**CASE AUTH/3447/12/20**

# VOLUNTARY ADMISSION BY SANOFI

## Failure to certify material in relation to Dupixent

**Sanofi made a voluntary admission about the failure to certify material in relation to Dupixent (dupilumab).**

**As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Sanofi.**

**When responding to the allegations in Case AUTH/3402/10/20 Sanofi discovered that material on the 'www.dupixent.co.uk' website was not certified. The material at issues was a Sanofi document referring to Dupixent and the NICE technology appraisal guidance which was a downloadable resource on the website for health professionals.**

**Sanofi explained that the material was due for reapproval in early August 2020. During the period from end March to November 2020 there was a transitioning of a multitude of relevant materials to a new approval system. The decision being that any materials not transitioned by final shutdown were to be considered withdrawn and only materials approved on the new system, Veeva PromoMats were effective and 'live'. The Sanofi document referring to Dupixent and the NICE technology appraisal guidance had not been re-approved as it was no longer required. When the website was being transitioned to PromoMats, the job had still been 'live', so it was not noticed by the relevant employees that it was not certified/approved at the time of the webpage certification in mid-August 2020. The result of this was that the document was not in fact certificated on Veeva PromoMats when it appeared on the website.**

**Sanofi therefore self-declared a breach of Clause 14.1 of the Code.**

**The Panel noted that it appeared from Sanofi's response in Case AUTH/3402/10/20 that its document referring to Dupixent and the NICE technology appraisal guidance was certified on 2 August 2018 and according to Sanofi was due for reapproval in early August 2020.**

**The Panel noted Sanofi's submission that any materials not transitioned to Veeva PromoMats (between the end of March and November 2020) by final shutdown of Zinc were to be considered withdrawn and only materials approved on Veeva PromoMats were considered to be effective and 'live'. The Panel noted Sanofi's submission that its document referring to Dupixent and the NICE technology appraisal guidance had not been re-approved and was still 'live' when the website was being transitioned to PromoMats; the relevant employees had not noticed that it was not certified/approved at the time of the webpage certification. The result was that the document was not certified on Veeva PromoMats when it appeared on the website and at the time of the complaint in**

**Case AUTH/3402/10/20 (October 2020). The Panel therefore ruled a breach of the Code as acknowledged by Sanofi.**

Sanofi made a voluntary admission about the failure to certify material in relation to Dupixent (dupilumab).

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Sanofi.

## VOLUNTARY ADMISSION

When responding to the allegations in Case AUTH/3402/10/20 Sanofi discovered that material on the 'www.dupixent.co.uk' website was not certified. The material at issues was a Sanofi document referring to Dupixent and the NICE technology appraisal guidance which was a downloadable resource on the website for health professionals.

Sanofi explained that the material was due for reapproval in early August 2020. During the period from end March to November 2020 across the whole of Sanofi and Sanofi Genzyme there was a transitioning of a multitude of relevant materials from the Zinc system/platform, due to its pending withdrawal from use, onto the Veeva PromoMats platform as the new review and approval system. The decision being that any materials not transitioned by final shutdown of Zinc were to be considered withdrawn and only materials approved on Veeva PromoMats were effective and 'live'. An employee had not arranged for the document to be re-approved as he/she considered that it was not required for the appropriate teams for which it was first made available. When the website was being transitioned to PromoMats, the job had still been 'live', so it was not noticed by the relevant employees that it was not certified/approved at the time of the webpage certification (MAT-GB-2001592 (v1.0)) in mid-August 2020. The result of this was that Sanofi's document referring to Dupixent and the NICE technology appraisal guidance was not in fact certificated on Veeva PromoMats when it appeared on the website.

Sanofi therefore self-declared a breach of Clause 14.1 of the Code.

## RESPONSE

Sanofi stated that it had identified that the material in question had not been appropriately reapproved for use in the course of the investigation of the complaints related to Case AUTH/3402/10/20. Sanofi therefore self-declared a breach of Clause 14.1 of the Code in addition to a breach of Clause 7.2 in respect of the incorrect prescribing information in that case.

As part of Sanofi's response in Case AUTH/3402/10/20 it confirmed the processes and standard operating procedures in place which covered the development, approval and withdrawal of materials and recorded training for all relevant members of staff involved in these activities. Sanofi had no other explanation except for human error for the breaches noted in its response.

## PANEL RULING

The Panel noted that Clause 14.1 stated that promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by one person on behalf of the company in the manner provided for by this clause, subject to the provisions of the supplementary information to this clause where relevant. This person must be a registered

medical practitioner or a pharmacist registered in the UK or alternatively, in the case of a product for dental use only, a UK registered dentist. The person certifying on behalf of the company must not be the person responsible for developing or drawing up the material.

The Panel noted that Clause 14.5 stated, *inter alia*, that material which was still in use must be recertified at intervals of no more than two years to ensure that it continues to conform with the relevant regulations relating to advertising and the Code.

The Panel noted that it appeared from Sanofi's response in Case AUTH/3402/10/20 that its document referring to Dupixent and the NICE technology appraisal guidance (ref SAGB.DUP.18.06.0858(1))' was certified on 2 August 2018 and according to Sanofi was due for reapproval in early August 2020.

The Panel noted Sanofi's submission that any materials not transitioned to Veeva PromoMats (between the end of March and November 2020) by final shutdown of Zinc were to be considered withdrawn and only materials approved on Veeva PromoMats were considered to be effective and 'live'. The Panel noted Sanofi's submission that its document referring to Dupixent and the NICE technology appraisal guidance had not been re-approved and was still 'live' when the website was being transitioned to PromoMats; the relevant employees had not noticed that it was not certified/approved at the time of the webpage certification (MAT-GB-2001592 (v1.0)) in mid-August 2020. The result was that Sanofi's document referring to Dupixent and the NICE technology appraisal guidance was not certified on Veeva PromoMats when it appeared on the website and at the time of the complaint in Case AUTH/3402/10/20 (October 2020). The Panel therefore ruled a breach of Clause 14.1 as acknowledged by Sanofi.

**Complaint received** **22 December 2020**

**Case completed** **29 March 2021**