

ELECTRONIC DRUG REGISTER FOR PHARMACY

The Poisons and Therapeutic Goods Regulation 2008 (the Regulation) requires a person who has possession of drugs of addiction at any place to keep a separate register (a **drug register**) at that place.

Clause 111(2) of the Regulation stipulates that a drug register is to be in the form of a book. However, clause 111(4) states that the Secretary of the Ministry of Health may from time to time approve the keeping of a drug register in any other form.

Approval of electronic drug registers for use by pharmacists in NSW is made on a case-by-case basis, following consideration of a written application, which must be sent by mail or email to:

The Chief Pharmacist
Pharmaceutical Services Unit
Legal and Regulatory Services Branch
NSW Ministry of Health
Locked Mail Bag 961
North Sydney NSW 2059

Email: pharmserv@doh.health.nsw.gov.au

Applicants are advised to refer to the Controlled Drugs Electronic Register (CDER) Vendor Resource Document (Version 1.19 – RELEASE), September 2013, produced by the Medical Software Industry Association (MSIA) in collaboration with the Department of Health, the Pharmacy Guild of Australia and State and Territory jurisdictions, prior to making an application to the NSW Ministry of Health (the Ministry), in order to ensure that their proposed software employs an appropriate implementation model of a CDER.

ELECTRONIC DRUG REGISTER

An electronic drug register (also referred to as a “Controlled Drugs Electronic Register (CDER)” and henceforth referred to as “the Register”) must be able to demonstrate that it meets all legislative requirements in NSW as set out in the Poisons and Therapeutic Goods Regulation 2008, noting particularly clauses 111, 112, 118, 119 and 124 (see **Appendix A**). The following criteria specify the system capability, administrative functions, security, responsibility and accountability features that the Register must be able to demonstrate. A set of scenarios that may be used by regulatory agencies to check on the compliance of electronic drug registers to the specified criteria is provided for the guidance of developers in **Appendix B**. A diagram illustrating the relationship between the pharmacist owner(s), the nominated authorised person (pharmacist-in-charge) and pharmacist users of the Register is provided in **Appendix C** for clarity.

1. System Capability and Security

- 1.1 The Register must be able to record the information for each drug of addiction (Schedule 8 (S8) drug) specified by its name (both generic and trade name), brand, form and strength.

- 1.2 The Register must operate as a stand-alone, i.e. a separate, independent program but may accept entries from a pharmacy dispensing program. Where entries are made as a secondary step from the dispensing program, the Register entry must take effect when the pharmacist confirms that the drug has been supplied.
- 1.3 Only one copy of the Register is to be maintained on a computer at any one premises.
- 1.4 The Register must be able to record the following information for each controlled drug:
 - a. Unique transaction number
 - b. Date of transaction
 - c. The type and nature of the entry or transaction (supply, receipt, adjustment, credit, transfer in/out, formulation, damage, loss, destruction, error/reversal, stock check/audit, see **Appendix D** for definitions)
 - d. Supplier or customer name and address including the company name, from whom stock has been received or to whom stock has been supplied
 - e. Stock quantity supplied (going out) or received (coming in)
 - f. Remaining balance of stock after addition or subtraction of quantity supplied or received for each individual transaction
 - g. Name of the person making the entry in the Register
- 1.5 The Register program must have an automatic log-off feature, after a reasonable idle period.
- 1.6 The Register program must be able to be forced to immediately log-off a user.
- 1.7 Alteration, obliteration or deletion of entries in the Register is prohibited.
- 1.8 The Register must issue a new sequential serial number, time and date for each entry (supply, receipt, adjustment, credit, transfer in/out, formulation, damage, loss, destruction, error/reversal, stock check/audit).
- 1.9 Each Register entry must record the stock balance following the movement which the entry records.
- 1.10 The Register must not allow the use of default key entry mechanisms, for example, the use of shortcuts or function keys to populate a Register entry.
- 1.11 The Register must make provision for recording the details of stock destruction, including creation of access codes for an authorised Ministry Officer/Inspector, henceforth referred to as an “authorised officer”.
- 1.12 The data stored in the Register must be secure and tamper-proof.
- 1.13 The data recorded by the Register must be retained for a period of 2 years from the date of the last entry.
- 1.14 Back-up and restore arrangements must meet IT industry standards and best practices, including safe storage and limited access off site.

