CASE AUTH/3804/7/23 **NO BREACH OF THE CODE**

HEALTH PROFESSIONALS v ETHYPHARM

Conduct of a representative

CASE SUMMARY

This complaint, received from a group of health professionals from an NHS Health Board, related to the conduct of an Ethypharm representative who allegedly stated factually incorrect information on their two most recent and unannounced visits.

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 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 17.4	**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 was received from a group of verified health professionals from an NHS Health Board about the conduct of an Ethypharm representative.

COMPLAINT

The complaint wording is reproduced below:

> "We have experienced difficulties over the past 9 months with the Aurum range of syringes (Calcium Chloride, Adrenaline and Amiodarone PFS). Several meetings have been conducted with Ethypharm as a result in an attempt to reach a way forward. This has unfortunately has not been possible given that the suggested resolutions will take too long to turnaround. We have made changes within the Health Board as a result and move away from use of their products. Following some of these meetings, one of the Ethypharm representatives has been arriving unannounced on site and has been stating factually

incorrect information to anyone who will listen, only to leave once challenged in a rush when caught out. We have now had two examples, the most recent being this week. Following discussion with the team in question, and several Pharmacists, we felt it pertinent to escalate this behaviour to yourselves. We will also be escalating via our ABPI representative on our Drug and Therapeutics group."

Further information (email 1)

"I have copied and pasted an e-mail I received from [named colleague] below to provide further detail. [Two named colleagues] will be able to elaborate if needed, and together with [third named colleague] can be considered points of contact.

'I have been away teaching for 2 days but had contact today from my colleague [named colleague] to say that [named representative] from Aurum appeared in the [named hospital] Resus Office yesterday unannounced. They were looking for me but [named colleague] spoke with [them] in my absence.

[Named representative] apparently began to discuss our "compatibility and user error issues" but was stopped by [named colleague] who again informed [them] this is not a compatibility or user error issue; and is a quality issue for Aurum PFS. At this point I understand [named representative] changed [their] line of response, to essentially blaming the manufacturer of the syringe barrel and stating the issues were in their quality control processes instead. I think [they] realised [named colleague] wasn't buying any of it and [they] left fairly quickly afterwards.

This is now the second time [named representative] has appeared in our offices unannounced and I think it is inappropriate for [them] to be doing this without an appointment."

Further information (email 2)

"Just in support of your request for further information/background I can also state that following strained dialogue with Aurum in which they repeatedly make admissions in meetings but then contradict them in writing, our health board have taken measures on patient safety grounds to seek alternative suppliers of emergency Pre-filled syringes and to move away from Aurum.

On two separate occasions now [named representative] (Aurum representative) has attended our offices unannounced and with no appointment.

- Initially on the 8th June 2023 where [they] informed colleagues that the incidents we had reported were down to our processes being insufficient and that human error was also to blame (this was never agreed at any point, and in fact the opposite had been agreed in meetings where Aurum representatives had acknowledged several deficiencies in their own Quality Assurance processes). [They] also stated that I had agreed for our health board to purchase adapters (I had not agreed to this at all). When [they were] informed that [their] timing was fortunate and that I was about to be contacted for a meeting via Microsoft Teams, [they] immediately left.

- Then on the 26th June [named representative] attended another of our offices, and was spoken to by my colleague [named colleague]. You have the details of this meeting already from [named colleague].

While I understand the impact that losing a significant account such as our (our health board covers approximately a third of [region]) may have on Aurum; the company have been evasive, opaque, and unprofessional in their responses to us. They have also misrepresented the content and agreements in the meetings we have when they provide written responses. To then have two unannounced visits to our offices by the Aurum representative where misinformation has continued to be attempted is I feel both unprofessional and unacceptable. Further visits will be unwelcome and I have instructed our offices now to simply turn [them] away if [they] arrive without an appointment."

When writing to Ethypharm, the Authority asked it to consider the requirements of Clauses 5.1, 17.2 and 17.4 of the Code.

