Minister for Health and Aged Care
Minister for Sport
THE HON SUSSAN LEY MP

Media Release

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Reform of Regulation of Medicines and Medical Devices

Cancer patients could potentially have access to some new medicines two years earlier than at present under changes to the regulation of medicines and medical devices announced today by the Turnbull government.

Delivering the government's response to the Review of Medicines and Medical Devices Regulation, chaired by Emeritus Professor Lloyd Sansom AO, Health Minister Sussan Ley said the government had accepted the majority of the recommendations of the Review that will bring significant benefits to consumers, the therapeutic goods industry and health professionals.

"Bringing medicines onto the Australian market quicker will be achieved, in part, by greater use of assessment of medicines by comparable overseas regulators like the US FDA and the European Medicines Agency," Minister Ley said.

"Provisional approvals will also be available which could result in certain life-saving medicines such as new cancer drugs coming to market two years sooner," Ms Ley said.

This will bring Australia into line with other international regulators and will increasingly see Australia become a 'world-first' destination for the registration of breakthrough medicines.

As highlighted in the independent Review's first report, Australian patients have to wait up to 15 months longer to access some breakthrough medicines than in US or Europe.

"It is a common complaint that certain high profile medicines are not brought to Australia and it is expected that implementing expedited pathways for registration of new medicines will result in many new medicines coming onto the Australian market.

"Greater use of assessment of medicines by comparable, trustworthy overseas regulators is estimated to bring medicines from companies that use this assessment pathway to market four and half months earlier than under the current regime."

These reforms will again see Australia punching above its weight in access to new medicines and will be complemented by the Coalition's ongoing commitment to list medicines recommended by the PBAC without fear or favour. This has seen the Coalition add about $4.5 billion worth of new medicines to PBS since coming to Government and there's billions more in the pipeline as advances in technology and treatments continue to grow.

Ms Ley said that other reforms will enable the Therapeutic Goods Administration (TGA) to more efficiently manage 60,000 notifications and approvals annually for patient specific access to unapproved products.

“It will also mean that patients will gain access to essential medicines under the Special Access Scheme faster. The reforms will introduce an online system for making and tracking SAS applications. It will also increase the number of medicines subject to streamlined approval through the SAS.

“Consumers will also benefit from more extensive post-market monitoring of products and better access to information about the effectiveness of complementary medicines.

“Under the reforms sponsors will be encouraged to publish on their website the evidence that it holds to support all indications included on the product as well as information that will assist consumers to compare complementary medicines.

“Advertising for therapeutic products will be simplified but there will be stricter penalties for non-compliance.”

Minister Ley said the reforms strike the right balance between consumer protection and reducing red tape for companies importing or manufacturing new medicines, medical devices or complementary medicines.

“The reforms will also foster innovation for small and medium sized enterprises by helping Australian businesses navigate the regulatory processes for the supply of therapeutic products in Australia.

“This includes assistance such as targeted regulatory guidance material, information sessions and assistance, the development of ‘how to’ manuals and dedicated helplines and advice on where to obtain further help.

“Offering information targeted at small and medium-sized enterprises, which may not have regulatory experience or expertise, will help ensure the commercial development of Australian ideas for innovative new therapeutic products occurring domestically rather than overseas.”

Minister Ley said she was confident that these reforms will allow Australian consumers to be confident about the safety, quality, and performance of therapeutic products available to them through Australian pharmacies, supermarkets and in hospital procedures.

The government allocated $20.4 million in the last federal budget to implement the reform measures to improve the regulation of therapeutic goods in Australia.

The reforms will be progressively rolled out by the TGA over the next 18 to 24 months, with new regulatory pathways for some medicines in place within 12 months.

Link to the Response report: https://www.tga.gov.au/mmdr

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