

# Electronic Storage and Supply of Medicines

## Background

Historically, the Poisons Act has expressly prohibited the use of an automated machine to supply a medicine or poison.

Over the last decade new technologies have emerged, particularly in health care settings, that provide suitable accountability to make supply from an automated device permissible. These technologies are used in a number of countries and there is sizeable published literature demonstrating how they can support healthcare workers. Automated supply machines can reduce medicines selection errors, increase healthcare efficiency and improve accountability over medicines by health practitioners.

For this reason the Medicines and Poisons Regulations 2014 allow the use of these machines when approved by the Department of Health.

In the legislation, the machines are termed an Electronic Storage and Supply Unit (ESSU). They are defined as any device that may be used for the storage of a Scheduled medicine. Permissible devices are those that still require the personal manipulation or attention of a person at the time of supply.

An ESSU would include a robotic device in a pharmacy or hospital pharmacy, an Automated Medicines Unit (AMU, ADM) on a hospital ward (such as a Pyxis® or Omnicell® brands), anaesthesia workstations or any other similar product.

## Using an Electronic Storage and Supply Units

An ESSU may only be installed on premises and used to store and supply Scheduled medicines if first approved by the Department of Health. The process to have a device considered for approval is outlined below.

Only persons ordinarily authorised to handle a medicine, such as a nurse, doctor or pharmacist, may access medicines from an ESSU.

Each ESSU will require a unique access code to be entered allow a person to access the machine and withdraw medicines. This access code can be in the form of password, biometric identifier (such as a fingerprint) or other person al identifier. An access code must not be shared or revealed to another person.

Access to the machine must be by use of this access code and through normal access procedures built into the machine. Bypassing codes, tampering with the machine or using any other access method is an offence against the legislation. Providing another person with access to the machine is not permitted. There are significant penalties for any breach of Regulations.

Each time the device is accessed it must make a record and uniquely identify the person withdrawing a medicine. This recorded identifier will be used as evidence that a person accessed a medicine in any legal proceedings.

## Applying for approval

A request to the Department to approve installation of an ESSU must be made in writing. Applicants must address all relevant criteria outlined below. In most cases approval will not be issued without physical inspection of the premises and a detailed review of the device(s) to be installed.

Any approval is specific to the medicines to be stored in the device, the individual device (brand, type and configuration), its location on the premises and the premises themselves. Any approval issued will be specific for the unit, procedures and systems as requested in the application.

The Department will not approve any unit unless sufficiently satisfied that the device and its installation on the premises are sufficiently secure.

Conditions may be place on an approval. Any conditions specified in the approval must be complied with during use of the device.

## Approval criteria

The criteria below are those that are expected to be addressed as a minimum, but should not be considered an exhaustive list of all possible considerations.

The written application should address each criteria in adequate detail. All questions should be addressed unless an item is not relevant. For example if a fingerprint is used as an access code this will not be changed at regular intervals and therefore this question is not relevant.

Based on the application, other information may be considered relevant and may be requested prior to making a decision.

If only Schedule 2, 3 or 4 medicines are to be stored and supplied then then the General Criteria should be answered. Approval will be issued for use of the ESSU to store and supply medicines in these Schedules ONLY.

If Schedule 8 medicines are to be stored then the General Criteria AND the Schedule 8 Criteria must be answered.

As the device and individual security arrangements may vary greatly for each installed device, the criteria must be individually answered for EACH device or unit to be installed. Where an answer is the same for each unit, such as how access codes are issued, this should be indicated in the application.

Any approval is based on the application provided. Any procedure, system or practice must be applied in the exact manner as outlined in the application. Any modification of storage or security arrangements requires prior approval of the Department. If approved under General Criteria, Schedule 8 medicines may not be stored at a later time unless, a new application for Schedule 8 medicines is made and approval given.

Any ESSU approved will be audited at intervals to ensure supply and storage of medicines remains in compliance with regulatory requirements.

