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Excessive pricing in the Pharma sector on the spotlight: The European Commission makes legally binding Aspen's price commitments

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On 10 February 2021, the European Commission ("EC") launched its highly anticipated decision by accepting and making legally binding the commitments¹ offered by Aspen Pharmacare Holdings Limited² and Aspen Pharmacare Ireland Limited ("Aspen") under Article 9 of Council Regulation ("EC") No. 1/2003. The investigation covered the whole of the European Economic Area ("EEA"), including Greece, with the exception of Italy, where the national competition authority had already fined Aspen €5 million in September 2016 for abusing its dominant position for the same medicines. Aspen has to reduce its prices in Europe for six critical cancer medicines by 73% on average and shall ensure the continued supply of these off-patent medicines for a significant period. This is the first excessive pricing case of the EC in the pharmaceutical sector. A Commitments decision does not constitute an

acknowledgement of infringement of EU competition law but legally binds the committing companies to respect the commitments they have offered.

Background to the case

On 15 May 2017, the EC initiated a formal investigation³ against Aspen for an alleged infringement of Article 102 of the Treaty on the Functioning of the European Union ("TFEU") by abusing its dominant position in several national markets by: (a) imposing unfair and excessive⁴ pricing practices regarding six crucial off – patent cancer medicines, containing active pharmaceutical ingredients (APIs)⁵ and (b) unfair and abusive negotiation practices with national authorities and/or parallel trade restrictions between Member States. In particular, Aspen's pricing

¹ https://ec.europa.eu/competition/antitrust/cases/dec_docs/40394/40394_5192_3.pdf.

² Aspen Pharmacare Holdings Ltd is a global pharmaceutical company headquartered in South Africa with several subsidiaries in the EEA.

³ See [here](#).

⁴ Excessive pricing is prohibited under Article 102 (a) of TFEU as an exclusionary practice. Excessive pricing results to deadweight loss of consumer welfare and allocative inefficiency. According to the Court of Justice ruling in *United Brands*, Case 27/76, *United Brands Company and United Brands Continental BV v EC Commission*, ECLI: EU:C: 1978:22, a dominant firm's price is excessive "if it has no reasonable relation to the economic value of the product supplied".

⁵ Namely, chlorambucil, melphalan, mercaptopurine, tioguanine and busulfan.

practices concerned cancer medicines, notably under the brand names Alkeran, Leukeran and Purinethol, mainly used in the treatment of rare hematological cancers. Some of these medicines are used only by small patient groups, such as elderly and frail. The EC, in order to access alleged **excessive pricing**, in essence deployed the *UBC* two – pronged legal test, whereby, if the price is found excessive when compared to its costs, it is examined if the price is unfair in itself or when compared to other competing products. According to the EC's preliminary assessment on Aspen's accounting data, it seemed that after the price increases, Aspen has persistently earned very high profits from its sale of these medicines in the EEA, both in absolute terms and in relevant terms. In particular, Aspen's prices exceeded its relevant costs of producing and selling the medicines by almost three hundred percent (300%) on average, that is, prices were almost four times the level of Aspen's costs, even after accounting for a reasonable rate of return. Additionally, Aspen's average EEA-wide profit levels were more than three times higher than the average profitability levels of a selection of similar, comparable businesses in the pharmaceutical industry.

Aspen's average profit levels were also higher than any of the Comparators individually. It is true that very high profit margins may be economically justified in some cases e.g., to

recoup significant investments into innovation, however, according to the EC's investigation this was not the case here (there was no commercial risk-taking activity, no investment in innovation - these medicines had been off-patent for 50 years-, Aspen did not materially improve the medicines or their distribution).

With reference to the abusive negotiations practices, according to the EC, Aspen managed to impose such excessive prices because patients and doctors had no alternatives to using these essential cancer medicines. The EC found that *inter alia* Aspen threatened even to withdraw the medicines from the national list of reimbursable medicines and in some cases was ready to even withdraw from normal supply in the market.

The legally binding Commitments:

- ❖ Aspen will reduce its net prices across the EEA for the six cancer medicines by an average of approximately 73%, which is (on average) below the price levels of 2012, before Aspen's price increases started;
- ❖ The reduced prices will be the maximum prices that Aspen can charge for a period of ten years from the entry into force of all the commitments; The prices in the commitments are net maximum prices, therefore Aspen is free to charge lower prices, after agreement with the national health authorities of the Member States;

- ❖ Aspen has committed to continue supply the relevant medicines for the next five years in all countries of the EEA where they are currently commercialized and, for an additional five-year period, will either continue to supply them or make its marketing authorisation available to other suppliers.

Next steps

The commitments apply with retroactive effect from 1 October 2019 and in that context Aspen will grant a transitory rebate to each appropriate beneficiary⁶ in the amount of the difference between Aspen's actual net sales and its hypothetical net sales had those same quantities been sold at the reduced net prices for the relevant products in each relevant country. The commitments will remain in force for a period of ten years and an independent trustee will monitor their implementation.

Aftermath of the decision

Aspen's decision is the first decision within the EC refers to excessive pricing in the pharmaceutical sector. Competition authorities are reluctant to engage in excessive pricing cases⁷, as the application of the "pricing" test raises several difficulties of

policy⁸ and of actual quantification. However, it seems that the EC assessed this legal basis as appropriate and necessary to tackle the particular issue regarding public health. On the other hand, the EC took the step to resolve this Art. 102 case with commitments, aiming for significant, immediate and long-lasting price decreases for all the medicines and all the countries covered by the preliminary investigation, as well as continued supply of the medicines covered by the decision. The speedy resolution of the problems that arose in the market by virtue of commitments fit well with the Commission's 'Pharmaceutical Strategy for Europe', seeking to ensure access to quality and safety of medicines, at the same time boosting the sector's competitiveness, and the Commission's Beating Cancer Plan⁹. Commissioner's Vestager stated that the decision provides clear guidance on the parameters on which prices are excessive¹⁰. Indeed, bright lines on what consists "excessive pricing", more than forty years since the *United Brands* ruling, are required¹¹.

⁸ *Inter alia*, cf. the repeatedly asserted statement that competition authorities do not act as price regulators.

⁹ https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_521.

¹⁰ https://ec.europa.eu/commission/presscorner/detail/en/statement_21_526.

¹¹ National competition authorities have also revisited the concept of excessive pricing in the pharmaceutical sector. See for example the recent CMA's investigation on in the supply of drugs used to treat bipolar disorder, available at <https://www.gov.uk/government/news/cma-to-investigate-the-supply-of-bipolar-drug>.

⁶ The beneficiaries are public and private entities in the Member States that ultimately paid or reimbursed Aspen's medicine prices. In Greece, Aspen will pay the Transitory Rebate to the Pharmaceutical Research and Technology Company (IFET) via a credit note.

⁷ OECD, DAF/COMP (2011) 18, "Excessive Pricing", p. 9, available at <http://www.oecd.org/competition/abuse/49604207.pdf>.

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