- 1.15 The Register must have an “auto-save” function to ensure that data is safe from loss due to interruption during processing.

2. Responsibility and Accountability

- 2.1 The Register must clearly identify the name of the person who is currently responsible for the keeping and reliable operation of the Register (henceforth referred to as the “authorised person”), usually the pharmacist-in-charge.
- 2.2 The Register must clearly identify for 7 years from the last entry details relating to previous authorised persons (i.e. name, period of appointment as the authorised person).
- 2.3 Only a person using an access code issued by the authorised person may make an entry.
- 2.4 The authorised person must make all registers available on request to an authorised officer.
- 2.5 An access code must be used in combination with a password known only by the person to whom the access code is issued, henceforth referred to as the “user”, usually another pharmacist.
- 2.6 The access code must be recorded whenever a user makes an entry.
- 2.7 The record of the access code cannot be changed.
- 2.8 The authorised person must keep a record of the access codes issued and the users to whom they were issued. The authorised person must ensure that other persons do not have access to that record.
- 2.9 In any legal proceedings, in the absence of proof to the contrary, the person to whom an access code has been issued is taken to have made the entry.

3. Administrative Functions

- 3.1 The person who receives or supplies the drug must make an entry in the Register on the day on which the transaction takes place.
- 3.2 Any damage that renders a product unusable or any other loss of a drug must be recorded in the Register by the person who damaged or lost the drug or first noticed its damage or loss.
- 3.3 The stock balance in the Register and the actual stock on hand must be reconciled at least twice a year as stipulated in Clause 118 of the Poisons and Therapeutic Goods Regulation 2008, and is recommended to be performed more frequently if there is a high level of activity. The balance and any adjustment must be recorded by the persons authorised to carry out the reconciliation.
- 3.4 Physical records, such as invoices and confirmations of delivery, which are used to validate entries made in the Register, must be retained by the authorised person for two years.
- 3.5 Electronic information held by the Register must be capable of being reproduced on paper on demand by an authorised officer.

- 3.6 The Register must be able to be connected to a printer to enable the printing of records.
- 3.7 A report must be able to be generated immediately on request by an authorised officer.
- 3.8 The Register must be able to produce reports displayed on-screen, in printed form, saved as an electronic file and able to be exported by email or other means, e.g. a USB device.
- 3.9 The Register reports shall include:
 - a. List all entries for the period (date to date) by drug
 - b. List all entries by date
 - c. List all current stock and balances
 - d. List all drugs previously recorded in register but not currently held
 - e. List all corrections (adjustment, credit, transfer in/out, damage, loss, destruction, error/reversal, for the period (date to date)
 - f. List all entries by patient for the period (date to date)
 - g. List all entries by supplier for the period (date to date)
 - h. List all entries by authorised officer
 - i. List all entries by user
 - j. List all entries/movements for each month suitable for submission to the Ministry in accordance with the reporting requirements, including by specified electronic means, as stipulated by the Ministry from time-to-time.

For further information or clarification of this document, contact the Duty Pharmaceutical Officer, Pharmaceutical Services during office hours on (02) 9391 9944.

This document has been produced by:

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Appendix A – Relevant clauses from the Poisons and Therapeutic Goods Regulation 2008

Poisons and Therapeutic Goods Regulation 2008



Division 5 Records of supply

Subdivision 1 Drug registers otherwise than for hospital wards

111 Drug registers to be kept

- (1) A person who has possession of drugs of addiction at any place must keep a separate register (a **drug register**) at that place.
- (2) A drug register is to be in the form of a book:
 - (a) that contains consecutively numbered pages, and
 - (b) that is so bound that the pages cannot be removed or replaced without trace, and
 - (c) that contains provision on each page for the inclusion of the particulars required to be entered in the book.
- (3) Separate pages of the register must be used for each drug of addiction, and for each form and strength of the drug.
- (4) The Director-General may from time to time approve the keeping of a drug register in any other form.

Maximum penalty: 20 penalty units.

