C/2024/6858

15.11.2024

Summary of Commission Decision

of 22 July 2024

relating to a proceeding under Article 102 of the Treaty on the Functioning of the European Union

(Case AT.40577 - VIFOR IV iron products)

(notified under document number C(2024) 5027)

(Only the English text is authentic)

(C/2024/6858)

On 22 July 2024, the Commission adopted a decision relating to a proceeding under Article 102 of the Treaty on the Functioning of the European Union. In accordance with the provisions of Article 30 of Council Regulation (EC) No 1/2003 ([1]), the Commission herewith publishes the names of the parties and the main content of the decision having regard to the legitimate interest of undertakings in the protection of their business secrets.

1. INTRODUCTION

(1) This Decision makes legally binding the Commitments offered by Vifor Pharma Participations Ltd. (as the economic successor of Vifor Pharma Ltd.), Vifor Pharma Management Ltd. and Vifor Pharma Deutschland GmbH (hereinafter referred together as 'Vifor') under Article 9 of Council Regulation (EC) No 1/2003 ('Regulation 1/2003') in a proceeding under Article 102 of the Treaty on the Functioning of the European Union (the 'Treaty').

2. PROCEDURE

(2) On 20 June 2022, the Commission opened proceedings with a view to adopting a decision under Chapter III of Regulation 1/2003 and, on 8 April 2024, adopted a preliminary assessment as referred to in Article 9(1) of Regulation 1/2003 which sets out the Commission's preliminary competition concerns (the 'Preliminary Assessment').

(3) On 16 April 2024, Vifor submitted commitments (the 'Initial Commitments') to the Commission in response to the Preliminary Assessment.

(4) On 22 April 2024, a notice was published in the *Official Journal of the European Union* pursuant to Article 27(4) of Regulation 1/2003, summarising the case and the Initial Commitments and inviting interested third parties to give their observations on the Initial Commitments within one month following publication.

(5) On 8 May 2024 and 27 May 2024, the Comission informed Vifor of the observation(s) received following publication of the notice. On 13 June 2024, Vifor submitted an amended proposal for commitments (the 'Final Commitments').

(6) On 4 July 2024, the Advisory Committee on Restrictive Practices and Dominant Positions was consulted and issued a favourable opinion.

(7) On 5 July 2024, the Hearing Officer issued his final report.

3. THE COMMISSION'S COMPETITION CONCERNS

(8) In the Preliminary Assessment, the Commission expressed competition concerns that Vifor (i) may may have held a dominant position in a number of national markets within the European Economic Area (the 'EEA') for the provision of intravenous ('IV') iron medicines, namely Austria, Germany, The Netherlands, Sweden, Spain, Finland, Ireland, Portugal and Romania (the 'Relevant Member States'); and (ii) may have abused such position by disseminating to healthcare

([1]) OJ L 1, 4.1.2003, p. 1. Regulation as amended by Regulation (EC) No 411/2004 (OJ L 68, 6.3.2004, p. 1).

professionals ('HCPs') ([2]) information that may have been objectively misleading about the safety of an IV iron medicine – namely Monofer sold by Pharmacosmos A/S ('Pharmacosmos') – which is the closest competitor of Vifor's flagship product in Europe, Ferinject. In particular, the evidence on the Commission's file suggests that, from 2010 and at least until 2022, Vifor disseminated in the Relevant Member States two main messages about the safety of Monofer, namely that (i) Monofer bears the serious safety risks historically associated with IV iron dextran compounds; and (ii) Monofer has an increased risk of hypersensitivity reactions ('HSRs') compared to Ferinject.

(9) According to the Commission's Preliminary Assessment, these messages may have been objectively misleading and not reflective of competition on the merits, as they were based on inaccurate and/or incomplete information not supported by appropriate scientific evidence, which was presented in a manner that was capable of confusing HCPs, instilling doubts in their minds as to Monofer's safety. In addition, these messages were capable of creating a negative perception of Monofer's safety and, as such, of discrediting it in the eyes of HCPs. The Commission also reached the preliminary view that these messages were capable of producing exclusionary effects and had no objective justification. Vifor's practices may have hindered Monofer's market entry and/or market uptake, raising concerns as to its compatibility with Article 102 of the Treaty.

