FRAMEWORK FOR USE OF AN ELECTRONIC DRUG REGISTER REQUIRING SINGLE SIGNATURE BY A LICENSED WHOLESALER

Introduction and scope

This document describes the framework for the use of electronic drug registers to record the movement of Schedule 8 medicines held by a wholesaler licensed to supply Schedule 8 medicines. It also contains the *Standards for Use of an Electronic Drug Register Requiring Single Signatures by a Licensed Wholesaler* (the Standards). For an electronic drug register to be valid to record the movement of Schedule 8 medicines held by a licensed wholesaler in NSW, the Standards must be complied with.

An electronic drug register that requires a single signature may be used to record transactions for Schedule 8 medicines (also known as drugs of addiction or controlled drugs) in various settings, including by a pharmaceutical wholesaler licensed to supply Schedule 8 medicines by wholesale (licensed wholesaler).

The electronic drug register use must be compliant with the *Standards for Use of an Electronic Drug Register Requiring Single Signature by a Licensed Wholesaler* described in this document.

Background

Persons authorised to be in possession of Schedule 8 medicines (such as medical practitioners, pharmacists, dental practitioners, veterinary practitioners and authorised persons at a licensed wholesaler business) must:

a) keep a drug register in the form of a book to record transactions of Schedule 8 medicines (unless another form has been approved)

b) enter the details relevant to each transaction in the drug register on the day of the transaction

for the purpose of confirming the balance on hand and confirming the associated transaction.

Transactions in a register include receipt, supply, administration, compounding/manufacture, credit, adjustment transfer in/out, error/reversal, stock check/audit, periodic audit, damage, loss, and destruction of Schedule 8 medicines.

Approval of electronic form of drug register

An Authorisation under the *Poisons and Therapeutic Goods Regulation 2008* (the Regulation) has been issued to approve the keeping of a drug register other than in the form of a book, where the use of the electronic drug register complies with the *Standards for Use of an Electronic Drug Register Requiring Single Signature by a Licensed Wholesaler* as described in this document.

The Authorisation also allows electronic confirmation of entries by the authorised person, instead of by a handwritten signature.

Definitions

'**authorised person**' means a person who is authorised to possess, supply or administer Schedule 8 medicines under the Regulation and who is required to make entries in a drug register. Only an authorised person can make a finalised entry in the electronic drug register. In any legal proceedings, in the absence of proof to the contrary, the authorised person to whom the unique access credential has been assigned is taken to have made the entry.

At the premises of a licensed wholesaler, the licensee is the 'authorised person' and is the person responsible for the keeping and reliable operation of the electronic register. The authorised person may delegate the responsibility to another person (user) within the organisation. The authorised person must keep a record of access codes issued and the users to whom they were issued. 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.

'**pending entry**' means an entry that is not required to be retained in the register. This entry may be created by a person who has authorised access to the electronic register or an entry captured from another system by way of a manual or automated procedure. The pending entry can be made into a finalised entry by an authorised person.

'**finalised entry**' means an entry that has been completed (or finalised) by an authorised person or an inspector, including following the review of a pending entry relevant to the transaction.

'inspector' means a person appointed under section 42 of the *Poisons and Therapeutic Goods Act 1966* (the Act) who can view, retrieve, print, copy, or make entries in an electronic drug register.

'**login**' of an individual means a password or other secret word, a device, a biometric identifier, a combination of these, or any other method of authenticating the identity of the individual at the point of access to an electronic drug register.

'**person responsible for the electronic drug register used at the premises**' means the person responsible for the day-to-day management and operation of the system in the facility. At the premises of a licensed wholesaler, the 'authorised person' is the licensee, a person currently responsible for the keeping and reliable operation of the electronic register. The authorised person may delegate the responsibility to another person (user) within the organisation.

'Schedule 8 medicine' means a medicine listed in Schedule 8 of the Poisons Standard, referred to as a 'drug of addiction' in the Act, and otherwise known as a 'Controlled Drug'.

