CASE/0796/11/25

VOLUNTARY ADMISSION BY CSL SEQIRUS

Alleged failures to disclose grants

CASE SUMMARY

A voluntary admission was received from CSL Seqirus concerning payments made to a healthcare organisation between 2020 and 2022. CSL Seqirus had identified that three grants made to a healthcare organisation based in France had not been disclosed, or had been incorrectly disclosed, contrary to the Code which required the annual public disclosure of certain transfers of value made to healthcare organisations located in Europe. It had further identified that no documented approvals or formal agreements were in place for any of these payments.

The outcome under the 2019 Code was:

Breach of Clause 19.2 (x2)	**Failing to document and keep on record a grant to a healthcare organisation**
Breach of Clause 24.1	**Failing to publicly disclose certain transfers of value made to a healthcare organisation located in Europe**

The outcome under the 2021 Code was:

Breach of Clause 2	**Bringing discredit upon, or reducing confidence in, the pharmaceutical industry**
Breach of Clause 5.1 (x2)	**Failing to maintain high standards at all times**
Breach of Clause 23.2	**Failing to have a written agreement in place for a grant**
Breach of Clause 28.1 (x2)	**Failing to publicly disclose certain transfers of value made to a healthcare organisation located in Europe**

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 CSL Seqirus about the above.

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VOLUNTARY ADMISSION

The voluntary admission wording is reproduced below:

> "We are writing to inform you about a recently conducted internal investigation that resulted in a number of findings and subsequent breaches of the ABPI Code. The internal investigation was instigated following a grant application which was received in June 2025, reviewed and then rejected by the Local Grants and Donation Committee. However, the investigation led to the detection of previous payments to the applicant organisation.
>
> The findings of the internal investigation showed that Seqirus made grants to the [named healthcare organisation] based in France. The Chairman of the [named healthcare organisation] was acting on behalf of the [named disease fund] which would receive the funds to support the [named global respiratory illness data surveillance network], a collaborative research platform and its surveillance and research.
>
> The investigation found that Seqirus made the following payments to the [named healthcare organisation] between 2020 and 2022:
>
> - **£265,000** on 20 April 2021
> - **£365,000** on 14 June 2022
> - **£100,000** on 30 June 2022
>
> We further found that:
>
> - the £265,000 grant provided in 2021 and the £100,000 provided in June 2022 had not been disclosed
> - The £365,000 grant provided in June 2022 was incorrectly disclosed against [named intermediary party] rather than the ultimate recipient, the [named healthcare organisation].
> - There were no documented approvals, formal agreements, or appropriate disclosure in place associated with any of the above grants
>
> We would like to note that the Seqirus UK Donations and Grants SOP DOC-000991455 released in 2024, has introduced a robust governance mechanism to ensure full compliance with the ABPI Code. Under this framework, all requests for financial support must be submitted to the Local Grants & Donations Committee and are reviewed by a multidisciplinary panel comprising Ethics & Compliance, Medical, and Legal representatives.
>
> As mentioned above, this process was rigorously applied in recently when a funding request to support the [named disease fund] (affiliated with the [named healthcare organisation]) was formally rejected. The committee concluded that the request did not meet the criteria for a donation, grant, or research support under the ABPI Code. This decision stands in contrast to those historic practices between 2020 and 2022, when multiple payments were made to the same foundation, highlighting the lack of oversight and governance as described at the time.

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We are confident that the established 2024 SOP and process now enables effective governance and documentation of grants and donations, and we remain fully committed to ensure that no such deviations occur again in the future.

We are committed to ensuring that comprehensive additional training is delivered across all levels of the UK organisation. This will ensure understanding of the ABPI Code and strengthen awareness of governance expectations with respect to grants and donations. In addition, we are undertaking a review of our current processes to assess whether further enhancements are needed to prevent any future deviations and ensure continued compliance with both internal standards and external regulatory requirements.

We regretfully acknowledge breaches of the ABPI Code, specifically Clause 5.1, as high standards were not maintained; Clause 23.2, due to the absence of a formal written agreement; and Clause 28.2, as two years' worth of grants were not appropriately disclosed."

When writing to CSL Seqirus, the PMCPA asked it to consider the requirements of the following clauses:

14 and 30 June 2022 payments

Given that the 14 and 30 June 2022 payments would have required a written agreement at that time and to have been disclosed by 30 June 2023, the 2021 Code applied to these payments.

CSL Seqirus was asked to provide any further comments it might have on the 14 and 30 June 2022 payments in relation to the requirements of Clauses 2, 5.1, 23.2 and 28.1 of the 2021 Code.

