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Australia changes drug approval norms to speed up approval process

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Singapore: With a view to speed up the approval process and improve access to breakthrough drugs, the Australian federal government is implementing new measures for approval of new medicines.

As per the changes being announced recently, any drug that has been listed by a comparable overseas regulator, including the US Food and Drug Administration and the European Medicines Agency, can now be fast-tracked for approval and sale in Australia.
The Australian Government allocated $20.4 million in the May budget to implement the changes, which will be rolled out over the next two years.

Stating that the new measures will help in quick approval of drugs and improve healthcare, the country's health minister, Ms Sussan Ley, said the Therapeutic Goods Administration (TGA) would be able to share information with those overseas regulators, meaning it would no longer have to start the lengthy approvals process from scratch, in every case.

"What we need to do is accept the evidence that is being presented to those overseas regulators, bring that information to Australia, ensure our TGA is happy and ultimately list those medicines earlier," she said.

She also mentioned that TGA will have a final say on the approval of the drugs though US and EU regulators are highest in quality. The regulatory changes would also allow pharmaceutical companies to list their drugs in Australia at the same time as they list them in larger, overseas markets, she said.