CASE AUTH/3682/8/22

COMPLAINANT v ACCORD

Conduct of a representative in relation to off-licence promotion of Methofill

CASE SUMMARY

This case concerned the conduct of a representative in relation to the off-licence promotion of Methofill (methotrexate).

The Panel ruled a breach of the following Clauses of the 2021 Code because in failing to inform a children's gastroenterology nurse that use of Methofill in the treatment of Crohn's Disease in children was outside of licence on receipt of the email request for materials and training devices, which the representative provided to the nurse later that day, the representative had promoted Methofill outside the terms of its marketing authorisation:

Breach of Clause 11.2	**Promoting a medicine outside the terms of its marketing authorisation**
Breach of Clause 17.2	**Representative failing to maintain a high standard of ethical conduct**

Accord appeared to have been let down by one employee; there was no evidence before it that similar interactions by other representatives had taken place. In this regard, and noting the actions of Accord once it was made aware of the representative's actions which included immediately instructing the representative to contact the nurse to clarify the licence of Methofill, prior to the patient being seen in clinic, the Panel ruled no breach of the following Clauses of the 2021 Code:

No Breach of Clause 5.1	**Requirement to maintain high standards**
No Breach of Clause 2	**Requirement that activities must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**

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

FULL CASE REPORT

An anonymous non-contactable pharmaceutical company employee complained about the conduct of an Accord representative and alleged off-licence promotion of Methofill methotrexate).

COMPLAINT

The complainant alleged that an Accord representative had been selling Methofill off-licence to nurses and that this had been raised during a Teams meeting in front of the entire team. The

complainant stated that they had been told that they were not under obligation to report this but thought it brought the industry into disrepute and that high standards had not been maintained.

The complainant did not provide any material to support his/her complaint.

When writing to Accord, the Authority asked it to consider the requirements of Clauses 11.2, 17.2, 5.1 and 2 of the Code.

RESPONSE

Accord stated that it was aware of the issue raised in this complaint and was in the process of addressing it as part of its continuous improvement activities, details of which were provided in its response letter. Nonetheless, Accord was very disappointed that this happened.

Details of the incident

In July 2022, a representative received an email from a Specialist Nurse for Children's Gastroenterology requesting some training material and devices for the Methofill prefilled injector. The representative responded that they could deliver these to the hospital department and did so that day. Accord stated that, unfortunately, the representative did not pick up or address the nurse's comment in the email that the intention was to use Methofill in a child for the treatment of Crohn's Disease. The summary of product characteristics (SPC) for the Methofill prefilled injector stated 'There is not sufficient experience in the paediatric population to recommend methotrexate for the treatment of Crohn's Disease in this population.'.

Accord stated that having discussed the matter with the representative as part of its investigation into this complaint, it seemed that, when they initially read the email from the nurse, they were focused on the request for training material and advice and was not thinking about the specific patient who the medicine had been prescribed for. When the representative met with the nurse later the same day, they provided the training devices and demonstrated how to use them. There was a discussion that the patient had a phobia of needles and that the device might therefore be suitable for them, but there was no discussion of use of the medicine in the treatment of Crohn's Disease specifically.

A few days later in early August 2022, the representative attended a weekly internal teleconference held for the purpose of representatives providing feedback on recent activities. In this meeting, the representative in question referred to their interaction with the Specialist Nurse for Children's Gastroenterology, that they had discussed a 13 year old patient and the use of Methofill. At this point, a senior employee halted the meeting in order to remind attendees that Methofill was not licensed for use in children for the treatment of Crohn's Disease and to also request that the representative contacted the nurse in question as soon as possible to explain this. Accord provided an email from an attendee present at the meeting confirming this and the minutes of the internal teleconference.

The representative spoke to the nurse the same day to clarify the Crohn's Disease indication and then followed this up with an email to the nurse a few days later as confirmation of the conversation.

Immediate action

Accord stated that, in addition to the actions described above, in early August 2022 the senior employee called a meeting for all those that promoted Methofill to inform them of the situation and that the entire team would undergo refresher training on the medicine.

Following certification of the refresher training and associated validation questions, a training session was rolled out via Teams in mid-August 2022 and a mop-up session was completed later in August 2022 for those that were on annual leave. Accord submitted that the refresher training was very clear on the licence indications for Methofill and the validation also emphasised this.

The validation required a 100% pass mark and Accord provided the completion record for the representative in question.

Accord submitted that, in addition to the above, the representative would undergo an internal performance review which would include additional coaching and joint calls with their manager and/or the sales training manager; a meeting had been arranged.