4. INITIAL COMMITMENTS, THE MARKET TEST AND THE FINAL COMMITMENTS

(10) The Initial Commitments offered by Vifor consist of two main obligations, i.e. the so-called 'Required Conduct' and the 'Prohibited Conduct' which can be summarised as follows:

— The 'Required Conduct' ([3]) is a comprehensive, multi-channel communication campaign, the main purpose of which is to rectify and undo the potential effects of the messages previously disseminated by Vifor regarding the safety of Monofer. It involves the dissemination of a succinct and factual communication (the 'Stakeholder Communication') ([4]) clarifying that there is no basis to consider Ferinject to have a superior safety profile, nor to call into question Monofer's safety. It also clarifies that Monofer is not a dextran, dextran-derived or dextran-based product and does not have an increased risk of HSRs compared to Ferinject. As part of the Required Conduct, Vifor commits to (i) disseminate the Stakeholder Communication to approximately 180 000 HCPs in the Relevant Member States ([5]) via email, mail and in-person meetings; (ii) publish prominently on Vifor's website(s) the Stakeholder Communication for a period of 36 months; (iii) publish the Stakeholder Communication in leading medical journals in each of the Relevant Member States; ([6]) and (iv) allow third parties to use the Stakeholder Communication.

— The 'Prohibited Conduct' ([7]) prevents Vifor, for a period of 10 years across the entire EEA, from engaging in external promotional and medical communications, in writing and orally, about Monofer's safety profile containing information that is neither based in Monofer's Summary of Product Characteristics ('SmPC') nor derived from randomised, controlled clinical head-to-head trials. Vifor also commits to implement a number of measures and safeguards to ensure compliance with the Prohibited Conduct, including setting up (i) internal mechanisms to ensure that all relevant external promotional and medical communications, as well as internal training materials are in line with the commitments prior to their use; (ii) internal mechanisms to address any isolated unauthorised miscommunications; (iii) a dialogue process between Vifor and Pharmacosmos, as well as the trustee in charge of monitoring Vifor's compliance with the commitments, to enable Pharmacosmos to raise and discuss any potential deviations of the commitments and (iv) annual internal compliance trainings and annual certification of compliance with the Prohibited Conduct.

([2]) HCPs refer to healthcare professionals involved in the prescription, procurement or dispensing of IV iron, such as doctors, nurses, midwives and pharmacists, as well as to representatives of tender authorities and other procurement bodies.
([3]) Initial Commitments, Section II.
([4]) Initial Commitments, Appendix 1.
([5]) Initial Commitments, Appendices 3 and 4.
([6]) Initial Commitments, Appendix 5.
([7]) Initial Commitments, Section III.

(11) In addition, the Initial Commitments prohibit Vifor from circumventing, directly or indirectly, any obligations contained therein ([8]). Finally, the Initial Commitments include reporting obligations on Vifor's implementation of the commitments, ([9]) as well as the monitoring of Vifor's compliance with the commitments by an independent monitoring trustee ([10]).

(12) There was one respondent to the market test, who generally welcomed the Initial Commitments and believed they would address the preliminary concerns expressed by the Commission, subject to a couple of minor suggestions to clarify the scope of the non-circumvention clause and to ensure consistency between the text of the Q&A document annexed as Appendix 2 to the Initial Commitments and the Stakeholder Communication annexed as Appendix 1.

(13) In response to these observations, Vifor submitted the Final Commitments addressing the limited comments received, as well as a few additional minor amendments concerning notably the relevant legal entities offering the Final Commitments, the timing of the communication campaigns, the introduction of an additional campaign by post for those HCPs whose email addresses are not available, a mechanism to identify leading medical journals and the deadline for addressing unauthorised communications.

5. **CONCLUSION**

(14) The Commission considers that the Final Commitments effectively meet the competition concerns identified in its Preliminary Assessment without being disproportionate.

(15) First, as regards effectiveness, the Required Conduct is designed to address any potential on-going anticompetitive effects of Vifor's past conduct on the market in the Relevant Member States through the implementation of a restorative communication campaign dispelling the implied safety risks associated with Monofer, which is particularly relevant in a rapidly expanding market. This will be ensured by the concise and straightforward nature of the Stakeholder Communication, the extensive coverage of the HCPs targeted by the Required Conducted and the multi-channel nature of the communication campaign.

(16) On the other hand, the Prohibited Conduct is designed to prevent the future dissemination of misleading messages, directly or indirectly, for a period of 10 years across the entire EEA, by prohibiting any oral or written communications on Monofer's safety that is neither based on Monofer's SmPC nor derived from head-to-head randomised controlled trials.

(17) In addition, Vifor committed to a number of measures and safeguards which will ensure compliance with the Prohibited Conduct and also raise awareness on good promotional and medical communications practice within the company, further minimising the risk of misconduct in the future.

(18) Second, as regards proportionality, Vifor has not offered less onerous commitments in response to the Preliminary Assessment that would address the Commission's concerns adequately.

(19) In light of the Final Commitments offered by Vifor, the Commission considers that there are no longer grounds for action on its part.

([8]) Initial Commitments, Section IV.
([9]) Initial Commitments, Section V.
([10]) Initial Commitments, Section VI.