

CASE AUTH/3839/10/23

VOLUNTARY ADMISSION BY IPSEN

Failure to sit the ABPI medical representative examination

CASE SUMMARY

This voluntary admission related to an Ipsen employee whose role entailed calling upon health professionals in Northern Ireland, that had not taken the ABPI medical representative's examination.

The outcome under the 2019 Code was:

Breach of Clause 9.1	Failing to maintain high standards
Breach of Clause 16.3	Failing to take the appropriate examination for medical representatives

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

FULL CASE REPORT

Ipsen Limited made a voluntary admission about the medical representative examination.

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 Ipsen.

VOLUNTARY ADMISSION

The voluntary admission wording is reproduced below:

"I am writing to notify the Prescriptions Medicines Code of Practice Authority (PMCPA) of a breach of clause 9.4 of the ABPI UK Code of Practice 2021 (Code), (clause 16.3 in the 2019 Code at the time of the incident), by Ipsen. In line with paragraph 5.6 of the Constitution and Procedure I write this letter as a voluntary admission and invite the PMCPA to treat it as such, understanding that this will result in a complaint against Ipsen in line with paragraph 5.3.

The complaint is in relation to an Ipsen employee in a promotional role who called upon healthcare professionals (HCPs) in Northern Ireland to promote Ipsen medicines. We are not able to verify that the individual employee ('Employee A'), passed the required examinations in the specified timelines as outlined in clause 9.4 of the Code.

Employee A started employment with Ipsen in April 2016, originally in a promotional role that only covered Ireland. However, in January 2019 they moved into a new

commercial role as the UK [commercial role], Northern Ireland. This was a commercial role calling on HCPs to promote Ipsen prescription only medicines (POMS) and would be considered to fulfil the definition of a representative as outlined in clause 1.19 of the Code. Ipsen is cognisant of the requirements of clause 9.4 of the Code and the fact that Employee A had been calling on customers for over 15 months without our having verified that they had fulfilled the requirements of this clause.

Overview of Employment History for Employee A

We feel it is important to establish a timeline of employment history for Employee A, both inside and outside of Ipsen, and the consequent requirements in relation to clause 9.4 of the Code.

Employee A joined the pharmaceutical industry in [North America] in 1994 and took up a UK-based role in 1997 as a representative within the UK division of the same pharmaceutical company for a period of 6 months (May-November 1997). In Dec 1997, they moved into a training role in Northern Ireland and Scotland with the same company in what was most likely a non-promotional role. From 2001 to 2007 they worked for another UK-based pharmaceutical company, later transitioning to a third UK-based pharmaceutical company post-merger as a [commercial manager] (a promotional role) for Northern Ireland and [county in Scotland]. They then took on another representative role in Northern Ireland with that same pharmaceutical company from 2007 to 2016. During these roles as a representative, and prior to their employment at Ipsen, the requirements of the training/accredited representative examination (as now outlined in the 2021 Code under clause 9.4) should have been completed by Employee A.

Employee A moved to Ipsen in April 2016 as a commercial manager for [therapy areas] in Ireland. This was a promotional role but did not cover Northern Ireland or any other parts of the UK. They subsequently moved into a promotional role as UK [commercial role] for Northern Ireland in January 2019. We acknowledge that the requirements of clause 9.4 should have been fulfilled at this point and we confirm that up until this point in time (from January 2019 to April 2020) Ipsen had not applied to the director of the PMCPA for any training exemption.

We can confirm that during their time with Ipsen Employee A has received all relevant company training on policies and procedures alongside IPHA and ABPI Code of Practice.

Code and Ipsen UKI Compliance and Governance Committee

In December 2019, Ipsen set up a Compliance and Governance Committee (CGC) consisting of [UK senior employees for various departments] to oversee all aspects of company compliance and governance for UK and Ireland.

At the beginning of 2020, the training team in conjunction with the CGC began a review of Ipsen processes to support the onboarding of new Key Account Managers (KAMs) and ensure all relevant ABPI representative qualifications were in place. As part of this review, the CGC requested an audit to be undertaken of all existing Ipsen staff in customer facing roles who were required to sit the ABPI Representative Exam to ensure they met the requirements of clause 9.4 of the Code.

