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Answer given by Mr Andriukaitis
on behalf of the European Commission
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Medicines in the EU are subject to a post-marketing surveillance for which obligations to marketing authorisation holders and competent authorities are set by the legislation[1]. Signals on safety risks are evaluated by the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) and a regulatory action is taken, as appropriate.

A recent scientific review by the EMA[2] recommended new measures to avoid valproate exposure in pregnancy (e.g. ban on use for migraine or bipolar disorder during pregnancy, a ban on treating epilepsy during pregnancy unless no other effective treatment available). These recommendations are reflected in the summary of product characteristics that is the basis of information for healthcare professionals on how to use the medicinal product safely and effectively.

The Commission does not have figures on the number of people affected in the EU. However, data may be available in some Member States.

Regarding compensation, it should be stressed that health policy, as well as the organisation and delivery of healthcare, is a Member State competence under Article 168 of the Treaty on the Functioning of the EU[3].

Overall, the Commission takes the view that the legal framework to monitor medicines has been continuously strengthened to ensure that the medicines which are made available to patients in the EU correspond to high standards of quality, safety and efficacy.

1 https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:348:0074:0099:EN:PDF and https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:348:0001:0016:EN:PDF

2 http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Valproate_and_related_substances/human_referral_prac_000066.jsp&mid=WC0b01ac05805c516f

3 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012E/TXT&from=EN