Question for written answer E-013287/2015
to the Commission
Rule 130
Nessa Childers (S&D)

Subject: Off-label use of misoprostol

A number of medicines containing misoprostol are authorised in the EU for gynaecological and obstetric uses.

A 2009 review of Cytotec, a misoprostol medicine with gastrointestinal indications, highlighted a high rate of off-label use with associated adverse events.

Although authorised drugs are available, the off-label use of misoprostol (e.g. Cytotec) continues for labour induction, pregnancy terminations and other misuses, and is even actively promoted on budgetary grounds in some Member States, such as Italy.

Does the Commission recognise the risk to patient safety that lies in promoting off-label use of misoprostol in Member States on budgetary grounds?

What is the Commission doing to prevent Member States from promoting off-label use of misoprostol on budgetary grounds, to ensure that the EU pharmaceutical legislation is respected, and to prevent the exposure of patients, namely mothers and new born children, to unnecessary risk?