CASE AUTH/3276/10/19

ANONYMOUS v IPSEN

Material posted on LinkedIn

An anonymous, non-contactable individual complained about material posted on LinkedIn by a UK employee of Ipsen Limited. The post made no direct mention of any medicines, but it did refer to positive results from the ENGAGE study which focussed on the use of Dysport (clostridium botulinum type A toxin-haemagglutinin complex).

The complainant noted that the LinkedIn post originated from the global section of Ipsen, headed by a UK employee. The LinkedIn post announced the positive results from the ENGAGE study with a quotation from the UK employee about Ipsen's mission statement. The first link within the post led to the International Parkinson and Movement Disorder Society page and the second link led to Ipsen's announcement of Dysport approval by the FDA (Food and Drug Administration in the US) for the treatment of upper limb spasticity in children, excluding cerebral palsy. The complaint stated that any number of people could see this announcement through the LinkedIn posting in the UK. Dysport was not licensed for children in the UK and the LinkedIn post would raise false hope for parents that the treatment would be widely available on the NHS. Not everyone who read the post would know what the FDA was.

The complaint stated that Ipsen had more than 85,000 followers worldwide; some of whom would be from the UK and it was not inconceivable that a proportion would be affected by the disease or be their carers. Friends and relatives of those who lived with the disease were constantly searching the Internet and this was not responsible advertising from Ipsen.

The detailed response from Ipsen is given below.

The Panel noted that the LinkedIn post stated 'We're delighted to share the positive first results from the ENGAGE study in patients with upper and lower limb spastic hemiparesis'. The post included links to the International Parkinson and Movement Disorder Society website and to the ENGAGE press release regarding its first results. The ENGAGE study was an international, multicentre, prospective, single-arm study initiated by Ipsen Global, which investigated the simultaneous treatment of Dysport in upper and lower limb spasticity (within its product licence) in adults along with a Guided Self-Rehabilitation Contract (GSC) – a personalised, diary-based rehabilitation programme. The LinkedIn post also included a photograph of a global employee, (who was based in the UK), alongside a quotation from the ENGAGE press release which stated 'At Ipsen we are constantly searching for ways to improve disease management and comprehensive care with a patient-centered approach'.

Firstly, the Panel had to decide whether the LinkedIn post and associated press release were subject to the Code. The Panel noted Ipsen's submission that the LinkedIn account

in question was owned by the Ipsen Global organisation based in France and that the LinkedIn post contained a quotation from a global employee based in the UK. In that regard, the Panel thus considered that a UK based company (Ipsen Global based, at least in part, in Slough) had contributed to the LinkedIn post albeit that the post was placed on LinkedIn by the Ipsen Global digital communications team based in France; the Panel considered that global Ipsen employees based in France and the UK had co-operated with regard to the content of the LinkedIn post. The Panel did not have details of the degree of cooperation but noted that at the very least a statement from a UK based global employee, taken from the ENGAGE press release, was included in the post.

The Panel noted Ipsen's submission that Ipsen UK was not involved in the generation, approval or publication of the post on the LinkedIn account. In the Panel's view, Ipsen UK was responsible for acts and omissions by UK based Ipsen global which came within the scope of the Code regardless of whether the UK company had any role in such matters. The issue therefore was whether the UK based global company's involvement was sufficient to bring the LinkedIn post within the scope of the UK Code.

The Panel noted that information or promotional material about medicines covered by Clause 28.1 which was placed on the Internet outside the UK would be regarded as coming within the scope of the Code, if: it was placed there by a UK company/with a UK company's authority; or it was placed there by an affiliate of a UK company, or with the authority of such a company and it made specific reference to the availability or use of the medicine in the UK. The Panel considered that that part of Ipsen Global, which operated from within the UK, was, for the purposes of the Code, a UK company.

In Panel's view, it could be argued that collaboration by the provision of and allowing a statement by a senior UK based medical employee to be placed on a global LinkedIn post, in France the UK based global company had given permission and thereby authority for such use. The Panel considered that the LinkedIn post thus came within the scope of the UK Code.

The Panel noted that the ENGAGE press release detailed the positive results on the combination of the use of Dysport and a Guided Self-Rehabilitation Contract in adult patients with upper and lower limb spastic hemiparesis. Results from ENGAGE had been presented at the International Congress of Parkinson's Disease and Movement Disorders (MDS) in France, in September 2019 and were positive both with regard to degree of limb movement and time to re-injection.

The Panel considered that there was a difference between making a press release available only to the press, to be published or not, or linking it on a social media platform with the expectation that people would read it. With regard to the latter, the Panel considered that the press release effectively promoted Dysport to the public. A breach of the Code was ruled. Given the positivity of the press release, the Panel considered that it would encourage members of the public to ask their health professional to prescribe Dysport. A breach of the Code was ruled.

The Panel noted that the ENGAGE study used Dysport for the treatment of adults with upper and lower limb spastic hemiparesis and so, in that regard, it had been used in accordance with its licence. No breach of the Code was ruled.

