CASE/0222/07/24

HEALTH PROFESSIONAL v ACCORD-UK

Conduct of a representative

CASE SUMMARY

This case was in relation to the actions of an Accord-UK Limited representative allegedly sharing internal, confidential information about the NICE evaluation of Orgovyx (relugolix). The complainant also alleged that the representative had previously been asked to limit their contact with the complainant's unit and pharmacy, given the lack of NICE approval for relugolix.

The outcome under the 2021 Code was:

Breach of Clause 17.2	**Representatives failing to maintain a high standard of ethical conduct**

No Breach of Clause 5.1	**Requirement to maintain high standards at all times**
No Breach of Clause 17.4	**Requirement that representatives must ensure that the frequency, timing and duration of calls, together with the manner in which they are made does not cause inconvenience and that the wishes of individuals on whom representatives call and the arrangements in force at any particular establishment must be observed**

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 about Accord-UK Limited was received from a contactable health professional.

COMPLAINT

The complaint wording is reproduced below:

> "I am a [job title of complainant] based in [named county]. The local representative has made statements to our urology team around decisions that NICE [(National Institute for Health and Care Excellence)] have made that are still in the confidential stage. These statements have been disclosed in order for a currently non-NICE approved product to be used within the ICS [(integrated care system)] against the trust policy. A complaint about this behaviour will also be lodged with NICE. Our [job title of complainant's colleague] has stated that this is to be treated confidentially but has stated that [they were] shown an internal Accord email confirming this information."

The complainant's response to a request for further information by the case preparation manager is reproduced below:

> "The decision around Relugolix from NICE is not yet final nor in the public domain, the information was given to my colleague following confidential discussions between NICE and Accord and subsequently disseminated via their local representative, [named representative].
>
> The discussion was had between myself and my [job title] colleague last Wednesday and had happened in the days prior. I have not been able to confirm with my colleague the exact time as [they have] not been available. This took place within [named hospital location 1]. I do not have a copy of the internal email that was shown, this would need to be sought from Accord.
>
> I am told that the representative used this information to ask for a pre NICE inclusion on the hospital formulary for relugolix. We have a policy in place that would discount the use of any product without NICE guidance in place and this representative, in my opinion, was trying to deliberately circumvent this policy. [Named representative] has previously been asked to limit [their] contact with the unit and with pharmacy given the lack of NICE approval for relugolix."

FURTHER INFORMATION FROM THE COMPLAINT

Following receipt of the complaint, Accord-UK requested (via the case preparation manager) further information from the complainant to aid its investigation. The following list of questions was sent to the complainant:

1. What date (and time) did the interaction occur between the Accord representative and the relevant member(s) of the Urology team occur where this confidential document was apparently shared?
2. Where (location within the hospital) did this interaction take place?
3. Was it a 1:1 interaction or a group meeting (e.g. MDT)?
4. Who was the interaction with? Accord does not need a name, but it would help their investigation if the profession was known – e.g. Urologist, Nurse, Pharmacist, etc?
5. Why the complainant thinks it was [named representative] that showed (or discussed) the internal confidential document? Is it certain that [named representative] was the individual that had the meeting with the Urology team? Accord's investigation to date shows that there may have been two or three interactions from different Accord employees with different healthcare professionals in the [named location] region?
6. Is it certain that the document shared was an email, and is it possible to confirm the date of the communication and who it was from within Accord? Accord acknowledges that you do not have a copy but could one be obtained from their colleague? Any information regarding the content of the document that was shared (e.g. email, internal memo, who it was from, etc).

The complainant's response to this request is reproduced below:

> "While the approach to me was from one of our consultant team, the initial meeting where the NICE guidance was referenced took place during a lunch meeting at our

[named location 2] site with our nurses. This meeting was with [named representative]. The email in question was read from and then shown on [their] mobile phone."

When writing to Accord-UK, the PMCPA asked it to consider the requirements of Clauses 5.1, 17.2 and 17.4 of the 2021 Code.

