



The Consumer Voice in Europe

Avastin vs Lucentis

Letter sent to Vice-President Almunia on November 7th, 2013

Contact: **Iliaria Passarani – health@beuc.eu**

Ref.: BEUC-X-2014-012 - 05/03/2014

Mr. Joaquín Almunia
Vice-President
European Commission
Rue de la Loi, 200

B – 1049 Brussels

Ref.: L2013_308/MGO/cm

Brussels, 7 November 2013

Subject: Avastin vs Lucentis

Dear Vice-President Almunia,

I write on behalf of the European Consumer Organisation (BEUC) to express our concerns with regard to potential anticompetitive practices put in place by Novartis and Roche for the sale of the pharmaceutical products Avastin and Lucentis.

Both drugs were developed by Genentech, which was acquired by Roche in 2009, with Novartis holding the licence to sell Lucentis outside of the US¹.

Although both drugs have been shown to be effective for the treatment of age related macular degeneration (AMD), a leading cause of blindness in high income countries, only Lucentis has been submitted for marketing authorisation and approved by the European Medicines Agency (EMA) for this therapeutic indication.

According to available scientific studies² the two products are equally effective to treat AMD. However, Lucentis is up to 50 times³ more expensive than Avastin. Despite evidence that Avastin works in macular degeneration, Roche is not willing to apply for the marketing authorization for this therapeutic indication and is actively discouraging its use for this condition, even going so far as taking legal action to prevent such off-label use.

.../...

¹ Novartis has two agreements with Genentech, Inc. USA, a subsidiary of Roche Holding AG (...). Novartis has licensed the exclusive rights to develop and market Lucentis outside the United States for indications related to diseases of the eye. As part of this agreement, Novartis paid Genentech/Roche an initial milestone and shared the cost for the subsequent development by making additional milestone payments upon the achievement of certain clinical development points and product approval. Novartis also pays royalties on the net sales of Lucentis products outside the United States. Lucentis sales of USD 2.4 billion (2011: USD 2.0 billion) have been recognized by Novartis" (cfr. Novartis Annual Report 2012, p. 239: <http://www.novartis.com/investors/financial-results/annual-results-2012.shtml>).

² Ingrid Torjesen. Avastin is as effective as Lucentis in treating wet age related macular degeneration, study finds. BMJ 2013; 347 doi:<http://dx.doi.org/10.1136/bmj.f4678> - ATT Research Group, Martin DF, Maguire MG, Ying G, Grunwald JE, Fine SL, et al. Ranibizumab and bevacizumab for neovascular age-related macular degeneration. N Engl J Med 2011;364:1897-908.

³ The average price of the products is about 32-62 euros for Avastin and 1488 for Lucentis (per dose). Source: BMJ.

We fear that the Roche decision not to seek the marketing authorization is the result of a secret agreement with Novartis to maintain on the market only the more expensive medicine Lucentis. We are also inclined to believe that the agreement includes the reporting to the EMA and national regulatory authorities of potential complications associated with the use of Avastin that would in reality be associated with the fact that Roche markets Avastin only in high dosages for cancer treatment and that the doses need to be manipulated by physicians in order to be used for eye treatment, leading to the risk of infections.

At present many ophthalmologists refuse to prescribe Avastin due to the fear of incurring civil or criminal liability, as a result of the complaints of Roche, and the consequent exclusion of Avastin from the national lists of off-label medicines covered by the national health care systems.

Moreover, many consumers who continue to use Avastin, by necessity (because their eye disease is not cured by Lucentis) or by choice (because they do not want to change a therapy already started), have to bear the cost directly and buy the medicine out of pocket since it is no longer reimbursed. The costs for consumers are not negligible, since the therapy requires multiple applications per year and the therapy can last several years.

Roche inertia against a possible extension of the indications of Avastin in the ophthalmic field despite the supporting scientific evidence as well as its initiatives vis-à-vis regulatory agencies and local governments to prevent off-label use appear peculiar as they are against normal business logic, typically geared to the maximization of profit through the sale of products. In our view this conduct is also influenced by the fact that Novartis holds 30% of the shares of Roche.

Should the anticompetitive strategy be proven, the use of Lucentis at the expense of an equivalent but much cheaper available alternative treatment (Avastin), would result in a substantial damage to EU national health care systems that can be estimated in hundreds millions euros.

Following the investigation recently conducted by the Italian Antitrust Authority on this case we ask the European Commission to carry out a similar investigation at a European scale, taking into account that the products in question have been centrally authorized by the European Medicines Agency and are available in most EU Member States. In particular we ask the European Commission to investigate if the above mentioned practices by Novartis and Roche violate Article 101 of the TFEU and if they cause detriment to consumers' health and welfare.

We remain at your disposal to further discuss our concerns.

Yours sincerely,

Monique Goyens
Director General