The Panel considered that high standards had not been maintained. A breach of the Code was ruled.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and reserved for such. The Panel considered that the particular circumstances of this case did not warrant a ruling of a breach of Clause 2 and no breach was ruled.

An anonymous, non-contactable individual complained about material posted on LinkedIn by a UK employee of Ipsen Limited. The post made no direct mention of any medicines, but it did refer to positive results from the ENGAGE study which focussed on the use of Dysport (clostridium botulinum type A toxin-haemagglutinin complex) which was marketed by Ipsen.

Dysport was mainly indicated for various disorders of spasticity in adults although it could be used to treat dynamic equinus foot deformity in ambulant paediatric cerebral palsy patients, two years of age or over.

COMPLAINT

The complainant noted that the LinkedIn post originated from the global section of Ipsen, headed by a UK employee. The LinkedIn post announced the positive results from the ENGAGE study with a quotation from the UK employee about Ipsen's mission statement. The first link within the post led to the International Parkinson and Movement Disorder Society page and the second link led to Ipsen's announcement of Dysport approval by the FDA for the treatment of upper limb spasticity in children, excluding cerebral palsy. The complaint stated that any number of people could see this announcement through the LinkedIn posting in the UK. Dysport was not licensed for children in the UK and the LinkedIn post would raise false hope for parents that the treatment would be widely available on the NHS. The complainant submitted that not everyone who read the post would know what the FDA was.

The complaint stated that Ipsen had more than 85,000 followers worldwide; some of whom would be from the UK and it was not inconceivable that a proportion would be affected by the disease or be their carers. Friends and relatives of those who lived with the disease were constantly searching the Internet and this was not responsible advertising from Ipsen.

When writing to Ipsen, the Authority asked it to consider the requirements of Clauses 2, 3.2, 9.1, 26.1 and 26.2 of the Code.

RESPONSE

Ipsen noted that the FDA press release referred to by the complainant was not the press release that was linked to the LinkedIn post in question. The actual press release that was associated with the LinkedIn post was related to the results from the ENGAGE study.

Ipsen was concerned to have received a complaint about the post as in its view, neither the post nor the content of the links contained within it, fell within the scope of the Code. Nonetheless, the post and linked content met Ipsen's high standards in terms of both the quality of the content and the company's robust internal procedures.

By way of background, Ipsen noted that in the UK, Dysport was indicated for symptomatic treatment of focal spasticity of:

- upper limbs in adults
- lower limbs in adults affecting the ankle joint due to stroke or traumatic brain injury
- dynamic equinus foot deformity in ambulant pediatric cerebral palsy patients, two years of age or older.

Dysport was also indicated in the UK for adults for symptomatic treatment of:

- spasmodic torticollis
- blepharospasm
- hemifacial spasm
- severe primary hyperhidrosis of the axillae, which did not respond to topical treatment with antiperspirants or antihidrotics.

Ipsen noted that its Ipsen UK office also housed one of three global organisations (the others being Paris, France and Cambridge, Massachusetts). There were therefore a number of employees in the UK office who were not part of Ipsen UK but were part of the global organisation which was tasked with managing Ipsen's affairs from a global, above country level. Both Ipsen UK and Ipsen Global were operated as entirely separate organisations, with different budgets, management and reporting lines. Ipsen Global did not control the activities of Ipsen UK nor *vice versa*. Any materials which were produced and approved by Ipsen Global for any affiliate worldwide (including Ipsen UK) would also require local review and approval by the relevant affiliate before use.

Ipsen provided details about the global employee who was based in the UK. The LinkedIn post was placed by a member of the Ipsen global external communications and digital team based in the Ipsen Paris Global organisation, on the Ipsen Global LinkedIn Feed mentioned above and not directly by the employee in the UK or on his/her personal feed. This practice was in line with the Social Media Policy outlined in the Ipsen Global Directive on Digital Activities.

Ipsen noted that Clause 28.2 of the Code stated that information which was placed on the Internet outside the UK would be regarded as coming within the scope of Code if: (i) it was placed there by a UK company/with a UK company's authority, or (ii) it was placed there by an affiliate of a UK company and made specific reference to the availability of a medicine in the UK. Ipsen thus submitted that the post and the associated press release would not be attributable to Ipsen UK and would fall outside of the scope of the Code because:

- the LinkedIn account in question was owned by the Ipsen Global organisation based in Paris, France;
- the post was created and placed on LinkedIn by the Ipsen Global digital communications team based outside of the UK, in Paris, France;
- the quotation within the LinkedIn post itself was from an Ipsen Global employee;
- Ipsen UK was not involved in the generation, approval or publication of the post on the LinkedIn account, nor did the material linked to the post direct a UK audience to the account;
- the post itself, including the URL did not reference Dysport and neither the LinkedIn post nor linked material specifically referred to the use of Dysport in the UK; and finally
- the LinkedIn post was not proactively targeted to UK users; the post was not sponsored and was not subject to 'pay for placement' to UK health professionals.