ACCORD-UK'S RESPONSE

The response from Accord-UK is reproduced below with some typographical errors corrected:

"Thank you for your letter dated 11th July concerning a complaint received about the above matter and potential breaches of the following Clauses:

- Clause 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.
- Clause 17.4: Representatives must ensure that the frequency, timing and duration of calls on health professionals and other relevant decision makers in hospitals, the NHS and other organisations, together with the manner in which they are made, do not cause inconvenience. The wishes of individuals on whom representatives want to call and the arrangements in force at any particular establishment must be observed. When briefing representatives, companies should distinguish between expected call rates and expected contact rates.
- Clause 5.1: High standards must be maintained at all times.

Background

Relugolix received marketing authorisation from the MHRA in June 2022 for advanced prostate cancer. It further received a license variation for Great Britain in December 2023 to include use in combination with radiotherapy as neoadjuvant or adjuvant treatment in high-risk localised or locally advanced hormone-sensitive prostate cancer. A timeline of NICE submission and internal briefings are summarised in Table 1.

The complainant has stated that an internal email referencing confidential information concerning discussions between Accord and NICE about relugolix was shared by a named Accord representative with the complainant's colleague. The allegation appears to be that this incident occurred in late June. The Complainant claims on an email dated 04th July 2024 that '*The discussion was had between myself and my […] colleague last Wednesday and had happened in the days prior*'. We assume that the 'last Wednesday' refers to 26th June and that the interaction between the named representative and the colleague occurred in the days prior to 26th June.

On request for further information, the Complainant has claimed '*While the approach to me was from one of our consultant team, the initial meeting where the NICE guidance was referenced took place during a lunch meeting at our [named location 2] site with our nurses. This meeting was with [named representative]. The email in question was read from and then shown on [their] mobile phone.'* Unfortunately, no further information was provided with regards to the exact date of the interaction or details of the confidential document shared despite our request for this information.

Table 1: Timeline of NICE and internal communications in date order

Activity	Detail	Date	Reference
MHRA approval	Advanced hormone sensitive prostate cancer	June 2022	SmPC
Extension of license	Combination with radiotherapy as neoadjuvant in high-risk localised or locally advanced hormone-sensitive prostate cancer	December 2023	SmPC
NICE submission	Dossier submission	17th January 2024	n/a
NICE decision – confidential	This is the decision made by NICE and communicated to Accord confidentially	17th June 2024	Verbal
Regular KAM meeting	Regular meeting where confidential nature of the NICE decision was reiterated, including information about an email coming out for internal purposes only.	24th June 2024	[Emails provided]
Internal Comms	Confidential Accord internal communication for internal use only	25th June 2024	[Email provided]
Estimated date of incident	Although not confirmed, the complainant refers to the incident occurring on 'last Wednesday'	Days prior to 26th June	[Email provided]
Complaint received by PMCPA	The date on the first email to the PMCPA from the Complainant	2nd July	n/a
NICE Final draft guidance (FDG)	NICE FDG published on website for consultation period	19th July 2024	n/a

Internal Investigation

In the morning of 25 June 2024 an internal email was circulated within Accord to all UK company staff providing an update on the ongoing discussions with NICE ('the internal email'). The email stated that the '*The committee concluded that it should be recommended for use in the NHS for all of its licensed indications*' and it was also clear that the appraisal process was not yet finalised. It was also very clear in emboldened and underlined text that **'This information is currently confidential between NICE and Accord so please do not share this information externally yet. It is just for internal awareness for now'**.

There was also a discussion on the morning of the 24th June (the day prior to the above internal email) at the weekly KAM meetings that was attended by [job titles of three employees identified by their initials]. All Oncology Speciality Brands KAMs

attended this meeting. It was made clear at this meeting by [two of the named employees] that an internal email coming out on the 25th June was for internal communication only and that the outcome by NICE was confidential news and not to be shared with anyone outside the organisation or the NHS.

Furthermore, having questioned the named representative as part of our investigation into this complaint, [they recall] that the information contained in the internal email was also discussed at a regular internal team meeting (as per above), again, it was emphasised that the information must not be shared until further instruction was received.

