CASE AUTH/3533/7/21

COMPLAINANT v ALLERGAN

Concerns about the conduct of employees on LinkedIn

An anonymous, non-contactable complainant complained about Allergan and its persistent behaviour on LinkedIn.

The complainant provided a screenshot of posts from a named senior Allergan employee based in the UK with over 500 connections and alleged that he/she had mostly UK-based followers including members of the public and UK health professionals.

The complainant stated that the employee consistently liked and shared posts which in the UK was known to be unacceptable.

The complainant stated that by referring to upcoming medicines that were going through the registration process like abicipar for patients with nAMD (neovascular age related macular degeneration) and ubrogepant which did not currently have UK or even European licences, but were being applied for, was no doubt prepping the market for the upcoming medicines. The complainant stated that proactively pushing out this information could be nothing other than pre licence promotion.

In addition, the complainant provided screenshots showing that the senior named Allergan employee above had liked a post by another Allergan employee regarding the use of Botox in upper limb spasticity in children which actively pushed out the Botox advertisement which was also unacceptable on a social media platform like LinkedIn. The complainant could not imagine it would have been certified as LinkedIn was not restricted to health professionals. The complainant could not see links to the prescribing information or adverse event reporting information.

The complainant stated that he/she would have expected better especially from senior employees. The named employee was UK-based and had mostly UK connections. How he/she thought that he/she was above the Code scope was mind boggling.

The complainant stated the posts might well have been from a year ago but the Code a year ago did not allow such behaviour and he/she could not see why they had not subsequently been taken down since the recent Instagram complaints where he/she would have expected robust training and rectifying.

The detailed response from Allergan is given below.

The Panel noted that the first LinkedIn post 'liked' by the named senior Allergan UK employee related to data presented at the 2019 congress of the American Academy of Ophthalmology which ran from 12-15 October 2019. The post appeared on the Allergan global corporate LinkedIn account and stated 'At #AAO2019 we presented two-year data

from CEDAR and SEQUOIA studies of investigational abicipar for patients with nAMD. Find out how this data could meet the unmet need for patients and eye doctors: http://bit.ly/2lJgA4B'.

The Panel noted that it was clear from the LinkedIn post that abicipar was not classified as a prescription only medicine when the LinkedIn post at issue was posted on the global LinkedIn account and 'liked' by the UK employee. Clause 26.1 only applied to prescription only medicines. On that very narrow technical point, the Panel ruled no breach of the Code.

The Panel did not have before it a copy of the information accessible from the link within the post. Nonetheless, the Panel considered, noting the content of the post which referred to abicipar, nAMD and how this study data could meet an unmet need, that 'liking' the LinkedIn post and, on the balance of probabilities, proactively distributing the content to his/her connections on LinkedIn, constituted the promotion of abicipar prior to the grant of its marketing authorisation. A breach of the Code was ruled.

The Panel noted that the second LinkedIn post 'liked' by the named senior Allergan UK employee related to the FDA approval of Ubrelvy (ubrogepant) on 23 December 2019. The post was made by a senior Allergan employee based outside of the UK on his/her LinkedIn account and stated 'We at Allergan are proud to announce that the FDA has approved UBRELVY (ubrogepant) for the acute treatment of migraine – it's the first oral treatment of its kind and an important new option for the millions of people suffering with migraine #migraine https://bit.ly/34QOEnt'. The post included an image which stated 'Allergan Receives U.S FDA Approval for UBRELVY for the Acute Treatment of Migraine with or without Aura i….' and included a reference to allergan.com.

The Panel considered, noting the content of the LinkedIn post, that 'liking' the LinkedIn post and, on the balance of probabilities, proactively distributing the content to his/her connections on LinkedIn, constituted, the promotion of Ubrelvy prior to the grant of its marketing authorisation. A breach of the Code was ruled.

The Panel noted that that Ubrelvy was not classified as a prescription only medicine when the LinkedIn post at issue and associated information was posted on the non-UK employee's LinkedIn account and 'liked' by the UK employee. Clause 26.1 only applied to prescription only medicines. On that very narrow technical point, the Panel ruled no breach of the Code.

