New risk minimization measures for valproate

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Valproate and related substances (VPA) are indicated for treating epilepsy and, depending on the country, bipolar disorder. According to the National Institute for Health and Care Excellence (1), VPA is recommended as a first-line treatment in children, young people and adults with newly diagnosed Generalized Tonic-Clonic Seizures (GTCS). In 2013, the International League Against Epilepsy (2) considered that VPA was possibly effective as initial monotherapy in patients (adults and children) with GTCS, in children with benign childhood epilepsy with centro-temporal spikes and in children with partialonset seizures, and was potentially effective as an initial monotherapy in patients with juvenile myoclonic epilepsy and in elderly patients with partialonset seizures. Following the publication of new studies suggesting that, in some children exposed *in utero* to VPA, problems in neurodevelopment may be long-lasting, the Pharmacovigilance Risk Assessment Committee (PRAC) at the European Medicines Agency started a benefit risk review of VPA in pregnancy and in women of child-bearing potential (WCBP). Following this review, in 2014 the PRAC recommended measures to strengthen warnings and restrictions on the use of VPA in WCBP, as well as recommendations for the development of educational materials. In March 2017, following an evaluation of the effectiveness of these risk minimization measures (RMMs), the PRAC initiated a new review. As a result, in February 2018, the PRAC recommended new RMMs which strengthen previous restrictions on the use of VPA and the set-up of a pregnancy prevention program, to ensure the appropriate use of VPA in WCBP and avoid any unnecessary fetal exposure to VPA. All the updated RMMs put in place will be presented during the session.