Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Procedure No: EMEA/H/A-31/1454

Medicinal products containing substances related to valproate

Divergent statement

We diverge on a single point of the PRAC recommendation. This is the statement which implies that counselling women where switching is not possible, without providing any quantification or qualification of such scenarios, will protect the unborn child from harm. We consider that it is unacceptable to create such an implication on the face of a regulated product's licence in relation to use in the context of a planned pregnancy. Sodium valproate is a powerful teratogen. Children exposed in utero are at high risk of serious developmental disorders (up to 30-40% of cases) and/or congenital malformations (approx. 10% of cases). The regulatory responsibility is to avoid ambiguity on the benefit-risk profile of a medicine at the population level. In line with same, the PRAC agrees that a contraindication is warranted in women of child-bearing potential where conditions of the Pregnancy Prevention Programme are not met. Outside of same, any individualised considerations of informed consent should be at the level of the individual patient and their specialist(s) rather than a matter for the product licence. It is not unique to this product that the right to self determination includes right to refuse treatment or select an alternative. Issues of informed consent are particularly complex in the context of the use of a medicine where the harm is to the unborn child. A generic reference to counselling as a sufficient measure for informed consent, on the face of the licence, is inappropriate in a situation where there needs to be individualized decision making.

CMDh Members expressing a divergent opinion:

- Nicole Kavanagh (IE)
- Keith McDonald (UK)