

The TGA does not regulate health professionals or clinical practice and 'off-label' use is a clinical decision made at the discretion of the prescriber who is responsible for obtaining informed consent for the 'off label' use from their patient.

There may be circumstances where the sponsor becomes aware of the 'off-label' use of its therapeutic goods which are included in the ARTG and requests a Special Access Scheme (SAS) notification or approval to ensure legal supply of the product under the therapeutic goods legislation. The TGA administers the SAS to enable access to unapproved therapeutic goods for individual patients on a case-by-case basis.

Application Number	Application Date	Decision Date	Form Type	Product Profile	Product Presentation	Indication	Status Reason
MB18/0038214	30/04/2018	2/05/2018	SAS-B	Leuprorelin	Injection	Delayed puberty	Approved
MB20/0274283	30/06/2020	1/07/2020	SAS-B	Leuprorelin	3.75mg Injection	Carcinoma	Approved
MA22-0653240	28/02/2022		SAS-A	Leuprorelin	Injection	Delayed puberty	Completed
MB22-0681166	19/04/2022	20/04/2022	SAS-B	Leuprorelin	Injection	Test	Approved
MB22-0742702	21/07/2022	22/07/2022	SAS-B	Leuprorelin	Injection	Delayed puberty	Approved
MB22-0744823	25/07/2022	26/07/2022	SAS-B	Leuprorelin	Injection	Test	Approved
MB22-0765195	18/08/2022	23/08/2022	SAS-B	Leuprorelin	Injection	IVF	Approved
MA22-0789000	19/09/2022		SAS-A	Leuprorelin	Injection	Delayed puberty	Completed
MB22-0793851	29/09/2022	30/09/2022	SAS-B	Leuprorelin	Injection	Test	Approved
MB22-0795145	3/10/2022	5/10/2022	SAS-B	Leuprorelin	Injection	Test	Approved
MB22-0802515	13/10/2022	17/10/2022	SAS-B	Leuprorelin	Injection	Test	Approved
MB22-0802522	13/10/2022	17/10/2022	SAS-B	Leuprorelin	Injection	Test	Approved
MB22-0825067	17/11/2022	21/11/2022	SAS-B	Leuprorelin	Injection	Test	Approved
MA23-0860950	22/01/2023		SAS-A	Leuprorelin	Injection	Test	Completed
MA23-0896266	20/03/2023		SAS-A	Leuprorelin	Injection	Test	Completed
MA18-0019528	22/01/2018		SAS-A	Goserelin	Injection	Carcinoma	Completed
MA18/0053762	29/06/2018		SAS-A	Goserelin	Injection	Carcinoma	Completed
MA20/0221535	26/01/2020		SAS-A	Goserelin	Implant	Carcinoma	Completed
MB21-0610059	17/12/2021	20/12/2021	SAS-B	Goserelin	Injection	Fertility preservation	Approved