The named representative was also very clear as part of the internal investigation that [they] had not discussed the content of the internal email, or in any other way shared the content, externally to anyone in the NHS as alleged. Furthermore, the named representative's CRM record shows no interactions in the [named location 2] region (Figure 1) between 25th June (when the internal communication was sent) and 26th June (the proposed date of when the discussion between the Complainant and [their] colleague). However, the named representative has had interaction with healthcare professionals in the [named location 2] area on two occasions outside the above dates in June and July; first one on the 19th June (before the internal email was released) and the second on 2nd July (date of when PMCPA received the complaint). The named representative denies sharing the content of the internal confidential email on any occasion.

Figure 1: CRM record for named representative in [named location 2] hospitals ([two named hospitals]) In June and July

[Screenshot provided showing six in-person interactions. The table below reproduces this information in redacted form]

Parent Account	**Account: Account Sub Type**	**Account: Specialty**	**Delivery Method**	**Date**	**Time**	**Duration**	**Detailed Products**
Hospital 1	Hospital Nurse	Clinical Oncology	In Person (1:1)	19/06/ 2024	14:11	20	Pelgraz PDF Pelgraz PFS
Hospital 2	Hospital Nurse	Respiratory/Lung Cancer	In Person (1:1)	19/06/ 2024	11:00	20	Pelgraz PDF Pelgraz PFS
Hospital 1	Hospital Nurse	Urology Oncology	In Person (1:1)	02/07/ 2024	12:44	10	Orgovyx
Hospital 1	Hospital Nurse	Urology	In Person (1:1)	02/07/ 2024	12:00	5	Orgovyx
Hospital 1			In Person (1:1)	02/07/ 2024	12:00	5	Orgovyx
Hospital 1			In Person (1:1)	02/07/ 2024	12:02	5	Orgovyx

We note that the complainant also refers to the named representative being asked '*to limit [their] contact with the unit and with pharmacy given the lack of NICE approval for relugolix*'. Whilst we do not know the identity of the complainant, during discussions with the named representative as part of the investigation into this complaint, [they] referred to an email communication with [named person]- at [named hospital location 1] ('the pharmacist'). In this email communication [the pharmacist] stated:

'*I appreciate you have been trying to get in touch both in person and over the phone. However, working in a large teaching hospital the patients are my priority. Therefore if I need to get in touch, I will contact you. Please do not bleep me from an external line. Please do not turn up on the ward again*'

The representative noted this instruction since receiving this email (on 20 October 2023). Please see [file provided] showing CRM data for the named representative who has only been in contact with this Pharmacist twice, and on no occasions since [their] email on 20th October 2023. Upon further questioning, the named representative stated that [they] did not bleep the Pharmacist from an external line but instead called the hospital switchboard to speak with the Pharmacist, however the operator used the bleep system to contact the Pharmacist without being asked to by the named representative. Furthermore, the named representative stated they would not go to the wards unless [they have] received prior approval from an HCP to do so. In this particular case with the Pharmacist, the named representative has stated [they] got approval from the nurses.

A download of the named representative's CRM data for the last 12-months provides evidence that the representative has not proactively called on any HCPs more than the recommended three times a year. Additionally, Accord has also recently conducted a 'Reactive vs Proactive training' as well as proof of validation for the KAMs.

To summarise, neither Accord nor the Complainant have been able to provide further evidence to substantiate a breach of the above Clauses."

PANEL RULING

This complaint related to the actions of a named Accord-UK representative. The complainant alleged that the representative had shared confidential information about the National Institute for Health and Care Excellence (NICE) evaluation of Orgovyx (relugolix). The complainant also alleged that the representative had previously been asked to limit their contact with the complainant's unit and pharmacy, given the lack of NICE approval for relugolix.

The Panel noted that relugolix was indicated for the treatment of adult patients with advanced hormone-sensitive prostate cancer, for the treatment of high-risk localised and locally advanced hormone dependent prostate cancer in combination with radiotherapy, and as a neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced hormone dependent prostate cancer.

With regard to the allegations in this case, 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 PMCPA's Constitution and Procedure stated that the 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 submit a formal complaint.

