic index?

− What class effects need to be considered and what are the risks?

− What are the risks of the medicine being used in an OTC environment?

− What other drug interactions need to be considered?

− What food and/or drink interactions need to be considered?

− Are there any other restrictions when taking the medicine ie, driving restrictions or operating machinery?

− Are there any special populations where exposure to the medicine needs to be restricted?

The contraindications for naloxone are minimal. Clinical research suggests that there are 'no absolute contraindications to the use of naloxone in an emergency. The only relative contraindication known is hypersensitivity to naloxone'.[25] As a result, comparatively few precautions need to be taken to ensure naloxone is not misused.

Three major considerations for the administration are:

1. Errors related to IV and IM administration - including needle sticks, administration injuries or infection from contaminated needles.
2. Awareness of possible opioid withdrawal post naloxone administration and how this may affect the psychological and physiological wellbeing of the patient as well as subsequent behaviour (such as using opioids shortly after administration to avoid withdrawal).
3. Observation, and often medical attention, is required after administration.

These considerations are all mitigated by supplying naloxone with appropriate equipment and instructions, offering both intranasal and injectable naloxone and the provision of community training programmes.

Naloxone has a high therapeutic index and thus dosing standards are straightforward and low risk. So much so that the FDA Aesthetic and Analgesic Product Advisory Committee voted against creating separate dosing standards for adults and children. Given its long history of safety, the simplicity of administration outweighs the possibility of adverse effects from over-dosing of naloxone.[26]

Other considerations for using in a general sales environment include awareness of use in patients with pre-existing cardiovascular disorders. These patients should be closely monitored post naloxone administration.

Although use by pregnant women is anecdotally safe, there are no adequate and well controlled studies for this group.[27]

5. Undesirable effects

[25]Matthew R. Jordan; Daphne Morrisonponce (2021). Naloxone. National Centre for Biotechnology Information.
[26] US Food and Drug Administration (2016). Meeting Materials, Anesthetic and Analgesic Drug Products Advisory Committee.
[27] https://obgyn.onlinelibrary.wiley.com/doi/abs/10.1111/ajo.12761

What are the known undesirable effects and the frequencies of these? Do these vary for special populations?

What are the risks and consequences of known undesirable effects?

Are there any significant safety concerns for the medicine under review?

Have there ever been any withdrawals of the medicine or other regulatory actions taken for safety reasons (during a time period or in a specific jurisdiction)?

Are there any withdrawal effects following cessation of use of the medicine?

There are no known safety concerns. The World Health Organization (WHO) points out that naloxone has been used in opioid overdose management for over 40 years, with minimal adverse effects beyond the induction of opioid withdrawal symptoms.[28]

Naloxone has no abuse potential, and WHO recommends that naloxone be made available to people likely to witness an opioid overdose, including emergency personnel and friends and family members of those using opioids.[29]

For those who are addicted to opioids, naloxone may cause withdrawal symptoms. Unlike withdrawal symptoms precipitated by withdrawal of other agents, opioid withdrawal is generally not life-threatening. Withdrawal symptoms induced by naloxone administration tend to dissipate in a period of 30–60 minutes due to the relatively short half-life of naloxone.[30] Signs and symptoms may include increased sweating, nausea, restlessness, trembling, vomiting, flushing, and headache.[31]

Other side effects of naloxone use are comparatively minimal given its lifesaving potential. These can include tachycardia, hypotension, hypertension, dizziness, headache, nausea, vomiting and musculoskeletal pain. Uncommon reactions include arrhythmia, bradycardia, tremors, diarrhoea, and a dry mouth.[32] According to this research, death as a result of naloxone administration is exceedingly rare. Research and surveying of persons who have administered naloxone also found that severe reactions to this medicine were rarely observed (<1% reported seizures).[33]

Most of these concerns are mitigated by the fact that in an emergency situation, naloxone administration is the best chance of survival for someone overdosing on opioids and is clinically indicated. Side effects are largely irrelevant in the decision on whether to use naloxone when a person is facing an imminent fatal opioid overdose.**6. Overdose**

– Is there a potential for overdose of the medicine?

