C/2026/3748

10.7.2026

Communication from the Commission published pursuant to Article 27(4) of Council Regulation (EC) No 1/2003 in Case AT.40998 – Sanofi Efluelda

(C/2026/3748)

1. Introduction

(1) According to Article 9 of the Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty ([1]), the Commission may decide – in cases where it intends to adopt a decision requiring that an infringement is brought to an end and the parties concerned offer commitments to meet the concerns expressed to them by the Commission in its preliminary assessment – to make those commitments binding on the undertakings. Such a decision may be adopted for a specified period and shall conclude that there are no longer grounds for action by the Commission. According to Article 27(4) of the same Regulation, the Commission shall publish a concise summary of the case and the main content of the commitments. Interested parties may submit their observations within the time limit fixed by the Commission.

2. Summary of the Case

(2) On 26 June 2026, the Commission adopted a preliminary assessment within the meaning of Article 9(1) of Regulation (EC) No 1/2003 concerning an alleged infringement of Article 102 of the Treaty on the Functioning of the European Union ('TFEU') by Sanofi S.A. ('Sanofi').

(3) According to the preliminary assessment, Sanofi may be dominant in the national markets for enhanced seasonal influenza vaccines in Germany and France (the 'Relevant Member States'), which it serves with its vaccine 'Efluelda'. The Commission has concerns that Sanofi may have abused a dominant position in the Relevant Member States in violation of Article 102 of the TFEU by disseminating a range of misleading messages to healthcare professionals ('HCPs', such as the doctors or pharmacists ultimately responsible for ordering and administering vaccines), included in particular in promotional materials and other sales-oriented communication. By doing so, Sanofi may have impeded the uptake of the rival enhanced seasonal influenza vaccine 'Fluad', which is produced by its competitor Seqirus UK Limited. The evidence on the Commission's file suggests that Sanofi's conduct started in 2024, that Sanofi's possible infringement in France may have started later than in Germany, and that Sanofi's messaging may have been more intense in Germany than in France.

(4) In particular, the Commission has concerns in relation to the following types of messages disseminated by Sanofi to HCPs:

(a) Claims suggesting that the evidentiary basis for Fluad's performance is weaker than that for Efluelda, despite their evidentiary bases having been deemed comparably strong by public health bodies entrusted with the scientific assessment of vaccines and/or involved in the definition of public immunisation policies – specifically, the European Centre for Disease Prevention and Control ('ECDC'), as well as the German and French National Immunisation Technical Advisory Groups ('NITAGs'). NITAGs in Germany (that is, the *Ständige Impfkommission*, or 'STIKO') and France (*Haute Autorité de Santé*, or 'HAS') also recommended Efluelda and Fluad for the elderly, on an equal footing;

(b) Misleading representations of national vaccination recommendations (for example, incorrectly suggesting that Sanofi's Efluelda would be the only seasonal influenza vaccine recommended or designed for the elderly, while in fact also Fluad is indicated for this patient population and was recommended);

(c) Claims incorrectly suggesting that STIKO's national vaccination recommendation in favour of Fluad remained subject to unresolved scientific objections from medical professional societies, while STIKO had in fact reviewed such objections and ultimately discarded them on scientific grounds before adopting its recommendation.

([1]) OJ L 1, 4.1.2003, p. 1. With effect from 1 December 2009, Articles 81 and 82 of the EC Treaty have become Articles 101 and, respectively, 102 of the TFEU. The two sets of provisions are in substance identical. For the purposes of this notice, references to Articles 101 and 102 of the TFEU should be understood as references to Articles 81 and 82 of the EC Treaty when applicable.

(5) The Commission's preliminary assessment is that such messages (i) may be objectively misleading, as they contain inaccurate and/or incomplete information that is capable of confusing its addressees (including by inducing them in error) and of discrediting a competing product, and (ii) may be capable of producing exclusionary effects, and that such messages are not objectively justified. In the Commission's preliminary view, Sanofi's communication campaign could therefore be qualified as an abuse of a dominant position under Article 102 TFEU in the Relevant Member States.

3. **The Main Content of the Offered Commitments**

(6) Whilst not agreeing with the Commission's preliminary assessment, Sanofi nevertheless offered commitments pursuant to Article 9 of Regulation (EC) No 1/2003, to meet the Commission's preliminary competition concerns. The proposed commitments mainly consist of three obligations, which can be summarised as follows:

(a) First, Sanofi is committing to publish for 24 months a written communication on its German website, acknowledging the ECDC's and STIKO's assessment, and clarifying that STIKO has assessed the evidence base for Efluelda and Fluad, and concluded that they both had a robust evidence base and they could both be recommended. Sanofi will also send via email or mail this written communication to HCPs who were the subject of previous communication campaigns in Germany. In addition, Sanofi is committing to publish for 24 months a written communication on its French website, clarifying in particular that the HAS' most recent recommendation treats Fluad and Efluelda as equivalent;

(b) Second, until the end of March 2030, Sanofi is committing to include in certain marketing and promotional materials for Germany related to enhanced seasonal influenza vaccines a reference to the STIKO recommendation in force at the time of their publication, with a sufficiently comprehensive and legible citation;

(c) Third, until the end of March 2030 and for its communications with HCPs related to enhanced seasonal influenza vaccines in both Germany and France, Sanofi is committing not to: (i) criticise, cast doubt on or contradict the applicable national vaccine recommendations issued by the relevant NITAG; (ii) highlight negatively Fluad or suggest that Efluelda is safer or more effective, unless such suggestion is based on the summaries of product characteristics (SmPCs) approved by the competent health agencies at EU or national level or on head-to-head comparative studies meeting specified criteria; (iii) use statements suggesting or implying that the evidence base supporting Fluad is weaker than that supporting Efluelda, including through mischaracterisation or selective presentation of scientific studies involving Fluad. In relation to so-called Key Opinion Leaders, Sanofi is committing not to include statements prohibited by points (i) to (iii) above when providing them with input for their interactions with HCPs in France and Germany, and to include in its new contracts with such Key Opinion Leaders a clause referring to its commitments.

(7) These commitments should address the Commission's concerns identified in the preliminary assessment and are without prejudice to any additional current or future limitations imposed by any other applicable laws governing the promotion and/or advertising of pharmaceutical products.

(8) The commitments are published in full in English on the website of the Directorate-General for Competition at:

https://competition-cases.ec.europa.eu/cases/AT.40998

4. **Invitation to make Comments**

(9) Subject to market testing, the Commission intends to adopt a decision under Article 9(1) of Regulation (EC) No 1/2003 declaring binding the commitments summarised above and published on the Internet, on the website of the Directorate-General for Competition.

(10) In accordance with Article 27(4) of Regulation (EC) No 1/2003, the Commission invites interested third parties to submit their observations on the proposed commitments. These observations must reach the Commission not later than 21 August 2026. Interested third parties are also asked to submit a non-confidential version of their comments, in which any information they claim to be business secrets and other confidential information should be deleted and replaced as required by a non-confidential summary or by the words 'business secrets' or 'confidential'.

(11) The comments should be reasoned and should set out the relevant facts. If you identify a problem with any part of the proposed commitments, the Commission would also invite you to suggest a possible solution.

(12) Observations can be sent to the Commission under reference number **AT.40998 – Sanofi Efluelda** either by e-mail (COMP-GREFFE-ANTITRUST@ec.europa.eu) or by post, to the following address:

European Commission
Directorate-General for Competition
Antitrust Registry
1049 Bruxelles/Brussel
BELGIQUE/BELGIË