

CASE AUTH/3824/09/2023

HEALTH PROFESSIONAL v NOVARTIS

Alleged misleading impression in relation to a representative's identity

CASE SUMMARY

This complaint, received from a health professional from their NHS email account, related to the conduct of a representative acting on behalf of Novartis. The complainant's overarching concerns were that the representative was misleading as to their identity and gave the impression they worked for NHS England on a call. The complainant also alleged that the caller did not identify themselves as being from Novartis until they were specifically asked if they were from a pharmaceutical company.

The outcome under the 2021 Code was:

No Breach of Clause 5.1	Requirement to maintain high standards at all times
No Breach of Clause 15.6	Requirement that promotional material and activities must not be disguised
No Breach of Clause 17.2	Requirement that representatives must maintain high standards of ethical conduct in the discharge of their duties and comply with all relevant requirements of the Code
No Breach of Clause 17.3	Requirement that representatives must not employ any inducement or subterfuge to gain an interview
No Breach of Clause 17.5	Requirement that representatives must not mislead as to their identity or that of the company they represent
No Breach of Clause 17.9	Requirement that representative's briefing material must comply with the relevant requirements of the Code and is subject to certification

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

FULL CASE REPORT

A complaint was received from a named, contactable health professional about Novartis.

COMPLAINT

"I am a GP at [named area]. I am deeply concerned about a small number of called [sic] calls that I am receiving to my practice from marketing departments of pharmaceutical companies under the masquerade of being from NHS sources. The latest this morning

was from Novartis, from a person with quite a complex title, in which they emphasised the fact that they were some form of NHS liaison and not making themselves entirely clear, even to me and certainly not to my reception staff, that they were indeed calling from a pharmaceutical company. The way a call was introduced to me by one of my reception staff was as NHS lipid liaison manager or something along those lines, which gave the impression that this was in fact somebody calling from NHS England and hence, the person in question was put through. Whilst I appreciate the contribution to my work as an NHS GP that pharmaceutical companies make and, having very happily collaborated and worked with (and still doing so with full disclosure), that sometimes companies need to communicate with GPs, I find it pretty reprehensible and underhand, but to use this tactic, particularly when the practice is overwhelmed.

Novartis is not the only company that has done this, I have received such calls in the past which have turned out to be not from a senior NHS source but in fact, from a pharmaceutical company.

I do not know what you can do about it but it does put the industry in a very poor light and tarnishes its professional image

I am but one GP but I am sure that this is quite a widespread practice amongst a few marketing teams.”

FURTHER INFORMATION FROM THE COMPLAINANT

Further information from the complainant is reproduced below:

“Sorry, I must add one important fact:

The person who called me this morning, did not identify themselves as being from Novartis at all until I directly asked them, if they were from a pharmaceutical company, and they did record the interaction, at which point, I started getting suspicious though even then I thought that they were conducting some form of NHS poll or interview.”

NOVARTIS' RESPONSE

The response from Novartis is reproduced below:

“The Complaint causes us concern and Novartis has taken its content seriously. Novartis is committed to operating in accordance with the required standards and meets the relevant requirements and expectations.

1. Background

The Complaint alleges that during a phone call to their GP practice, a representative of Novartis Pharmaceuticals UK Limited (**Novartis**) misrepresented to the practice staff that they worked for the NHS and that they did not disclose that they were calling on behalf of Novartis until they were asked by the anonymous complainant.

2. Relevant provisions of the Code

A summary of the clauses of the Code that Novartis has been asked to consider in this response is given in Table 1 below.

Table 1: Alleged Breaches

Clause	Code Clause
5.1	High standards must be maintained at all times.
15.6	Promotional material and activities must not be disguised.
17.2	Representatives must maintain a high standard of ethical conduct in the discharge of their duties and comply with all relevant requirements of the Code.
17.3	Representatives must not employ any inducement or subterfuge to gain an interview. No fee should be paid or offered for the grant of an interview.
17.5	In an interview, or when seeking an appointment for one, representatives must at the outset take reasonable steps to ensure that they do not mislead as to their identity or that of the company they represent.
17.9	Representatives' briefing material must comply with the relevant requirements of the Code and, in particular, is subject to the certification requirements of Clause 8. Briefing material must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code. Companies must prepare detailed briefing material for medical representatives on the technical aspects of each medicine which they will promote. A copy of such material must be made available to the Medicines and Healthcare products Regulatory Agency (MHRA) and the PMCPA on request.

3. Novartis' Response

The Complaint stated that the Novartis representative introduced themselves as a 'NHS lipid liaison manager'. One of our products, called Leqvio®, is relevant to the area of lipids and, as such, we have focused our investigation into the promotional campaign for Leqvio®.