'**standard user**' means a person who has been granted access to the electronic drug register for the purpose of making a pending entry. A standard user cannot make a finalised entry.

'**system authorising officer**' means the person who authorises the operation of the system within a licensed wholesaler business. The person whose designation permits the authorisation of the operation of an electronic drug register at that business should have an appropriate level of seniority and understanding of the system, including security risks they are accepting on behalf of their facility.

'**the Regulation**' means the NSW *Poisons and Therapeutic Goods Regulation 2008*.

'**the Act**', means the NSW *Poisons and Therapeutic Goods Act 1966*

'**user**' means a person who has been granted access to the electronic drug register.

Standards for Use of an Electronic Drug Register Requiring Single Signature by a Licensed Wholesaler

These Standards ensure secure and appropriate use of an electronic drug register. The Standards describe the requirements:

1. For the electronic drug register system (Section 1)
2. For the system authorising officer (Section 2)
3. For the person responsible for the electronic drug register used at the premises (Section 3)
4. For an authorised person (Section 4)
5. For each user of the electronic drug register (Section 5)

Section 1: Electronic drug register functionality, security and audit

An electronic drug register may be implemented as a standalone solution or a segment of an enterprise solution.

Standard

1.1 The system must authenticate users before they are granted access to the system.

1.2 The system must implement a strong user authentication mechanism which comply with contemporary industry and government standards. The Australian Signals Directorate's *Australian Government Information Security Manual* (ISM) and Australian Government's *Protective Security Policy Framework* (PSPF) provide guidance. Multi-factor authentication is preferable to single-factor authentication.

1.3 The system must uniquely identify users and authenticate users on each occasion that access is granted to the system.

1.4 Access to information in the system must be via a set of role-based access controls with least access privileges (i.e. read, write, modify).

Standard role-based profiles must be implemented based on responsibilities of user types/roles.

1.5 User's access rights and privileges granted must be securely administered.

1.6 Audit logs must be retained for a minimum of two (2) years.

1.7 Audit logs should include information about access to, use of, and date and time of use of the system by users, log on attempts (successful or unsuccessful), successful/failed use of any privileged accounts, account changes, and changes (actual or attempted) to system security settings and controls.

1.8 Password setup, maintenance and storage, where applicable, must accord with industry and government standards. The Australian Signals Directorate's *Australian Government Information Security Manual* (ISM) and Australian Government's *Protective Security Policy Framework* (PSPF) provide guidance.

1.9 Where the system allows a user to change their own password, any change must be based on proper authentication of the user and must prevent any disclosure of the password during the operation.

1.10 The log on procedure must be designed, implemented and configured to prevent unauthorised access and to disclose the minimum of information about the system before the user logs in.

1.11 The system must allow a user to log out on demand.

1.12 The system must terminate a session when the user logs out of the system.

1.13 The system must ensure accounts are locked after a maximum of 5 failed log on attempts.

1.14 The system must require a user to re-authenticate after a maximum of 15 minutes of user inactivity.

1.15 The system must prevent a unique access credential being retained after log out.

1.16 The system must record a user's unique identifier against every entry added or modified by the user.

1.17 The system must allow users to make finalised entries for transactions that are required to be recorded in a register.

1.18 The system must allow a finalised entry to record the particulars required under subclause 112(1) of the Regulation relevant to the transaction (e.g. quantity manufactured, received or supplied, date and time of day, the name

and address of the person or company to, from, or by whom the medicine was manufactured, received or supplied, quantity held after the transaction).

1.19 The system must display the stock balance (i.e. balance at hand) following a transaction in the system.

1.20 Where a transaction is an adjustment to the stock balance (i.e. balance at hand), the system must allow for a reason to be recorded against the transaction.

1.21 The system must allow the witness to the destruction of Schedule 8 medicines at a licensed wholesaler to record the witnessing of the destruction in the relevant entry in the drug register.

1.22 The system must assign a unique reference number for each finalised entry with the time and date of the transaction.