ETHYPHARM'S RESPONSE

The response from Ethypharm is reproduced below:

"Ethypharm acknowledges receipt of a complaint concerning the conduct of one of our Key Account Managers. Ethypharm takes the ABPI Code of Practice very seriously and is always committed to maintaining high standards and ensuring compliance with the Code in all its relevant activities. We acknowledge that there have been several communications between [named health board] and Ethypharm regarding issues with the Aurum range of prefilled syringes. These communications received from [named health board] involved issues that may potentially impact patient safety, and as such Ethypharm felt that it had the duty to take necessary action to investigate the safety issues reported to us.

Therefore, Ethypharm considers that it and its representative have acted within the scope of their duties when dealing with adverse event reporting.

[Copy provided] outlines the response that was initially sent to [named health board] from our Product Quality Complaints (PQC) department. [Named health professional], at [named health board], responded to this communication via our customer services department to say that the response letter did not address the concerns raised by them. It was at this point that our local Key Account Manager, [named representative], initiated communications with [named lead pharmacist] to discuss and follow up on this matter. It was agreed with the [named lead pharmacist] that a Teams meeting would be useful to discuss these issues. This Teams meeting took place on 3rd February 2023 and was attended by our Key Account Manager, as well as [three health professionals].

The issues experienced with the product were discussed and [named health board] expressed their dissatisfaction with the response they had received from Ethypharm, thus requesting further analysis to be conducted by us. From this juncture onwards, all interaction between our Key Account Manager and various healthcare professionals (HCPs) at [named health board] has been to discuss and follow-up on this matter.

Ethypharm has conducted an investigation of this matter, including a thorough interview with the Key Account Manager involved, and scrutiny of [their] contacts with [named health board].

Below we have addressed the alleged breaches of the code with the information obtained during our investigation.

1) **<u>Alleged breach of 17.2 (15.2) Representatives must maintain a high standard of ethical conduct in the discharge of their duties and comply with all relevant requirements of the Code.</u>**

- The further information attached to the complaint states '*To then have two unannounced visits to our offices by the Aurum representative where misinformation has continued to be attempted is I feel both unprofessional and unacceptable*.'
    - As previously stated, the two '*unannounced visits*' were part of an ongoing issue and were necessary to provide information to ensure the safe use of prefilled syringes.
    - There was no attempt to spread '*misinformation*' rather to ensure patient safety is maintained when using the Aurum range of prefilled syringes. It should be noted that the Aurum range of prefilled syringes have been used widely for 27 years.
    - We reiterate that these visits were conducted in a professional manner and were fully compliant with the provisions of clause 17.4 of the 2021 ABPI Code of Practice.
- We are fully confident that our Key Account Manager has acted properly at all times in relation to this matter and entirely in accordance with requirements of the provisions of clause 17.2 of the 2021 ABPI Code of Practice.

2) **Alleged breach of 17.4 (15.4) 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.**

- The complaint states '…one of the Ethypharm representatives has been arriving unannounced on site and has been stating factually incorrect information to anyone who will listen, only to leave once challenged in a rush when caught out.'

    - *As per clause 17.4, follow-up on reports of an adverse reaction are not included in the call frequency count. Therefore, we believe that, as explained below, the Key Account Manager's follow-up visits are exempt from the call count.*
    - **Supplementary information on clause 17.4 regarding no of visits and safety issues:**

- *'Companies should arrange that the frequency of visits does not cause inconvenience. The number of calls made on a doctor or other prescriber by a representative each year should not normally exceed three on average. This does not include the following which may be additional to those three visits:*
  - *attendance at group events/meetings, including audiovisual presentations and the like*
  - *a visit which is requested by a doctor or other prescriber or a call which is made in order to respond to a specific enquiry*
  - *a visit to follow up a report of an adverse reaction*

- A further three subsequent complaints were raised by [named health board] regarding 'blocked' prefilled syringes. These complaints were thoroughly investigated and were found to be suspected of being blocked by use with incompatible connectors. Our Key Account Manager maintained contact with [named health board] during this period.

