Question for written answer E-003644/2013
to the Commission
Rule 117
Michael Cashman (S&D)

Subject: Studies by EU companies promoting the use of a medicinal product in non-EU countries

In our previous question (E-005894/2012) we noted that:

– Some pharmaceutical companies based within the EU promote expensive brand-name pharmaceutical products under the guise of post-marketing observational studies, especially in low-income countries;

– Participating doctors may be paid to convert a person onto the newly marketed agent, with most patients remaining on the medicine after the study is over;

– These studies often do not generate any published results, which suggests that they are of a marketing rather than a scientific nature;

– As a comparison, companies based in the US do not have recourse to such practices, owing to the very strict guidelines for pharmaceutical manufacturers issued by the Office of Inspector General of the Department of Health and Human Services, which deal with kickbacks and other illegal forms of remuneration;

– The EU directive on pharmacovigilance (post-authorisation safety studies) was amended in 2010 to state that 'studies shall not be performed where the act of conducting the study promotes the use of a medicinal product' (Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010).

Following its answer to the above question, will the Commission consider expanding the EU legislation so as to stop European pharmaceutical companies from conducting studies which promote the use of a medicinal product in non-EU countries?

Does the Commission agree that such legislation would help to mitigate the risk of some companies conducting observational trials in non-EU countries, where they might recruit a doctor to conduct such a trial who then modifies the patient's treatment without that treatment being funded by the company?