112 Entries in drug registers

- (1) On the day on which a person manufactures, receives, supplies, administers or uses a drug of addiction at any place, the person must enter in the drug register for that place such of the following details as are relevant to the transaction:
 - (a) the quantity of the drug manufactured, received, supplied, administered or used,
 - (b) the name and address of the person to, from, or by, whom the drug was manufactured, received, supplied, administered or used,

- (c) in the case of a drug that has been administered to an animal or supplied for the treatment of an animal, the species of animal and the name and address of the animal's owner,
 - (d) in the case of a drug that is supplied or administered on prescription:
 - (i) the prescription reference number, and
 - (ii) the name of the authorised practitioner by whom the prescription was issued,
 - (e) in the case of a drug that has been administered to a patient, the name of the authorised practitioner (other than a veterinary practitioner) by whom, or under whose direct personal supervision, the drug was administered,
 - (f) in the case of a drug that has been administered to an animal, the name of the veterinary practitioner by whom, or under whose direct personal supervision, the drug was administered,
 - (g) in the case of a drug that has been administered by a person authorised to do so by an authority under Part 8, details of the circumstances requiring administration of the drug,
 - (h) in the case of a drug that has been used by a person who is in charge of a laboratory, or is an analyst, the purpose for which the drug was used,
 - (i) the quantity of drugs of addiction of that kind held at that place after the transaction takes place,
 - (j) any other details approved by the Director-General.
- (2) Each entry in a drug register must be dated and signed by the person by whom it is made.
- (3) The Director-General may, by order in writing, exempt any person or drug of addiction, or any class of persons or drugs of addiction, from any or all of the requirements of this clause.
- (4) Such an exemption may be given unconditionally or subject to conditions.
- Maximum penalty: 20 penalty units or imprisonment for 6 months, or both.

Subdivision 3 Records generally

118 Periodical inventory of stock of drugs of addiction

- (1) The person responsible for maintaining a drug register (including a ward register) at any place:

- (a) must, during the prescribed periods, make an accurate inventory of all drugs of addiction at that place, and
 - (b) must endorse the relevant drug register, immediately under the last entry for each drug of addiction, with the quantity of each drug of addiction actually held and the date on which the inventory was made, and
 - (c) must sign each entry.
- (2) The prescribed periods for the purposes of subclause (1) (a) are:
- (a) March and September each year, or
 - (b) if the Director-General determines some other periods, either generally or in specified circumstances, the periods so determined.
- (3) A person who assumes control for a period of one month or more over any place at which drugs of addiction are held must, immediately on assuming control, make an inventory and endorse the drug register as if the inventory were an inventory made under this clause.

Maximum penalty: 20 penalty units.

119 Loss or destruction of registers

Immediately after a drug register (including a ward register) is lost or destroyed, the person responsible for keeping the register:

- (a) must give written notice to the Director-General of that fact and of the circumstances of the loss or destruction, and
- (b) must make an accurate inventory of all drugs of addiction held at the premises concerned and enter, in a new drug register, the particulars of the drugs so held.

Maximum penalty: 20 penalty units.

124 Loss or theft of drugs of addiction

A person who is authorised to be in possession of drugs of addiction must immediately notify the Director-General if the person loses a drug of addiction or if a drug of addiction is stolen from the person.

Maximum penalty: 20 penalty units.

Appendix B - Scenarios for electronic drug registers in pharmacy

Administrative and Security Functionality

Scenario 1

- Enter into the Register the name of the person who is currently responsible for the keeping and reliable operation of the Register, i.e. the “authorised person” and demonstrate that this entry cannot be modified by any other user.

Scenario 2

- Display a report which clearly identifies the entry details relating to previous authorised persons (i.e. name, period of appointment as the “authorised person”).

Scenario 3

- Demonstrate making an entry in the Register (by the authorised person) of the issuing of an access code to a user (e.g. an employee pharmacist).

Scenario 4

- Display a record of the access codes issued by the authorised person and the users to whom they were issued. This scenario must demonstrate that ONLY the authorised person can access this record (and produce it on demand by an authorised officer).

Scenario 5

- Demonstrate that only a person using an access code issued by the authorised person may make an entry in the register, by the use of an access code in combination with a password known only by the person (user) to whom the access code is issued.

