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The AMF Enforcement Committee fines a biotech company for failing to disclose inside information as soon as possible, and one of its co-founders and one of its shareholders for unlawful disclosure or use of inside information

In its decision of 24 March 2022, the Enforcement Committee imposed a fine of €1 million on AB Science for failing to disclose inside information as soon as possible, relating to the strong likelihood of receiving an unfavourable opinion for a marketing authorisation application for a medicinal product. It also imposed fines of €50,000 and €500,000 on Olivier Hermine, co-founder of AB Science, and Grégory Pépin, one of its shareholders, for having respectively unlawfully disclosed and used this same information, and another inside information also relating to a marketing authorisation application for another medicinal product. However, the Committee cleared another co-founder of the company of alleged use of one of this inside information.

The Enforcement Committee was asked to investigate two breaches of inside information relating to the strong likelihood that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) would issue a negative opinion on the marketing authorisation application for masitinib, AB Science's flagship product, for treating

mastocytosis (the first information) and for treating amyotrophic lateral sclerosis (ALS) (the second information).

The Committee considered that the first information had become precise in nature, not as from 7 March 2017, the date specified in the statements of objection, but on 7 April 2017, the date on which AB Science had received the report of the CHMP rapporteurs analysing the company's last answers to their questions, and concluding that the application for marketing authorisation should be refused. The Committee found that this information had only been made public on 17 May 2017, and that it was likely to have a significant impact on AB Science share price, noting that financial analysts presented AB Science's research into the treatment of mastocytosis as one of the essential data to be taken into account in determining the share price, and that AB Science's communication to investors was in line with this view. It further pointed out that the clinical study for the treatment of mastocytosis was, at that time, one of AB Science's most advanced clinical studies, with the objective of obtaining its first marketing authorisation in human medicine. The Committee concluded that this information was considered inside information from 7 April 2017, and remained so until 17 May 2017, when it was made public by AB Science.

As regards the breaches relating to this information, the Committee first held that AB Science had not demonstrated that it had a legitimate interest in deferring its disclosure and that it had therefore breached its obligation to make it public as soon as possible. It then found that Mr Hermine, co-founder of AB Science, co-chairman of its scientific committee and director of its clinical strategy, had breached its obligation to refrain from disclosing this insider information, noting that he had become aware of it through his duties and had then disclosed it to Mr Pépin, a shareholder of the company. It found that Mr Pépin had breached his obligation to refrain from using this inside information, both for actions taken on his own behalf and for those taken on behalf of investment funds. However, the Committee cleared another co-founder of AB Science of alleged use of this information, for operations made before the information became precise.

Regarding the second piece of information, concerning the strong likelihood of a negative opinion by the CHMP on the use of masitinib for treating ALS, the Committee noted that it became precise in nature on 21 March 2018, the date of the oral explanation meeting with the CHMP, which is the last adversarial stage in the examination of a marketing authorisation application, and at the end of which the members of the CHMP unanimously adopted a negative trend vote. The Committee also noted that this information was made public only on 19 April 2018. It also mentioned that the ALS clinical study was AB Science's most advanced programme at the time and the company had no marketing authorisation for human medicine. Furthermore, a year earlier, AB Science's share price had fallen following the announcement of the denial of the marketing authorisation application for masitinib in the treatment of mastocytosis. This information was therefore likely to have a significant

influence on AB Science share price. For the Committee, this was inside information as from 21 March 2018.

On the basis of serious, precise and consistent evidence, showing the existence of a plausible transmission circuit resulting from several exchanges between Mr Hermine and Mr Pépin, the timing of Mr Pépin's operations at stake, which began a few moments after the end of one of their telephone conversations, the atypical nature of his operations, and the lack of convincing justification to explain them, the Committee found that that the breaches of the obligations to refrain from disclosing and using inside information allegedly committed by Mr Hermine and Mr Pépin were clearly established.

An appeal may be lodged against this decision.

Main appeal lodged by the AMF's Chairman before the Paris Court of Appeal against decision 2022-03

By Judgement dated May 2, 2024 (22/09062), the Paris Court of Appeal (i) dismissed the main appeal lodged by the AMF's Chairman against the Enforcement Committee's decision of March 24, 2022 and (ii) reversed the said decision, but only insofar as it imposed a fine of one million euros on AB Science, and, ruling again, imposed a fine of 800,000 euros on this company.

Appeal lodged by AB Science before the Paris Court of Appeal against decision SAN 2022-03

By Judgement dated May 2, 2024 (22/09062), the Paris Court of Appeal (i) dismissed the main appeal lodged by the AMF's Chairman against the Enforcement Committee's decision of March 24, 2022 and (ii) reversed the said decision, but only insofar as it imposed a fine of one million euros on AB Science, and, ruling again, imposed a fine of 800,000 euros on this company.

About the Enforcement Committee

The Enforcement Committee, which is made up of judges and professionals, has total freedom to make decisions. It can impose sanctions on any person or company whose practices contravene laws and regulations that fall within the jurisdiction of the AMF. It ratifies settlement agreements signed by the Secretary General and respondents. And it takes

part in the AMF's educational efforts by clarifying financial regulations when explaining its decisions.

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SAN-2022-03 - Décision de la Commission des sanctions du 24 mars 2022 à l'égard de la société AB Science et de MM. Alain Moussy, Olivier Hermine, Grégory Pepin

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