CASE AUTH/3264/10/19

ANONYMOUS v MERZ

Cross-border activity between UK and Ireland

An anonymous individual complained about unethical behaviour by Merz across the UK and Ireland with regard to Bocouture (botulinum toxin type A).

The complainant alleged cross border trading of Bocouture from Northern Ireland where it was licensed into the Republic of Ireland where it was not licensed. The complainant alleged that Bocouture was ordered and picked up by a Merz employee from a distributor in Northern Ireland and delivered to a customer at a named medical group based in Dublin. The complainant alleged that this was unethical, underhanded and concerning.

The complainant further alleged that Merz employees demonstrated controlling and threatening communication with the intention of directing sales of Merz medicines or medical devices through the Merz preferred distributing partners only. The complainant stated that a number of aesthetic clinics had told him/her that Merz employees were stating that product concerns or adverse event queries would not be supported if the Merz product in question had not been bought through the Merz UK affiliate business preferred partners. The complainant stated that such behaviour went against all ethical reporting requirements of drug and product safety concerns and was against ABPI and PMCPA principles. The bullying behaviour was to support the financial endeavours of the Merz UK business and did not account for patient safety.

The detailed response from Merz is given below.

The Panel noted that it appeared that the UK registered health professional worked in both Northern Ireland and the Republic of Ireland. The Panel noted that the health professional had ordered Bocouture to be delivered to his/her clinic in Northern Ireland where the medicine was licensed. According to Merz's Deviation Report Form the ordered product, however, was to be used by the health professional to treat patients at his/her clinic in the Republic of Ireland where Bocouture was not licensed.

The Panel noted Merz's submission that at no point was Bocouture promoted to health professionals in the Republic of Ireland. The Panel noted that the complainant bore the burden of proof and had not provided evidence to show that Bocouture had been promoted to the UK health professional contrary to the requirements of the Code and no breach was ruled.

The Panel noted that in an attempt to rectify a shipping error a Merz UK employee collected Bocouture from a warehouse in Northern Ireland and delivered it to the health professional at his/her clinic based in the Republic of Ireland. The Panel noted Merz's submission that the employee only promoted devices and was therefore unaware of the

potential Good Distribution Practice (GDP) and Code of Practice implications of his/her actions.

The Panel considered that in personally delivering Bocouture to the Republic of Ireland where it was not licensed meant that the employee had not maintained high standards and a breach was ruled.

The Panel noted that as part of the CAPA process relevant staff attended training with regards to the licensing status of Bocouture in Northern Ireland and the Republic of Ireland and the potential GDP/ABPI considerations. The Panel considered that in failing to provide this important training earlier, particularly considering the potential of employees and health professionals working across Northern Ireland and the Republic of Ireland, meant that Merz had failed to maintain high standards and a breach was ruled.

The Panel noted Merz's submission that it could find no evidence of 'controlling and threating communication or evidence that communication by representatives that 'adverse event queries would not be supported by Merz UK and Ireland if the product is not bought from a preferred partner' had occurred.

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 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 Panel noted Merz's submission that representatives were briefed in detail regarding the changing relationship with the company's pharmacy wholesalers. According to Merz, the parameters within which Merz UK was able to operate under the new arrangements with its preferred partners were clearly briefed to both sales and medical teams.

The Panel considered that the complainant had not shown, on the balance of probabilities, that the Merz employees had not maintained a high standard of ethical conduct by demonstrating controlling and threatening communication with the intention of directing sales of Merz medicines or medical devices through the Merz preferred distributing partners. No breach of the Code was ruled in that regard.

Whilst the Panel queried whether stating in its Q&A document that Merz might be unable to provide '… product support to clinics' could have been misinterpreted as potentially meaning support with product concerns or adverse event queries which would be of concern. The Panel noted Merz's submission that pharmacovigilance was of the highest priority as illustrated by the annual training recently completed by all Merz Pharma UK employees, pharmacy wholesalers and third party consultants. Merz insisted on a pharmacovigilance agreement between Merz UK and any third party to ensure the safe and effective use of its medicines and devices. The Panel also noted Merz's submission that any change in the support offered to customers was purely commercial. The Panel considered that whilst the Q&A could have been worded more clearly, on balance, there was no evidence to show that Merz product concerns or adverse event queries would not be supported by the Merz UK and Irish business if the Merz product in question had not

been bought through the Merz UK affiliate business preferred partners as alleged. No breach of the Code was ruled in this regard.

