Life Saving Drugs Program

Fact sheet for pharmacists

This document provides answers to some common questions about the roles and responsibilities of pharmacies and 'authorised persons' in the supply and storage of LSDP medicines.

What is the LSDP?

The Australian Government provides fully subsidised access for eligible patients with ultra rare life-threatening diseases to essential medicines through the LSDP.

A list of currently subsidised medicines for specific conditions can be found on the LSDP website.

The LSDP Expert Panel assesses applications to include new medicines on the LSDP. It provides advice to the Australian Government Chief Medical Officer (CMO), including on reviews of existing LSDP medicines. The CMO advises the Minister for Health and Aged Care (the Minister) on medicines suitable for listing.

The Department of Health and Aged Care (the department) orders medicines for delivery to a nominated pharmacy on behalf of patients. The sponsor delivers the medicines directly to pharmacies to store and dispense to LSDP patients for treatment in a hospital or at home (if appropriate).

What are the contact details for the LSDP in the department?

The LSDP can be contacted via:

Telephone: (02) 6289 2336Email: LSDP@health.gov.au

• Fax: (02) 6289 8537

Common questions

Authorised person

I have been nominated as an authorised person. What does this mean?

As an authorised person you are a representative for your pharmacy to receive LSDP medicines and be a contact for all matters relating to the supply of LSDP medicines to patients who attend your pharmacy. It is important that you familiarise yourself with the requirements in this document.

You will need to be available to sign for LSDP stock deliveries, including carefully checking stock to ensure it matches the proof of delivery docket (POD) and is not compromised.

You are also responsible for ensuring that the patient's dispensing record is provided to the LSDP by the 7th day of each month. The LSDP will send a reminder email on the 1st day of each month.

Who nominates the authorised person?

Through the initial LSDP application process, the treating physician nominates a pharmacy that has agreed to dispense the LSDP medicine to the patient.

The pharmacy nominates a primary contact and one or more secondary contacts as authorised persons to receive and dispense LSDP medicines from the location from which the patient is to receive treatment.

Pharmacies may make changes to the authorised persons list at any time by emailing the LSDP (lsdp@health.gov.au).

What do I do if I do not wish to be an authorised person or a supplying pharmacy?

If you do not wish to be an authorised person, you will need to inform the pharmacist in charge so they can make alternative arrangements.

If your pharmacy does not wish to participate in the supply of LSDP medicines, the pharmacy needs to inform the treating physician so they can make alternative arrangements.

The treating physician will inform the LSDP of the new arrangements.

What must the authorised person do when LSDP medicine is delivered?

An authorised person from the list provided to the LSDP must be available at the time of delivery to confirm the following:

- the amount and type of LSDP medicine against the POD docket for each patient
- where applicable, the stock has arrived via appropriate cold chain logistics
- at the time of delivery, the stock is 'intact' (not broken or otherwise compromised)
- the batch number and expiry date against the POD docket included in the delivery.

Please contact the LSDP within 24 hours of receipt and call the number provided on the POD docket to notify the sponsor if stock received:

- does not match what is listed on the POD docket and/or
- you believe that the LSDP stock that you have received has been compromised.

Do not sign the POD docket unless the delivery is correct.

The authorised person signs the POD docket and faxes or emails a copy to the sponsor. This confirms delivery of the LSDP medicine.

Ensure that the LSDP medicine is handled and stored in accordance with the Therapeutic Goods Administration (TGA) approved Product Information (PI). Current PI documents can be downloaded for each LSDP medicine by searching the TGA website.

How long should I keep the packing slips, proof of delivery and dispensing records?

You are not required to keep the packing slips/PODs once these have been emailed or faxed to the sponsor. However, you are required to keep a dispensing record for at least 12 months (and in line with any other applicable state/territory requirements).

Ordering and dispensing

How is the LSDP medicine ordered?

The LSDP orders the LSDP medicines monthly for each eligible patient direct from the sponsor.

Quantities for ordering are based on the patient's dispensing record which must be provided to the LSDP every month. The LSDP medicine for a month is delivered prior to the end of the preceding month.

Can a patient collect more than one month's supply of LSDP medicine at a time?

No. Due to the high cost of LSDP medicines, the LSDP only orders and provides one month's supply of medicine for each patient at a time.

Why does the LSDP require a dispensing record of LSDP medicines?

Pharmacies are required to maintain a dispensing record for each patient. The LSDP orders LSDP medicine for eligible patients based on the information provided on the dispensing record. It is essential that dispensing records are accurate and received every month to ensure that the correct stock is ordered for the patient. The LSDP will provide the template for the dispensing record to pharmacies. Please contact the LSDP if you do not have a copy of this template.

