

HORMONAL REPLACEMENT THERAPY SHORTAGES

- The TGA has been notified of shortages of all strengths of Estradot and Estalis products and 3 of the 4 strengths of EstradermMX. The TGA has also been notified of the discontinuation of Climara.
- The shortages of Estalis and Estradot are due to manufacturing issues.
- Estraderm patches are in shortage due to an increase in demand as a result of the shortages of the other products, alongside the discontinuation of Climara. Details of these shortages are as follows:
 - On 15 March 2024, Sandoz Pty Ltd notified the TGA that due to the manufacturing issues, the shortages of all strengths of Estradot (estradiol) transdermal patches have been extended until between mid-June to mid-September depending on the strength.
 - Juno Pharmaceuticals has notified the TGA of the shortage of Estraderm MX 50, 75 and 100 until the beginning of August 2024, due to an unexpected increase in demand.
 - All strengths of combination HRT transdermal patches such as Estalis Sequi and Estalis Continuous have also been affected. These shortages are expected to resolve between early June to early August 2024.
- Other dosage forms of HRT such as tablets, gels and vaginal suppositories remain available.
- Patients who are unable to source the products they have been prescribed are encouraged to talk to their pharmacist in the first instance about securing stock from alternative sources. Medical practitioners are best placed to advise patients on switching to alternative therapies, if required.
- The TGA has approved the importation of overseas-registered alternatives to all strengths of estradiol-containing transdermal patches under section 19A of the *Therapeutic Goods Act 1989*. These are not currently approved on the Pharmaceutical Benefits Scheme (PBS).
- On 17 May 2024 the TGA published updated web statements with advice for consumers and healthcare professionals about the shortages of HRT medicines, and information about the availability of section 19A alternatives. This page will be updated as the situation evolves.
- On 10 May 2024, the department issued a Notice under the Deed to all Community Service Obligation Distributors (CSODs) to allow wholesalers to constrain supply and facilitate equitable distribution of estradiol transdermal patches.
- This Notice allows individual CSODs to utilise their expertise in relation to the supply of medicines, to independently determine the practices they can adopt to support equitable supply of these patches.
- Information on recent actions taken by the TGA to examine its shortages management processes, including public consultation, was provided to the Committee during Outcome 1.8 on 5 June 2024.
- In early 2024, the TGA publicly consulted to better understand the nature, extent and urgency of problems currently impacting the supply of medicines in Australia, including shortages and discontinuations of medicines. We received feedback on challenges and barriers experienced by consumers, health professionals and industry in predicting, responding to, and communicating about medicine shortages and discontinuations. This feedback will be used to develop a workplan for proposed future reform.