The Panel noted that the third LinkedIn post 'liked' by the named senior Allergan UK employee related to the FDA and EMA filing of abicipar in September 2019. The post appeared on the Allergan global corporate LinkedIn account and stated 'Our [senior employee, name] described how FDA and EMA filing acceptances of investigational Abicipar further our legacy in developing innovative treatment options to address unmet needs for patients with diseases of the eye. https://bit.ly/2A4zqhC'. The post included an image of the senior employee with a quote 'Today's announcement reinforces Allergan's continued commitment to eye care innovation and means patients are one step closer to receiving what we believe to be a transformative treatment that will help address unmet needs for nAMD patients'.

The Panel noted that abicipar was not classified as a prescription only medicine in the UK when the LinkedIn post at issue was posted on the global LinlkedIn account and 'liked' by the UK employee. Clause 26.1 only applied to prescription only medicines. On that very narrow technical point, the Panel ruled no breach of the Code.

However, the Panel considered, noting its content, that 'liking' the LinkedIn post and, on the balance of probabilities, proactively distributing the information to his/her connections on LinkedIn constituted the promotion of abicipar prior to the grant of its marketing authorisation. A breach of the Code was ruled.

The Panel noted that the fourth post 'liked' by the named senior Allergan UK employee was a disease awareness post concerning chronic migraine, and specifically talked about its prevalence in the US. The post appeared on the Allergan global corporate LinkedIn account and stated 'Affecting more than 3.3 million people in the US, Chronic Migraine is more than just a headache. If all those people made up a city, it'd be the 3rd largest city in the U.S.! Learn more about the disease and the treatment options: hhttps://bit.ly/2Qmv6DL# PainAwarenessMonth'. The Panel did not have the information within the link that readers were invited to access to learn more but noted Allergan's submission that the post linked to a website entitled 'mychronicmigraine.com', a US-based disease awareness website with no product mention. The Panel queried Allergan's submission in this regard noting that the post referred to learning more about treatment options.

Nonetheless, the Panel noted that the complainant bore the burden of proof and, on the evidence available, the Panel did not consider that he/she had established that the LinkedIn post in question was promotional and that in 'liking' the post, the Allergan employee had promoted any medicine. The Panel therefore ruled no breach of the Code.

The Panel noted that the fifth LinkedIn post cited by the complainant, which had been 'liked' by the Allergan UK employee, related to the FDA approval in June 2019 of a licence application (variation) of Botox for upper limb spasticity in paediatric patients. The post appeared on the Allergan global corporate LinkedIn account and stated 'Allergan is excited to announce that the FDA has approved Allergan's sBLA for BOTOX (onabotulinumtoxinA) for its 10th therapeutic indication. Click here for more info: https://bit.ly/2Xmta28 and to see full product info including Boxed Warning & Medication Guide click here: https://bit.ly/2hc9XJ8'.

The Panel noted that from the screenshot provided by the complainant, it appeared that clicking on the link took readers to information headed 'Manage Your Child's Upper Limb Spasticity with BOTOX' below which it described Botox as a prescription only medicine injected into muscle to treat increased muscle stiffness in people 2 years of age and older with spasticity. The Panel noted Allergan's submission that this indication (upper limb spasticity in paediatrics) was not licensed in the UK and the post was not targeted at UK health professionals.

The Panel noted that in 'liking' the LinkedIn post, which included the product name and links to product information, the UK employee had, on the balance of probabilities, proactively distributed the information to his/her connections on LinkedIn, which would likely include UK based individuals who did not meet the Code's definition of a health

professional or other relevant decision maker, and therefore promoted Botox, a prescription only medicine, to the public. The Panel ruled a breach of the Code.

The Panel considered that the employee's connections on LinkedIn would, on the balance of probabilities, have also included health professionals. In the Panel's view, a UK employee of Allergan performing an activity which would likely proactively disseminate information to his/her connections on LinkedIn was considered to be promotion of Botox, a prescription only medicine, and the material should have been certified and had not been. Prescribing information and an adverse event reporting statement should have been provided and had not been. The Panel therefore ruled breaches of the Code.

The Panel noted Allergan's submission that when the named employee engaged with the relevant social media content, he/she was receiving training on the Allergan social media policy. The Panel noted that the social media policy provided by Allergan (COMP-CORP-POL-104) was dated 15 December 2016 and stated in a section headed 'Use of Personal Social Media to Discuss Allergan-Related Topics 'In certain circumstances, as defined under local policy, colleagues may retweet or repost approved, unaltered messages posted by Allergan corporate on Social Media. Consult your local policies, Legal Department or Global Compliance for more specifics'. Allergan made no submission about any relevant 'local' policies at the time of the activity in question (2019).