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[28] World Health Organization (2014). Community management of opioids overdose. Geneva, World Health Organization.
[29] World Health Organisation (August 2021). Opioid Overdose
[30] Daniel Wermeling (2015). Review of naloxone safety for opioid overdose: practical considerations for new technology and expanded public access. Therapeutic Advances in Drug Safety.
[31].Drugs.com. Naloxone side effects, updated December 2021. Retrieved from https://www.drugs.com/sfx/naloxone-side-effects.html
[32] Rachael Rzasa Lynn and JL Galinkin (2018). Naloxone dosage for opioid reversal: current evidence and clinical implications. Therapeutic Advances in Drug Safety 9(1): 63-88.
[33]Lauren Enteen et al., (2010). Overdose Prevention and Naloxone Prescription for Opioid Users in San Francisco. Journal of Urban Health. Bulletin of the New York Academy of Medicine, Vol 87, No. 6.

– *What are the consequences of overdose of the medicine?*

– *Are there any reports of overdose of the medicine?*

We know of no example of naloxone overdose in humans.[34]

7. Medication errors and abuse/misuse potential

– *Would reclassification affect the risk of unnecessary use?*

– *Is the medicine be provided with necessary tools to allow correct dosing eg, liquids supplied with a measuring device?*

– *What are the reported medication errors post-market?*

– *What are the reported cases of abuse/misuse/accidental overdose?*

– *How would reclassification affect import considerations?*

– *What is the addiction potential of the medicine?*

There is no risk that naloxone will be misused, as it has no effect on those who have not used opioids.[35] It has no addiction potential. We know of no reported cases of abuse, misuse or accidental overdose.

The medicine is packaged in single doses, and currently provided in a pack of five ampoules or two nasal sprays.

We would like to see organisations and medical professionals able to provide naloxone in the existing packaging widely to those who use opioids and other drugs. They would also provide syringes, needles, and alcohol swabs (for the ampoules), along with appropriate information on how to prepare and administer the naloxone, how to prevent an overdose, and information on aftercare. An example of such information can be found online at Health Navigator.[36]

8. Communal harm and / or benefit

– *What are the possibilities of community harm resulting from wider use of the medicine in question (eg, the development of antibiotic resistance in bacteria or increased immunisation rates)?*

– *What are the possibilities of community benefit resulting from wider use of the medicine in question (eg, greater herd immunity as a result of improved access to a communicable disease vaccine)?*

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[34] New Zealand Data Sheet for DBL Naloxone Hydrocholoride Injection USP 400 micrograms/mL solution for injection.

[35] World Health Organization (2014). Community management of opioids overdose. Geneva, World Health Organization.

[36] See: https://www.healthnavigator.org.nz/media/11976/naloxone-pamphlet-v4.pdf

Community harm from naloxone is extremely unlikely. Naloxone is being provided in communities in many countries around the world and has been repeatedly shown to save lives, with minimal risk.[37] Misperceptions that naloxone increases drug use or riskier drug use in at risk populations has been debunked by research.[38]

An average of 46 people in New Zealand die each year from non-intentional opioid overdose (5-year average from 2014-2018). Some of these deaths result from 'recreational' due use and some are the result of overdose from prescription medicines.[39] Other than alcohol, opioids are the substances that cause the most non-intentional deaths each year, according to coronial data.[40] In addition, around 1,000 people each year are discharged from hospital after overdosing on opioids.[41]

Naloxone distribution to at risk populations has increased in New Zealand over the last few years, despite the existing legal classification making this difficult. Anecdotally, it is already reported to have saved lives.[42]

The Drug Foundation estimates at least 85,000 people could benefit from take-home naloxone, including those who use prescription opioids, people on opioid substitution therapy and people who inject illicit drugs.

At the moment there are only a few thousand packs of naloxone distributed each year. With more, we could save dozens of lives and hundreds of hospitalisations each year.

With easier access to naloxone, we would also be more prepared for an opioid crisis, should one reach our shores in the future. This could happen through contamination of opioids used here for injecting (with fentanyl, for example), or through contamination of other drugs that are used recreationally, such as methamphetamine or MDMA. This is increasingly an issue overseas.[43, 44]

9. Integrated benefit-risk statement

− A summary of the reclassification benefits

− A summary of the reclassification risk of harm

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[37] World Health Organization (2021). Study to prevent deaths from opioids overdose shows promising results. Geneva, World Health Organization.