Representative training

Accord stated that, as with all of its sales force, the representative in question had received detailed and tailored training in relation to Methofill, as well as the Code, and provided the dates when the representative had completed training on Methofill indication validation, Methofill role play validation and Accord sales team ABPI and SPC introduction and validation, which had all been completed prior to the incident in question.

Accord submitted that a total of 7 training modules were certified and formed part of the product and disease training; training Module 6 contained the licensed indication and dosing information. In addition, representatives received further training regarding the ABPI Code and SPC introduction and validation. Accord submitted that, in particular, it was very clearly stated in the 'SmPC field sales training' that a medicine must only be promoted within the terms of its marketing authorisation and that 'off-label' discussions with health professionals were forbidden.

Further, all representatives received annual refresher training on the Code, which was completed by the representative in question in 2021 and 2022. The sales teams also regularly discussed (every 2 months) published PMCPA cases that were considered relevant to their role; the most recent of these sessions took place in mid-August 2022 when a case involving representative conduct was discussed.

Representative conduct

Accord stated that it had reviewed the records in its Customer Relationship Management (CRM) system for calls documented by the representative in question over the last 3 months and there was no evidence that they had had any discussions with health professionals about the use of Methofill in the treatment of Crohn's Disease in children. In addition, the complainant's manager had informed Accord that they had never witnessed this conduct in joint calls with the representative. The CRM records for the representative for the last 3 months were provided.

There was one further entry in the CRM system by this representative (dated 26 July 2022) which suggested that a nurse had raised the use of Methofill in paediatrics for Crohn's Disease. However, the representative confirmed in their interview that the discussion was with a nurse in

the adult gastroenterology department of the hospital whilst the representative was attempting to arrange a meeting to discuss the medicine; the nurse referred to having seen paediatric patients on Methofill, but the representative made no comment and did not discuss the matter further.

Therefore, according to Accord, this appeared to be a very regrettable, temporary lapse in judgement by the representative. Accord acknowledged that the representative did act in a manner contrary to the requirements of Clause 11.2 and it accepted that this clause had been breached. Further, it agreed that the representative had failed to maintain a high standard of ethical conduct, in breach of Clause 17.2. However, given the comprehensive training and briefing provided to the representative on both the medicine and the Code, and the fact that Accord addressed it swiftly and comprehensively once it became aware of it, Accord did not consider that it had failed to maintain high standards or that it had reduced confidence in, or brought into disrepute, the industry and hence Accord refuted any breach of Clauses 5.1 and 2.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure for the Prescription Medicines Code of Practice Authority stated that anonymous complaints would be accepted but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant had not provided any details relating to a specific incident and could not be contacted for further information.

The Panel noted that Accord was aware of the issue raised by the complainant, had instigated an investigation into the matter, implemented a corrective action and communicated to staff a preventive action plan prior to the Authority's receipt of the complaint.

Accord submitted that the complaint related to an email received by a representative from a children's gastroenterology nurse stating that a child would be starting on Methofill for Crohn's disease the following week and requesting training material for the self-injector and asking about trainer devices.

The Panel noted that the representative replied to the email and agreed to provide the requested items later that day; the CRM entry recorded the delivery of the requested items and noted that the request related to a new paediatric patient about to receive Methofill for Crohn's Disease and that the health professional would consider for other new patients if they had a 'good experience'.

The Panel noted that Methofill had a number of different therapeutic indications, one of which was for the treatment of mild to moderate Crohn's disease either alone or in combination with corticosteroids in adult patients refractory or intolerant to thiopurines and Section 4.2 of the SPC stated 'There is not sufficient experience in the paediatric population to recommend methotrexate for the treatment of Crohn's disease in this population'. The Panel noted, therefore, that use in children with Crohn's disease would be inconsistent with the SPC and off-label.

It appeared to the Panel that the representative first became aware of an issue when a senior employee interrupted the weekly team meeting during their report to remind attendees that

Methofill was not licensed for use in children with Crohn's disease and to request that the representative contact the nurse as soon as possible.

The Panel noted that the representative subsequently called the nurse, the same day as the team meeting, and left a voicemail message which they followed up with an email requesting a call back. It also noted a phone entry in the CRM system that same day documenting that they had spoken to the nurse and reminded them that use of Methofill in paediatric Crohn's patients was off-label. Whilst the Panel noted a slight discrepancy between the time the email was sent requesting the nurse to call the representative back and the actual phone call with the nurse recorded in the CRM, it appeared, from the company's investigation and interview with the representative, that the representative had spoken to the nurse and made them aware of the off-label use before the paediatric patient was seen in the clinic later that day. The Panel was concerned that the representative did not follow up this phone call with an email until 3 days later as they 'did not get the chance'.