The Panel considered that Allergan had failed to maintain high standards and a breach of the Code was ruled.

The Panel was extremely concerned that a senior UK Allergan employee had, on the balance of probabilities, proactively distributed information that promoted a prescription only medicine on social media. The Panel noted that promotion prior to the grant of a marketing authorisation was an example of an activity likely to be in breach of Clause 2. The Panel noted its comments and rulings above, including its concerns with the lack of clear guidance for UK employees in the company's social media policy at the time of the activity and the seniority of the named employee and considered that in promoting medicines prior to the grant of its marketing authorisation, including to members of the public, Allergan had brought discredit upon, and reduced confidence in, the pharmaceutical industry and, on balance, a breach of Clause 2 was ruled.

An anonymous, non-contactable complainant complained about Allergan and its persistent behaviour on LinkedIn.

COMPLAINT

The complainant provided a screenshot of posts from a named senior Allergan employee based in the UK with over 500 connections and alleged that he/she had mostly UK-based followers including members of the public and UK health professionals.

The complainant stated that the employee consistently liked and shared posts which in the UK was known to be unacceptable.

The complainant stated that by referring to upcoming medicines that were going through the registration process like abicipar for patients with nAMD (neovascular age related macular

degeneration) and ubrogepant which did not currently have UK or even European licences, but were being applied for, was no doubt prepping the market for the upcoming medicines. It was well known that you could not promote a medicine before the marketing authorisation and so proactively pushing out this information could be nothing other than pre licence promotion. The complainant stated that this came up in conversation with a friend of his/hers who would be classed as a member of the public and suffered from migraines. The complainant was shocked to learn that senior employees were sharing such information with people who did not have the background to assess what this meant for them.

In addition, the complainant provided screenshots showing that the senior named Allergan employee above had liked a post by another Allergan employee regarding the use of Botox in upper limb spasticity in children which actively pushed out the Botox advertisement.

The complainant stated that actively sharing advertisements for Botox being used in the licensed paediatric upper limb spasticity was also unacceptable on a social media platform like LinkedIn. The complainant could not imagine it would have been certified as it was known that LinkedIn was not restricted to health professionals. The complainant could not see links to the prescribing information or adverse event reporting information.

The complainant stated that with such a poor track record on social media, he/she would have expected better especially from senior employees within the business. They were not above the requirements of the Code. The named employee was as a UK-based employee and had mostly UK connections. How he/she thought that he/she was above the Code scope was mind boggling.

The complainant stated the posts might well have been from a year ago but the Code a year ago did not allow such behaviour and he/she could not see why they had not subsequently been taken down since the recent Instagram complaints where he/she would have expected robust training and rectifying.

When writing to Allergan, the Authority asked it to consider the requirements of Clauses 2, 3.1, 4.1, 4.9, 9.1, 14.1 and 26.1 of the Code.

RESPONSE

Allergan stated that it was fully committed to strict adherence to the Code and all applicable laws and regulations. As a member of the ABPI, Allergan was dedicated to applying high standards at all times across all areas of its business and, similarly to the PMCPA, it took any complaint seriously.

Allergan submitted that in 2019, when the individual named in the complaint engaged with the relevant social media content, Allergan and AbbVie were still separate companies as the acquisition had not been completed. At that time, Allergan employees, including the named individual, were receiving training on the Allergan social media policy and they were provided with the AbbVie social media reference guide upon acquisition.

As part of the ongoing process of integrating the AbbVie and Allergan businesses, and in the context of the annual global refresher training on high standards for social media, the AbbVie corporate social media policy had been rolled-out to all employees across AbbVie and Allergan legal entities in February 2021. This, together with other local awareness measures, was aimed

at ensuring that the integrating business would operate with the same high standards as the AbbVie legal entity was operating in the area of social media.

Also, in the light of the above, Allergan strongly believed that engagements with social media content going back to 2019 was a very historic behaviour that was not indicative of the meaningful progress that the companies and Allergan employees had made in the meantime.

