



## THE COMPETITION COUNCIL SANCTIONED ROCHE ROMANIA WITH FINES OF 12,8 MILLION EURO

The Competition Council sanctioned the pharmaceutical company Roche Romania SRL with fines totalling lei 59,967,944 lei (Euro 12,857,897) for abuse of dominant position on the market of oncological products in Romania. The sanctions were applied following two investigations opened in 2017.

In the first investigation, the competition authority found that between 2017 and 2019, Roche manufacturer adopted a commercial strategy aimed at eliminating competition during the auctions and at delaying the entry of similar medicines on the market.

During 2017, Roche's behaviour manifested in the context of participating in the centralized public procurement for medicines containing the Rituximab and Trastuzumab substances within the National Oncology Program as well as in 47 tenders organized at the hospital level for supplying the same medicines.

In order to avoid to monopolize the medicine distribution market, the legislation in force provides that a manufacturer is obliged to supply medicines to at least three distributors.

Thus, although Roche marketed the medicines containing Rituximab and Trastuzumab to the partner distributors, who were also competitors in these auctions, the price offered to the distributors was higher than its offered price.

In this way, Roche eliminated the competition in the auction because the distributors were not able to participate in these procedures under reasonable conditions so that to ensure them to carry out their activity effectively and profitably.

At the same time, this strategy was motivated by the intention to delay and make harder the access to the market of similar drugs containing Rituximab and Trastuzumab substances (Mabthera and Herceptin) competing with Roche products.

The medicine distributors did not sell exclusively Roche products and, as a result, if they would have won a tender for medicines containing active substances Rituximab and Trastuzumab, during the contract they could have replaced Roche products with similar, cheaper medicines of other manufacturers.

As a result, Roche's actions created certain barriers to market entry, with closing effects, thus delaying the appearance of biosimilar alternatives, which contributed to strengthening the dominant position of Roche.

"This strategy implemented during the participation in the public procurement procedures to delay the access on the market of biosimilar products affects the CNAS budget allocated to the national oncology program. Thus, by reimbursing the price of innovative drugs, it pays significantly higher costs in comparison with those for cheaper biosimilar medicines. Therefore, the saving achieved by the Ministry of Health is apparent in short term, we estimate that, in the case of the national auction, in long term, the biosimilar alternatives could bring savings of approx. 7.1 million Euro to the budget of the national oncology program" said Mr. Bogdan Chirițoiu, President of the Competition Council.

For this behaviour, Roche was sanctioned with fine of lei 44,168,105 (9.47 million Euro).

The medicines having the active substances Rituximab, Trastuzumab and Bevacizumab are used for several oncological disease, including: chronic lymphocytic leukaemia, breast cancer, ovarian cancer, kidney cancer, s.a.

In the second investigation, the Competition Council found that, in the same period of 2017 - 2019, Roche implemented a strategy to prevent the selling of competing, cheaper medicines containing the active substance Erlotinib.

The Roche strategy included the directing the patients to their most expensive product, Tarceva, through the Roche Patient Card and the Roche Call Center, and covering the price difference that patients should have had to pay when purchasing Tarceva, in order for them not to buy another similar medicine. Through the budget allocated for reimbursement of Tarceva, the state would have been able to reimburse for more similar medicines for patients. Thus, according to estimates, they have allocated additional amounts of more than 2 million lei from the National Health Insurance Fund (UNFASS) budget for the reimbursement of the medicine produced by Roche, unless the patients would have opted for a similar alternative of the same medicine.

"The companies producing innovative medicine need to focus on developing and placing new, more efficient medicines on the market to bring improvements to the patients' condition and not on exploiting the patent medicine for which there are cheaper alternatives" said the President of the Competition Council.

For this behaviour, Roche Romania SRL was sanctioned with 15,799,839 lei (3,387,688 Euro).

Tarceva is a medicine that contains the active substance Erlotinib and is used in the treatment of lung cancer and pancreatic cancer.

The innovative medicine is a new medicine protected by the patent when it is launched on the market.

The generic medicine contains the same active substance in the same amount as the innovative medicine.

We recall that the competition authority has drawn attention several times (following the analysis of the pharmaceutical market) that the penetration rate of generic (cheaper) medicines is lower than in other EU countries, although they are with at least 35% cheaper than their innovative variants.

During the investigations, the Competition Council carried out unannounced inspections at the company headquarters, the documents raised being analysed in the specific procedure. The unannounced inspections are authorized by the Bucharest Court of Appeal and are justified by the need to obtain all the information and documents necessary to clarify the possible anti-competitive behaviour.

The competition authority's decision will be published in a non-confidential form on the institution's website, [www.consiliulconcurentei.ro](http://www.consiliulconcurentei.ro) and can be appealed to the Bucharest Court of Appeal.

January 2020

**Press Office:**

Tel: 0372.129.710; 021.405.44.02; email: [presa@consiliulconcurentei.ro](mailto:presa@consiliulconcurentei.ro)