The Panel noted its rulings and comments above but did not consider that the particular circumstances of this case were such as to warrant a breach of Clause 2 which was a sign of particular censure. No breach of Clause 2 was ruled.

An anonymous individual complained about unethical behaviour by Merz across the UK and Ireland with regard to Bocouture (botulinum toxin type A).

Bocouture (botulinum toxin type A) was indicated for the temporary improvement in the appearance of upper facial lines in adults below 65 years when the severity of these lines had an important psychological impact for the patient: moderate to severe vertical lines between the eyebrows seen at maximum frown (glabellar frown lines) and/or; moderate to severe lateral periorbital lines seen at maximum smile (crow's feet lines) and/or moderate to severe horizontal forehead lines seen at maximum contraction.

COMPLAINT

The complainant alleged cross border trading of Bocouture from Northern Ireland where it was licensed into the Republic of Ireland where it was not licensed. The complainant alleged that Bocouture was ordered and picked up by a named Merz employee from an aesthetics distributor in Northern Ireland and delivered to an Irish customer at a named medical group based in Dublin. The complainant alleged that this direct marketing and support of an unlicensed medicine into Ireland was unethical, underhanded and concerning.

The complainant further alleged that two Merz employees demonstrated controlling and threatening communication with the intention of directing sales of Merz medicines or medical devices through the Merz preferred distributing partners only. The complainant stated that a number of aesthetic clinics had told him/her that the two Merz employees were stating that product concerns or adverse event queries would not be supported by the Merz UK and Irish business if the Merz product in question had not been bought through the Merz UK affiliate business preferred partners. The complainant stated that such behaviour went against all ethical reporting requirements of drug and product safety concerns and was against ABPI and PMCPA principles. The bullying behaviour was to support the financial endeavours of the Merz UK business and did not account for patient safety.

When writing to Merz, the Authority asked it to consider the requirements of Clauses 2, 3.1, 9.1 and 15.2 of the Code.

RESPONSE

Merz stated that in its view the complainant's allegations fell outside the remit of the Code as the alleged incidents took place in the Republic of Ireland.

Chronology of events concerning 'Cross border trading of an unlicensed medicine':

Friday 5 April 2019

Merz explained that on Friday 5 April 2019 an Irish member of Merz staff received an email from Merz Customer Services, highlighting that Xeomin instead of Bocouture had been shipped to a customer's Northern Ireland clinic. The course of action taken was an attempt to rectify a shipping error in response to an urgent request from a UK registered doctor who had prescribed Bocouture.

The customer had patients booked for treatment the following day and therefore demanded that the problem be rectified. Merz Customer Services advised that they would not be able to deliver a replacement order until Monday, 8 April.

The employee called his/her manager for advice who suggested that the customer source an alternative brand of toxin from the local wholesaler. The customer was unhappy with this as Bocouture had been prescribed for the patients.

Another Merz employee was contacted to ascertain whether any partner pharmacy wholesaler would be able to deliver the order to the customer's Northern Ireland clinic. Two partners confirmed that they would be able to supply the product, however the customer did not have accounts with either. It was confirmed to Merz commercial manager by one of Merz' then partner wholesalers that the clinic could place their order through a wholesaler but would not be able to deliver at such short notice.

It was too late to arrange a courier for the order therefore the Merz employee collected it from the Northern Ireland warehouse and delivered it directly to the customer at his/her clinic in the Republic of Ireland where he/she was at the time.

Monday 8 April 2019

Merz senior management, knowing what had occurred on Friday 5 April, ensured a deviation CAPA was raised. The relevant staff were all spoken to directly to ensure that the process deviation, Good Distribution Practice (GDP) implications and Code of Practice implications of this course of action were clear and understood and what alternative actions were appropriate in the future.