This current complaint concerned a matter that was very similar to that in Case AUTH/3291/12/19 and Allergan considered that, for this reason, it should not go ahead.

Paragraph 5.2 of the Constitution and Procedure clarified this:

> 'If a complaint concerns a matter closely similar to one which has been the subject of a previous adjudication, it may be allowed to proceed at the discretion of the Director if new evidence is adduced by the complainant or if the passage of time or a change in circumstances raises doubts as to whether the same decision would be made in respect of the current complaint. The Director should normally allow a complaint to proceed if it covers matters similar to those in a decision of the Panel where no breach of the Code was ruled and which was not the subject of appeal to the Appeal Board.'

Allergan stated there had been no new substantive evidence provided in this complaint or any change in circumstances that raised doubt as to whether the same ruling would be made.

Allergan stated that it was confident that the individual's engagements with five social media items flagged in the complaint occurred around the time that the original content was initially posted on social media (further details below) and that there was no other subsequent activity by the same individual. Furthermore, the particular content flagged in the complaint had been immediately deleted upon receipt of the complaint, and both Allergan and AbbVie continued to take active steps to reinforce the importance of all employees in the UK adhering to the high standards of social media conduct set out by the companies through training and communication. Therefore, Allergan believed its policies and procedures in relation to social media were robust and up-to-date and, as such, Allergan was not in breach of Clause 9.1 of the Code.

Allergan provided more detail below regarding the content and context of the posts cited, and copies of the original posts were provided:

- The first post related to some data presented at AAO 2019 – the 2019 congress of the American Academy of Ophthalmology – which ran from 12-15 October 2019.
- The second post related to the FDA approval of Ubrelvy (ubrogepant) – the product was approved 23 December 2019.
- The third post related to the FDA and EMA filing of abicipar – this occurred in September 2019.
- The fourth post was a disease awareness post discussing chronic migraine.
- The fifth and last post cited related to the FDA approval of a supplemental biologics licence application (variation) for upper limb spasticity in paediatric patients – this indication was approved in June 2019.

An exact date of the individual's interaction with the posts could not be determined due to the way historical interactions were maintained on LinkedIn, however, discussions with the

individual confirmed that such interaction would only have occurred at the time when the information was made public and communicated via Allergan global corporate social media accounts, or [named senior employee], of Allergan who was not based in the UK. All posts were made prior to the ruling of Case AUTH/3291/12/19 on 16 March 2020. The content of all posts referred to information dated 2019. Allergan would emphasise the fact that while the nature of social media meant that posts existed until deleted, nevertheless, the content was generally only active and appeared on an individual's LinkedIn feed for a short period of time around the time of the specific engagement (ie the 'like' or the 'share'). In order to interact with the post, a significant time period after the date of posting, one would have to consciously navigate their way on to an individual's LinkedIn profile and search through historical activity.

Allergan stated that with specific regard to the second post and the alleged pre-licence promotion of Ubrelvy, Allergan clarified that, neither at present, nor at the time of the individual's engagement with the social media content, was there any pending application for a marketing authorisation for the respective product either with The Medicines and Healthcare products Regulatory Agency (MHRA), or with the European Medicines Agency (EMA). Furthermore, there was currently no intention to submit an application for a marketing authorisation for that product to the UK's MHRA. Therefore, Allergan believed that, when considering that the relevant social media interactions took place approximately 18 months ago and were related to a product that was, and remained for the foreseeable future, unavailable in the UK, this could not reasonably be considered a strategic attempt at stimulating interest from a UK audience in a prescription-only medicine to prepare the market for those products. Past PMCPA cases reinforced the fact that mentioning the name of a product that was only available overseas was not tantamount to unlicensed promotion (Case AUTH/2853/6/16). As such, Allergan submitted that it was not in breach of Clause 3.1 of the Code.

The third post related to the Food and Drug Administration (FDA) and EMA filing of abicipar and the EMA filing was subsequently withdrawn. There were no current plans to re-file for a licence in the UK. As discussed above, this was posted in September 2019, prior to the ruling of Case AUTH/3291/12/19 on 16 March 2020.

The fourth post was a disease-awareness post concerning chronic migraine, and specifically talked about its prevalence in the US. The post linked to a website entitled 'mychronicmigraine.com', a US-based disease-awareness website with no product mention.

