Sale of naloxone as a Schedule 3 (Pharmacist Only) medicine

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Target audience: Pharmacists.

Purpose
To inform pharmacists of the regulatory requirements for selling naloxone as a Schedule 3 (Pharmacist Only) medicine.

Background
From 1 February 2016, naloxone when used for the treatment of opioid overdose is classified as Schedule 3 (S3; Pharmacist Only) in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). For all other purposes, naloxone is classified as Schedule 4 (S4; Prescription Only).

Currently, all naloxone products commercially available in Australia are labelled as S4—these do not conform to the labelling requirements for sale as S3.

Requirements for selling naloxone as an S3 medicine
Pharmacists are required to comply with Section 277 of the Health (Drugs and Poisons) Regulation 1996 pertaining to the sale of S3 medicines (e.g. determine therapeutic need, attach a compliant label, provide advice on use). In addition to these requirements, alterations need to be made to the S4 naloxone product to comply with the requirements for S3 sale. These include:

- removing / obscuring any reference pertaining to the use of the product for indications other than the treatment of opioid overdose
- removing / obscuring reference to the product as a ‘Prescription Only’ medicine.

Selling a fit-for-purpose S3 naloxone product
Pharmacists should ensure that naloxone supplied as an S3 medicine is fit-for-purpose to treat opioid overdose. This may involve providing customers with any additional equipment required to administer the injection in an emergency (e.g. needle).

Quality standards
Pharmacists are reminded that the selling of naloxone as an S3 medicine is covered by legislation requiring pharmacists to adopt and comply with a quality standard for selling S2 and S3 medicines. To sell an S2 or S3 medicine, a pharmacist must:

- have prepared or adopted a quality standard for selling S2 or S3 poisons
- in selling the S2 or S3 poison, comply with the quality standard.

For more information please contact:

Medicines Regulation and Quality
Phone: 07 3328 9808
Fax: 07 3328 9821
Email: MRQ@health.qld.gov.au