# Pharmacovigilance Risk Assessment Committee (PRAC) has initiated the implementation of temporary precautionary measures while reviewing Esmya

**Budapest, Hungary – 09 February 2018 –** Gedeon Richter Plc. announced today that the European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) has initiated the implementation of temporary precautionary measures as a part of its review procedure on drug induced liver injury potentially related to Esmya (ulipristal acetate). PRAC considers that until a thorough assessment of the available data is performed within the ongoing review, temporary measures are needed to minimise potential risks to patients.

The PRAC has recommended regular liver monitoring for women taking Esmya for uterine fibroids. The PRAC is also recommending that no new patients should be started on Esmya and no patients who have completed a course of treatment should start another one. Treatments commenced prior to this decision are allowed to be completed. PRAC recommendations are temporary measures to protect patients' health. The final decision depends on the conclusion of the review of Esmya, which was started in December 2017 and is expected to be completed before end of May 2018.

Richter is determined to work with PRAC and provide the necessary information to allow them to complete a fair assessment in a timely manner.

Richter takes patient safety seriously. Richter continues to believe that all the available data for Esmya support a favourable benefit-risk profile and is committed to providing this unique treatment option to women suffering from uterine fibroids.

**About Esmya**

To date more than 700,000 patients have been treated with Esmya, based on the post-marketing database in Europe. In completed clinical trials, over 7,100 subjects have been exposed to ulipristal acetate and 1,972 subjects received repeated doses of ulipristal acetate. No signs of liver toxicity were identified during the development program of UPA.

Richter, has provided PRAC with a thorough analysis for all cases of liver toxicity in women receiving Esmya, and based on the analysis, the causal relationship to Esmya could not be established due to the confounding factors such as the use of other medications, viral infection and potential underlying conditions of the liver in some of these patients.

**About Richter**

Gedeon Richter Plc. (www.richter.hu), headquartered in Budapest/Hungary, is a major pharmaceutical company in Central Eastern Europe, with an expanding direct presence in Western Europe, in China and in Latin America. Having reached a market capitalisation of EUR 4.1 billion (US$ 4.9 billion) by the end of 2017, Richter's consolidated sales were approximately EUR 1.4 billion (US$ 1.6 billion) during the same year. The product portfolio of Richter covers many important therapeutic areas, including Women's Healthcare, Central Nervous System, and Cardiovascular areas. Having the largest R&D unit in Central Eastern Europe, Richter's original research activity focuses on CNS disorders. With its widely acknowledged steroid chemistry expertise, Richter is a significant player in the Women's healthcare field worldwide. Richter is also active in biosimilar product development.

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