With specific regard to the post flagged in the complaint on the alleged promotion of Botox on LinkedIn, this specific indication (upper limb spasticity in paediatrics) was not licensed in the UK and the post was not targeted at UK health professionals.

In all cases the posts were put out on the Allergan corporate social media account, managed out of the US or by the named senior employee who was not based in the UK and were not intended for a UK audience. As a result, Allergan did not feel that the Code applied to these posts with respect to the requirements of Clauses 4.1, 4.9 and 14.1.

The reason Allergan believed it was prudent to provide the above clarification was to, first, show the lengths it took to find such social media activity of an Allergan employee on LinkedIn, and secondly, made it clear that since those posts from 2019 (a period in which the PMCPA had already sanctioned Allergan for the same reasons), Allergan had implemented robust compliance systems to support its employees in paying due care and attention when engaging on social media.

In summary, Allergan submitted that the matters alleged in this case relating to LinkedIn were not in breach of the Code:

- The Panel should not allow complaints to go ahead that were based on closely similar matters that had already been dealt with in Case AUTH/3291/12/19.
- Revisiting historical issues that had been addressed through meaningful remedial actions, served only to hinder progress in this important area.
- The products and/or indications mentioned in the original posts were not and would not be available in the UK.
- None of the original content was intended for a UK audience.

Allergan stated that it took its responsibility for compliance with the Code very seriously as it continuously endeavoured to maintain these high standards in all its activities.

PANEL RULING

The Panel noted Allergan's submission that the complaint should not have proceeded as, in its view, under Paragraph 5.2 there had been no new evidence provided by the complainant or any change in circumstances that raised doubt as to whether the same ruling would be made to that in Case AUTH/3291/12/19 and the posts at issue in this current case, Case AUTH/3533/7/21, which predated the undertaking given in Case AUTH/3291/12/19. The Panel noted that the undertaking in Case AUTH/3291/12/19 was dated as being signed on 16 March 2020.

The Panel noted that Paragraph 5.2 of the Constitution and Procedure stated: 'If a complaint concerns a matter closely similar to one which has been the subject of a previous adjudication, it may be allowed to proceed at the discretion of the Director if new evidence is adduced by the complainant or if the passage of time or a change in circumstances raises doubts as to whether the same decision would be made in respect of the current complaint. The Director should normally allow a complaint to proceed if it covers matters similar to those in a decision of the Panel where no breach of the Code was ruled and which was not the subject of appeal to the Appeal Board'.

The Panel noted that Case AUTH/3291/12/19 concerned the posting of a Botox pack-shot and the re-posting of a video containing the Botox pack-shot on the company's Instagram account and reference to Botox being the injectable product of the year at the Aesthetics Awards 2019 on a senior employee's personal Instagram page, whereas the current case concerned LinkedIn and the proactive dissemination of information as a result of an Allergan UK employee's interaction with LinkedIn posts. The Panel considered that the content of materials was also a relevant factor in relation to whether matters were closely similar. It was not simply a question of how material was distributed. The Panel noted the requirements of Paragraph 5.2 of the Constitution and Procedure and considered that the differences between Case AUTH/3291/12/19 and Case AUTH/3533/7/21 were such that they were not closely similar and therefore Case AUTH/3533/7/21 should proceed, and the merits of the case be considered.

The Panel noted Allergan's submission that an exact date of the individual's interaction with the five LinkedIn posts in question could not be determined due to the way historical interactions were maintained on LinkedIn, however, discussions with the individual confirmed that such interaction would only have occurred at the time when the LinkedIn posts were made public. The Panel noted Allergan's submission that the content of all of the LinkedIn posts referred to information dated 2019.