As part of this internal audit, all but one employee - Employee A - was found to have the necessary documentation in place to confirm compliance of clause 9.4 of the Code. For Employee A, there was no record of an ABPI certificate on file and neither could the ABPI confirm that Employee A had successfully completed the requirements of clause 9.4. Upon discovering this information, Employee A was immediately instructed to cease all promotional activity until a resolution could be found. That resolution included only being able to work in a non-promotional capacity.

Following review of the Ipsen process which unfortunately failed to identify Employee A as having not fulfilled the requirements of clause 9.4 of the Code when they transitioned through an internal move from Ireland to Northern Ireland, the CGC subsequently initiated the following CAPAs:

- Update current SOP and processes to ensure a robust documented process is put in place by HR to ensure that ABPI representative exam certificates (where required) are checked and recorded in the personal HR file of all new starters and existing employees transitioning to a promotional role. This has been put into place with immediate effect. This process also includes contractors filing temporary cover for a representative role e.g. during maternity/paternity cover.

Overview and Next Steps

Having provided a detailed overview of the current situation of a proactive internal audit identifying one employee only of not fulfilling the requirements of clause 9.4 of the Code and the resulting CAPAs put into place, Ipsen proposes the following actions:

- 1) A complaint is raised against Ipsen for a breach of clause 9.4 of the Code.

At Ipsen, we are constantly striving to adhere to the Code and maintain high standards at all times. Whilst Employee A should have fulfilled the requirements of clause 9.4 prior to their commencement of employment with us we recognise that as soon as Employee A moved into a UK representative role within Ipsen in January 2019, the requirements of clause 9.4 of the Code applied and, unfortunately, this was missed until early 2020. We hope the proactive discovery of this error, the swift and appropriate instruction to Employee A to cease all promotional activity, and the resulting CAPAs we have put into place provides reassurance to the PMCPA around our standards, policies and processes.”

When writing to Ipsen, the PMCPA asked it to consider the requirements of Clauses 9.1 and 16.3 of the 2019 Code which was the applicable Code when the breach took place. The case preparation manager noted the wording in the 2021 Code was similar for Clauses 5.1 and 9.4.

IPSEN'S RESPONSE

The response from Ipsen is reproduced below:

“Further to your correspondence on the 16th October in connection with Ipsen Limited’s (Ipsen) voluntary admission to breaching the ABPI Code of Practice (**Code**) (as communicated by Ipsen by email on 16th October), please find set out herein our

response to the clause breaches you have asked us to consider, being clauses 16.3 and 9.1 of the 2019 Code.

As outlined in our original communication, the complaint relates to an Ipsen employee who, for a period of their current employment at Ipsen, was in a promotional role and calling upon healthcare professionals (HCPs) in Northern Ireland to promote Ipsen medicines. We have not been able to verify that the individual employee (**Employee A**) passed the required examinations in the specified timelines as outlined in clause 16.3 of the 2019 Code.

Employee A started employment with Ipsen in April 2016, originally in a promotional role that only covered Ireland and, therefore, not subject to the training requirements of the ABPI Code. However, in January 2019, they moved into a new commercial role as the UK [commercial role], Northern Ireland. This was a commercial role calling on HCPs to promote Ipsen prescription only medicines (**POMS**), and would be considered to fulfil the definition of a representative as outlined in clause 1.7 of the 2019 Code. Ipsen is cognisant of the requirements of clause 16.3 of the 2019 Code and the fact that Employee A had been calling on customers for over 15 months without our having verified that they had fulfilled the requirements of this clause.

1. Considerations to breaching clause 16.3 of the 2019 Code

In relation to clause 16.3 of the 2019 Code, Ipsen admits to a voluntary breach of this clause. However, in making this admission, we feel it is important to re-establish a timeline of employment history for Employee A, both inside and outside of Ipsen, and the consequent requirements in relation to clause 16.3 of the 2019 Code.