  - Our Key Account Manager has visited [named health board] sites four times during the past 12 months regarding Aurum prefilled syringes. Twice to [named hospital], the first time on 8th June 2023 to speak with the resus officers. This was a call to find out if they were still using the Aurum range. During this call it was agreed that the Key Account Manager would bring connector compatibility posters the following week. The second visit to [named hospital] was, as agreed, a week later, on the 16th of June 2023. During this visit the Key Account Manager did not speak to anyone regarding Aurum and left the posters with the paediatric team in their offices next door.
  - The Key Account Manager has also visited [named hospital] on the 23rd of June 2023. During this visit he left connector compatibility information with the pharmacy department.
  - On the 26th of July 2023 our Key Account Manager visited [second named hospital] and spoke with the [manager], to find out whether [named health board] have now stopped purchasing our Aurum prefilled syringes.
  - Please note that our Key Account Manager did not visit any sites on 26th of June 2023 as is claimed in the further information from the complainant.
  - We believe that this level of calling is consistent with the provisions of clause 17.4 of the 2021 ABPI Code of Practice.
  - The information that the Key Account Manager provided in these calls was not '*factually incorrect'* and was consistent with the responses from our PQC team following extensive investigations into the issues with the 'blocked' prefilled syringes.
  - Our Key Account Manager did not state this information to 'anyone who will listen'. Our Key Account Manager has shared this information only with HCPs involved in the use and training of the Aurum range of prefilled syringes, who would need to be aware of the need to use compatible connectors as an urgent safety issue.

- The further information from the complainant also states, '*On two separate occasions now the Aurum representative has at[t]ended our offices unannounced and with no appointment*.'

    - As previously mentioned above, we accept that our Key Account Manager made these calls, but that they were consistent with the provisions of clause 17.4 of the 2021 ABPI Code of Practice and the need to follow-up on safety concerns.

- Regarding these calls, the further information goes on to state '*Initially on the 8th of June 2023 where [they] informed colleagues that the incidents, we had reported were down to our processes being insufficient and that human error was also to blame (this was never agreed at any point, and in fact the opposite had been agreed in meetings where Aurum representatives had acknowledged several deficiencies in their own Quality Assurance processes). They also stated that I had agreed for our health board to purchase adapters (I had not agreed to this at all). When [they were] informed that [their] timing was fortunate and that I was about to be contacted for a meeting via Microsoft Teams, they immediately left*.'

    - During the meeting on 8th of June 2023, our Key Account Manager spoke with 2 Resuscitation Officers about the issues with 'blocked' syringes and how detailed analysis had established that they were the result of using incorrect connectors. They did not state that the procedures at [named health board] were '*insufficient'* and that '*human error was to blame*'. They did however discuss the following information regarding labels on the Aurum boxes. One end of the box contains a label with batch-specific information, and the other end has a plain white label, serving as the tamper-evident seal. The batch-specific label can sometimes close so neatly that the box may appear to have not been opened. The tamper-evident seal tears in such a way that it does not close neatly. However, if only the batch-specific label is checked then a previously opened box could feasibly be mistaken for an unopened box. This might explain how an apparently unopened prefilled syringe may be 'blocked' if it had previously been connected to an incompatible needle-free connector and then replaced in the box. Ethypharm are taking measures to enhance the visibility of the tamper-evident seal and are currently undergoing a change control process to add the word 'TAMPER' in red to the tamper seal, making it more distinguishable.
    - During previous meetings Aurum representatives have not '*acknowledged several deficiencies in their own Quality Assurance processes'* however, discussion has taken place concerning the labels as detailed above.
    - Our Key Account Manager did not state that anyone at the Health Board had agreed to purchase adaptors.
    - Upon being told that the person our Key Account Manager was visiting was '*about to be contacted for a meeting via Microsoft Teams*', our Key Account Manager respectfully left in order to allow the call to take place.