20 April 2021 payment

Given that the 20 April 2021 payment would have required a written agreement at that time, the 2019 Code applied. However, given the disclosure of that payment would not have been required until 30 June 2022, the 2021 Code applied. CSL Seqirus was asked to provide any further comments it might have on this matter in relation to the 20 April 2021 payment and the requirements of:

- Clauses 2, 9.1 and 19.2 of the 2019 Code in relation to the absence of the written agreement (these are the 2019 Code equivalents of Clauses 2, 5.1 and 23.2 respectively of the 2021 Code).
- Clauses 2, 5.1 and 28.1 of the 2021 Code regarding the failure to disclose.

CSL Seqirus was asked to note that the case preparation manager had changed its proposed reference to Clause 28.2, to Clause 28.1 because the latter was the operative clause that required disclosure.

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CSL SEQIRUS' RESPONSE

The response from CSL Seqirus is reproduced below with some typographical errors corrected:

> "Thank you for your letter in which you notified us of your intention to progress our recent voluntary admission as a case.
>
> We have addressed your points as laid out in your letter.
>
> June 2022 payment
>
> Our internal investigation found that:
>
> - The £365,000 grant provided in June 2022, and paid on the 21st of June 2022, was incorrectly disclosed against [named intermediary party] rather than the ultimate recipient.
> - There were no documented approvals, formal agreements, or appropriate disclosure in place associated with any of the above grants
>
> We regretfully therefore accept breaches of clauses 2, 5.1, 23.2 and 28.1 of the 2021 Code in relation to the June 2022 payments.
>
> June 2020 payment
>
> We need to correct the date on this payment, the application form was from June 2020, with the payment made on 2nd July 2020.
>
> - The €100,000 grant provided in June 2020, paid on 2nd July 2020, had not been appropriately disclosed by the 30th of June 2021
> - There were no documented approvals, formal agreements, or appropriate disclosure in place associated with any of the above grants
>
> We regretfully accept breaches of clauses 2, 5.1, 23.2 and 28.1 of the 2021 Code in relation to the June 2020 and June 2022 payments.
>
> April 2021 payment
>
> Our internal investigation found that:
>
> - The £265,000 grant provided in April 2021 had not been appropriately disclosed by the 30th of June 2022
> - There were no documented approvals, formal agreements, or appropriate disclosure in place associated with any of the above grants,
>
> We regretfully therefore accept breaches of clauses 2, 9.1, 19.2 of the 2019 Code and clause 2, 5.1 and 28.1 of the 2021 Code in relation to the April 2021 payments.
>
> We have included all documentation relevant to these grants for your review, the application form is the only documentation we can locate other than financial records in relation to these grants.

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Seqirus had a presence on the executive committee, and our internal investigation has concluded that Seqirus employees did attend these committees during the period 2021-2022.

At the time these grants were made, no formal local internal governance existed. A local un-controlled document, the 'Navigator', was a reference document for UK employees, however as it was not controlled, we have no formal training records etc. We have included the 'Navigator' in force at the time of these grants.

As previously communicated, the Seqirus UK Donations and Grants SOP (DOC-000991455), released in 2024, introduced a robust governance framework to ensure full compliance with the ABPI Code. Under this SOP requests for financial support must be submitted to the Local Grants & Donations Committee and reviewed by a multidisciplinary panel comprising Ethics & Compliance, Medical, and Legal representatives.

We are confident that the 2024 SOP and process now provides effective governance and documentation for grants and donations. Nevertheless, we have initiated a detailed review of the SOP to ensure it remains fit for purpose and to deliver training to all relevant stakeholders upon launch of the updated SOP.

We also included our Transparency Reporting SOP, released in 2024 and currently under internal review to strengthen the process.

We previously committed ourselves to delivering comprehensive additional training across all levels of the UK organisation. We also reaffirm our commitment to correcting any entries on Disclosure UK and ensuring that all missing data from the past three years is entered into the Disclosure portal by the end of January 2026, with this timeline only in place due to the upcoming holiday season.

Finally, we remain committed to strengthening our employees' understanding of the ABPI Code and enhancing internal governance to ensure full compliance with the ABPI Code of Practice."

FURTHER INFORMATION FROM CSL SEQIRUS

On receipt of CSL Seqirus's initial response, it was noted that it's correction of the payment date for one of the grants, from June 2022 to July 2020, meant that the applicable Code was the 2019 Code instead of the 2021 Code. CSL Seqirus was subsequently asked to respond to Clauses 24.1, 19.2, 9.1 and 2 of the 2019 Code in relation to the July 2020 payment. CSL Seqirus' response is reproduced below:

"Thank you for your email received 23rd June 2026, in which you asked CSL Seqirus to confirm tis[sic] position regarding the 2020 payment and the requirements of the 2019 Code of Practice.

<u>June 2020 payment</u>

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The application was received in June 2020, and payment was made on 2nd July 2020. This transfer of value should have been disclosed in March 2021.

