Question for written answer E-003511/2018
to the Commission
Rule 130
Mireille D'Ornano (EFDD)

Subject: Change in the formula for Levothyrox and its consequences

The formula for Levothyrox, which is used to treat hypothyroidism, was changed in France in 2017. This triggered a wave of side effects: fatigue, headaches, insomnia, vertigo, joint and muscle pain and hair loss. According to the national authorities, out of 3 million users, 500 000 abandoned this drug at the end of 2017, including 1 200 who filed a complaint against the manufacturer, Merck.

Analyses carried out abroad, at the request of the French Association of Thyroid Patients (AFMT), apparently show that 'the content of levothyroxine, the only hormonally useful component of the drug, is very significantly lower than the specifications in force.' Furthermore, the Association 'notes (...) the very abnormal presence of dextrothyroxine', another molecule, formerly used to treat cholesterol, 'which could explain the very atypical values seen in many patients/victims'. The results are troubling but have been dismissed by the manufacturer as well as by the French Medicines Agency (ANSM: National Agency for the Safety of Medicines and Health Products).

In the context of its pharmacovigilance competences, does the Commission, through the European Medicines Agency, have any information on suspected side effects related to the new formula and possible anomalies in the composition of this medicinal product?