

CASE AUTH/3733/1/23

VOLUNTARY ADMISSION BY GRÜNENTHAL

Failure to retain documentation in relation to certification

CASE SUMMARY

This case was in relation to a voluntary admission about the retention of certified documentation.

Noting the importance of storing and maintaining certain documentation relating to certification in line with the requirements of the Code, that certification underpinned self-regulation, and its concern that Grünenthal had failed to conduct due diligence to ensure it met the standards expected in relation to the subject matter of the admission, the Panel ruled a breach of the following Clauses of the 2021 Code:

Breach of Clause 5.1	Failing to maintain high standards
Breach of Clause 8.6	Failing to preserve certificates and material in the form certified

**This summary is not intended to be read in isolation.
For full details, please see the full case report below.**

FULL CASE REPORT

A voluntary admission about the retention of certified documentation was received from Grünenthal. 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 Grünenthal Limited.

COMPLAINT

Grünenthal submitted a voluntary admission in which it stated that during a handover meeting for a departing colleague, it was found that a number of certified hard copy items along with signatures had not been returned and filed. This related to approximately 30 hard copy items. Grünenthal believed this related to Clause 8.6 of the 2021 Code and also to maintaining high standards. Grünenthal stated that it immediately set up a deviation from the SOP [Standard Operating Procedure] in the Quality Management System, and a root cause analysis was conducted. A combination of factors were identified: human error, organisational change, remote working and potentially the move to its new office contributed to this event.

Grünenthal identified Corrective and Preventative Actions, as listed in its response below.

When writing to Grünenthal the Authority asked it to consider the requirements of Clauses 5.1 and 8.6 of the 2021 Code as cited by Grünenthal in its voluntary admission.

RESPONSE

In response Grünenthal referred to breaches of Clauses 5.1 and 8.5 of the 2021 Code and listed its corrective and preventative actions.

- Grünenthal immediately conducted a review of certificates in the hard copy archive to ensure no other omissions. (Clause 8.5)
- The lead medical signatory attended the new office to review and counter sign re-prints of the already certified hard copy materials. Materials were up to date. (Clause 8.5)
- A monthly in-person, onsite, job bag review would be scheduled on the first Thursday of every month, between the medical and marketing teams to sign and archive all hard copy materials. (Clause 5.1)
- The medical lead and marketing leads had been informed that attendance was mandatory (or designated delegate). (Clause 5.1)
- The incoming Medical Director would revise the UK certification SOP to ensure the new process was adhered to. (Clause 5.1)
- Compliance would chair this meeting until the new Medical Director started in role in late February 2023. (Clause 5.1)

PANEL RULING

The Panel noted a voluntary admission had been received from Grünenthal in relation to the failure to retain certain certified documents. The Panel noted this related to approximately 30 certified hard copy items along with signatures which had not been returned and filed by a member of staff. This matter only came to light when the member of staff was carrying out a handover meeting prior to departure from the company.

The Panel noted Grünenthal had cited Clause 8.6 and referred to high standards in its original voluntary admission, dated January 2023, and the case preparation manager had asked Grünenthal to respond to Clauses 8.6 and 5.1 however, in Grünenthal's response letter, dated February 2023 the Panel noted Grünenthal referred to Clauses 8.5 and 5.1 of the 2021 Code. The Panel noted that the substance of Grünenthal's original admission and response related to Clause 8.6 and the Panel therefore considered the admission in relation to that Clause.

The Panel noted that Clause 8.6 stated, among other things, that companies must preserve certificates. Material in the form certified and information indicating the persons to whom it was addressed, the method of dissemination and the date of first dissemination must also be preserved. Companies must preserve certificates and the relevant accompanying information for not less than three years after the final use of the material or the date of the event/meeting and produce them on request from the Medicines and Healthcare products Regulatory Agency (MHRA) or the PMCPA.

The Panel noted that it did not have a copy of Grünenthal's relevant standard operating procedure. The Panel noted the importance of storing and maintaining certain documentation relating to certification in line with the requirements of Clause 8.6 the Code. The Panel considered that Grünenthal had failed to satisfy the requirements of Clause 8.6 and ruled a **breach of Clause 8.6** as admitted by Grünenthal.

The Panel was concerned that a significant number of materials (approximately 30 in total) had been identified by Grünenthal as not meeting the requirements of both internal processes and

those of the Code in relation to preservation of certificates and materials. The Panel considered that certification underpinned self-regulation and was concerned that Grünenthal had failed to conduct due diligence to ensure it met the standards expected in relation to the subject matter of the admission. The Panel noted Grünenthal's admission that high standards had not been maintained and ruled **a breach of Clause 5.1**.

Complaint received 30 January 2023

Case completed 15 November 2023