There were no documented approvals, formal agreements, or appropriate disclosure in place associated with this grant.

CSL Seqirus regretfully acknowledges that high standards have not been maintained.

We therefore acknowledge breaches of clauses 2, 9.1, 19.2 and 24.1 of the 2019 Code in relation to the June 2020 payment."

PANEL RULING

A voluntary admission was received from CSL Seqirus concerning payments made to a healthcare organisation between 2020 and 2022.

CSL Seqirus had identified through an internal investigation that three grants made to a healthcare organisation based in France, between 2020 and 2022, to support a collaborative research platform and its surveillance and research, had not been disclosed, or had been incorrectly disclosed. It had further identified that no documented approvals or formal agreements were in place for any of these payments.

The Panel noted that the Case Preparation Manager had considered this case to be an exception to the pilot limitation period policy and had proceeded to refer this case to the Panel for consideration.

The Panel considered each of the payments made to the healthcare organisation in turn.

<u>July 2020 payment</u>

CSL Seqirus originally submitted that a grant of €100,000 provided to the healthcare organisation in June 2022 had not been disclosed. However, CSL Seqirus later corrected the payment date to July 2020. The Panel noted that whilst the initial voluntary admission referred to £100,000, CSL Seqirus' response clarified the amount as €100,000, which the Panel accepted as the correct figure.

CSL Seqirus submitted this grant had not been appropriately disclosed by 30 June 2021 and there were no documented approvals or formal agreements in place for the grant.

CSL Seqirus submitted that the application was received in June 2020, therefore the Panel considered that the 2019 Code was applicable at the time.

Clause 19.2 of the 2019 Code stated that the provision of medical and educational goods and services in the form of donations, grants and benefits in kind to institutions, organisations or associations that are comprised of health professionals and/or that provide healthcare or conduct research are only allowed if, amongst other things, they are documented and kept on record by the company.

The Panel acknowledged CSL Seqirus' submission that no documented approvals or formal agreements were in place for this grant. CSL Seqirus submitted that the only documentation

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that it had been able to locate in relation to this payment was a financial record, which the Panel noted was a "Request for Payment" made on 30 June 2020. In the Panel's view, the request for payment did not constitute a record as required by Clause 19.2, and the Panel ruled a **breach of Clause 19.2** of the 2019 Code, as acknowledged by CSL Seqirus.

Clause 24.1 of the 2019 Code stated:

> *"Companies must document and publicly disclose certain transfers of value made directly or indirectly to health professionals and healthcare organisations located in Europe."*

Clause 24.2 of the 2019 Code stated that transfers of value covered by Clause 24.1 included *"donations, grants and benefits in kind provided to institutions, organisations and associations in accordance with Clause 19.1 and 19.2"*.

The Panel acknowledged CSL Seqirus' submission that this grant had not been appropriately disclosed by 30 June 2021. The Panel, therefore, ruled a **breach of Clause 24.1** of the 2019 Code, as acknowledged by CSL Seqirus.

April 2021 payment

CSL Seqirus submitted that a grant of £265,000 provided to the healthcare organisation in April 2021 had not been disclosed by 30 June 2022 and that there were no documented approvals or formal agreements in place for the grant.

As the application was made in April 2021, the 2019 Code was applicable in relation to the requirement for companies to document and keep a record of donations, grants or benefits in kind, as stated in Clause 19.2 of the 2019 Code.

The Panel acknowledged CSL Seqirus' submission that no documented approvals or formal agreements were in place for this grant. The only documentation that it had been able to locate in relation to this grant was a "gift request form for companies". In the Panel's view, the gift request form did not constitute a record as required by Clause 19.2. The Panel, therefore, ruled a **breach of Clause 19.2** of the 2019 Code, as acknowledged by CSL Seqirus.

Disclosure of this payment would have been due in June 2022, therefore the 2021 Code was applicable in relation to disclosure.

Clause 28.1 of the 2021 Code stated:

> *"Companies must document and publicly disclose annually certain transfers of value made directly or indirectly to health professionals, other relevant decision makers and healthcare organisations located in Europe. This includes any employee of a pharmaceutical company whose primary occupation is that of a practising health professional."*

Clause 28.2 of the 2021 Code stated that transfers of value covered by Clause 28.1 included *"donations and grants provided to healthcare organisations, institutions and other organisations in accordance with Clause 23".*

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The Panel acknowledged CSL Seqirus' submission that this grant had not been appropriately disclosed by 30 June 2022. The Panel, therefore, ruled a **breach of Clause 28.1** of the 2021 Code, as acknowledged by CSL Seqirus.

June 2022 payment

CSL Seqirus submitted that a grant of £365,000 provided to the healthcare organisation in June 2022 had been incorrectly disclosed against an intermediary party rather than the ultimate recipient, and that there were no documented approvals or formal agreements in place for the grant.

