Question for written answer E-001561/2018
to the Commission
Rule 130
Lola Sánchez Caldentey (GUE/NGL)

Subject: Depakine and other medicines containing valproate

Medicines containing valproate (such as Depakine, among others) have been approved in the EU for the treatment of epilepsy and bipolar disorders, and, in some Member States, for the prevention of migraines. If taken during pregnancy, valproate is known to pose a significant risk of birth defects and developmental problems in the baby. Thousands of cases of abnormalities and other permanent side effects have been reported in the Member States. In 2008, and once again in 2018, the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) recommended that its use should be restricted and that warnings to patients should be stepped up[1]. Despite those efforts, however, many Member States, including Spain, have failed to follow the PRAC's recommendations, and use of the drug has actually increased[2].

More than 90 000 people, including 9 000 women of childbearing age, are taking valproate (Depakine) every day in Spain, and they are not being given the necessary information about the potential risks and side effects[3].

1. Could the Commission share the latest data it has on how many people in the EU have suffered side effects (such as birth defects and developmental problems) as a result of valproate use?
2. What has been done to compensate the victims, and what steps have been taken to amend the pharmacological recommendations in respect of valproate? Has consideration been given to withdrawing it from the market?
3. Does the Commission take the view that, in this case, pharmacovigilance legislation has been successful in safeguarding public health[4]?

1 http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/02/news_detail_002903.jsp&mid=WC0b01ac058004d5c1
2 Report (U/EPIL/V1) by the Spanish medicines agency (AEMPS) on the use of medicines, 11 September 2017.
3 https://www.icf.uab.cat/assets/pdf/productes/bg/es/bg311.18e.pdf
4 Pharmacoepidemiology and drug safety 2016; 25: 725-732. Published online on 22 January 2016, Wiley Online Library (wileyonlinelibrary.com) DOI: 10.1002/pds.3967.