Employee A joined the pharmaceutical industry in [North America] in 1994, and took up a UK-based role in 1997 as a representative within the UK division of that same pharmaceutical company for a period of 6 months (May-November 1997). In December 1997, Employee A moved into a training role in Northern Ireland and Scotland with the same company in, what was most likely, a non-promotional role. From 2001 to 2007, Employee A worked for another UK-based pharmaceutical company, later transitioning to a third UK-based pharmaceutical company post-merger as a [commercial manager] (a promotional role) for Northern Ireland and [county in Scotland]. They then took on another representative role in Northern Ireland with that same pharmaceutical company from 2007 to 2016. During these roles as a representative, and prior to their employment at Ipsen, the requirements of the training/accredited representative examination (as outlined in the 2019 Code under clause 16.3) should have been completed by Employee A.

Employee A moved to Ipsen in April 2016 as a commercial manager for [therapy areas] in Ireland. This was a promotional role but did NOT cover Northern Ireland or any other parts of the UK and, therefore, not subject to the training requirements of the ABPI Code. They subsequently moved into a promotional role as UK [commercial role] for Northern Ireland in January 2019. We acknowledge that, at this point, the requirements of clause 16.3 should have been fulfilled and we confirm that, up until this point in time (from January 2019 to April 2020), Ipsen had not applied to the director of the PMCPA for any training exemption.

We can confirm that during their time with Ipsen, Employee A has received all relevant company training on policies and procedures alongside IPHA and ABPI Code of Practice.

Code and Ipsen UKI Compliance and Governance Committee

In December 2019, Ipsen set up a Compliance and Governance Committee (**CGC**) consisting of [UK Senior Employees for various departments] to oversee all aspects of company compliance and governance for UK and Ireland.

At the beginning of 2020, the training team in conjunction with the CGC began a review of Ipsen processes to support the onboarding of new Key Account Managers (KAMs) and ensure all relevant ABPI representative qualifications were in place. As part of this review, the CGC requested an audit to be undertaken of all existing Ipsen staff in customer facing roles who were required to sit the ABPI Representative Exam to ensure they met the requirements of clause 16.3 of the 2019 Code.

As part of this internal audit, all but one employee - Employee A - was found to have the necessary documentation in place to confirm compliance of clause 16.3 of the 2019 Code. For Employee A, there was no record of an ABPI certificate on file and neither could the ABPI confirm that Employee A had successfully completed the requirements of clause 16.3. Upon discovering this information, Employee A was **immediately** instructed to cease all promotional activity until a resolution could be found. That resolution included being able to work in a non-promotional capacity only, with Employee A commencing a training role.

Following review of the Ipsen process which, unfortunately, failed to identify Employee A as having not fulfilled the requirements of clause 16.3 of the 2019 Code when they transitioned through an internal move from Ireland to Northern Ireland, the CGC subsequently initiated the following Corrective and Preventative Actions (**CAPAs**):

- Update current SOP and processes to ensure a robust documented process is put in place by HR to confirm that ABPI representative exam certificates (where required) are checked and recorded in the personal HR file of all new starters and existing employees transitioning to a promotional role. This has been put into place with immediate effect. This process also includes contractors filling temporary cover for a representative role e.g. during maternity/paternity cover.

2. Considerations to breaching clause 9.1 of the Code

Although Ipsen is making this voluntary admission to breaching clause 16.3 of the 2019 Code, we believe the circumstances around this breach, including prior employment and the CAPA actions we have taken, do not merit a ruling of breaching clause 9.1 of the 2019 Code (failing to maintain high standards).

- Ipsen takes compliance, and its obligations under the Code, very seriously. That is why Ipsen had put into place a Compliance and Governance Committee (**CGC**) in late 2019. It was through the actions of this CGC that an internal audit was carried out, in which we identified the breach of clause

16.3 and Employee A was immediately discharged of her duties in a promotional capacity. The CGC then undertook a root cause analysis and put appropriate CAPAs into place including updates made to our current SOP and processes. As a result, we have maintained full compliance to this matter ever since.