1.23 The system must prevent a finalised entry from being altered or deleted under any circumstances.

1.24 The system may allow data elements relevant to a transaction to be transmitted from another computer system, such as a segment of an enterprise solution, including invoicing or warehousing systems. These pending entries may be made into a finalised entry by an authorised person.

1.25 The system must retain, and make available, finalised entries for a period of two (2) years.

1.26 The system must allow a user to immediately produce the following reports in electronic form and in printed form at the premises where the system is used:

a) All current stock balances

b) All finalised entries for a stated period (date to date) for a stated Schedule 8 medicine

c) All finalised entries on a stated date

d) All finalised entries to a stated person or company for a stated period (date to date)

e) All finalised entries from a stated supplier for a stated period (date to date)

f) All finalised entries by a stated authorised person.

(Note on compliance: It should be possible to export all types of records contained in the system, regardless of format or the presence of the generating application, to safeguard against the loss of data if the application is discontinued, no longer supported or suffers catastrophic failure).

1.27 The system must retain the name of the person responsible for the electronic drug register.

1.28 The system must retain the name of any previous person responsible for the electronic drug register for a period of two (2) years commencing on the date they cease to be responsible, or where the system is used in a public institution, for a period of seven (7) years.

1.29 System components (hardware, software, networks, cloud services) and any interfaces must have security measures that safeguard records.

1.30 System back-up and restore arrangements must accord with industry and government standards. The Australian Signals Directorate's *Australian Government Information Security Manual* (ISM) and Australian Government's *Protective Security Policy Framework* (PSPF) provide guidance.

Section 2: Requirements for the system authorising officer

Standard

2.1 The person must approve use of the electronic drug register at the premises.

2.2 The person must be satisfied that the electronic drug register meets the standards set out in this framework document.

2.3 The person must implement a protocol that ensures that:

a) access authorisations needed by users are adequately approved

b) users are issued with a login that identifies them to the system and is attached to the unique identity of the user

c) a record is kept of all user types/roles and their responsibilities

d) persons responsible for the register used at the premises and persons who must make entries in the register can meet the legal requirements set out in the Regulation or a licence issued under the Regulation

e) persons responsible for the register and authorised persons are informed that the electronic drug register used at the premises meets the standards

f) access control procedures are monitored and enforced

g) repeated lockouts by users are investigated before reauthorising access

h) user's rights and privileges are removed on the same day as a user no longer has authorised access or has a legitimate business need to access the system

i) system entries are available immediately both in electronic form and in printed form to an inspector appointed under section 42 of the Act.

j) an inspector appointed under section 42 of the Act has immediate access to the system to make finalised entries

k) written notice is given to the Secretary, NSW Health in accordance with the Regulation if any records in the system, or the system itself is lost or destroyed [clause 119]

l) during any system downtime, drug register entries are made in a book compliant with the Regulation [clause 111], such that:

   i. the book contains consecutively numbered pages

   ii. the book is bound so that the pages cannot be removed or replaced without trace

   iii. the book contains provision on each page for the inclusion of the particulars required to be entered

   iv. separate pages of the book must be used for each Schedule 8 medicine, and for each form and strength of the medicine

   v. the book must be retained for a period of two (2) years commencing on the date of the latest entry.

m) when any downtime has ceased, if the details in the book are not entered in the electronic register, the stock balance (i.e. balance on hand) for each medicine must be entered in the electronic register and the fact that a book was used recorded in the system.

Section 3: Requirements for the person responsible for the electronic drug register used at the premises

Standard

3.1 The person must ensure the system is available to persons who require access to make entries.

Section 4: Requirements for the authorised person using the electronic drug register

Standard

4.1. The authorised person must keep secure the assigned unique access credential used to make a pending entry and a finalised entry.

Section 5: Requirements for each user of the electronic drug register

Standard

5.1. The user must use their login to perform all actions in the system.

5.2. A user must not use another user's login to access the system.

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