competition commission
south africa

Press Release
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COMPETITION COMMISSION PROSECUTES A MULTINATIONAL HEALTHCARE COMPANY, ROCHE, FOR EXCESSIVE PRICING OF A BREAST CANCER TREATMENT DRUG

The Competition Commission has today filed a referral with the Competition Tribunal for prosecution of Switzerland based multinational healthcare company, Roche Holding AG ("Roche AG"), and its subsidiaries, F Hoffman La Roche AG ("Roche Basel") and Roche Products (Pty) Ltd ("Roche SA"), for alleged excessive pricing of a breast cancer treatment drug, Trastuzumab, in contravention of sections 8(a) and 8(1)(a); of the Competition Act.

The Commission's referral also alleges that the excessive price of Trastuzumab constitutes a violation of basic human rights including the right of access to healthcare enshrined in the Bill of Rights as it denies access to life saving medicine for women living with breast cancer.

The alleged excessive pricing of Trastuzumab by Roche took place in both the private and public healthcare sector in South Africa. Trastuzumab is a first line treatment life-saving drug which stops the development of an aggressive type of breast cancer called Human Epidermal Growth Factor Receptor 2 Positive (" HER2+") breast cancer. Trastuzumab is used to stop the development of these tumour cells to prevent the cancer from spreading and death. In South Africa, Trastuzumab is sold under Roche's brand name Herceptin in the private healthcare sector, and under the brand name Herclon in the public healthcare sector.

The Constitutional Court has recently endorsed the centrality of the Bill of Rights to the interpretation of the Competition Act. Consequently, the Commission further found that Roche's conduct also infringed several constitutional rights which include the right to equality under section 9 of the Constitution, the right of access to healthcare services under section 27 of the

Constitution, the right to dignity under section 10 of the Constitution, and the right to life under section 11 of the Constitution.

The Commission's investigation found that the excessive pricing conduct took place between January 2011 and November 2020 in the South African private healthcare sector, and in the South African public healthcare sector during the period 9 November 2015 to July 2020. In view of the fact that Roche had declined to provide the Commission with its cost data (despite the Commission pursuing all available legal channels, including the diplomatic channels), allegedly on the basis that, that cost data sits in Switzerland, the Commission considered three competitive benchmarks in its assessment, namely:

- Trastuzumab biosimilar manufacturing cost estimates – Commission relied on a body of knowledge that provides a calculation algorithm to estimate the manufacturing cost of Trastuzumab biosimilars;

- Prices of a biosimilar drug supplied in South Africa – Commission relied on the price of a biosimilar drug supplied in both the private sector and public sector South Africa since 2019. A biosimilar medicine is one that has the same active properties and similar clinical outcomes as an originator biologic medicine; and

- Value-based price benchmarks – The Commission relied on ratios estimating the additional value/benefit attributable to Trastuzumab against the income per capita (a proxy of the affordability of Trastuzumab).

The Commission estimated that over 10 000 breast cancer (HER2+) patients (nearly 50% of the total number of newly infected patients in the private and public healthcare sectors) were unable to receive treatment with Trastuzumab between 2011 and 2019 because of the excessive prices Roche charged for the medicine.

"The Commission has prioritized this case because the impact of excessive pricing of Trastuzumab falls heavily on women, particularly poor women, who cannot access essential treatment because they cannot afford to pay for it. This is so even for the minority of women who belong to medical schemes. The Commission is obligated to pursue this case in light of the fundamental rights implicated by the conduct, all of which are enshrined in our Constitution.

The Commission has asked the Tribunal to impose a maximum penalty against Roche, for its alleged harmful and life-denying pricing conduct," says Competition Commissioner Tembinkosi Bonakele.

[ENDS]

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BACKGROUND:

On 13 June 2017, the Commissioner initiated a complaint against Roche AG and Genentech Incorporated (a wholly-owned subsidiary of Roche AG) in terms of section 49B(1) of the Act for an alleged contravention of sections 8(a), 8(c) and 9(1) of the Act.
On 6 December 2021, the Commissioner amended its complaint initiation to include Roche Basel and Roche SA for an alleged contravention of sections 8(a), 8(c) and 9(1) of the Act.
The alleged contravention relates to the sale and supply of the drug Trastuzumab. Trastuzumab is sold under Roche's brand names Herceptin and Herclon, and is used in the treatment of an aggressive type of breast cancer called Human Epidermal Growth Factor Receptor 2 Positive ("HER2+") breast cancer.
The Commission's investigation found that the excessive pricing conduct took place between January 2011 and November 2020 in the South African private healthcare sector, and in the South African public healthcare sector during the period 9 November 2015 to July 2020. In view of the fact that Roche had declined to provide the Commission with its cost data (despite the Commission pursuing all available legal channels, including the diplomatic channels), allegedly on the basis that, that cost data sits in Switzerland, the Commission considered three competitive benchmarks in its assessment, namely:

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- Value-based price benchmarks – The Commission relied on ratios estimating the additional value/benefit attributable to Trastuzumab against the income per capita (a proxy of the affordability of Trastuzumab).

The competitive benchmarks used by the Commission show that Roche's pricing of Trastuzumab is significantly out of kilter with all the above three comparator benchmarks. Competitive price benchmarks are price benchmarks used to assess whether the price of a product is excessive.

In its findings, the Commission found the prices charged by Roche for Trastuzumab in South Africa were unreasonably high and at unaffordable levels which impeded access this live-saving drug by patients suffering from breast cancer both in the private and public healthcare sectors. For example, a 12-month course of Herceptin in the private sector costs approximately R355 000 for 17 cycles of treatment for a period of one year. In the public sector, an equivalent treatment with Herclon costs approximately R160 000.

In the private sector, the excessive cost of Herceptin impeded access to patients on medical schemes in mainly two ways.

- Firstly, Herceptin was only offered to medical aid members with comprehensive medical aid cover prior to Herceptin being included as a PMB since March 2019. Patients on non-comprehensive schemes, typically lower-income members, therefore had to pay for the drug out-of-pocket if they wished to obtain access to it.

- Secondly even patients on comprehensive medical cover were, because of the excessive prices charged by Roche, subjected to higher co-payments for treatment with Herceptin than they would otherwise have had to pay, which also restricted access to this life-saving medicine.

In respect of the public healthcare sector, the Commission's findings show that, if Government had been able to purchase Trastuzumab at a reasonable price, a substantial number of patients would have accessed the life-saving drug.

The Commission also found that the excessive prices charged by Roche for Trastuzumab could not be justified even when allowing for reasonable compensation for research and development ("R&D") and innovation.

The Commission estimated that over 10 000 HER2+ patients (nearly 50% of the total number of newly infected patients in the private and public healthcare sectors) were unable to receive treatment with Trastuzumab between 2011 and 2019 because of the excessive prices Roche charged for the medicine. The impact of excessive pricing of Trastuzumab falls heavily on women, particularly poor women, who cannot access essential treatment because they cannot afford to pay for it. This is so even for the minority of women who belong to medical schemes.