As the application was made in June 2022, the 2021 Code was applicable at the time.

Clause 23.2 of the 2021 Code stated that donations and grants to healthcare organisations, patient organisations or other organisations are only allowed if, amongst other things, there was a written agreement in place for each donation or grant.

The Panel acknowledged CSL Seqirus' submission that no documented approvals or formal agreements were in place for this grant. The only documentation that it had been able to locate in relation to this grant was a "gift request form for companies", which did not meet the requirements of this clause. The Panel, therefore, ruled a **breach of Clause 23.2** of the 2021 Code, as acknowledged by CSL Seqirus.

The requirements of Clause 28.1 of the 2021 Code with respect to disclosure are outlined above.

The Panel acknowledged CSL Seqirus' submission that this grant had been incorrectly disclosed against an intermediary party. The Panel noted that the intermediary was the [named intermediary party] and the ultimate recipient was the [named healthcare organisation], which was distinct and unrelated to the [named intermediary party]. The Panel, therefore, ruled a **breach of Clause 28.1** of the 2021 Code, as acknowledged by CSL Seqirus.

High standards (Clause 5.1)

The Panel noted that CSL Seqirus was asked to respond to Clause 9.1 of the 2019 Code (for the 2020 and 2021 grants) and Clause 5.1 (for the 2022 grant). As the clause regarding high standards was the same in both Codes, the Panel decided to make its overall rulings under Clause 5.1 of the 2021 Code.

The Panel noted CSL Seqirus' submission that at the time of the grants, no formal local governance existed. A reference document was available to UK employees which was in force at the time. This document stated that the award of a grant and the contractual agreement must be certified in advance. However, no formal training records could be provided by CSL Seqirus as the document was not controlled.

The Panel was concerned to note CSL Seqirus' failure to adequately document grants made to a healthcare organisation over a period of three years, contrary to the company's own reference document and the Code, and its lack of any formal UK policies at the time. The Panel considered that CSL Seqirus had failed to maintain high standards in relation to the requirement

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that companies must document and have written agreements in place for grants, and it ruled a **breach of Clause 5.1** of the 2021 Code, as acknowledged by CSL Seqirus.

The Panel noted that disclosure of transfers of value was an important part of self-regulation. The Panel noted that the transfers of value that had not been disclosed for payments made in 2020 and 2021 amounted to €100,000 and £265,000 respectively. The transfer of value that had been incorrectly disclosed amounted to £365,000.

The Panel noted that the reference document for UK employees stated that disclosure requirements applied to the provision of grants, and that transfers of value related to interactions with healthcare organisations with regard to grants must be disclosed. The Panel was concerned to note the company's failure to adequately document and therefore disclose these payments, contrary to the company's own reference document and the Code, over a period of three years, resulting in a failure to disclose an excess of £700,000 of payments. The Panel considered that the company had failed to maintain high standards in this regard, and it ruled a **breach of Clause 5.1** as acknowledged by CSL Seqirus.

Upholding confidence in the industry (Clause 2)

A ruling of a breach of Clause 2 was a sign of particular censure and was reserved for such use. The Panel decided to make a single overall ruling in relation to Clause 2 as multiple rulings were not proportionate in the circumstances of this case.

The Panel noted it's rulings of breaches of the Code above, and considered that the matters at issue did not relate to a single administrative error or isolated failure, but instead demonstrated multiple and prolonged deficiencies in the company's systems, governance and oversight.

Payments totalling an excess of £700,000 had been made to a healthcare organisation without the required documentation or public disclosure. CSL Seqirus had only become aware of the issue following a grant application from the same healthcare organisation in 2025, which had been reviewed and subsequently rejected by the company's Local Grants and Donations Committee.

CSL Seqirus failed to identify that there had been no valid written agreements in place with the healthcare organisation for a period of three years. Multiple payments to the healthcare organisation were made throughout that period. The Panel was concerned about the number of governance and oversight processes that had failed, including the company's arrangements for approving grants, maintaining accurate records, and ensuring the disclosure of transfers of value as required by the Code. In the Panel's view, the cumulative nature of these failings demonstrated wider systemic issues rather than an isolated occurrence.

The Panel noted the importance of transparency and thus the importance of disclosing transfers of value; in the Panel's view such disclosure contributed to public confidence in the arrangements between pharmaceutical companies and healthcare organisations. The Panel considered that the failure to disclose substantial payments to a healthcare organisation over a period of three years, compounded by the lack of appropriate documentation for these payments, was a serious matter such that it brought discredit upon, and reduced confidence in, the pharmaceutical industry. The Panel ruled a **breach of Clause 2**, as acknowledged by CSL Seqirus.

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Complaint received	**7 November 2025**
Case completed	**4 August 2026**

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