

Life Saving Drugs Program (LSDP) Frequently Asked Questions (FAQs)

What is the purpose of the LSDP?

Medicines to treat rare diseases may have a very high cost per patient because they are often more expensive and difficult to develop. These medicines may fail to meet the comparative cost effectiveness criteria required for Pharmaceutical Benefits Scheme funding. The LSDP enables the Government to provide subsidised access, for eligible patients, to these expensive lifesaving drugs for rare life threatening conditions. It offers physical, emotional and financial relief.

What are the main changes to the LSDP?

Key changes include:

- the adoption of a definition of a 'rare disease', that being a disease prevalence of 1:50,000 people or less in the Australian population (around 500 people). This is in line with the current LSDP prevalence rates.
- developing explanatory materials to support the criteria to specify that lifesaving medicines are those that extend lifespan, including through the measurement of substantial reduction to the level and duration of disability, which will lead to a significant increase in life extension.
- implementation of more transparent and rigorous clinical efficacy and cost effectiveness assessment of medicines, delivered through the establishment of an expert panel which will provide advice and assistance to the Commonwealth's Chief Medical Officer (CMO).
- introduction of a mechanism where medicines listed on the LSDP will be subject to a review of usage and financial costs after 24 months, ensuring use and performance of the medicine is in line with the recommendations and expectations at listing. Similar reviews will be undertaken on all existing LSDP medicines over the first two years from the commencement of the new program.
- the negotiated application of pricing policies to new and existing medicines on the LSDP, as per those applying to Pharmaceutical Benefits Scheme (PBS) listed medicines.
- streamlining administration of the LSDP, and implementing cost recovery arrangements from sponsors for listing considerations and management of their agreements.

These improvements to the LSDP are designed to deliver certainty to patients and stakeholders.

What is the purpose of the changes?

These changes will allow the Australia Government to safeguard the sustainability of the LSDP whilst ensuring that patients with rare and life threatening diseases continue to get subsidised access to very expensive medicines.

Will the changes to the LSDP affect patient's access to fully-subsidised medicines?

No. First and foremost, eligible patients will retain ongoing access to medicines currently available through the LSDP.

What impact will there be on treating physicians/hospitals?

The role of treating physicians/hospitals in arranging supply of medicines for eligible patients will not change.

Will new medicines for rare diseases still need to apply to the Pharmaceutical Benefits Advisory Committee (PBAC) for listing on the Pharmaceutical Benefits Scheme (PBS)?

Yes. All new medicines for rare diseases will still need to be considered first by the PBAC for potential listing on the PBS. If the PBAC considers the new medicine clinically effective but not cost effective, so not suitable for the PBS, the sponsor of the medicine may then apply for inclusion on the LSDP.

What will be the role of the new Expert Panel?

The Expert Panel will consider applications for listing medicines against the program criteria that include whether the new medicine is effective in extending lifespan and represents value for money.

What is the process for Review for medicines currently listed on the LSDP?

As part of the changes, new medicines will be subject to a review of usage and financial costs after 24 months, ensuring use and performance of medicines is in line with recommendations of the CMO and the Expert Panel. Reviews of existing LSDP medicines will also be undertaken in the first two years from the commencement of the new program.

Will there be further consultation on the LSDP reforms?

The Government will continue to consult with key stakeholders in implementing the improvements.

When will the reforms be implemented?

It is proposed that the changes to the current LSDP will be implemented by 1 July 2018.

All inquiries should be addressed to lsdp@health.gov.au