Thursday 2 May 2019

As part of the CAPA process the rest of the Merz team, including those outside of the Republic of Ireland, attended a workshop facilitated by the medical team. This workshop covered the licensing status of Bocouture in Northern Ireland and the Republic of Ireland and explained the potential GDP/ABPI considerations. It was stated that no samples or stock should be delivered into the Republic of Ireland and that any requests for information regarding Bocouture from customers in the Republic of Ireland should be referred directly to medical information as it was an unlicensed medicine in the Republic of Ireland.

Thursday 11 July 2019

To ensure that any new starters or any employees who might have missed the previous session were aware of the GDP/ABPI process regarding Bocouture, during the company conference, the Merz team was again reminded of its obligation to understand the standard operating procedures (SOPs) covering GDP and the implications of Bocouture being licensed in Northern Ireland and unlicensed in the Republic of Ireland. An additional briefing was conducted at this

meeting regarding Merz's changing commercial relationship with its pharmacy wholesale distribution partners.

Tuesday 4 September 2019

In order to complete the CAPA process the Merz sales team was again trained on the importance of understanding the principles of GDP and the implications regarding the license for Bocouture in Ireland. A session was run by the medical department including a Q&A session in order to address any potential questions from the team.

Background & the context of this incident

The Merz employee named by the complainant promoted the devices within the Merz portfolio (not prescription only medicines (POMs)) and, as such, had been unaware of the potential implications of this action to rectify a shipping error. As a result of the CAPA process, the employee, had since taken the ABPI examination for representatives.

The induction training programme (ITC) for representatives had been reviewed to ensure specific detailed training on GDP compliance issues. The annual GDP update training was delivered to all Merz employees in early October as part of the Merz SOP on ongoing training.

Merz initiated a series of ABPI Code clubs in July 2017 that had become part of the ongoing training programme for staff involved in activities which came within the scope of the ABPI Code and were mandatory for all Merz Pharma UK employees, including those working on the devices portfolio. The Code clubs focused on different clauses and were also mandatory for all of the UK management team to reinforce the company's compliance culture.

Compliance culture

Merz submitted that the complaint fell outside of the remit of the ABPI Code as the incidents took place in the Republic of Ireland, were not promotional and related entirely to the physical distribution of product. The GDP issue was dealt with immediately and captured in the CAPA and deviation process. This process was in place to ensure that the highest standards concerning Merz products and their promotion and safe use were applied at all times.

Regarding the allegation of 'controlling and threatening communication' and 'withdrawal of support for adverse event reporting' by staff in Republic of Ireland, pharmacovigilance (PV) of products was of the highest priority to Merz as illustrated by the annual training recently completed by all Merz Pharma UK employees, pharmacy wholesalers and third party consultants. Merz insisted on a pharmacovigilance agreement between Merz UK and any third party to ensure the safe and effective use of its medicines and devices. A robust CAPA and deviation process was in place, as highlighted during a recent PV audit by Merz's global organisation.

Merz UK medical affairs regularly presented updates on the Code to the sales teams at regional and team meetings. All permanent members of the promotional team were expected to undertake the ABPI examination and were coached regularly in the field by the sales managers.

Review of the potential breaches

Clause 15.2 (high standard of ethical conduct for representatives)

Merz stated that it was difficult to defend against an allegation made with no evidence however, having investigated thoroughly it found no evidence of 'controlling and threatening' communication and found it highly questionable to have occurred from the Merz employees.

Regarding the accusation of unethical behaviour and lack of support for pharmacovigilance of its products, this accusation appeared to have arisen in response to its representatives highlighting the preferred partner status of two pharmacy wholesalers and the ceasing of trading with another. With no supporting evidence for the complaint it was difficult to know what actions the complainant would propose were in need of defence. Merz stated following a thorough investigation, it had found no evidence that communication by employees that 'adverse event queries would not be supported by Merz UK and Ireland if the product is not bought from a preferred partner' had occurred.

Merz stated that its employees were briefed in detail regarding the changing relationship with its pharmacy wholesalers. The parameters within which Merz UK was able to operate under the new arrangements with its preferred partners were clearly briefed.

Since Clause 15.2 was specific to 'ethical' conduct Merz submitted that the employees' actions had been in any way unethical; they had attended various meetings, including ABPI Code club sessions, PV training and Code sessions. The employees had received exemplary appraisals and met all objectives regarding Code compliance and Merz values.