With regard to LinkedIn, the Panel noted that it was different to some other social media platforms in that it was a business and employment-orientated network and was primarily, although not exclusively, associated with an individual's professional heritage and current employment and interests; its application was not limited to the pharmaceutical industry or to health care. In the Panel's view, it was of course not unacceptable for company employees to use personal LinkedIn accounts. The Panel noted that compliance challenges arose when the personal use of social media by pharmaceutical company employees overlapped with their professional responsibilities or the interests of the company. The Panel noted that material could be disseminated or highlighted by an individual on LinkedIn in a number of ways, by posting, sharing, commenting or 'liking'. The Panel understood that if an individual 'liked' a post, it increased the likelihood that the post would appear in his/her connections' LinkedIn feeds, appearing as '[name] likes this'. In the Panel's view, activity conducted on social media that could potentially alert one's connections to the activity might be considered proactive dissemination of material. In addition, an individual's activity and associated content might appear in the individual's list of activities on his/her LinkedIn profile page which was visible to his/her connections; an individual's profile page was also potentially visible to others outside his/her network depending on the individual's security settings. Company employees should assume that such activity would, therefore, potentially be visible to both those who were health professionals or other relevant decision makers and those who were members of the public. In that regard, it was imperative that they acted with extreme caution when using all social media platforms, including LinkedIn, to discuss or highlight issues which impinged on their professional role or the commercial/research interests of their company. Whether the Code applied would be determined on a case-by-case basis, taking into account all of the circumstances including, among other things, content and distribution of the material. If an employee's personal use of social media was found to be in scope of the Code, the company would be held responsible. The Panel considered that companies should assume that the Code would apply to all work-related, personal LinkedIn posts/activity by their employees unless, for very clear reasons, it could be shown otherwise. Any material associated with a social media post, for example, a link within a post, would be regarded as being part of that post. Companies must have comprehensive and up-to-date social media policies that provide clear and unequivocal guidance on what was, and what was not, acceptable and it was extremely important that employees were trained upon them and followed them.

The Panel understood that employees might feel inclined to endorse their company's corporate social media posts or posts made by colleagues but noted that depending on the content such activity might or might not fall within the scope of the Code. Companies would be well advised to cover the possibility of that activity in their social media policies. This was particularly important if UK employees were likely to follow the social media accounts of affiliates that had codes, laws and regulations that differed to the UK.

The Panel noted that the first LinkedIn post 'liked' by the named senior Allergan UK employee related to data presented at the 2019 congress of the American Academy of Ophthalmology which ran from 12-15 October 2019. The post appeared on the Allergan global corporate LinkedIn account and stated 'At #AAO2019 we presented two-year data from CEDAR and SEQUOIA studies of investigational abicipar for patients with nAMD. Find out how this data could meet the unmet need for patients and eye doctors: http://bit.ly/2IJgA4B'.

The Panel noted that Clause 3.1 prohibited the promotion of a medicine prior to the grant of its marketing authorisation. Once the marketing authorisation had been granted Clause 26.1 prohibited the promotion of prescription only medicines to the public.

The Panel noted the arrangements for abicipar at the time of the post in relation to the application for a marketing authorisation. According to Allergan, FDA and EMA filing for a licence occurred in September 2019, prior to the congress which was held in October 2019, and the EMA filing was subsequently withdrawn. There were no current plans for Allergan to re-file for a licence in the UK.

The Panel noted that it was clear from the LinkedIn post that abicipar was not classified as a prescription only medicine when the LinkedIn post at issue was posted on the global LinkedIn account and 'liked' by the UK employee. Clause 26.1 only applied to prescription only medicines. On that very narrow technical point, the Panel ruled no breach of Clause 26.1 of the Code.

The Panel did not have before it a copy of the information accessible from the link within the post. Nonetheless, the Panel considered, noting the content of the post which referred to abicipar, nAMD and how this study data could meet an unmet need, that 'liking' the LinkedIn post and, on the balance of probabilities, proactively distributing the content to his/her connections on LinkedIn, constituted the promotion of abicipar prior to the grant of its marketing authorisation. A breach of Clause 3.1 was ruled.

The Panel noted that the second LinkedIn post 'liked' by the named senior Allergan UK employee related to the FDA approval of Ubrelvy (ubrogepant) which was approved on 23 December 2019. The post was made by a senior Allergan employee based outside of the UK on his/her LinkedIn account and stated 'We at Allergan are proud to announce that the FDA has approved UBRELVY (ubrogepant) for the acute treatment of migraine – it's the first oral treatment of its kind and an important new option for the millions of people suffering with migraine #migraine https://bit.ly/34QOEnt'. The post included an image which stated 'Allergan Receives U.S FDA Approval for UBRELVY for the Acute Treatment of Migraine with or without Aura i….' and included a reference to allergan.com.