Scenario 6

- Demonstrate that the access code must be recorded whenever a user makes an entry. (This could be in combination with Scenarios related to “Register entries”, see below.)

Scenario 7

- Demonstrate that the record of the access codes cannot be changed.

Scenario 8

- Demonstrate that the Register program will have an automatic log-off feature, after a reasonable idle period and that an immediate log-off can be forced by a user.

Scenario 9

- Demonstrate that alteration, obliteration or deletion of entries in the Register is prohibited and therefore cannot be performed.

Scenario 10

- Demonstrate that the Register issues a new sequential serial number, time and date for each entry (supply, receipt, adjustment, credit, transfer in/out, formulation, damage, loss, destruction, error/reversal, stock check/audit). This could be in combination with Scenarios related to “Register entries”, see below.

Scenario 11

- Demonstrate that each entry must record the stock balance following the movement which the entry records.

Scenario 12

- Demonstrate the provision for the recording of details of destruction/seizure of stock, including the issuing of access codes to authorised Ministry of Health Officers/Inspectors in the relevant entry.

Scenario 13

- Demonstrate how data in the Register is backed-up.

Scenario 14

- Demonstrate the ‘auto-save’ function of the Register data.

Register entries for pharmacies

Scenario 15

- Demonstrate the dispensing of an S8 drug to a patient, clearly identifying the patient’s name and address, the prescriber and dispensing pharmacist and how making this entry also makes a parallel entry in the Register in systems that are ‘linked’ to each other.

Scenario 16

- Demonstrate the receipt of an S8 drug from a supplier, clearly identifying the name and address of the supplier and the receiving pharmacist

Scenario 17

- Demonstrate how an adjustment made to the Register for the loss of a drug due to damage (e.g. breakage), including how the user makes a ‘comment’ to explain the adjustment.

Scenario 18

- Demonstrate how an adjustment made to the Register for the loss of a drug due to an unexplained loss (e.g. suspected theft), including how the user makes a ‘comment’ to explain the adjustment.

Scenario 19

- Demonstrate how an adjustment or reversal is made because of a dispensing error, (e.g. the wrong drug and/or the wrong quantity was selected during dispensing) and how making this entry also makes a parallel entry in the controlled drug register in systems that are ‘linked’ to each other, including how the user makes a ‘comment’ to explain the adjustment in the Register.

Scenario 20

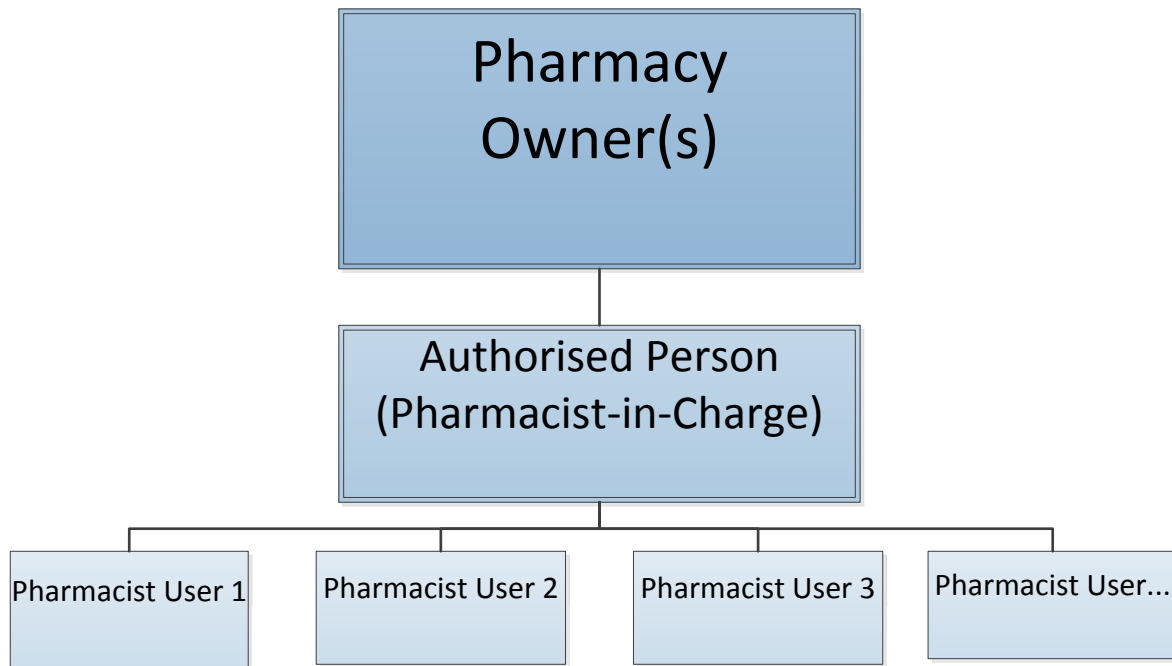
- Demonstrate that an audit/stock check has been made and that the quantity found is in agreement with the Register. (Otherwise one of the previous scenarios will apply to make an “adjustment”.)