Recognising the relatively narrow definition of Clause 15.2 relating to ethical standards Merz noted the culture of the organisation which was driven and reinforced with a high degree of regularity from both a corporate and local leadership perspective. One company value was to 'Deliver trusted results'; the supporting sub-text stated:

> 'Quality, ethics and excellence are at the heart of what we do, patients really matter and we will always be honest.'

At a local level all new employees were taken through an induction process that included Merz's values and also reinforced its compliance mantra that Merz would '***never compromise patient safety nor mislead healthcare professionals'***. This was widely understood by all staff to the extent that they could recite it.

Clause 9.1 (high standards)

Employees were briefed in detail regarding the changing relationship with the company's pharmacy wholesalers. The parameters within which Merz UK was able to operate under the new arrangements with its preferred partners were clearly briefed. The briefing document was provided and Merz stated that it demonstrated that any change in the support offered to customers was purely commercial. Certain commercial offers and training would no longer be available to customers if they used distributors that did not have preferred partner status.

This new arrangement was clearly explained as a necessary change in the business model to stop product reaching the customer that was sourced through unverifiable routes over which Merz UK had no GDP oversight. Merz noted that the UK had seen a proliferation of small importers and distributors in the aesthetic medicine segment and devices were not yet subject

to the Falsified Medicines Directive, meaning that the provenance of product could not be guaranteed. Merz took patient safety very seriously and had made efforts to ensure that health professionals could be sure that the products they received were both genuine and had been handled in accordance with GDP. Merz stated that its pharmacovigilance obligations were clear and, just as it took GDP seriously, it took GPhVP extremely seriously. All staff and appropriate suppliers were trained annually (tracked by an online Quality Management platform) and a recent PV audit gave rise to no serious or critical findings.

Clause 3.1 (promotion of a medicine prior to a licence)

Merz submitted that at no point was Bocouture promoted to health professionals in the Republic of Ireland. As outlined above, an employee delivered stock in response to an urgent request by a UK registered doctor who had written the prescriptions for the medicine required and placed the order beforehand. The course of action was taken in the attempt to rectify a shipping error in response to an urgent request from a UK registered doctor who wished to use Bocouture.

Clause 2 (bringing the industry into disrepute)

Merz submitted that since Clause 2 was a sign of particular censure reserved for serious, multiple or repeated breaches Merz did not consider that these unsubstantiated complaints constituted such a breach.

Summary

Merz stated that it continued to take compliance seriously and it was a very real part of its leadership culture. As a small company Merz's limited resources inevitably meant that the company would not be perfect all of the time, but its intent was genuine.

PANEL RULING

The Panel noted that the Code applied, *inter alia*, to the promotion of medicines to members of the UK health professions and to other relevant decision makers. The Panel noted that Clause 3.1 stated that a medicine must not be promoted prior to the grant of the marketing authorization which permits its sale or supply.

The Panel noted that it appeared that the UK registered health professional worked in both Northern Ireland and the Republic of Ireland. The Panel noted that the health professional had ordered Bocouture to be delivered to his/her clinic in Northern Ireland where the medicine was licensed. According to Merz's Deviation Report Form the ordered product, however, was to be used by the health professional to treat patients at his/her clinic in the Republic of Ireland where Bocouture was not licensed.

The Panel noted Merz's submission that at no point was Bocouture promoted to health professionals in the Republic of Ireland. The Panel noted that the complainant bore the burden of proof and had not provided evidence to show that Bocouture had been promoted to the UK health professional contrary to the requirements of Clause 3.1 and no breach was ruled.

The Panel noted that in an attempt to rectify a shipping error a Merz employee collected Bocouture from a warehouse in Northern Ireland and delivered it to the health professional at his/her clinic based in the Republic of Ireland. The Panel noted Merz's submission that the

employee promoted devices not prescription only medicines (POMs) and was therefore unaware of the potential Good Distribution Practice (GDP) and Code of Practice implications of his/her actions.

The Panel considered that in personally delivering Bocouture to the Republic of Ireland where it was not licensed meant that the employee had not maintained high standards and a breach of Clause 15.2 was ruled.