### Acceptable Uses

Approval will be considered for the supply of Schedule 2, 3, 4 and 8 poisons only.

The unit may not allow direct to consumer/patient supply. There must be physical intervention by an authorised health practitioner during supply.

An authorised health practitioner is who is a class of person authorised to obtain, possess, use, administer or supply a poison under Poisons Legislation.

## General criteria for approval of an Electronic Storage and Supply Unit

### Organisation Details

* Name of applicant
* Position or authority of applicant
* Name of organisation
* Contact details
* Details of authorisation to obtain and possess medicines – i.e. health practitioner registration type and number OR poisons licence / permit number

### Description

* What brand and specific model of device(s) is/are to be used?
* If the unit is not a standard model, what is the exact storage and supply configuration?
* Please include the manufacturer’s brochure or equivalent with specifications/features of the device

### Governance

* Who in the organisation has overall responsibility for the devices?
* Who is nominated as responsible for each unit?
* Who is the IT system administrator?

### Premises

* If not a hospital, what are the general after-hours security arrangements for the premises?
* Where exactly is the device located on the premises?
* What is the work function or nature of this location? Theatre, General ward, Clinic, etc.
* Is the area accessed or accessible by the general public? What is the nature of this access?
* Is the unit itself potentially accessible by the general public?
* What proportion of each day (Monday to Sunday) is the device in use and observed?
* What arrangements are in place for general security of the area outside these hours?

### Security

* What is the weight of unit?
* Is the unit mobile?
* Is the unit permanently fixed? How is it fixed and to what is it fixed?
* If not, is the unit chained, tethered or otherwise secured? How is it secured and to what is it secured?
* Is the unit video monitored?
* Is the area video monitored?
* Is the unit alarmed for movement, tampering or other?
* Is the area alarmed for movement, break-in or other?
* Are these alarms back to base monitored?
* Who are they monitored by?
* What is the response procedure for an alarm?
* What are the area lighting arrangements?
* Is there direct line of the unit by staff when not in direct use?
* Is the unit further protected by the location, for example stored in a dedicated room?
* Is the room locked? How is the room accessed?

### Authorised Persons

* What persons / class of persons will be authorised to access the unit?
* Will different persons / class of persons have different levels of access depending on their role?
* How does the unit alert to attempts at access by unauthorised persons?

### Access Codes

* What type of access code is used?
* Is there an organisational policy on access codes and their security?
* How are access codes issued?
* Who is responsible for issuing the codes?
* Is each access code individual for the person?
* How are access codes removed (e.g. for staff termination, resignation)?
* How sophisticated is the access code? Numbers, Letters, Case Sensitive?
* How often must the access code be altered?
* Can an access code be reused?
* What unique system identifier is connected to each person’s access code?
* How are records made and maintained for each system identifier and access code issued?

### Usual Access Procedure

* What is the procedure for withdrawing medicines from the unit?
* Can all items be accessed or only the item requested?
* How are medicines returned to the unit?
* What is the lockout period?
* Can the unit be left open?

### Alternative Access Procedure

* Is there an access override feature?
* What is the nature of this override facility?
* If keys (or other devices) are used, who has access to these and how are they kept secure?
* Is each key/device specific to an individual unit?
* How is issue of keys/devices tracked and whereabouts accounted for?

### Downtime Procedures

* What is the nature of the power supply to the unit?
* What is the downtime procedure?
* How is public access prevented during downtime?
* What security or other features are in place to prevent unauthorised access by staff during downtime?
* If authorised access is possible during downtime, how are records of authorised access and supply maintained during downtime?

### Restocking

* How is the unit replenished?
* Who has access to the unit for replenishment of medicines?
* Is there only access to the selected medicine to replenish one draw at a time?
* Is an inventory record created when medicines are restocked?