The Panel noted Allergan's submission that with regard to the alleged pre-licence promotion of Ubrelvy, neither at present, nor at the time of the individual's engagement with the social media content, was there any pending application for a marketing authorisation for the product either with the MHRA or the EMA. The Panel further noted Allergan's submission that there was currently no intention to submit an application for a marketing authorisation for that product to the MHRA. The Panel noted Allergan's submission that considering the relevant social media interactions took place approximately 18 months ago and were related to a product that was, and remained for the foreseeable future, unavailable in the UK, it could not reasonably be considered a strategic attempt at stimulating interest from a UK audience in a prescription only medicine to prepare the market for those products. The Panel noted that, in that regard, Allergan referred to Case AUTH/2853/6/16 which, in Allergan's view, reinforced the fact that mentioning the name of a product that was only available overseas was not tantamount to unlicensed promotion. In the Panel's view, Ubrelvy was still, nonetheless, unlicensed in the UK and the circumstances of this case were different to those in Case AUTH/2853/6/16 which involved a malaria vaccine for use in the Sub-Saharan African countries where malaria was highly endemic and the company in that case had submitted that use in the UK was precluded as there would be little, if any, therapeutic need. The Panel considered, noting the content of the LinkedIn post, that 'liking' the LinkedIn post and, on the balance of probabilities, proactively distributing the content to his/her connections on LinkedIn, constituted, the promotion of Ubrelvy prior to the grant of its marketing authorisation. A breach of Clause 3.1 was ruled.

The Panel noted that that Ubrelvy was not classified as a prescription only medicine when the LinkedIn post at issue and associated information was posted on the non-UK employee's LinkedIn account and 'liked' by the UK employee. Clause 26.1 only applied to prescription only medicines. On that very narrow technical point, the Panel ruled no breach of Clause 26.1 of the Code.

The Panel noted that the third LinkedIn post 'liked' by the named senior Allergan UK employee related to the FDA and EMA filing of abicipar which occurred in September 2019. The post appeared on the Allergan global corporate LinkedIn account and stated '[senior employee, named] described how FDA and EMA filing acceptances of investigational Abicipar further our legacy in developing innovative treatment options to address unmet needs for patients with diseases of the eye. https://bit.ly/2A4zqhC'. The post included an image of the senior employee with a quote from him/her stating 'Today's announcement reinforces Allergan's continued commitment to eye care innovation and means patients are one step closer to receiving what we believe to be a transformative treatment that will help address unmet needs for nAMD patients'.

The Panel noted Allergan's submission that this post related to the FDA and EMA filing of abicipar in September 2019 and that the EMA filing was subsequently withdrawn and there were no current plans to re-file for a licence in the UK.

The Panel noted that abicipar was not classified as a prescription only medicine in the UK when the LinkedIn post at issue was posted on the global LinlkedIn account and 'liked' by the UK employee. Clause 26.1 only applied to prescription only medicines. On that very narrow technical point, the Panel ruled no breach of Clause 26.1 of the Code.

However, the Panel considered, noting its content, that 'liking' the LinkedIn post and, on the balance of probabilities, proactively distributing the information to his/her connections on LinkedIn constituted the promotion of abicipar prior to the grant of its marketing authorisation. A breach of Clause 3.1 was ruled.

The Panel noted that the fourth post 'liked' by the named senior Allergan UK employee was a disease awareness post concerning chronic migraine, and specifically talked about its prevalence in the US. The post appeared on the Allergan global corporate LinkedIn account and stated 'Affecting more than 3.3 million people in the US, Chronic Migraine is more than just a headache. If all those people made up a city, it'd be the 3rd largest city in the U.S.! Learn more about the disease and the treatment options: hhttps://bit.ly/2Qmv6DL# PainAwarenessMonth'. The Panel did not have before it the information within the link that readers were invited to access to learn more but noted Allergan's submission that the post linked to a website entitled 'mychronicmigraine.com', a US-based disease awareness website with no product mention. The Panel queried Allergan's submission in this regard noting that the post referred to learning more about treatment options.

Nonetheless, the Panel noted that the complainant bore the burden of proof and, on the evidence available, the Panel did not consider that he/she had established that the LinkedIn post in question was promotional and that in 'liking' the post, the Allergan employee had promoted any medicine. The Panel therefore ruled no breach of Clauses 3.1 and 26.1.

