Italy: The Italian Competition Authority fines Roche and Novartis for Cartelizing Sales of two major Ophthalmic Medicines

On 27 February 2014, the Italian Competition Authority (ICA) found that Roche and Novartis infringed Article 101 TFEU by taking part in an anti-competitive agreement in the market for ophthalmic drugs used to treat some serious vascular eyesight conditions, including age-related macular degeneration (AMD), the main cause of blindness in developed countries.

The investigation started in February 2013 on the basis of complaints filed by an association of private hospitals and the Italian Ophthalmologic Association. The evidence gathered shows that starting in 2011 Roche and Novartis set up a complex collusive strategy, with a view to avoiding the commercial success of Lucentis being hindered by the ophthalmic applications of Avastin. They colluded to create an artificial product differentiation between Avastin and Lucentis, and to claim that Avastin is more dangerous than Lucentis, in order to influence prescriptions by doctors and health services for eyesight conditions.

Originally, the use of Avastin was approved for the treatment of some forms of cancer. Yet since mid-2000 it has been used off-label to treat common eyesight conditions in accordance with the Italian regulatory framework. Lucentis, a more recently developed drug which contains an active substance similar to Avastin, has received regulatory approval upon request of Genentech – a subsidiary of Roche – in the US, and of Novartis everywhere else, specifically for some of these eyesight conditions. However, there is a significant difference in price between them: while an injection of Lucentis in Italy costs € 900 (down from an earlier price of € 1 700), the price of an off-label injection of Avastin tops at € 81.

The efforts of Roche and Novartis intensified as a growing number of independent comparative studies supported the equivalence of the two drugs for ophthalmic uses.

The economic rationale of the companies’ conduct stems from the relationship between the Roche and Novartis groups: while Roche collects significant royalties from the sales of Lucentis, which was developed by its subsidiary Genentech, Novartis benefits directly from Lucentis’ sales and holds a more than 30% share in Roche.

According to the ICA, this illicit collusion may have hindered access to treatment for many patients and caused the Italian National Health Service to bear additional expenses estimated at € 45 000 000 in 2012, while increased future costs might possibly exceed € 600 000 000 per year.

In light of the seriousness of the infringement, the ICA imposed on Roche and Novartis fines totalling respectively € 90 500 000 and € 92 000 000.

See press release and decision (in Italian)