Question for written answer E-014558/2015 to the Commission

Rule 130

Piernicola Pedicini (EFDD), Tiziana Beghin (EFDD), David Borrelli (EFDD) and Laura Agea (EFDD)

Subject: Use of anti-depressants in children and teenagers

A scientific study recently published in the *British Medical Journal* entitled 'Restoring Study 329: Efficacy and harms of paroxetine and imipramine in treatment of major depression in adolescence' has shown the clinical efficacy of paraxotine, which is used to treat depression in teenagers, to be no greater than that of a placebo. Besides not being efficacious in curing depression, the substance has also been shown to have a number of side effects, including the increase in suicidal tendencies. Study 329, which was published in 2001, was used by the multinational pharmaceutical company GlaxoSmithKline (GSK), whom the US courts later found guilty of consumer fraud, as the basis for marketing its product. In 2005, the Committee for Medicinal Products for Human Use (CHMP) recommended that the product information be updated to include a warning on the risk of suicidal behaviour in children and adolescents arising from the use of paraxotine, of other serotonin-specific reuptake inhibitors (SSRIs) and of serotonin-norepinephrine reuptake inhibitors (SNRIs).

Can the Commission therefore state:

- Whether it will launch a procedure for referral to the European Medicines Agency for the evaluation of medicinal products under Article 31 of 2001/83/EC, for the substances indicated above?
- Whether it will open an enquiry to ascertain whether GSK's conduct did not violate EU antitrust rules by giving an unfair advantage to its product and penalising other companies across Europe, while also being detrimental to adolescents suffering from depression?

1078290.EN PE 570.894