Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 28-31 October 2019

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News 31/10/2019

[**PRAC**](https://www.ema.europa.eu/en/glossary/prac)**recommends measures to minimise risk of serious side effects with Lemtrada for multiple sclerosis**

EMA’s safety committee ([PRAC](https://www.ema.europa.eu/en/glossary/prac)) recommended restricting Lemtrada for use in adults with relapsing remitting multiple sclerosis that is highly active despite adequate treatment with at least one disease-modifying therapy or if the disease is worsening rapidly with at least two disabling relapses in a year and brain-imaging showing new damage.

The [PRAC](https://www.ema.europa.eu/en/glossary/prac) had issued [interim measures](https://www.ema.europa.eu/en/news/use-multiple-sclerosis-medicine-lemtrada-restricted-while-ema-review-ongoing) on Lemtrada while reviewing reports of serious reactions. The [PRAC](https://www.ema.europa.eu/en/glossary/prac" \t "_blank" \o "Pharmacovigilance Risk Assessment Committee -  the committee that is responsible for assessing all aspects of the risk management of medicines for human use.   More information can be found under 'Pharmacovigilance Risk Assessment Committee (PRAC)'.)completed the review and recommended that Lemtrada must no longer be used in in patients with certain heart, circulation or bleeding disorders or in patients who have auto-immune disorders other than multiple sclerosis.

The recommendations reflect [PRAC](https://www.ema.europa.eu/en/glossary/prac)’s review of reports concerning rare but serious effects, including deaths, from immune-mediated conditions (caused by the body’s defence system not working properly) and serious disorders of the heart, circulation and bleeding.

More information is available below.

[**PRAC**](https://www.ema.europa.eu/en/glossary/prac)**recommends cautious use of Xeljanz for all patients at high risk of blood clots**

The [PRAC](https://www.ema.europa.eu/en/glossary/prac) concluded that Xeljanz (tofacitinib) could increase the risk of blood clots in the lungs and in deep veins in patients who are already at high risk.

The [PRAC](https://www.ema.europa.eu/en/glossary/prac) recommended that Xeljanz should be used with caution in patients at high risk of blood clots. In addition, the maintenance doses of 10 mg twice daily should not be used in patients with ulcerative colitis who are at high risk unless there is no suitable alternative treatment. Patients older than 65 years of age should be treated with Xeljanz only when there is no other appropriate treatment.

These recommendations follow the [PRAC](https://www.ema.europa.eu/en/glossary/prac)’s review of an ongoing study in patients with rheumatoid arthritis and an increased risk of cardiovascular disease. The study showed an increased risk of blood clots in deep veins and in the lungs with both the 5 mg and 10 mg twice daily doses of Xeljanz as compared with patients taking TNF-inhibitors (medicines that help reduce inflammation).

More information is available below.