



Australian Government

Department of Health

Life Saving Drugs Program – Drug Supply Fact Sheet

You have been nominated as the ‘Authorised Person’ to dispense drug stock to an eligible patient who receives subsidised treatment through the Life Saving Drugs Program (LSDP).

Through the LSDP, the Australian Government provides subsidised access for eligible patients to expensive and life saving drugs, and currently funds fourteen medicines for nine rare conditions.

Further information is available at www.health.gov.au/lscp

Key Messages:

1. LSDP stock is ordered and owned by the Commonwealth.
2. Once delivered, the LSDP stock is not to be transferred to any other location without written permission from the Department.
3. If stock is compromised, quarantine the LSDP stock and liaise directly with the supplier to ascertain whether the affected stock is still usable.
4. Arrangements for compromised stock to be replaced must be made and paid for locally.
5. Stock reallocation is only to be arranged by the Department.
6. Notify the Department if the patient:
 - is enrolled in a clinical trial;
 - requests a change of dispensing location;
 - ceases treatment; or
 - is non-compliant to treatment.
7. Notify the Department if there are changes to the contact details of the Authorised Person(s) or the treating physician.
8. The Department can be contacted by phone on (02) 6289 2336 or by email at lscp@health.gov.au (please quote the patient ID).

The following page lists some frequently asked questions (FAQs) to assist you as the Authorised Person to manage and dispense expensive and life saving drugs supplied to eligible patients through the LSDP.

FAQs

1. How is LSDP stock ordered?

For each eligible patient, LSDP stock is ordered directly from the supplier by the Department and delivered to the nominated delivery location.

Rationale: The LSDP stock is extremely expensive and is ordered and paid for by the Commonwealth. Ownership of this stock remains with the Commonwealth.

2. Why is each eligible patient allocated a unique identifier which is quoted on the stock at the time of delivery?

The Department does not provide the patient's name to the suppliers to protect a patient's privacy.

Individuals are referred to using their initials and a unique identifier (e.g. X01) which is internally generated by the Department. Please keep a record of this number and quote it when you communicate with the Department about the patient.

3. Why does the LSDP require a dispensing record?

The Department will order LSDP stock for eligible patients based on the information provided on the dispensing record. If a dispensing record is not provided when requested, the Department will not be able to place an order for that particular patient.

Rationale: Pharmacists are asked to maintain a dispensing record for each patient. The Department will provide a template for this dispensing record. The Department will audit these details approximately every three months to review patient compliance and determine future order/supply requirements. The Department will notify you of an upcoming audit by email prior to the audit date and request a copy of the dispensing records.

4. What should I do in cases of vial damage, wastage or contamination?

Quarantine the stock and contact the supplier directly as soon as possible if there is any vial damage, wastage or contamination (e.g. through spillage, power outages, improper preparation of infusions). If it is determined that the stock is unusable you will have to order the stock directly from the supplier, and your organisation will have to bear the cost.

5. What do I do with expired stock?

Do not use stock after the expiry date on the product. Quarantine the stock and contact the supplier directly to ascertain whether the expired stock is still suitable for use. The Department will not replace any expired stock as it is important for the pharmacists to notify the Department at least one month prior to the stock expiry to avoid wastage, so that the stock can be transferred to a location where it can be used prior to expiry.

Rationale: It is the pharmacists' responsibility to rotate the stock and ensure the stock with shorter expiry date is used before stock with longer expiry date, and to notify the Department at least one month prior to the expiry date.

6. Can I or the supplier reallocate the LSDP stock to another patient/hospital if they require a dose?

No.

Rationale: Supplies must remain allocated to the patient for whom it was ordered. Adequate stock rotation procedures should be in place to ensure stock is used prior to its expiry date. Additionally, the Commonwealth owned stock should not be relocated/transferred without written permission from the

Department.

7. *Do I need to order LSDP stock on behalf of patients?*

Not unless the stock supplied by the Commonwealth is compromised as a result of temperature excursion, vial damage, wastage, contamination, or expiry of stock and cannot be used or if stock levels are low due to variations from subsidised doses.

Rationale: Stock orders placed by the Department are based on the normal use of subsidised doses. Your assistance with monitoring stock levels is greatly appreciated. Stock that sustains damage and cannot be used for patient treatment will not be replaced by the Commonwealth. Any variation from the subsidised doses may lead to low stock levels. The Commonwealth will not provide additional stock due to variations from subsidised doses. Your organisation will have to source replacement stock and bear the cost.

8. *If I order the LSDP stock from the suppliers, will the stock be reimbursed by the Department?*

No.

Rationale: The Department will not provide reimbursement to pharmacies who order stock directly from suppliers. If you order the stock directly from the suppliers, your organisation will have to bear the cost.

9. *Who nominates the 'Authorised Person'?*

Through the initial LSDP application process, the treating physician nominates a primary and secondary contact to receive and dispense LSDP stock from the location from which the patient is to receive treatment. The names of these people are entered into the Department's records as Authorised Person(s).

10. *What do I do as the Authorised Person when LSDP stock is delivered?*

You need to be available to confirm that the stock has been received in good condition and to ensure that the stock is handled in accordance with the Therapeutic Goods Administration (TGA) approved Product Information (see FAQ 13).

At the time of stock delivery, we request that you completely unpack the delivery to ensure that vials are not broken.

Once you have checked the amount and type of stock, as well as the expiry date against the Proof of Delivery (POD) document provided, the POD document needs to be signed and fax/returned as requested. By signing the POD document that accompanies the order, you confirm that the stock was received in good condition.

Should the stock supplied not comply with the stock ordered, please contact the Department on (02) 6289 2336 within 24 hours of receipt.

11. *Why do I need to notify the Department when there is a change to an 'Authorised Person'?*

Helping the Department maintain the most up to date contact information ensures the most efficient service delivery.

Please notify the Department immediately about any relevant personnel or staffing changes.

12. *How long should I keep the packing slips/Proof of Deliveries/dispensing records?*

As a general guidance, you are not required to keep the packing slips/Proof of Deliveries once these have been returned/faxed as requested.

However, you are required to keep a dispensing record for at least 12 months.

13. How should LSDP stock be stored and handled?

All LSDP stock should be stored and handled in accordance with the storage requirements specified in the TGA approved Product Information. The Product Information is available from the TGA website: www.tga.gov.au

14. Will I be notified when stock comes in?

Yes. You will receive an email regarding the LSDP stock order for your patient/s approximately every three months.

Rationale: Following the approval of a new patient or once every three months, you will be advised of the drug, subsidised dose and number of vials to be supplied for each patient.

15. What should I do when a patient requests a change of dispensing location?

The treating physician must email to the Department to confirm details of the relocation.

Rationale: If a patient wishes to change treatment location, the Department must be contacted in the first instance to arrange approval of any changes to the dispensing and treatment location. The responsible pharmacist at the new dispensing location will need to confirm that they accept responsibility for future receipt and dispensing of a patient's LSDP stock.

16. Why do I need to notify the Department if a patient is enrolled in a clinical trial?

Patients participating in a clinical trial are not eligible for subsidised treatment through the LSDP. Arrangements will be made to relocate any unused stock and new orders will not be placed until clinical trial participation has ended and eligibility for LSDP subsidised treatment has been reapproved.

17. Why do I need to notify the Department in cases where a patient ceases treatment?

LSDP stock is very expensive and it remains the property of the Commonwealth. If the patient no longer requires the use of the LSDP stock, arrangements will be made to relocate any unused stock and new orders will not be placed.