Question for written answer E-015728/2015
to the Commission
Rule 130
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Subject: The health risks to EU citizens of off-label use

In October 2015 it was reported that, following the administration of 'Avastin' outside its authorised indication, a third of patients who underwent treatment for an eye condition at the Careggi Hospital in Italy suffered a serious infection, which could result in a loss of sight.

The pharmaceutical company Roche has never asked for authorisation for its medicine 'Avastin' to be used for maculopathy, while Novartis sells its medicine 'Lucentis', authorised for the treatment of maculopathy, at a much higher price than 'Avastin', leading to off-label use of the latter to save costs.

The prescribing of off-label medicines can expose patients to health risks and should only occur when there is a concrete medical need. A recent study published in *JAMA Internal Medicine* shows that the health risks associated with off-label prescriptions increase by 44 % compared to an authorised alternative.

Parliament expressed concerns over off-label prescription in its resolution of 19 May 2015 on safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance, and called for careful regulation in this field.

Despite this, Italy revised its regulation to promote the practice of off-label use to save costs.

1. Will the Commission set a regulatory framework to ensure that Member States stop putting patients at risk?

2. Can the Commission verify whether Roche and Novartis are cartelising the market?