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The Turkish Competition Authority imposes fines on two pharmaceutical companies for engaging in concerted practices to expand the use of a specific drug *(Roche / Norvatis)*

ANTICOMPETITIVE PRACTICES, AGREEMENT (NOTION), CONCERTED PRACTICES, MARKET SHARING, RELEVANT MARKET, PHARMACEUTICAL, SANCTIONS / FINES / PENALTIES, TURKEY

Turkish Competition Authority, *Roche / Norvatis*, Case 21-04/52-21, 22 January 2021 (Turkish)

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e-Competitions News Issue Preview

The Turkish Competition Board ("Board") decided that Novartis and Roche violated Article 4 of the Law No. 4054 on the Protection of Competition ("Law No. 4054") by way of engaging in concerted practice to expand the use of Lucentis as opposed to Altuzan, both of which are the drugs used for the treatment of eye diseases, while Lucentis is more expensive than Altuzan [***1***].

In its competitive assessment, the Board firstly examined whether Altuzan and Lucentis can be considered as competing products. Having found that Altuzan and Lucentis are competing products, the Board assessed that the conducts of Novartis and Roche amount to a concerted practice and imposed administrative fines on the said undertakings.

Background

The preliminary investigation against Novartis and Roche was initiated based on an application for complaint of 22.01.2019. The complainant stated that Roche and Novartis engaged in a cartel to expand the use of Lucentis, which is more expensive than the drug named Altuzan. The applicant referred to certain authorities' decisions including the decision of the Italian Competition Authority dated 27.02.2014 [*2*] ("ICA's Decision") which found that Roche and Novartis violated Article 101 of the Treaty on the Functioning of the EU through their Italian subsidiaries that made an anti-competitive agreement to expand the use of Lucentis and to increase the doubts about the security of using Altuzan for the treatment of macular degeneration (i.e. an eye-related disease).

Altuzan is the registered drug of Roche whose active ingredient is Bevacizumab (i.e. an anti-VEGF molecule). Bevacizumab has been developed by Genentech Inc. ("Genentech"), a wholly owned subsidiary of Roche, for the use in oncological treatment. However, Bevacizumab has also been tested for the treatment of age-related macular degeneration. According to Roche, upon the observation of the side-effects of Bevacizumab arising in the treatment of age-related macular degeneration, Genentech developed Ranibizumab (i.e. an anti-VEGF molecule) for the relevant treatment. As the Board noted in the decision, Genentech has transferred the marketing and sales rights of Altuzan (Avastin) containing Bevacizumab to Roche, and transferred the marketing and sales rights of Lucentis containing Ranibizumab to Novartis (outside the USA). Lucentis is the registered drug of Novartis whose active ingredient is Ranibizumab and is used for the treatment of age-related macular degeneration. Accordingly, under the license agreement signed between Genentech and Novartis, Novartis pays licensing fees to Genentech. Hence, the said licensing fees are indirectly paid to Roche.

With respect to the relationship between Roche and Novartis, the Board also noted that the holding company of Novartis (i.e. Novartis AG) has a minority shareholding in the holding company of Roche (i.e. Roche AG) which does not confer any control rights.

The Assessment on the Relevant Product Market

In its analysis on whether Altuzan and Lucentis can be considered in the same relevant product, the Board assessed the information submitted by the parties, scientific studies and relevant foreign authorities' decisions (including ICA's Decision considering the two relevant drugs as substitutes even if Altuzan is used off-label and the decision of the High Court of Justice in the UK [*3*] stating that the relevant drugs can be used as substitutes) as well as reports published by the relevant authorities [*4*] and analysed the information given by the ophthalmologists to decide on the demand-based substitutability relationship.

After the assessment of the information obtained from these sources, the Board found that the side-effects and success of the active ingredients of the two drugs in the treatment of macular degeneration are similar. The Board also noted that although Lucentis are used more prevalently by ophthalmologists, this is not because they think that Altuzan is less effective or has more side effects than Lucentis. Hence, the Board reached the conclusion that Altuzan and Lucentis can be used as substitutes to each other and in fact, Altuzan is preferable for reducing the public's medicine expenditures as it is lower priced. Against this background, the relevant product market is defined as: "anti- VEGF molecules administered intraocularly" and the medicines that fall under this relevant product market are stated to be: Altuzan, Lucentis, and Eylea.

The Board's Finding of Violation

In its assessment on the violation, the Board firstly highlighted the substitutability of the relevant two drugs and stated that Bevacizumab was the first anti-VEGF molecule used in the relevant eye treatments both in the world and in Turkey. [*5*] The Board then noted that the use of Bevacizumab for the relevant treatment is very common in most countries. Hence, the Board decided that the findings based on the scientific studies, practices of doctors, public regulations, and court decisions follow that Bevacizumab should have been commonly used for eye treatments. Accordingly, the Board found that Roche's inaction to actively utilize the sales potential of Altuzan, which has a lower price, in this area is not reasonable for an undertaking operating independently based on its the strategic and commercial benefits. Indeed, Roche acted on the contrary and stated that Bevacizumab is not suitable for such a treatment. In this regard, the Board emphasized that since Genentech is the subsidiary of Roche, Roche generates turnover from the sales of Lucentis (the competitor product) through the licensing fees paid by Novartis to Genentech.

As for the parties' conducts, the Board noted, among others, that;

- Roche applied to Turkish Medicines and Medical Devices Agency for including the following explanation to the usage instructions of its own product, i.e. Altuzan: "Altuzan is not suitable for intravitreal use." although in the original document relevant to the same drug, it is only stated that the drug "is not formulated for intravitreal use". The Board noted that a drug can be suitable for a certain treatment although it is not formulated for that particular treatment.

