Minister for Drugs Policy
Ministear airson Poileasaidh Dhrugaichean
Angela Constance BPA/MSP

T: 0300 244 4000
E: scottish.ministers@gov.scot

Scottish Government
Riaghaltas na h-Alba
gov.scot

Gillian Martin MSP
Convenor, Health Social Care & Sport Committee

10 November 2022

Dear Committee Convener,

I am writing to inform you of the actions we have taken in response to a Medicines and Healthcare products Regulatory Agency (MHRA) National Patient Safety Alert and Class 4 Medicines Defect Information - 'Caution in Use' Medicine Notification regarding Prenoxad® 1mg/ml Solution for Injection which issued on 10 November 2022.

Prenoxad® is an injectable form of Naloxone – a medication that can reverse opioid overdose – which is available in a pre-filled syringe, manufactured by Macarthys Laboratories (Trading as Martindale Pharma, an Ethypharm Group Company).

A Caution in Use (CIU) Medicine Notification is used when there is no threat to patients or no serious defect likely to impair product use or efficacy. These are generally used for minor defects in packaging or other printed materials. CIU notices may also be issued where a defect has been identified but due to supply concerns a product cannot be recalled, and in these instances the alert is used to provide advice to healthcare professionals. The latter applies to this Prenoxad notification.

The problem emerged when it was reported that a very limited number of Prenoxad® packs in a batch marketed in France were missing needles (three packs out of a batch of 9000 kits). All complete Prenoxad® packs should contain two needles.

Although no reports of UK packs with missing needles have been received to date, the potential for packs to contain fewer than two needles in all distributed batches cannot be excluded. We know that in Scotland, tens of thousands of Prenoxad® kits have been distributed from the batches that could potentially be affected. As a result, we are following the MHRA advice and are taking steps to ensure that everyone, including health professionals and members of the public, know how to check their kits and how to access replacement kits should they identify any issues. You can find National Patient Safety Alert here: CLASS 4 NOTIFICATION - CAUTION IN USE (publishing.service.gov.uk).

The National Naloxone Programme has been and will continue to be a key component of our work to deliver our National Mission to reduce drug deaths and harm across Scotland, and I am determined that this potential defect does not disrupt supply or reduce public confidence in the programme.

We are therefore working closely with the MHRA, NHS Scotland and the third sector to ensure that people clearly understand what to do, that kits are checked, and if any defects are found, that packs are replaced as soon as possible in order to be ready to use in case of overdose related emergency. We are also working with stakeholders to produce really clear, illustrated guidance on how people can check their kits that third sector partners and others can share with those who carry their own kits.

Your sincerely,

ANGELA CONSTANCE
Minister for Drugs Policy