The Panel queried Accord's submission that the representative had been focused on the request for training materials and training devices and 'was not thinking about the specific patient for which the medicine had been prescribed'. The Panel noted the nurse's initial email regarding the intended use of the medicine in a child with Crohn's disease, together with their job title as a specialist nurse for children's gastroenterology, the name and logo of the Children's Hospital; the record entered into the CRM by the representative clearly stated the request related to a paediatric patient with Crohn's disease.

In the Panel's view, it was abundantly clear from the initial email and CRM record that the request related to off-label use of Methofill in a child with Crohn's disease. The Panel was deeply concerned that the representative had not immediately alerted the nurse to the fact that this would constitute off-label use and to refer to the statement in the SPC that there is not sufficient experience in the paediatric population to recommend methotrexate for the treatment of Crohn's disease in this population.

Whilst the Panel understood that it was the prescriber's decision whether to prescribe the medicine off-label, and that it appeared from the nurse's email that the decision to prescribe Methofill for this particular patient had already been made, the Panel considered that it was the representative's duty to make immediately clear that such use would be off-label; such use should also have been reported to the company's scientific service.

The Panel noted that during Accord's investigation, it had identified a further entry in the CRM with this representative which suggested that a different nurse had raised the use of Methofill in paediatric patients with Crohn's Disease; Accord submitted that the representative had explained during the investigation that this referred to a discussion with a nurse in an adult gastroenterology department whilst they were arranging a meeting to discuss the medicine; the nurse had referred to having seen paediatric patients on Methofill, but the representative made no comment and did not discuss the matter further. In the Panel's view, it was unacceptable for the representative to have made no comment when alerted to potential off-label use; it formed part of a representative's ethical conduct and duty to have informed the nurse that use of Methofill in paediatric patients with Crohn's disease was off-label. Accord's subsequent actions, in this regard, was not available to the Panel, nor was it an alleged matter. Accord solely stated that the representative's manager had confirmed that they had never witnessed any discussions with health professionals about the use of Methofill in the treatment of Crohn's Disease in children in joint calls with the representative.

Turning to the incident in question with the children's gastroenterology nurse, whilst it appeared that once alerted to the issue by a senior colleague, the representative had contacted the nurse again, prior to the paediatric patient being seen in clinic, to clarify the licence, the Panel, nonetheless, considered that by not immediately informing the nurse that use of Methofill in the treatment of Crohn's Disease in children was outside of licence on receipt of the email request for materials and training devices, which they provided to the nurse later that day, that the representative had promoted Methofill outside the terms of its marketing authorisation and a **breach of Clause 11.2** was ruled, as acknowledged by Accord. The Panel considered in doing so, the representative had failed to maintain a high standard of ethical conduct in the discharge of their duty and the Panel ruled a **breach of Clause 17.2**, as acknowledged by Accord.

Turning to the conduct of the company, and whether Accord had maintained high standards, the Panel noted that Accord had trained and validated the representative in question with regard to Methofill prior to the incident in question and, following the incident, Accord had arranged for refresher training and further validation for the entire team. It appeared to the Panel that Accord had promptly instigated an investigation into the matter and had implemented a corrective action and communicated to staff a preventive action plan prior to the Authority's receipt of the complaint. In particular, the Panel noted a senior employee had halted the representatives' meeting to remind attendees that Methofill was not licensed for use in paediatric Crohn's patients and had instructed the relevant representative to contact the nurse as soon as the meeting ended and prior to the patient being seen. The Panel considered that the company had been let down by one employee; the Panel had no evidence before it that similar interactions by other representatives had taken place. In this regard, noting the actions taken by Accord, the Panel did not consider the complainant had established that Accord had failed to maintain high standards and therefore the Panel ruled **no breach of Clause 5.1**.

Clause 2 was a sign of particular censure and was reserved for such use. Whilst the Panel was extremely concerned that the representative's conduct had resulted in the promotion of Methofill outside the terms of its marketing authorisation, as described above, the representative was, nonetheless, instructed to make contact with the nurse to clarify the licence of Methofill, which appeared to occur prior to the patient being seen in clinic. Taking account all the circumstances of this case, and noting its ruling of no breach of Clause 5.1, the Panel did not consider that, on balance, the complainant had established that Accord had brought discredit upon the industry. The Panel, on balance, ruled **no breach of Clause 2**.

Complaint received **5 August 2022**

Case completed **14 July 2023**