

EN

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Answer given by Mr Várhelyi
on behalf of the European Commission
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The European Medicines Agency (EMA) is responsible for hosting and maintaining EudraVigilance¹ - the EU system for collecting and monitoring reports of suspected side effects. According to the EMA, a small number of reports on off-label use in gender dysphoria have been received, mainly outside the EU for leuprorelin (seven spontaneous cases, all non-EU) and a few EU cases for triptorelin (nine spontaneous cases in total from 2012–2025).

It is also important to note there has been no EU pharmacovigilance signal procedure related to the off-label use of Gonadotropin-Releasing Hormone agonists (GnRH-agonists) in the context of gender dysphoria. Additionally, all GnRH-agonists are subject to regular EU-wide safety assessments.

It is important to note that patients receiving such treatment are typically under the care of specialised healthcare professionals who closely monitor their health and overall wellbeing and who are primarily tasked to raise awareness about, or address particular adverse reactions.

¹ <https://www.ema.europa.eu/en/human-regulatory-overview/research-development/pharmacovigilance-research-development/eudravigilance>.