Further to the receipt of this Complaint, we searched our customer relationship management system but found no records of any call made to this practice. In addition, we discussed the Complaint with our Community Account Manager for this area and he confirmed that he did not make any calls to practices in this area at the time of the Complaint.

In addition to having a team of Novartis Community Account Managers, Novartis has engaged a 3rd party vendor, [named third party] to provide a virtual Key Account

Manager service in support of the Novartis promotional campaign for Leqvio® (the '**VKAM service**').

We note that in the complaint was made almost contemporaneously to the call complained of- the email of complaint was sent to PMCPA at lunchtime on 20 September and refers to the call made to them 'this morning'.

Novartis and [named third party] have no record of a call made to that practice on 20 September 2023.

[named third party] confirmed that one of their virtual Key Account Managers did call the complainant's practice on 18th September 2023 (2 days before the date mentioned in the Complaint). We have provided [named third party]'s record that the call took place on 18th September 2023.

3.1. **Clauses 15.6, 17.3 and 17.5**

Novartis engaged [named third party] in September 2022 to provide the VKAM service. Further to this, [named third party] prepared a scheduling script for use by [named third party]'s employees assigned virtual Key Account Managers on behalf of Novartis.

This script provides rules of engagement, specific instructions, and a script to guide the activity of [named third party] Connection Agents. [named third party] have confirmed that this script was also used by its virtual Key Account Managers when making their calls to GP practices.

The Rules of Engagement section of the script provides as follows:

'At all times, the Connection Agent must maintain a high standard of ethical conduct and comply with all relevant requirements. At the start of all interactions, personnel must state:

- *Their name and job title*
- **The fact that they are calling on behalf of Novartis**
- *The purpose of the telephone call'*

Further, the script section of the document provides as follows:

'The greeting

Good morning, this is [connection agent's full name] calling on behalf of the pharmaceutical company Novartis.

Background / context

My role is to schedule a promotional meeting to support the doctor with the management of patients with raised LDL cholesterol.

Purpose / benefit

During the call, the importance of LDL cholesterol and Novartis' LDL-lowering therapy will be discussed.'

In addition, [named third party] conducts regular trainings with its employees assigned to the VKAM service on how to maintain high standards when engaging with healthcare professionals. For example, on 27th September 2023, [named third party] provided the training to its employees on the following topic:

'Provide direction to the Leqvio vKAM team to use transparent language when engaging with customers including the words to use that have been agreed with Novartis. Remind vKAMs not to send calendar invites or reminders to HCPs.'

Further to the Complaint, [named third party] conducted an interview with the relevant virtual Key Account Manager to ascertain whether she disclosed that she was working on behalf of Novartis and the reason for the call.

During the interview, the relevant virtual Key Account Manager was asked specifically if she recalled how she introduced herself on the 18 September call. The relevant virtual Key Account Manager said *'according to the guidance: [named virtual Key Account Manager] from the cardiovascular team at Novartis who are working with NHSE and the AHSN to roll out an inclisiran programme'*. The virtual Key Account Manager said that the relevant GP *'agreed to continue the call and [named virtual Key Account Manager] explained which patients might benefit from Leqvio and top line results from trial.'* The virtual Key Account Manager did not recall the GP being annoyed or unhappy and the call was not ended prematurely.

Finally, [named third party] conducts a daily huddle call with the employees assigned to the VKAM service to discuss any issues arising and again no issues were raised about the call to this practice.

Conclusion:

Given the detailed instructions/trainings provided by [named third party] to its assigned employees, the fact that no issues were raised at the team huddle and the statements of the relevant virtual Key Account Manager, the position of Novartis is that the virtual Key Account Manager introduced themselves correctly to the GP and did make clear the purpose of the call in accordance with the agreed script and their training. For these reasons, there has been no breach of clauses 15.6, 17.3 and 17.5.

3.2. Clause 17.9

Novartis has provided a number of briefings on Leqvio ® to [named third party] to provide to their assigned employees since September 2022.

All of these briefings were reviewed and approved by Novartis' medical team in accordance with Clause 8 of the Code.

Conclusion: No breach of clause 17.9

3.3. Clauses 5.1 and 17.2

All [named third party] virtual Key Account Managers are ABPI qualified, and the relevant virtual Key Account Manager had obtained a medical representative certificate from the ABPI.

All [named third party] virtual Key Account Managers must read and sign off on their understanding of [named third party]'s standard operating procedures on compliance with the ABPI Code and a record is kept of completion.

In addition, as mentioned above, [named third party] conducts regular trainings with its employees assigned to the VKAM service on how to maintain high standards when engaging with healthcare professionals.

Finally, as detailed in our response to the alleged breach of clauses 15.6, 17.3 and 17.5, the virtual Key Account Manager's statements and the evidence maintained by [named third party] does not suggest any misconduct.

Conclusion: We are confident that the service provided by [named third party] is robust and run to the highest of standards. As such, there has been no breach of Clauses 5.1 and 17.2.

