

Case AUTH/3799/7/23

VOLUNTARY ADMISSION BY GRÜNENTHAL

Failure to take the appropriate examination within the required timelines

CASE SUMMARY

This voluntary admission related to a Grünenthal employee, within its market access department whose role entailed calling upon health professionals, that did not take the appropriate ABPI Examination within the first year of employment as a representative, contrary to the requirements of Clause 9.4.

The outcome under the 2021 Code was:

Breach of Clause 9.4	Failing to take an appropriate examination within the first year of employment as a representative and passing it within two years of starting such employment
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**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 was received from Grünenthal.

VOLUNTARY ADMISSION

The voluntary admission wording is reproduced below:

“We are writing to inform you that a Grünenthal Ltd employee in the role of [job title] within our Market Access department did not start or take the appropriate ABPI Exam modules prior to the end of their first year of employment; contrary to the requirements of clause 9.4. This employee started their employment at the company in February 2022 however the employee completed their first module on 23rd April 2023 when in fact all modules should have been taken by 21st February 2023. This issue was discovered as part of an internal monitoring exercise and upon further investigation we have since discovered that the wrong date of starting industry was entered into the ABPI exams website.

The date entered in the ABPI website was 15th August 2022, which according to our records is the date the employee conducted an in-field call on a health professional (as opposed to their actual start date at Grünenthal & the industry). Subsequently the employee has informed us that has now completed all modules and has provided us with their certificate.

Although the employee has now passed all modules within the 2-year deadline i.e., prior to 21st February 2024, we recognise that our employee should have taken all modules by 21st February 2023 according to the corrected start date; and, if unable to do that, an

extension request should have been submitted. This was not done because this issue only very recently came to light following our internal monitoring exercise and further investigation carried out by our Interim Compliance Officer who started on 1st June 23. For your information, our previous Compliance Officer left Grünenthal on 28th April 23, so we were unfortunately without a dedicated resource for approximately one month.

Corrective and Preventative Actions

This issue has been escalated to our senior leadership team in UK and to our global compliance committee, to take necessary action. Further, following our ongoing internal investigation we will prepare and implement a corrective action plan, including process revision, training, and internal communications to ensure that this issue does not recur in the future.

Initially we have contacted the ABPI Exams team to inform them of the issue of the incorrect start date of the employee subject of this issue.

Grünenthal Ltd takes compliance with the Code of Practice very seriously and sincerely regrets the events described, we eagerly anticipate your response.”

When writing to Grünenthal, the Authority asked it to consider the requirements of Clause 9.4 of the Code.

GRÜNENTHAL'S RESPONSE

The response from Grünenthal is reproduced below:

“1. Summary of issue:

Following our voluntary admission letter of 14 July 2023, we are writing to provide our comments in accordance with the deadline set of 02 August 2023.

As previously explained, we believe that the employee should have taken all modules relevant to their role by 21 February 2023, which unfortunately did not happen.

2. Correction:

Employee subject of this case ‘employee’

- The employee has now provided their correct start date in the industry (21 February 2022) to the ABPI Exams team so that their records can be updated.
- The employee started their first module on 23 April 2023 and has now completed and passed all modules which is in advance of the 21 February 2024 deadline applicable (corresponding with their corrected start date) to pass all modules and achieve the examination.
- The employee has received guidance on the requirements of clause 9.4 and has been reminded of who to contact if they are unsure of something with regard to the Code.
- The employee will also receive refresher training on the Code of Practice and the Grünenthal Code of Conduct to ensure that they are full conversant with the requirements of both.

Conclusion of the monitoring exercise

The internal monitoring exercise that led to the discovery of this issue has now been concluded and we can confirm that all other existing employees that are required to pass the examination have now provided us with copies of their certificates to confirm that they have done so; with the exception of one employee who confirmed that they have passed the exam but is awaiting a new copy of their certificate.

3. Corrective & Preventative Actions**Changes in practice, made with immediate effect:**

The requirement to provide the Human Resources (HR) department with copies of certificates within 30 days of joining the company has been added to the onboarding checklist for all new employees who have already passed the examination.

New starters that are also new to the pharmaceutical industry will receive the correct deadline(s) for taking and subsequently passing their exams in writing from HR (in consultation with the Compliance Department 'Compliance'); once their start date is confirmed, along with written instructions to ensure that they enter the correct date when they register with the ABPI Examinations team.

The compliance induction training presentation given to all new starters at the company has been updated to ensure that all new starters are aware of the requirements of clause 9.4. specifically, and to remind them to check with their Line Manager, HR and / or Compliance if they are unsure about anything with regards to this obligation and the date(s) & timeline(s) that apply to them in their role.

Internal monitoring:

The progress of new starters will be monitored by their Line Manager, and HR on an individual basis, and Compliance will conduct a biannual monitoring exercise to check the examination status of all new employees to reduce the risk of this issue recurring in the future.

Policies, standard operating procedures:

The relevant internal policies and procedures will be updated to reflect the changes implemented above and will be communicated accordingly to all staff as soon as possible.

Communications:

Once Case AUTH/3799/7/23 is complete we will issue a communication to inform all staff, explaining what happened, and the actions that have, or will be taken to ensure that this issue does not reoccur in the future.

Once again, Grünenthal takes compliance with the Code of Practice very seriously and sincerely regrets the events described, however we are pleased that we have been able to address the issue and subsequently reduce the risk of future reoccurrence. We eagerly anticipate your response.”

PANEL RULING

The voluntary admission related to a Grünenthal employee within its market access department whose role entailed calling upon health professionals; Grünenthal submitted as part of an internal monitoring exercise, it was discovered that the employee did not start or take the appropriate ABPI Exam modules prior to the end of their first year of employment contrary to the requirements of Clause 9.4.

Grünenthal submitted that upon further investigation it was discovered that the employee's start date (August 2022) had been entered incorrectly into the ABPI examination website; it had subsequently informed the ABPI examinations team of the issue. Grünenthal had since implemented training, improved processes including the requirement for HR to send written deadlines for new starters and ensuring HR were provided a copy of the certificate those who had already passed the exam within 30 days of starting and a biannual monitoring exercise to check the examination status of all new employees. Internal policies and procedures were yet to be updated to reflect the changes implemented.

The Panel considered companies were expected to have robust policies and procedures in place to ensure compliance with the Code. In this regard, the Panel was concerned with the lack of measures in place which could have prevented the issue.

Clause 9.4 stated representatives must take an appropriate examination within their first year of employment as a representative and must pass it within two years of starting such employment. The relevant supplementary information allowed the Director to agree to an extension in the event of failure to take an appropriate examination within the first year, subject to the representative taking an examination within a reasonable time.

The Panel noted the employee started their employment in February 2022 and although they had passed all modules within the required two years, they had not taken the examination within the first year of their employment and no request for an extension had been submitted. The Panel therefore ruled a **breach of Clause 9.4**.

Complaint received **14 July 2023**

Case completed **12 August 2024**