

REGULATORY ISSUES: NALOXONE SCHEDULE 3

Source: Pharmaceutical Services Unit, NSW Ministry of Health

From 1 February 2016 naloxone “for the treatment of opioid overdose” is in Schedule 3 of the Poisons List (Pharmacist Only Medicine), i.e. can be supplied by a pharmacist without prescription. NSW MoH takes this to mean that all currently registered single-ingredient naloxone medicines are in S3 (all brands, strengths, pack sizes and dose-forms).

The standard NSW requirements for any S3 medicine apply. E.g.:

- the pharmacist must personally hand the medicine to the customer (thus a prescription is still required when a customer orders online or by mail);
- pharmacists are not compelled to supply it on demand but must make a professional assessment of the suitability of the medicine;
- the medicine may be supplied directly to the intended patient or to another person e.g. a relative or carer;
- there is no explicit legislated limit to the quantity that may be provided or the age of the customer: pharmacists can supply only “in a quantity and for a purpose that accord with the recognised therapeutic standard of what is appropriate in the circumstances”.

There is no additional requirement to record the customer’s name or other details of the supply.

As the three product sponsors are not yet supplying S3-labelled packs (with consumer directions) and seem unlikely to be able to comply with this legal requirement for at least several months, pharmacists supplying it will need to over-label it with a standard dispensing label (as per Appendix A of the Poisons and Therapeutic Goods Regulation 2008) i.e. including date, (intended) patient name, full directions for use etc. This is particularly important as the Consumer Medicine Information (CMI) (which is not easy to find) is not particularly helpful for a customer purchasing naloxone. (It seems mainly designed to be given to a patient after administration.)

In addition pharmacists should orally counsel the customer and use the guidance provided by professional organisations, the Pharmacy Council and the Ministry of Health.

It is not an offence to possess naloxone.

The 3 major wholesalers to NSW pharmacies do not at present have a large quantity of stock.

Existing non-pharmacy supply routes remain legal and are unaffected.

Naloxone 400mcg preloaded syringes remain on the PBS as a general supply item and free as a “Doctor’s Bag” emergency drug item and Medicare has given no indication that it intends to change this.