- Requirements for clause 16.3, and similar clauses outlined in previous Codes, should have been fulfilled by Employee A prior to her employment with Ipsen. As noted above, Employee A was employed in multiple roles with other UK pharmaceutical companies where she had been calling on UK Health care professionals in a promotional capacity, between 1997 and 2016
- When Employee A commenced employment with Ipsen, it was initially only covering Ireland and the requirements of the IPHA Code had been fulfilled. She also completed a number of company trainings in relation to holding a promotional role. We did not check if Employee A had completed an external accredited ABPI Code of practice training as she was taking on a role only calling on HCPs in Ireland and not the UK. It was only on moving to a new promotional role in 2019 that she commenced calling on UK based HCPs with the geography of her role expanded to cover Northern Ireland. Unfortunately, we did not check her credentials in relation to clause 16.3 of the 2019 Code at this time and this gap was proactively identified in the root cause analysis and subsequent CAPAs put into place by Ipsen's CGC, including the immediate instruction to Employee A to cease all promotional activity.

Overview and Next Steps

Having provided a detailed overview of the current situation, the fact that a proactive internal audit identified one employee only of not fulfilling the requirements of clause 16.3 of the 2019 Code and the resulting CAPAs which were put into place, Ipsen voluntarily admits to a breach of clause 16.3 of the 2019 Code.

At Ipsen, we are constantly striving to adhere to the Code and maintain high standards at all times. We hope the proactive discovery of this error, the swift and appropriate instruction to Employee A to cease all promotional activity, and the resulting CAPAs we have put into place provides reassurance to the PMCPA of our high standards, robust policies and processes and there being no breach of clause 9.1 of the 2019 Code."

PANEL RULING

The voluntary admission related to a UK Ipsen employee whose role entailed calling upon health professionals in Northern Ireland; Ipsen submitted as part of its review to support the onboarding of new sales representatives and ensuring all relevant ABPI representative qualifications were in place, it had conducted an audit of all existing Ipsen staff in customer facing roles who were required to sit the ABPI Representative Exam. Ipsen submitted as part of its internal audit, one employee was found to have no record of an ABPI certificate on file and was immediately instructed to cease all promotional activity.

A representative was defined in Clause 1.7 of the 2019 Code as someone who called on members of the health professions and administrative staff in relation to the promotion of medicines. In the Panel's view, such people would often have job titles other than 'representative' and noted Ipsen acknowledged the employee's commercial role would be considered to fulfil the definition of a representative.

Clause 16.3 stated that representatives must pass the appropriate ABPI representatives examination. They must take the appropriate examination within their first year of such employment. Prior to passing the appropriate examination, they might be engaged in such employment for no more than two years, whether continuous or otherwise. The relevant supplementary information gave the Director discretion to grant an extension in the event of failure to comply with either time limit subject to the representative taking or passing the examination within a reasonable time.

The Panel noted Ipsen's submission that prior to their employment at Ipsen, the employee held a number of promotional roles in the UK which would have required the employee to have completed the representative examination. The employee commenced a promotional role in Ireland with Ipsen in April 2016 but did not cover Northern Ireland or the rest of the UK. In January 2019, the employee then moved into another promotional role at Ipsen for Northern Ireland, thus becoming subject to the training requirements of the Code.

As the UK employee's role was promotional in nature, the Panel considered that the roles and responsibilities associated with the role, as acknowledged by Ipsen, satisfied those of a representative set out in the Code. The employee was therefore required to have taken the appropriate examination within their first year of employment as a representative and have passed it within two years. The Panel considered that failure to do so was contrary to the requirements of the Code and a **breach of Clause 16.3 of the 2019 Code** was ruled as acknowledged by Ipsen.

The Panel noted with concern that the voluntary admission had been submitted to the PMCPA in October 2023 but that Ipsen became aware of the issue in April 2020. Whilst the Panel took account of Ipsen's submission that the individual had been employed in multiple roles with other UK pharmaceutical companies where they had been calling on UK health professionals in a promotional capacity, this did not mitigate the fact that Ipsen were expected to have their own robust policies and procedures in place to ensure compliance with the Code. In this regard, the Panel was concerned with Ipsen's lack of due diligence when employees transferred roles within the company and queried whether its onboarding process was also sufficiently robust. The Panel considered that the lack of robust process amounted to a failure to maintain high standards and ruled a **breach of Clause 9.1 of the 2019 Code**.

Complaint received **16 October 2023**

Case completed **18 September 2024**