- Novartis sued for the cancellation of the amendment in the Communiqué on Healthcare Practices requiring the use of Bevacizumab for the first stage of the treatment of macular degeneration.

- An association of undertakings whose members include Novartis and Roche also sued for the cancellation of the relevant amendment and such an association of undertaking is expected to act in the interest of Roche.

- Novartis spread the misleading information to defame Altuzan before doctors and administrative/judicial authorities.

- A document on Lucentis' marketing strategy containing commercial secrets has been seized during the on-site inspection in Roche. The Board noted that since such a document cannot be obtained from publicly available sources, it showed the existence of conduct between Roche and Novartis and raised the doubt that Roche supports the marketing of Lucentis.

The Board also referred to the ICA's Decision imposing 90 million EUR administrative fine on both Novartis and Roche for the reason that they tried to create a wrongful perception that Avastin (Altuzan) and Lucentis are different, and decided that, Novartis and Roche acted in the same way as underlined in the ICA's Decision and the relevant conducts were part of a strategy pursued by the undertakings globally.

All in all, the Board decided that Novartis and Roche engaged in a concerted practice for the purposes of deterring the use of Altuzan and shifting the demand to Lucentis.

The Board then made an assessment under the Article 5 of the Law No. 4054 on whether an individual exemption may be granted to the conducts of the investigated undertakings. On this note, the Board stated that considering the substitutability between Altuzan and Lucentis, the agreement between the parties is of a horizontal nature. The Board then noted that agreements that restrict the competition and that are unlikely to create economic benefits cannot satisfy the exemption conditions. In the case at hand, the Board assessed that the agreement between Roche and Novartis on expanding the use of Lucentis excessively restricted competition as the conducts of the undertakings as per the agreement caused the doctors who are not sensitive to the prices not to use Altuzan. This has led to a significant increase in the healthcare costs and significant damages to consumers. Accordingly, the Board concluded that Novartis and Roche cannot benefit from an individual exemption under the Article 5 of the Law No. 4054.

As for the defense of the undertakings, one of arguments raised by the parties was that the ICA's Decision should not be taken as a reference. Accordingly, Roche submitted that EU countries with long-established competition policies such as Germany, England, Belgium, Sweden, and Spain have not made similar claims as regards to the practices of Roche and Novartis and that the investigation/Parties' conduct/market in Italy are quite different than those in Turkey. The Board responded to these arguments by stating that the fact that there no similar claims about the relevant undertakings in other countries do not mean that the Board cannot examine a valid claim in

Turkey. The Board also stated that the ICA's Decision was not the mere source of judgment and the Board decided by evaluating the conduct and market in Turkey while the ICA's Decision underlines the fact that the said undertakings follow the same strategy globally.

Finally, Roche and Novartis also argued that the Board failed to provide any evidence showing the common will, contact or communication between the parties which may be used as evidence for cartel. In response to this, the Board stated that the infringement in the case at hand concerns a concerted practice as opposed to a cartel. Accordingly, the parties allocated the market so that Altuzan would only be used for cancer treatment and would not be used in the market where Lucentis is sold. Also, according to the Board, the customers in the relevant market that are public bodies and doctors who create the demand were indirectly allocated based on misleading information. Hence, there was concerted practice which is governed under the cartel section of the Regulation on Fines to Apply in Cases of Agreements, Concerted Practices and Decisions Limiting Competition, and Abuse of Dominant Position ("Regulation on Fines").

The Board's Assessment on the Monetary Fine

With respect to the determination of the fine, the Board took into consideration the duration of the violation. The Board analyzed that the infringement have begun on 29.12.2011 when Roche applied to Turkish Medicines and Medical Devices Agency to add an explanation of "Altuzan is not suitable for intravitreal use." to Altuzan's usage instructions. The last finding about the infringement is the e-mail of 22.03.2019 internally circulated in Novartis which includes a presentation about the defamation on the use of Altuzan in the treatments of eye diseases. Consequently, the Board decided that the starting point of reference for determining the duration of the violation and the expiry dates are 28.12.2011 and 22.03.2019 and therefore the Board concluded that the violation lasted more than 7 years. Since the violation lasted more than 5 years, the Board applied an aggravated fine on both Novartis and Roche in light of the Regulation on Fines.

Conclusion

Overall, the Board's Novartis and Roche decision is important as it constitutes a recent example of (i) how the Board evaluated the developments in other jurisdictions and (ii) how the Board evaluated the conducts in the pharmaceutical industry as concerted practice. Further, the Board's approach as to the substitutability of two drugs and the duration of violation is noteworthy.

[*1*] The Board's Novartis-Roche decision dated 21.01.2021 and numbered 21-04/52-21.

[*2*] Autorità Garante della Concorrenza e del Mercato, decision no. 24823, proceedings I760 RocheNovartis/Farmaci Avastin e Lucentis, 27.02.2014.

[*3*] In the High Court of Justice, Queen's Bench Division Administrative Court, Neutral Citation Number: [2018] EWHC 2465 (Admin), Case Nos: CO/5288/2017, CO/5357/2017, Londra, *https://www.bailii.org/ew/cases/EWHC/Admin/2018/2465.html*

[4] ee e.g. a report published by the European Commission available at *https://ec.europa.eu/health/sites/health/files/files/documents/2017_02_28_final_study_report_on_off-label_use_.pdf*

[5] David Hutton, Paula Anne Newman-Casey, Mrinalini Tavag, David Zacks, and Joshua Stein, "Switching To Less Expensive Blindness Drug Could Save Medicare Part B $18 Billion Over A Ten-Year Period", 10.1377/hlthaff.2013.0832 HEALTH AFFAIRS 33, NO. 6 (2014): 931.