If there is a change to the patient's medicine after the dispensing record is submitted, please contact the LSDP on as soon as possible. This includes changes such as where an additional order or change to an existing order may be required or where a patient no longer requires their next order(s).

Can the authorised person or the sponsor reallocate the LSDP medicine to another patient or hospital for any reason?

No. Reallocation of LSDP medicine can only be arranged by the LSDP. This includes the reallocation or transfer of stock between pharmacies for the same patient.

If you have 'left over' stock due to patients no longer needing LSDP medicines, please notify the LSDP as soon as possible so that the stock can be reallocated for use prior to expiry.

Expired and damaged stock

What do I do with expired stock?

Do not use stock after the expiry date on the product. Quarantine the stock and contact the LSDP.

It is the pharmacy's responsibility to rotate the stock and ensure stock with shorter expiry dates is used before stock with longer expiry dates, and to notify the LSDP if stock is approaching expiry.

It is important that the LSDP is notified at least two months prior to the stock expiry so that the stock can be transferred to a location where it can be used prior to expiry to avoid wastage.

The department does not subsidise or pay for replacement of stock that has expired. If stock expires because it has not been rotated, the pharmacy will be responsible for the cost of replacement.

What should I do in cases of vial damage, contamination or loss of LSDP medicine?

Quarantine the stock and notify the LSDP immediately of any compromised LSDP medicine issues (e.g. vial damage or contamination of the product).

If the product is found to be faulty prior to the POD docket being signed by the authorised person, the sponsor must replace the stock at no cost to the Commonwealth or the pharmacy.

If the stock has been lost or compromised due to expiry, spillage, power outages, or improper preparation or administration of infusions, the pharmacy must order and pay for replacement stock through the sponsor. Please contact the LSDP for advice.

How do I order a LSDP medicine directly from the sponsor in the case of vial damage, contamination or expired LSDP medicine?

The LSDP team can provide you with the contact details of the sponsor. The sponsor will arrange an invoice for the pharmacy and delivery of replacement stock.

The department will not reimburse the cost of any stock ordered directly from sponsors.

How do I find out the cost of the LSDP medicine for insurance purposes?

Please email your request to the LSDP at LSDP@health.gov.au.

The LSDP will contact the sponsor to facilitate this request. Release of this information is at the sponsor's discretion and the sponsor may require the pharmacy to enter into a non-disclosure agreement.

Funding of medicines on the LSDP

Are co-payments charged for LSDP medicines?

No. LSDP medicines are not part of the PBS and therefore are not subject to a PBS patient copayment.

Who pays the dispensing/servicing cost of LSDP medicines in a public and private hospital and community pharmacy?

The LSDP provides fully subsidised access for eligible patients to expensive life-saving medicines for ultra-rare and life-threatening diseases. The department will not pay a dispensing/servicing cost to the hospital or community pharmacy.

Where a pharmacy (community or public/private hospital) agrees to participate in the provision of LSDP medicines to patients under the program, the pharmacy must not charge patients a copayment or similar fee for this service.

Can I charge a 'cooler' or consumables fee to the LSDP patient?

Pharmacies may charge a reasonable fee for the provision of a 'cooler' or similar transport and handling material as required, provided the patient is advised of the cost and agrees prior to the LSDP medicine being provided.

Supply and handling of LSDP medicines

What is the LSDP patient unique identifier?

The LSDP issues a unique identifier (e.g. X01) to each patient to protect the patient's privacy. Sponsors are advised of the patient's unique identifier rather than the patient's name.

Please keep a record of the unique identifier and quote it when you communicate with the LSDP about the patient.

Can someone other than the patient collect the LSDP medicine?

Yes. This could include patient caregivers, guardians or contract nurses (in the case of home infusion, for example).

LSDP medicine can also be sent directly to the hospital unit where the patient is receiving the treatment immediately prior to their attendance for treatment (as per hospital procedure).

It is the responsibility of the authorised person to take reasonable steps to verify that the medicine is being dispensed for the immediate use of the LSDP patient. If you are not sure, please do not provide the LSDP medicine and contact the patient or their treating physician to confirm.

How should LSDP medicine be stored and handled?

It is the responsibility of the dispensing pharmacist to ensure the patient is aware of the transport, storage and handling requirements for the LSDP medicine.

What should I do if a patient requests a change of dispensing location?

You must inform the treating physician and they must inform the LSDP of the details of the new dispensing location. The LSDP will then arrange transfer and delivery of any LSDP medicine to the new location.

Where can I find information for patients?

New patients can download the LSDP fact sheet for patients.

Patients should also be provided with the most current consumer medicines information from the <u>TGA website</u> when commencing on the LSDP or as requested/required.