3) <u>Alleged Breach of 5.1 (9.1) High standards must be maintained at all times.</u>

- We believe that our Key Account Manager has acted professionally at all times. As already stated, suspected 'faulty' syringes are a serious safety issue. Ethypharm is confident that, following detailed analysis, the issues experienced by [named health board] are not due to faulty syringes, but rather a result of the syringes being connected to incompatible needle-free connectors. Ethypharm is keen to ensure that all potential users of the Aurum range of prefilled syringes are aware of the dangers of using incorrect needle-free connectors and as such the company, including our Key Account Managers, have provided relevant information on this were deemed appropriate.
- The further information from the complainant states '*I can also state that following strained dialogue with Aurum in which they repeatedly make admissions in meetings but then contradict them in writing, our health board have taken measures on patient safety grounds to seek alternative suppliers of emergency Pre-filled syringes and to move away from Aurum*.'
    - No examples have been provided regarding this complaint which we refute. We maintain that our Key Account Manager acted with high standards and that their discussions were fully consistent with the communications sent from our PQC department.
- The further information also claims '*the company have been evasive, opaque, and unprofessional in their responses to us*'
    - We believe that we have acted professionally in all communications with [named health board]. Our responses have all been made in a timely manner and addressed the concerns of [named health board]. The investigations into the 'blocked' syringes complaints have been diligent and scientific in their approach. The responses sent back have been clear in their findings and respectful. All communications from our Key Account Manager have been in line with these responses.

To aid in the assessment of this claim I am attaching copies of all the email communications our Key Account Manager had with HCPs working in [named health board] regarding Aurum over the past 12 months [copy provided]; and a timeline of our Key Account Manager's interactions, including call notes [copy provided].

Ethypharm does not set Key Account Managers call rate targets nor does it monitor or incentivise on this basis.

In summary, Ethypharm affirms that our Key Account Manager, in accordance with Clause 5.1, maintained high standards during interactions with [named health board] HCPs. Patient safety remained central to his activities, and he endeavoured to ensure effective and safe usage of the Aurum range of prefilled syringes. Our Key Account Manager's conduct was fully in compliance with the provisions of clause 17.2 of the Code. Furthermore, our Key Account Manager's interactions with [named health board] were entirely consistent with the gravity of the issue and were not intended in any way to cause inconvenience. Given the complainant's indication of a desire to cease communication, our Key Account Manager respects this decision and will therefore refrain from further visits regarding this matter.

No examples have been provided by the complainant as to when we have '*misrepresented the content and agreements in the meetings we have when they (we) provide writ[t]en responses*'. On the contrary, we believe that our verbal communications and written communications have always been consistent and clear.

Ethypharm and its representative have acted within the scope of their duty when dealing with adverse event reporting. Therefore, clauses 5.1, 17.2 and 17.4 have not been breached."

PANEL RULING

This complaint, received from a group of health professionals from an NHS Health Board, related to the conduct of an Ethypharm representative who allegedly stated factually incorrect information on their two most recent and unannounced visits.

The Panel noted there had been several communications between the Health Board and Ethypharm regarding prefilled syringes since the Health Board's complaint to the pharmaceutical company in December 2022 regarding blocked syringes. While Ethypharm's investigation found the syringes to be blocked due to incompatible connectors, the Health Board maintained that the syringes were blocked due to being faulty.

The Panel noted the complainants referred to 8 June 2023 and 26 June 2023 as the unannounced visit dates, the latter of which actually appeared to have been conducted on 26 July 2023.

The Panel noted, after being made aware of a yellow card report in April 2023, the representative had made contact with a health professional to arrange a meeting, but this was declined and there appeared to be no further contact in relation to this. This was followed by a further yellow card report in May which the representative followed up by email on 7 June 2023 to the same health professional offering to deliver materials on connector compatibility to which they were asked to "just pop them in the post" to pharmacy.