### Supply Records

* What information/data fields are recorded for each supply?
* Do these records include: Date, Time, Medicine, Quantity, Authorised Person?
* How is a person’s system identifier attached to each record of supply?
* Can a record be altered or modified?
* Can a record be deleted or overwritten?
* In what form is the record kept and how does this compare to industry standards?
* How long is the record kept?
* What backup arrangements are in place?
* Can the unit provide hard copies of every record made?
* Provide a sample record.

### Refrigerated medicines

* Is a refrigerator module part of the unit?
* What is the locking mechanism for the refrigerator?
* How is the refrigerator accessed?

## Schedule 8 Criteria

### Schedule 8 medicines

* Will Schedule 8 medicines be stored in the machine?
* What is the expected quantity (number of individual doses) to be stored at any one time?

### Schedule 8 Security

* What materials are used in the unit outer construction?
* What materials are used in construction of individual storage compartments?
* How is the device designed to withstand attempts at physical attack or unauthorised access?

### Schedule 8 Access

* In what way are any procedures for Schedule 8 medicines outlined above different to standard procedures for other medicines?
* How is Schedule 8 access restricted to only those staff authorised to obtain and possess these medicines?
* Is each Schedule 8 item stored in an individual tray?
* Are the individual compartments containing Schedule 8 medicines locked?
* What compartment locking mechanism is used?
* How are the locking mechanisms designed to withstand physical attack?
* Can a Schedule 8 tray be accessed while withdrawing another item?
* Are two authorised persons required to input access codes to withdraw a Schedule 8 medicine?
* Can more than one person access the machine at once during alternative access or downtime use?

### Schedule 8 Register

* Does the unit keep an integrated Schedule 8 Register?
* Who is the authorised person responsible for the unit Register?
* What information/data fields are recorded for each supply?
* Do the records include: Date, Time, Patient Name, Prescriber Name, Medicine, Quantity, Authorised Person Name, Inventory Balance?
* How is a person’s system identifier attached to each transaction record?
* Can a record be altered or modified?
* Can a record be deleted or overwritten?
* In what form is the record kept and how does this compare to industry standards?
* How long is the record kept?
* What backup arrangements are in place?
* Can the unit provide hard copies of every record made?
* Can a sample record be provided?
* Can a record of inspection be made by a departmental investigator?

### Schedule 8 Inventory

* What is the procedure to conduct an inventory?
* How often is an inventory conducted?
* How does the device enforce the inventory at required intervals?
* Are two authorised persons required to take or confirm an inventory?
* How is a record of the inventory recorded by the unit?
* What is the procedure to report Schedule 8 discrepancies?
* How does the Register allow for correction / inventory adjustment of a physical discrepancy?

### Schedule 8 Destruction

* Does the unit allow for recording of an item that is to be destroyed?
* Is the transaction individually labelled?
* Is there a field for reason for destruction?
* Who is authorised by the unit to destroy a Schedule 8?
* Are two authorised persons required to destroy a Schedule 8?

## Other Considerations

There are many other considerations for an organisation planning to install ESSU. The following are not mandatory issues to address in an application to the Department however it is strongly recommended that these are addressed by organisational policies and procedures prior to installation and use of an ESSU.

* Staff training
* Unit dose medicine repackaging practices
* Use of added patient safety features such as bar coding
* Management of general inventory discrepancies
* Returned medicines and waste
* Cleaning, maintenance and repairs – especially with respect to medicines in situ
* Patency, stability and integrity of stored medicines – especially with respect to fridges
* Redundancy – e.g. alternative supply sources should a machine malfunction
* Policy on storage of hazardous medicines (e.g. chemotherapy) – including cleaning
* Organisational policies on medicines staff use and responsibilities - see Institute for Safe Medicines Practice Guidelines at: <http://www.ismp.org/tools/guidelines/ADC_Guidelines_final.pdf>
* Safety Self-Assessment - see Institute for Safe Medicines Practice Survey at: <https://www.ismp.org/selfassessments/ADC/Survey.pdf>