[38] Alexander Bazazi et al., (2010). Preventing Opiate Overdose Deaths: Examining Objections to Take-Home Naloxone. US National Library of Medicine. National Institutes of Health.

[39] Ministry of Health (2021). Obtained 30 August 2021 under the Official Information Act 1982.

[40] National Coronial Information System (June 2021). NCIS factsheet: Drug-related deaths in NZ in 2018. Retrieved from https://www.ncis.org.au/research-and-publications/ncis-factsheets/new-zealand-mortality-data-series/

[41] Ministry of Health (2021). Obtained 30 August 2021 under the Official Information Act 1982.

[42] Russell Brown (2021). Overdose prevention: a walk in the park? Wellington, Matters of Substance (NZ Drug Foundation).

[43] Joseph Palamar et al., (2021). Shifting awareness among electronic dance music party attendees that drugs may contain fentanyl or other adulterants. International Journal of Drug Policy, vol 97, 103353.

[44] Kenneth Tupper et al., (2018). Initial results of a drug checking pilot program to detect fentanyl adulteration in a Canadian setting. Drug and Alcohol Dependence, vol 190, pp 242-245.

– A summary of the need for the medicine at the classification proposed – Precedent – how are other medicines in the same class classified?

The benefits for the proposed reclassification of naloxone are significant. It will both save the lives of people currently using opioids and dying of overdose in New Zealand, as well as support the nation in moving from being grossly underprepared to respond to an opioid epidemic, to a position of preparedness.

We can see no single downside to reclassifying naloxone to general sales. This medicine has a high therapeutic index, no abuse potential, and no contraindications in a person facing an imminent fatal opioid overdose. The literature cited in this report is a small sample of research that unanimously indicates that having accessible naloxone saves lives.

The current classification was intended to help make naloxone more easily available in New Zealand but unfortunately, progress has been slow. A reclassification now would speed up access significantly. We intend to apply to Pharmac to fund naloxone more broadly than under the current PSO mechanism. We anticipate that we will be more likely to be successful with the ampoules, which are significantly less expensive than the nasal spray. It is therefore extremely important that we can access naloxone ampoules under general sales as well as under prescription/PSO.

10. Risk mitigating strategies

– Are there any risk mitigation strategies required? If so, what risk mitigation strategies are required eg, healthcare professional education; integration of care; consumer information to be provided etc?

– What is the evidence that these proposed risk mitigation strategies would be effective?

– What post-market surveillance activities would be carried out?

– Is the proposed reclassification supported by professional bodies?

As stated, the provision of naloxone is not associated with increased risk of harm or death for the population using it.[45] To ensure that naloxone is effectively used by communities at high risk of opioid overdose, we would suggest implementation of the following:

- Effective and simple instructions for use of injectable and intranasal naloxone.
- Providing naloxone with the appropriate equipment for safe use (especially for injectable) to reduce any safety concerns from improper or unclean injecting practices.
- Offering training for those supplying and receiving the naloxone to understand the product and its use, including peers, whānau and at-risk individuals or communities on administering naloxone. This includes peer-to-peer training models that have proven effective overseas.[46]

Additionally, we also see the benefit in providing more widespread naloxone training and education to healthcare providers, alcohol and other drug practitioners, police and other workforce engaging with people who use drugs.

[45] https://www.sciencedirect.com/science/article/abs/pii/S0091743519304153
[46] https://www.sciencedirect.com/science/article/abs/pii/S0277953617301594

There is substantial international literature cited in this application that suggests these strategies are proven to be effective and increase the confident and health literacy of participants as well as reduce administration error.

We believe this application is well supported by professional bodies, although we have not had time to test the exact wording of our proposal. Everyone we have spoken to on this issue, including opioid substation treatment providers, psychiatrists, DHB staff, various government officials, St Johns, KnowYourStuff and the Needle Exchange Programme, have similarly expressed their frustration at the current classification, which has played a part in preventing widespread distribution of naloxone.

The Drug Foundation is well-positioned as an organisation to support the development of New Zealand-specific strategies for distributing naloxone, scoping training and evaluating impact.