Reports

Scenarios 21 – 61

- Demonstrate the ability of the Register to produce the following reports
 1. ‘on-screen’
 2. in printed form
 3. saved as an electronic file
 4. able to be exported by email or other means, e.g. USB device:
 - i. List all entries for the period (date to date) by drug
 - ii. List all entries by date
 - iii. List all current stock and balances
 - iv. List all drugs previously recorded in register but not currently held
 - v. List all corrections (adjustment, credit, transfer in/out, damage, loss, destruction, error/reversal) for the period (date to date)
 - vi. List all entries by customer for the period (date to date)
 - vii. List all entries by supplier for the period (date to date)
 - viii. List all entries by prescriber for the period (date to date)
 - ix. List all entries by user access code for the period (date to date)
 - x. List all entries/movements for the period (date to date) in an approved format suitable for submission to the Ministry of Health in accordance with current reporting requirements, including by electronic means in a format specified by the Ministry of Health, e.g. comma delimited, including the fields:
 - Unique transaction number.
 - Name, dosage form, strength of an S8 drug.
 - Date of transaction.
 - The type and nature of the entry or transaction (supply, receipt, adjustment, credit, transfer in/out, formulation, damage, loss, destruction, error/reversal, stock check/audit).
 - Name and address of person to whom supplied or of the company from whom obtained.
 - The prescription number (in the case of supply on prescription).
 - The prescriber’s name (in the case of supply on prescription).
 - Stock quantity supplied (going out) or received (coming in).
 - Remaining balance of stock after addition or subtraction of quantity supplied or received.
 - Name of person making the entry in the Register (using an access code).

Appendix C - Diagram illustrating the relationship between the pharmacy owner(s), the nominated authorised person and users of the electronic drug register



Appendix D – Definitions of transactions in an electronic drug register

Supply – The supply of a schedule 8 drug on prescription (by a pharmacy), resulting in a stock movement outward.

Receipt – The receipt of a schedule 8 drug by a pharmacy, resulting in a stock movement inward.

Adjustment – An entry made in the Register to explain a balance which is not in agreement with the Register balance, in order to bring the Register balance into agreement with the physical stock count, for example when stock is removed for destruction.

Credit – The return of stock to a supplier.

Transfer In/Out – Stock which has been moved, for example from one pharmacy to another without being purchased or dispensed.

Formulation – Stock used for the preparation of a compounded medicine.

Damage – Any loss of stock that renders the product unusable.

Loss – Loss of stock, for example due to theft.

Destruction – Stock that has been disposed of in the presence of an authorised Ministry of Health Officer/Inspector, a Police officer or other person authorised for this purpose under the Poisons and Therapeutic Goods Act 1966.

Error or reversal – An entry made to account for a supply or receipt that has been mistakenly made, for example where a Register entry made was for the wrong drug, form, strength or quantity or as a “supply” instead of a “receipt”.

Stock check or audit – Confirmation of a Register balance as part of an audit by an authorised Ministry of Health Officer/Inspector a Police officer or other person authorised for this purpose under the Poisons and Therapeutic Goods Act 1966, or as a result of a prescribed periodical inventory of stock of Schedule 8 drugs by a pharmacist.