Ethypharm's notes stated the representative visited the hospital the following day on 8 June to deliver connector compatibility charts and sample syringes but as they were unable to speak with the health professional, they left the materials with pharmacy. The representative then called in to the resuscitation training team and discussed the issue of the syringes with two health professionals the representative had not seen before.

The complainants stated that as part of this 8 June visit, the representative advised the incidents reported were due to insufficient processes and human error by the Health Board which they disagreed with; the complainants alleged representatives had acknowledged several deficiencies in the company's quality assurance processes and that the representative stated one of the complainants agreed for the Health Board to purchase adapters which was not so.

With regard to the 26 July visit, Ethypharm submitted that the representative was at a different hospital visiting other departments and decided to visit its resuscitation department to obtain an update on connector compatibility and its use of their products. The complainants submitted the representative started to discuss "compatibility and user error issues" with a health professional but after being stopped, changed their response to "blaming the manufacturer of the syringe barrel and stating the issues were in their quality control processes instead".

The Panel noted the complaint broadly related to allegations regarding “factually incorrect” information to “anyone who will listen” and repeated admissions in meetings which were then contradicted in writing. Ethypharm disagreed with all allegations in this regard.

The Panel understood that the blocked syringes was a patient safety issue but noted the parties’ accounts differed; it was not for the Panel to determine which party’s findings for the syringes being blocked were factually correct. It was for the Panel to consider the conduct of Ethypharm and its representatives in its communications with the health board.

The Panel noted that it appeared that much of this case related to one party’s word against another. It was difficult in such cases to determine where the truth lay. As stated in the introduction to the Constitution and Procedure, a complainant had the burden of proving their complaint on the balance of probabilities and a judgement had to be made on the available evidence, bearing in mind the extreme dissatisfaction usually necessary on the part of an individual before they were moved to actually submit a complaint.

Nonetheless, given the information before it, the Panel decided it was not possible to determine precisely what had been said verbally during the interactions 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. **No breach of Clause 17.2** was ruled.

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 supplementary information to Clause 17.4 stated, among other things, that the number of calls made on a doctor or other prescriber by a representative each year should not normally exceed three on average. This did not include attendance at group meetings and the like, a visit requested by the doctor or other prescriber or a visit to follow up a report of an adverse reaction, all of which could be additional to the three visits allowed.

Ethypharm submitted that its representative’s visits constituted follow-ups of reports of an adverse reaction which were not included in the call frequency count. In this regard, the Panel noted the timeline of communication provided by Ethypharm appeared to outline that complaints and yellow card reports had been made at least three times between December 2022 and June 2023 which were followed up by the representative. The Panel additionally noted that the representative’s visits did not appear to all be to a single health professional but several, including resuscitation officers, pharmacists and nurses.

The Panel noted that it was clear that the staff had been upset and this was most unfortunate. The Code required that representatives’ calls should not cause inconvenience to those upon whom they call. Representatives should be mindful of the impression created by their conduct particularly when they did not have appointments.

The Panel took account of the email trail which included one example of the representative being declined a visit which appeared to have been adhered to. There did not appear to be any written communication before the Panel asking the representative not to visit nor did the Panel

have the Health Board's policy before it in relation to representative visits without an appointment.

On the information before it and taking into account the above, the Panel did not consider the complainants had shown, on the balance of probabilities, that the representatives had called on the health professionals in a manner that caused inconvenience, taking into account frequency or timing, or did not observe the wishes of individuals. **No breach of Clause 17.4** was ruled.

Ethypharm submitted that its representative's interactions were not intended to cause inconvenience and given the complainants' desire to cease communication, further visits would be refrained. The Panel noted Ethypharm's submission that its representatives were not set call rate targets nor are they monitored or incentivised on this basis.

While the Panel understood that the Health Board would have been a large customer for Ethypharm, covering a significant region for the representative, the Panel did not consider it had not been established that Ethypharm had failed to maintain high standards, taking into account its rulings of no breaches above. **No breach of Clause 5.1** was ruled.

Complaint received **28 July 2023**

Case completed **6 November 2024**