Legislative Context

Under section 4 of the Health (Drugs and Poisons) Regulation 1996 (HDPR) manufacturing is a regulated activity and includes the packing or repacking of drugs or poisons. Manufacturing without a licence is an offence under sections 45, 139 and 226 of the HDPR. In the event that a prescriber, for clinical and/or safety reasons, orders a quantity of a scheduled medicine that is less than the manufacturer’s original pack, a registered nurse or indigenous health worker may be required to repack medicines in containers other than the manufacturer’s original pack. Under section 4(4) of the HDPR a registered nurse or indigenous health worker is deemed not to be manufacturing a controlled or restricted drug or poison by only packing or repacking it under a certified written policy, about packing or repacking controlled or restricted drugs or poisons, published by the department.

Intent

The intent of this document is to fulfil the requirements of a certified written policy about packing or repacking controlled or restricted drugs or poisons (scheduled medicines). Packing or repacking of scheduled medicines by authorised registered nurses or indigenous health workers in line with the requirements of this document is not manufacturing according to the HDPR.

Scope

This policy applies to registered nurses or authorised indigenous health workers who, as part of their practice, are authorised to supply medicines.1

This policy only applies if the facility does not employ a pharmacist or, if the facility employs a pharmacist, the pharmacist is absent from the facility at the time the medicine is supplied. The policy does not apply to the issuing of medicines for administration to inpatients or enable small batch manufacturing.

The actions of a rural and isolated practice area registered nurse, a registered nurse who is practising as a sexual health nurse or an authorised indigenous health worker must be in accordance with the relevant Drug Therapy Protocol and Health Management Protocol. The actions of a registered nurse(s) who are approved to supply a scheduled medicine under HDPR s18(1) must be in accordance with the conditions of the approval.

Principles

Where possible, the original manufacturer’s pack should be used.

Where a prescriber has requested a lesser quantity than the original pack size, and this is not in accordance with agreed local health service policies, a registered nurse, authorised indigenous health worker should confirm with the prescriber that a quantity less than the original pack size is necessary before proceeding. A rural and isolated practice endorsed registered nurse acting under a drug therapy protocol should consider the therapeutic need to supply a quantity less than the original pack.

1 Under sections 67, 68, 164A, 175, 176, 252B, 263 and 263A or authorised to supply granted under a s18(1) approval of the HDPR
Where a prescriber authorises the supply of a medicine on the Queensland Health Non-inpatient Rural and Remote Medication Record, a quantity less than the original pack size should only be supplied if local Hospital and Health Service (HHS) policies require a smaller specified amount to be supplied, such as one month’s supply.

When repacking a scheduled medicine for supply a registered nurse or authorised indigenous health worker must:

- repackage the medicine in an appropriate container that complies with sections 164 and 165 of the Health Regulation (1996) and sections 10, 11 and 12 of the HDPR with particular regard to:
  1. maintaining the integrity of the product by protecting it from damage by moisture and/or light; and
  2. restricting access to the product by using a reclosable container with a childproof closure as required
- not use a container permanently marked with the name of a scheduled medicine as a container for a different scheduled medicine;
- label the repackaged medicine in accordance with the requirements of sections 85, 198 and 276 of the HDPR;
- include the batch number and expiry date from the manufacturer’s packaging on the new package, unless otherwise evident on the immediate wrapper of the medicine;
- not supply a medicine that will expire before the patient will (reasonably) have taken all the doses (where an expiry date does not indicate a specific day, the expiry is taken to be the end of the month indicated); and
- keep any remaining medicine in the original container and clearly indicate that this no longer contains the original quantity by marking a cross in indelible ink over the quantity shown on the pack label.

Where possible, a registered nurse or authorised indigenous health worker should have another appropriately qualified person checks the details on the original container and on the new package against the medication order. Development of relevant local guidelines will assist in ensuring the opportunity for error is kept to a minimum.

**Dose Administration Aids (DAAs)**

DAAs are well-sealed, tamper-evident devices that allow individual medicine doses to be organised according to the prescribed dose schedule. While DAAs can assist people to take their medicines safely and support adherence, there are also risks including errors in packing and misuse of the DAA. DAAs should only be used when there is a clear and realisable benefit to the patient in terms of a superior health outcome. Wherever possible a DAA should be filled (or checked) by a pharmacist.

The principles in this policy also apply to the repacking of medicines into a DAA.

A registered nurse acting within the scope of this policy may repack medicines into a DAA in the following circumstances:

- The type of DAA used is endorsed by the Director of Pharmacy at the HHS. DAAs where the compartments are re-usable, washable and not tamper-evident (for example a Dossett™ box) must not be used.
- DAAs must only be prepared in a clean and tidy facility with sufficient space, good lighting and temperature control. DAAs should not be prepared in a patient’s home.
A documented procedure is in place for safe packaging of the specific type of DAA in use and registered nurses who will prepare DAAs have received instruction from a pharmacist in the safe and reliable filling of DAAs. The professional manager of the person filling the DAA is responsible for ensuring that training is provided and competency assured.

This documented procedure should include:

- Steps to minimise errors including checking procedures to ensure that the DAA contains the correct medicines
- Assessment of the suitability of medicines to be packed in the DAA. The stability of medicines in a DAA and environmental conditions should be considered. The person filling the DAA must ensure that medicines that readily degrade outside their original packaging are not packed into the DAA
- The requirements for labelling DAAs as per Sections 85, 198 and 276 of the HDPR, or any subsequent legislation
- DAA filling records for each DAA packed that include the name of the person for whom the DAA is prepared, the medicines packed including batch/expiry date, the date of packing, the identity of the person who packed the DAA and the date the DAA was checked and by whom. This filling record should be retained for at least 6 months
- Quality assurance processes such as audits by a pharmacist employed by an HHS.

DAAs must only be provided to a patient after a documented assessment of patient needs and the patient’s ability to use the specific type of DAA proposed. The decision to provide a DAA should be confirmed with a medical practitioner, nurse practitioner or a pharmacist from the HHS.

DAA packed under this policy must be used directly by the patient or their carer, not by another health professional.

Certification
Certified at Brisbane on this day of 2018
To take effect on the 31 August 2018

Dr SUSAN BALLANTYNE
Senior Medical Officer
Chief Medical Officer and Healthcare Regulation Branch