In considering the complainant's first allegation, the Panel observed that the timeline and detail of events as described by the complainant was somewhat unclear. While noting that the Panel was not an investigatory body and it was not for the Panel to make out the complaint, the Panel considered that the information provided by the complainant described the following sequence of events:

- The first interaction with the named representative took place at some point in "the days prior" to Wednesday, 26 June 2024. The complainant alleged that the named representative had shown the complainant's colleague an internal Accord-UK email (on their mobile phone) with information about the NICE approval of relugolix. It was not clear to the Panel whether this interaction took place at location 1, location 2, or at another unspecified location.

- On Wednesday, 26 June 2024, the complainant spoke to a colleague, who told them of the interaction described above (being shown an email by the named representative).

- The second of the interactions described by the complainant occurred at some point after the first interaction and on or before 2 July 2024. The complainant alleged that the named representative made statements about the confidential NICE approval of relugolix during a lunch meeting at location 2 with the urology team.

- The complaint was made to the PMCPA on 2 July 2024 at 14:05.

The Panel noted that its interpretation of the timeline differed from that of Accord-UK. The Panel based the timeline above on the following points from the information provided by the complainant:

- "… the information was given to my colleague … and **subsequently** disseminated via their local representative …" [emphasis added]
- "The discussion was had between myself and my [job title] colleague last Wednesday …"
- [In reference to the complainant's colleague] "… had happened in the days prior" [to last Wednesday].

The Panel then considered the timeline of NICE and internal communications submitted by Accord-UK; in particular:

- 17 June 2024 – NICE decision made and communicated to Accord-UK confidentially
- 24 June 2024 – Confidential nature of the NICE decision reiterated verbally to staff at the regular Key Account Manager (KAM) meeting, which was attended by the named representative
- 25 June 2024 – Confidential Accord-UK internal communication issued (for internal use only)
- 19 July 2024 – NICE final draft guidance published.

Accord-UK submitted that its internal investigation had shown that the named representative recalled the discussion at the team meeting and the internal email which emphasised that the NICE information must not be shared until further instruction was received. Accord-UK submitted that the named representative had not discussed the content of the internal email, or in any other way shared the content, externally to anyone in the NHS.

Accord-UK provided the Panel with an extract from its customer relationship management (CRM) system showing interactions in the region of 'named location 2' in June and July 2024. Accord-UK submitted that there were no interactions in that region between 25 June 2024 (when the internal email was issued) and 26 June 2024 (the date of the discussion between the complainant and their colleague). The CRM system extract showed two in-person interactions on 19 June and four in-person interactions on 2 July.

The Panel observed that the CRM system extract provided by Accord-UK was brief but detailed the name of the hospitals in which the interactions took place, and the date, time and duration of the interactions. Each interaction was recorded against a particular product (Pelgraz or Orgovyx), and for the first four interactions, there were additional details that appeared to show information about the role and specialty of the health professional.

With regard to the first interaction, in which the complainant alleged that the named representative showed the complainant's colleague the confidential email, the Panel observed that there were no records on the CRM extract that appeared likely to correspond with this. The only interactions recorded in "the days prior" to 26 June were on 19 June, which was before the internal email had been sent. The Panel noted, however, that the CRM records before them were limited to location 2. The Panel could not make out from the information provided by the complainant where the alleged interaction had taken place. The Panel took into account that the complainant did appear to know about the existence of a confidential, internal Accord-UK email.

With regard to the second interaction (the lunch meeting with the urology team at which the named representative allegedly made statements about the confidential NICE approval of relugolix), the Panel observed that there were four interactions recorded at one hospital in location 2 on 2 July. Two of these interactions were labelled as "Hospital Nurse" and "Urology" or "Urology Oncology"; the other two had no information in these two data fields. All four interactions were recorded against the product "Orgovyx" (relugolix). The four interactions were recorded as taking place at 12:00 (for 5 minutes), 12:00 (for 5 minutes), 12:02 (for 5 minutes) and 12:44 (for 10 minutes).

The complaint to the PMCPA was made at 14:05 on 2 July. In the Panel's view, it was a reasonable interpretation of the available evidence that one or more of the CRM records from 2 July in the period of 12:00 to 12:44 represented the alleged lunch meeting, and that the complainant made their complaint immediately following this meeting.

Clause 17.2 required that representatives must maintain a high standard of ethical conduct in the discharge of their duties and comply with all relevant requirements of the Code.