The Panel noted that the fifth and last LinkedIn post cited by the complainant, which had been 'liked' by the Allergan UK employee, related to the FDA approval of a supplemental biologics

licence application (variation) of Botox for upper limb spasticity in paediatric patients; this indication was approved by the FDA in June 2019. The post appeared on the Allergan global corporate LinkedIn account and stated 'Allergan is excited to announce that the FDA has approved Allergan's sBLA for BOTOX (onabotulinumtoxinA) for its 10th therapeutic indication. Click here for more info: https://bit.ly/2Xmta28 and to see full product info including Boxed Warning & Medication Guide click here: https://bit.ly/2hc9XJ8'.

The Panel noted that from the screenshot provided by the complainant, it appeared that clicking on the link took readers to information headed 'Manage Your Child's Upper Limb Spasticity with BOTOX' below which it described Botox as a prescription only medicine that is injected into muscle to treat increased muscle stiffness in people 2 years of age and older with spasticity. The Panel noted Allergan's submission that this specific indication (upper limb spasticity in paediatrics) was not licensed in the UK and the post was not targeted at UK health professionals.

The Panel noted that in 'liking' the LinkedIn post, which included the product name and links to product information, the UK employee had, on the balance of probabilities, proactively distributed the information to his/her connections on LinkedIn, which would likely include UK based individuals who did not meet the Code's definition of a health professional or other relevant decision maker, and therefore promoted Botox, a prescription only medicine, to the public. The Panel ruled a breach of Clause 26.1.

The Panel considered that the employee's connections on LinkedIn would, on the balance of probabilities, have also included health professionals. In the Panel's view, a UK employee of Allergan performing an activity which would likely proactively disseminate information to his/her connections on LinkedIn was considered to be promotion of Botox, a prescription only medicine, and the material should have been certified as required by Clause 14.1 and had not been. The Panel considered that the disseminated material should have included prescribing information and an adverse event reporting statement and did not. The Panel therefore ruled a breach of Clauses 4.1, 4.9 and 14.1.

The Panel noted Allergan's submission that when the named employee engaged with the relevant social media content, he/she was receiving training on the Allergan social media policy. The Panel noted that the social media policy provided by Allergan (COMP-CORP-POL-104) was dated 15 December 2016 and stated in a section headed 'Use of Personal Social Media to Discuss Allergan-Related Topics 'In certain circumstances, as defined under local policy, colleagues may retweet or repost approved, unaltered messages posted by Allergan corporate on Social Media. Consult your local policies, Legal Department or Global Compliance for more specifics'. The Panel noted that Allergan made no submission about any relevant 'local' policies at the time of the activity in question (2019).

The Panel noted that Allergan was confident that there was no other subsequent activity by the same individual and that the particular content at issue had been deleted immediately upon receipt of the complaint, and both Allergan and AbbVie continued to take active steps to reinforce the importance of all employees in the UK adhering to the high standards of social media conduct set out by the companies through training and communication.

The Panel, nonetheless, noting its comments and rulings above, considered that Allergan had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel was extremely concerned that a senior UK Allergan employee had, on the balance of probabilities, proactively distributed information that promoted a prescription only medicine on social media. The Panel noted that promotion prior to the grant of a marketing authorisation was an example of an activity likely to be in breach of Clause 2. The Panel noted its comments and rulings above, including its concerns with the lack of clear guidance for UK employees in the company's social media policy at the time of the activity and the seniority of the named employee and considered that in promoting medicines prior to the grant of its marketing authorisation, including to members of the public, Allergan had brought discredit upon, and reduced confidence in, the pharmaceutical industry and, on balance, a breach of Clause 2 was ruled.

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During its consideration of this case, the Panel noted Allergan's submission that although Botox had a marketing authorisation for certain indications, it did not have a marketing authorisation for upper limb spasticity in paediatrics in the UK. The Panel noted that there was no allegation that Allergan was promoting Botox for an unlicensed indication as the complainant referred to the upper limb spasticity in paediatrics indication as licensed which was not so in the UK. The Panel noted that such a claim was likely to constitute promotion of an unlicensed indication as set out in Clause 3.2 of the 2019 Code. The Panel requested that its concerns were drawn to Allergan's attention.

Complaint received **5 July 2021**

Case completed **14 December 2021**