Pharmacovigilance Risk Assessment Committee (PRAC) published new recommendations subsequent to the latest Esmya® referral

Budapest, Hungary – 4 September 2020 – Gedeon Richter Plc. announces today that based on the review of all available data on safety and efficacy, the Pharmacovigilance Risk Assessment Committee (PRAC) considers that the benefit-risk balance of all medicinal products containing ulipristal acetate 5 mg is not favourable and recommends the revocation of the marketing authorisations.

Richter is expecting the final CHMP (Committee for Medicinal Products for Human Use) endorsement of this recommendation and is working closely with the PRAC to make sure that all steps of this decision are implemented in order to safeguard patient safety.

For details of the decision please visit:
https://www.ema.europa.eu/en/medicines/human/referrals/ulipristal-acetate-5mg-medicinal-products

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 capitalization of EUR 3.6 billion (USD 4.1 billion) by the end of 2019, Richter's consolidated sales were approximately EUR 1.6 billion (USD 1.7 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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