The Panel noted that following the incident a deviation CAPA was raised. According to Merz certain employees were all spoken to directly to ensure that the process deviation, implications of this course of action were clear and understood and what alternative actions were appropriate in the future. As part of the CAPA process the rest of the team, attended a workshop facilitated by the medical team which covered the licensing status of Bocouture in Northern Ireland and the Republic of Ireland and explained the potential GDP/ABPI considerations. It was stated that no samples or stock should be delivered into the Republic of Ireland and that any requests for information regarding Bocouture from customers in the Republic of Ireland should be referred directly to medical information as it was an unlicensed medicine in the Republic of Ireland. The Panel considered that in failing to provide this important training earlier, particularly considering the potential of Merz employees and health professionals working across Northern Ireland and the Republic of Ireland, meant that Merz had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel noted the complainant's allegation that two Merz employees had demonstrated controlling and threatening communication with the intention of directing sales of Merz medicines or medical devices through the Merz preferred distributing partners only. Further, that they had stated that product concerns or adverse event queries would not be supported by the Merz UK and Irish business if the Merz product in question had not been bought through the Merz UK affiliate business preferred partners.

The Panel noted Merz's submission that it could find no evidence of 'controlling and threating communication or evidence that communication by employees that 'adverse event queries would not be supported by Merz UK and Ireland if the product is not bought from a preferred partner' had occurred.

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 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 Panel noted Merz's submission that staff were briefed in detail regarding the changing relationship with the company's pharmacy wholesalers which highlighted the preferred partner status of two pharmacy wholesalers and the ceasing of trading with another. According to Merz, the parameters within which Merz UK was able to operate under the new arrangements with its preferred partners were clearly briefed.

This new arrangement was explained as a necessary change in the business model to stop product reaching the customer that was sourced through unverifiable routes over which Merz UK had no GDP oversight. The Panel noted Merz's submission that the briefing document demonstrated that any change in the support offered to customers was purely commercial.

Certain commercial offers and training would no longer be available to customers if they used distributors that did not have preferred partner status.

The Panel noted that the Merz Distribution Partnerships Q&A document dated July 2019 stated in response to the question regarding what happened if a customer did not move and continued to purchase Merz products from the named non-preferred pharmacy wholesaler that Merz may be unable to extend a full range of partnership support to you and your clinic for our Medical Devices portfolio. This could include:

- Invitations to Educational Meetings, Events and Congress
- Direct training and product support to clinics
- Marketing and PR support (approved brands only)
- Local Merz Aesthetic Account Manager support
- Exclusive notification for new product launches
- Access to relevant special offers and product promotions.

The reason given was that the named non-preferred partner might choose to source its Merz products from overseas and when it was sourced from outside the UK Merz UK did not benefit from the business growth and therefore, the costs involved in supporting clinics who used non-UK sourced products no longer became viable. Merz UK also had no oversight into the distribution conditions of any product that might have typically been shipped across a number of destinations and routes.

The Panel considered that the complainant had not shown, on the balance of probabilities, that the Merz employees had not maintained a high standard of ethical conduct by demonstrating controlling and threatening communication with the intention of directing sales of Merz medicines or medical devices through the Merz preferred distributing partners. No breach of Clause 15.2 of the Code was ruled in that regard.

Whilst the Panel queried whether 'product support to clinics' as stated in the Q&A document could have been misinterpreted as potentially meaning support with product concerns or adverse event queries which would be of concern, the Panel noted Merz's submission that pharmacovigilance was of the highest priority as illustrated by the annual training recently completed by all Merz Pharma UK employees, pharmacy wholesalers and third party consultants. Merz insisted on a pharmacovigilance agreement between Merz UK and any third party to ensure the safe and effective use of its medicines and devices. The Panel also noted Merz's submission that any change in the support offered to customers was purely commercial. The Panel considered that whilst the Q&A could have been worded more clearly, on balance, there was no evidence to show that Merz product concerns or adverse event queries would not be supported by the Merz UK and Irish business if the Merz product in question had not been bought through the Merz UK affiliate business preferred partners as alleged. No breach of Clause 9.1 was ruled in this regard.

The Panel noted its rulings and comments above but did not consider that the particular circumstances of this case were such as to warrant a breach of Clause 2 which was a sign of particular censure. No breach of Clause 2 was ruled.

Complaint received 24 October 2019

Case completed **13 February 2020**