4. Overall Conclusion

It is unfortunate that the complainant has been moved to contact the PMCPA about the call they received on 20 September 2023. However, no call was made on that date by or on behalf of Novartis. To the extent that the complainant may have been referring to the call made on 18 September, the opinion of Novartis is that the evidence above shows that high standards have been maintained at all relevant times and Novartis therefore fully refutes any breaches of Clauses 5.1, 15.6, 17.2, 17.3, 17.5 and 17.9 of the 2021 Code.'

FURTHER INFORMATION

'There have been substantial changes in structure/teams within Novartis and at our external partner in the time that has passed since this matter first arose. Investigating the history and then dealing with these requests, over a year after submitting our response to the initial complaint, has required a large amount of resource to be diverted from other activities.

As stated in our initial response of 13 October 2023 ('**Novartis Response**'), we would like to reiterate that Novartis has *no record* of a call placed by or on behalf of Novartis to a GP practice in [named area] on 20 September 2023.

It is therefore unclear that the call that led to the Complainant contacting PMCPA was placed by or on behalf Novartis.

In the spirit of transparency and collaboration, we provided details of a call placed by one of [named third party] virtual Key Account Managers to a GP practice in [named area] on 18 September 2023, i.e. 2 days before the date mentioned in the Complaint.

To the extent the anonymous complainant may have been referring to the call made on 18 September 2023, we concluded that high standards were maintained at all relevant times and provided evidence in support of our conclusions.

In response to your requests for further information, our responses are set out below:

1. The official job title of the Key Account Manager (KAM) to be used in their capacity as a representative for Novartis

The official job title is 'sales representative'.

2. Any briefing document(s) or equivalent that outlines the script to be used by representatives when engaging with health professionals is intended for 'Connection Agents'

As mentioned in Novartis Response, '[named third party] have confirmed that this script was also used by its virtual Key Account Managers when making their calls to GP practices'.

In addition to the script and with regard to how the vKAMs are expected to introduce themselves, the remote detailing consent process SOP makes clear in the 'Call Delivery' section:

'3. vKAM introduces themselves (company name and purpose of the call)'

With regard to the discussion with health professionals after vKAMs have introduced themselves, the briefing documents used are those previously provided in Novartis Response.

3. Any relevant training undertaken by the representative prior to the date of the call, noting Exhibit 3 post-dates the complaint

As mentioned in the remote detailing consent process SOP:

'Sales calls are delivered by vKAMs. These are high quality industry reps with significant field experience and ABPI accreditation. All vKAMs are trained and validated by the client company prior to delivering sales calls.'

In addition to the training on 'Customer engagement/transparent access language' provided in September 2023, [named third party] provided vKAMs sales validation training in October 2022.

Novartis also provided extensive training to vKAMs on a wide range of topics, including 'UK INVOLVE ABPI Code of Practice Module 6 - Interactions with HCPs, ORDMs and HCOs'. The training record shows that this module was completed

on 9 November 2022 by the vKAM who placed the call to a GP practice in [named area] on 18 September 2023.

4. Any material(s) used during the call at issue with the health professional

As already mentioned, it is entirely unclear that the call we have voluntarily provided information for is in fact the call at issue in the Complaint as the dates do not match. With regard to the call on 18 September 2023 to a GP practice in [named area], the materials used would have been those mentioned in response to 2. above.

5. A copy of the remote detailing consent process SOP that has been completed by the representative in question

Confirmation that this SOP was read and understood by the vKAM who placed the call to a GP practice in [named area] on 18 September 2023 was provided in Novartis Response.

We have set out in full our response to this complaint and anticipate that this additional information will further demonstrate that there was no breach by Novartis of Clauses 5.1, 15.6, 17.2, 17.3, 17.5 and 17.9 of the 2021 Code in relation to the Complaint.”

PANEL RULING

This complaint, received from a health professional from their NHS email account, related to the conduct of a representative acting on behalf of Novartis. The complainant’s overarching concerns were that the representative was misleading as to their identity and gave the impression they worked for NHS England on a call. The complainant also alleged that the caller did not identify themselves as being from Novartis until they were specifically asked if they were from a pharmaceutical company.

Novartis submitted it had engaged a third party to provide virtual representative support for its promotional campaign for Leqvio (inclisiran) and that neither its third party provider, nor Novartis itself, had a record of a call made on 20 September 2023 as alleged by the complainant. Its third party provider did confirm, however, that one of its virtual representatives had called the complainant’s practice on 18 September 2023. The Panel considered the precise date of the call was not material to its rulings in this case.

Novartis, in its response, made reference to a scheduling script for “connection agents” who were described in the document as individuals that booked the appointments between health professionals and representatives. It was unclear to the Panel in the circumstances of this case whether a connection agent had booked an appointment with the health professional prior to the virtual representative’s call.

