Schedule to License to Operate Pharmacy Conditions

Pharmacy Accuracy Checking Technician Activities

In accordance with the Licence to Operate Pharmacy, every pharmacy must comply with the requirements of the Health and Disability Service Standards Pharmacy Services Standard NZS 8134.7:2010.3. As the role of the PACT is not defined within the Standards, Medsafe issues a Licence to Operate Pharmacy with an additional condition to enable a certified PACT to independently conduct accuracy checks as follows:

- final accuracy check of a dispensed prescription *(excluding class A and B controlled drugs)*
- accuracy check of a repackaged medicine *(excluding class A and B controlled drugs)*
- accuracy check of a de-blistered medicine *(excluding class A and B controlled drugs)*
- accuracy check of each ingredient *(excluding class A and B controlled drugs)* for a non-aseptically compounded medicine.

When conducting these activities, the following requirements of Standard 5, Health and Disability Services Pharmacy Services Standard NZS 8134.7:2010, may be completed by a PACT, subject to the following limitations:

STANDARD 5.2: GOOD DISPENSING PRACTICE **A disciplined dispensing procedure shall ensure that the appropriate product is selected and dispensed accurately and efficiently.**	
Criteria 5.2.3 (f)	All prescription forms clearly record who dispensed the prescription and the pharmacist responsible for the final check for completeness and accuracy
LIMITATION 5.2.3(f)	The prescription form must record the identity of: • the pharmacist conducting the clinical check, and • the PACT responsible for conducting the final accuracy check.
STANDARD 5.15: COMPOUNDING PROCEDURES **Compounding procedures shall ensure that the medicines prepared are of the required quality**	
Criteria 5.15.5	The identity, and weight (or volume) of each ingredient shall be checked by a pharmacist
LIMITATION 5.15.5	The identity of the PACT accuracy checking the identity and weight (or volume) of each ingredient must be recorded on the compounding document. Note. Reconstitution of antibiotics is not considered compounding.
STANDARD 5.29: RECORDS FOR REPACKING OF MEDICINES **For regularly repacked products a copy of the master batch document shall be used to make the record.**	
Criteria 5.29.1(j)	The signature or initials of the pharmacist checking/releasing the finished product shall be recorded
LIMITATION 5.29.1(j)	The identity of the PACT accuracy checking/releasing the finished repackaged product must be recorded on the batch document.
STANDARD 5.34: REPACKING OF MEDICINES **There shall be a defined step where the finished (repackaged)product is compared with its specifications and released or rejected**	
Criteria 5.34.1	The requirements in 5.25 shall be met: 5.25.1 – the decision to release the final product shall be made by the pharmacist taking responsibility for quality. 5.25.2 - the assessment and decision shall be recorded
LIMITATION 5.34.1	A PACT may make the decision to release a repackaged product. Compliance with criterion 5.25.2 is required.

STANDARD 5.39: DE-BLISTERING OF MEDICINES **Documented and systematic procedures shall be followed when medicines are removed from their original strip packaging**	
Criteria 5.39.2(e)	The batch record shall include the identity of the pharmacist checking the end product
LIMITATION 5.39.2(e)	The identity of the PACT accuracy checking de-blistered medicines must be recorded on the batch record sheet. Note. The new expiry date must be assigned by a pharmacist, refer 5.39.2(f).
Criteria 5.39.6	Only one medicine shall be de-blistered at a time, with the process finished and checked off by the pharmacist before another medicine de-blistering process begins.
LIMITATION 5.39.6	Only one medicine shall be de-blistered at a time, with the process finished and checked off by the PACT, before another medicine de-blistering process begins.
STANDARD 5.41: FINISHED COMPLIANCE, DOSE OR UNIT PACK **There shall be a defined step where the finished pack is checked by a pharmacist for quality sand accuracy of dispensing and released or rejected.**	
Criteria 5.41.2	The final check shall be recorded both on the pack and on a document that contains the pharmacist identity and date, which remains on the pharmacy premises.
LIMITATION 5.41.2	The identity of the PACT conducting the final accuracy check must be recorded both on the pack and on a document that contains the identity and date of the check, which remains on the pharmacy premises.
STANDARD 5.42: AUTOMATED PACKING AND DISPENSING – AUTOMATED DEVICES **Good dispensing practices shall be established and followed for safe and accurate medicine packing and dispensing**	
Criteria 5.42.4	Thorough checking of the end product shall be undertaken by a pharmacist before release of the product for supply
LIMITATION 5.42.4	The identity of the PACT accuracy checking medicines packaged by an automated packing or dispensing device must be recorded on the corresponding record.
STANDARD 5.47: CHECKING THE FINISHED PRODUCT **The pharmacist shall be responsible for checking the contents and label of every packed medicines prior to supply to a consumer**	
Criteria 5.47 (5.47.1 – 5.47.6 inclusive)	The pharmacist shall comply with the requirements of these criteria
LIMITATION 5.47	When accuracy checking the finished product, the PACT shall have regard to the criteria 5.47.1 to 5.47.6 (inclusive).

Schedule Conditions

1. This Schedule does not apply to a licence holder where an additional operating condition prohibits PACT activities being conducted at the pharmacy.
2. The licence holder is responsible for ensuring compliance by the pharmacy with the current PACT Governance, Operational and Training Frameworks.