The Panel noted that the complainant stated that their hospital had a policy in place that would discount the use of any product without NICE guidance in place, and alleged that the named representative was trying to deliberately circumvent this policy by asking for a pre-NICE inclusion on the hospital formulary for relugolix. However, the Panel considered that, from the complainant's wording "I am told", it did not appear that this request was made to the

complainant themselves. The Panel considered that there was no evidence provided to support this allegation.

The Panel was concerned that a health professional had felt the need to make a formal complaint to the PMCPA. The Panel noted that while there were some differences between the complaint and the company's response, there was some evidence to corroborate points in the complainant's allegations. The Panel took into account the following:

- At the time of making the complaint (2 July), the complainant appeared to be aware that NICE had communicated its decision on relugolix to Accord-UK; the NICE final draft guidance was not published online until 19 July
- The complainant appeared to be aware of a confidential internal Accord-UK email relating to the NICE decision on relugolix; Accord-UK confirmed that a confidential email about the NICE decision was sent to staff on 25 June
- In the Panel's view, the absence of a record of the alleged interaction between the named representative and the complainant's colleague did not prove that no such interaction had taken place (considering the CRM extract was limited to location 2)
- There were interactions recorded on the CRM that, in the Panel's view, were likely to correspond to the lunch meeting described by the complainant

Taking into consideration the above, and on the balance of probabilities, the Panel considered the representative had shared confidential information from NICE with health professionals, against the explicit instructions of the company. In doing so, the representative had failed to maintain a high standard of ethical conduct in the discharge of their duty. A **breach of Clause 17.2** was ruled.

The Panel considered the complainant's second allegation: that the named representative had previously been asked to limit their contact with the complainant's unit and pharmacy, given the lack of NICE approval for relugolix.

Clause 17.4 stated, among other things, that representatives must ensure that the frequency, timing and duration of calls on health professionals and other relevant decision makers in hospitals, the NHS and other organisations, together with the manner in which they were made, did not cause inconvenience. The wishes of individuals on whom representatives wanted to call and the arrangements in force at any particular establishment must be observed.

The Panel noted that the complainant provided no further detail beyond the alleged interactions described above.

Accord-UK provided a document detailing the proactive and reactive meetings for the named representative for the period of 1 June 2023 to 30 June 2024. The Panel considered that this document showed no evidence that the named representative had acted contrary to the requirements of Clause 17.4.

Accord-UK also provided the Panel with an email to the named representative dated 20 October 2023, where a pharmacist had explained, "working in a large teaching hospital the patients are my priority. Therefore if I need to get in touch, I will contact you. Please do not bleep me from an external line. Please do not turn up on the ward again." The Panel noted that the CRM record for interactions between the named representative and that pharmacist showed no interactions after receipt of the email.

The Panel noted that Accord-UK's internal policy relating to proactive and reactive calls reiterated Code requirements in relation to the frequency of calling upon health professionals, how to differentiate between reactive and proactive calls and recording the interactions on the internal CRM system.

The Panel noted that the complainant bore the burden of proof and had to establish their case on the balance of probabilities. In the Panel's view, the complainant had not established that any interactions with the named representative had caused inconvenience, taking into account frequency, timing and the wishes of individuals. The Panel ruled **no breach of Clause 17.4**.

The email sent to Accord-UK employees on 25 June 2024 included a bold, underlined statement stating "This information is currently confidential between NICE and Accord-UK so please do not share this information externally yet. It is just for internal awareness for now." The Panel also took into account Accord-UK's submission that at a regular KAM meeting on 24 June, it was verbally reiterated to staff that they should not be sharing the NICE approval externally.

The Panel therefore considered that Accord-UK had taken reasonable steps to mitigate any risk of the confidential NICE information being shared externally. Noting the actions taken by Accord-UK, The Panel did not consider that the complainant had established that Accord-UK had failed to maintain high standards in this regard. Noting its ruling of no breach of Clause 17.4, above, the Panel did not consider that there were any additional factors that indicated that Accord-UK had failed to maintain high standards. The Panel therefore ruled **no breach of Clause 5.1**.

Complaint received **2 July 2024**

Case completed **1 August 2025**