Novartis submitted that, as part of its investigation into this complaint, the third party provider had interviewed the representative that had conducted the call. That representative stated that they had introduced themselves to the health professional as “[name] from the cardiovascular team at Novartis who are working with NHSE and the AHSN to roll out an inclisiran programme” and that the health professional “agreed to continue the call and [name] explained which patients might benefit from Leqvio and top line results from trial.” The representative did not recall the GP being annoyed or unhappy and the call was not ended prematurely.

Novartis submitted that the virtual representatives used the same scheduling script as the connection agents which provided rules of engagement including that “at the start of all interactions, personnel must state: ...the fact that they are calling on behalf of Novartis”. The script also directed the caller to say “...calling on behalf of the pharmaceutical company Novartis” and “my role is to schedule a promotional meeting to support the doctor with the management of patients with raised LDL cholesterol.”

The Panel noted the importance of clear documentation and briefing materials. The Panel queried why the scheduling script, labelled as being for use by the connection agents, did not make clear it was also intended for representatives as submitted by Novartis in its response; the Panel would have expected virtual representatives and connection agents to have separate and bespoke scripts rather than both using the same one, noting their distinct job roles.

Novartis additionally provided a remote detailing consent process SOP which included that a virtual representative “introduces themselves (company name and purpose of the call)” and “confirms permission to continue with the sales call and records permission” with “the wording used to gain permission must make it clear that the HCP [healthcare professional] is being asked to provide permission to receive promotional information about a prescription-only medicine over the telephone”.

The Panel noted the complainant’s concerns regarding their impression that the representative was from NHS England, but the Panel also took account of the processes and briefing documents submitted by Novartis.

While the master briefing document for Leqvio material instructed representatives to make reference to NHS England on several slides, the Panel considered it was sufficiently clear that this was a collaboration with NHS England. For example, Slide 2, an introduction to inclisiran, included that it had been “identified by NHSE&I [NHS England and NHS Improvement] as a medicine to be adopted systematically and at scale, and Novartis, the AAC [accelerated access collaborative] and the NHSE&I are collaborating to deliver a novel population health management approach to lipid management with inclisiran”. Slide 19 was titled “NHS England, the AAC and your local AHSN [academic health science network] are working with Novartis to roll out a national programme to help address the cardiovascular burden” and referenced “a pioneering collaboration between NHS England, Novartis and the AHSN which is using a population health management approach to offer lipid treatment to a large at-risk patient population”.

The Panel observed that both the scheduling script and remote detailing SOP included instructions to make clear that the representative was calling from Novartis. Neither made reference to NHS England. Therefore, in the Panel’s view, the briefing material itself did not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code on the evidence before it. The Panel ruled **no breach of Clause 17.9**.

With regard to the representative call at issue, the Panel noted the difficulty in dealing with complaints based on one party’s word against the other; it was often impossible in such circumstances to determine precisely what had happened.

The introduction to the PMCPA Constitution and Procedure stated that a complainant had the burden of proving their complaint on the balance of probabilities. The Panel considered,

however, that a high degree of dissatisfaction was usually required before an individual was moved to complain.

Clause 15.6 stated that promotional material and activities must not be disguised. Clause 17.3 stated that a representative must not employ any inducement or subterfuge to gain an interview. Clause 17.5 stated that in an interview, or when seeking an appointment for one, representatives must, at the outset, take reasonable steps to ensure that they do not mislead as to their identity or that of the company they represent.

The Panel noted that it was clear that the complainant had been upset and this was most unfortunate. The Panel was concerned that a doctor had felt the need to escalate this matter to a complaint to the PMCPA noting the doctor alluded to having received a number of calls, and not just from Novartis.

The Panel considered it was extremely important, particularly in the context of job titles and descriptions, that reference to “NHS England” or any other official body during a call was not misleading and that company personnel make it explicitly clear that they are acting on behalf of a pharmaceutical company at the outset of interactions.

Nonetheless, given the information before it, the Panel decided it was not possible to determine precisely what had been said verbally during the interaction and thus it had not been established that the representative had failed to maintain a high standard of ethical conduct in the discharge of their duties. The Panel ruled **no breach of Clause 17.2**.

It followed that it had not been established, on the balance of probabilities, that the interaction constituted disguised promotion, nor that the representative had employed subterfuge or misled as to their identity. On that basis, the Panel ruled **no breach of Clauses 15.6, 17.3 and 17.5**.

The Panel took account of the evidence before it, including the training records, procedures and briefing documents submitted by Novartis. Noting its rulings of no breaches of the Code above, the Panel considered it had not been established that Novartis had failed to maintain high standards. The Panel therefore ruled **no breach of Clause 5.1**.

Complaint received **20 September 2023**

Case completed **02 December 2024**