BEUC The European Consumer Organisation

The Consumer Voice in Europe

Ms. Margrethe Vestager
Commissioner
Competition
European Commission
Rue de la Loi, 200

B – 1049 Brussels

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Subject: Competition in the pharmaceutical sector

Dear Commissioner Vestager,

I write on behalf of The European Consumer Organisation (BEUC), to share with you our views on competition in the pharmaceutical sector.

In the Council conclusions on "Strengthening the balance in the pharmaceutical systems in the EU and its Member States" adopted in June 2016 the Council invited the European Commission to "*Continue and where possible intensify, including through a report on recent competition cases following the pharma sector inquiry of 2008/ 2009, the merger enforcement pursuant to the EC Merger Regulation (Regulation 139/2004) and the monitoring, methods development and investigation - in cooperation with national competition authorities in the European Competition Network (ECN) - of potential cases of market abuse, excessive pricing as well as other market restrictions specifically relevant to the pharmaceutical companies operating within the EU, such in accordance with Articles 101 and 102 of the Treaty on Functioning of the European Union*".

We understand the European Commission is currently drafting the above mentioned report and we would like to provide you with three cases of potential market abuse and excessive pricing that have been initiated by our Italian member Altroconsumo[1] and that we think should be further investigated at European level.

1. Aspen Pharma

On 14 October 2016, the Italian Antitrust Authority[2] fined the multinational pharmaceutical company Aspen Pharma for 5 million euros for abusing of its dominant position and fixing unfair prices for some of its products.

Alkeran (melphalan), Leukeran (chlorambucil), Thioguanin (thioguanine) and Purinethol (mercaptopurine) are life-saving and irreplaceable drugs used in the treatment of some forms of cancer (e.g. leukemia, non-Hodgkin lymphoma, multiple myeloma) especially among children and elderly people.

[1] file:///C:/Users/ipa/Downloads/Segnalazione%20Antitrust_Epatite%20C%20(12).pdf

[2] http://www.agcm.it/stampa/comunicati/8419-a480-rincari-di-farmaci-oncologici-antitrust-multa-la-multinazionale-aspen-per-5-milioni-di-euro.html

These products do not have a direct substitute and, despite the fact that their patents expired a long time ago, there is no generic version available either.

After purchasing this group of medicines from GlaxoSmithKline, Aspen Pharma started negotiations with the Italian Medicines Agency (AIFA) to obtain a significant price increase, despite the absence of any valid economic justification.

According to the Italian Antitrust Authority, Aspen Pharma adopted a particularly aggressive negotiating strategy which reached a climax when Aspen threatened to interrupt the supply of those medicines to the Italian market. By means of such negotiation, Aspen obtained a very high price increase, ranging between 300% and 1500% of the initial price, which AIFA would not have otherwise accepted.

2. Roche - Novartis

On 6 March 2014 the Italian Antitrust Authority[3] fined the pharmaceutical companies Roche and Novartis respectively 92 and 90,5 million euros for a cartel aimed at blocking the sale of an eye treatment 10 times cheaper than the one on the market. BEUC Italian member Altroconsumo took part to the case.

According to the Italian Authority the companies colluded to exclude the cheap drug Avastin (bevacizumab), used in the treatment of age related macular degeneration - the most common eyesight condition in the elderly - as well as other serious sight problems, and channel demand towards the much more expensive drug Lucentis (ranibizumab).

According to available scientific studies[4] the two products are equally effective to treat age related macular degeneration. Also the European Medicine Agency Committee for medicinal Products for human use CHMP agreed that *"detailed safety information provided from the CATT and IVAN studies is reassuring and no evidence can be provided that bevacizumab is systemically more unsafe than ranibizumab and vice-versa"* [5].

The Italian Antitrust Authorities' report is unequivocal. The excerpts of correspondence between Roche and Novartis' representatives clearly show that the two companies set up specific strategies to artificially distinguish the two products and to unduly influence the choice of doctors and healthcare systems. The anticompetitive agreement caused the Italian National Health Service to sustain additional expenses estimated at over EUR 45 million in 2012, while increased future costs might exceed EUR 600 million per year. Due to the economic crisis, many EU Member States face difficulties in paying for medicines and ensuring access to treatments. This makes such practices even more deplorable.

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[3] http://www.agcm.it/trasp-statistiche/doc_download/4112-i760-provvedimento.html

[4] - Comparison of Age-related Macular Degeneration Treatments Trials (CATT) Research Group, Ophthalmology Volume 119, Number 7, July 2012.
- Alternative treatments to inhibit VEGF in age-related choroidal neovascularisation: 2-year findings of the IVAN randomised controlled trial, The Lancet, July 2013.

[5] EMA/CHMP/332848/2012 - CHMP Type II Variation Assessment Report, "Avastin Report".

3. Gilead

According to a report[6] of the US Senate, the pharmaceutical company Gilead adopted a pricing strategy to maximise revenue for its Hepatitis C medicine Sovaldi and prepare the market for its other even higher priced anti-Hepatitis C product, Harvoni - with no consideration of the consequences on consumers' health. Thanks to its strategy Gilead maintained a dominant position on the market also after similar products became available. Moreover, Gilead imposed to the EU medicines agencies a price which is, in our view, disproportionate in relation of the costs for research and development it sustained to bring the product on the market.

These practices undermine consumers' access to essential medicines and put profits before people health.

Taking into account that all the products in question are used in many Member States, we ask the European Commission to investigate if the above mentioned practices have been adopted in other EU countries in violation of Article 102 a) of the Treaty on the Functioning of the EU and if they caused detriment to consumers' health and welfare.

We remain at your disposal to discuss this further.

Yours sincerely,

Monique Goyens
Director General

C/c: Dr. Vytenis Andriukaitis – Commissioner for Health and Food Safety

[6]https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20(Full%20Report).pdf