Ipsen submitted that the above information confirmed that neither the LinkedIn post nor the quotation within it, was connected to Ipsen UK. Consequently, the post and any linked material did not come within the scope of the Code.

Ipsen noted that the LinkedIn post hosted two website links:

- Link 1: International Parkinson and Movement Disorder Society LinkedIn Landing Page
- Link 2: The ENGAGE press release.

Ipsen noted that the LinkedIn post did not contain a link to an FDA press release as alleged by the complainant, however, for completeness, it had commented below on both the alleged link (the FDA press release) and the actual link (the ENGAGE press release) contained within the LinkedIn post.

Ipsen stated that the first link took the reader to the International Parkinson and Movement Disorder Society LinkedIn landing page. The Society was responsible for running the yearly congress of the International Congress of Parkinson's Disease and Movement Disorders, ie the MDS conference referred to in both the LinkedIn post itself and the associated ENGAGE press release.

With regard to the allegation that the LinkedIn post referred the reader to a press release about the approval of Dysport by the FDA in paediatrics (an unlicensed indication in the UK for Dysport), Ipsen submitted that that FDA press release was never, at any point, included within the LinkedIn post in question; the URL within the post could not have been changed without removing the post completely and subsequently reuploading, which did not occur.

The source of the FDA press release in question was the Ipsen US affiliate, and this was stated in the press release itself – Cambridge, Mass. In addition, the FDA press release was not and never had been hosted on the 'News Center>Press Releases' section on the Ipsen website, instead it was posted on 'Business Wire', an independent US based website, which the US affiliate used to distribute its press releases. Ipsen could not be sure how the complainant had accessed this FDA press release, given that it was unavailable on any Ipsen owned channels.

Unfortunately, this seemed to highlight a mistaken attempt by the complainant to link the post to a completely different and unrelated press release that had no relevance to the ENGAGE study results. Ipsen UK had not and would not provide any links that directed members of the public to information about unlicensed indications for its products and was deeply concerned at the complainant's false allegation. Ipsen was confident that the post and associated links complied with Clauses 2 and 9.1 of the Code in maintaining high standards and not bringing discredit upon, or reducing confidence in, the pharmaceutical industry.

Ipsen noted that the second link within the LinkedIn post was to the ENGAGE press release. The quotation in the LinkedIn post stated 'We're delighted to announce the positive first results from the ENGAGE study in patients with upper and lower limb spastic hemiparesis'. This post was linked to the press release on this study developed by Ipsen Global and published on 23 September 2019; the press release was developed as the first results of the ENGAGE study were presented at the MDS international congress held in Nice, France from September 22-26, 2019, as two respective posters.

The ENGAGE study was an international, multicentre, prospective, single-arm study initiated by Ipsen Global, which investigated the simultaneous treatment of Dysport in upper and lower limb spasticity (within its product licence) in adults along with a Guided Self-Rehabilitation Contract (GSC) – a personalised, diary-based rehabilitation programme, where patients were asked carry out exercises in their GSC tailored to their individual needs and with a focus on the Primary Treatment Target (PTT) limb. The positive results of this study demonstrated crucial data on the benefits of a self-rehabilitation protocol used in conjunction with Dysport treatment for upper and lower limb, as well as data on treatment strategies and outcomes for both upper and lower limb spasticity (rather than focusing on either upper limb or lower limb treatment), which were all current key evidence gaps.

Ipsen noted that the study design for ENGAGE also provided insights into real-world clinical practice, in particular muscle selection for treatment and administration with Dysport as it allowed investigators the flexibility of choosing varied muscle groups in the primary target limb, rather than predefined muscle groups seen in previous Phase III pivotal Dysport studies in the treatment of adult upper and lower limb spasticity.

The first results of the ENGAGE study were presented at the MDS congress, which was a recognised international conference of high scientific standing. Health professionals who attend this congress were conversant with the therapeutic use of botulinum toxin type A, including Dysport within its product licence.

Ipsen stated that in spite of its position that the ENGAGE press release did not fall within the scope of the Code, for completeness it would demonstrate its compliance with Clauses 3.2, 26.1 and 26.2 of the Code. The intention of the ENGAGE press release was to provide factual, balanced, non-promotional information about the positive results of a Dysport clinical trial, in line with its licensed indication. It did not raise unfounded hopes of successful treatment nor was it misleading. Furthermore, the ENGAGE press release did not advertise Dysport, as there were no promotional claims made within it. Neither the LinkedIn post nor the associated URL referred to Dysport.

The focus of the ENGAGE press release was to demonstrate that the study results highlighted the value of combining Dysport treatment with a systematic rehabilitation protocol, enabling patients to take an active role in their own rehabilitation. The press release was therefore newsworthy as the results of the ENGAGE study reflected meaningful functional outcomes for patients which had not been observed in previous Dysport studies. Furthermore, the press release was developed by Ipsen Global and published from the global organisation based in Paris, France. In addition, the ENGAGE study did not include any UK sites. Taking all these points into consideration, Ipsen submitted that the press release did not fall within the scope of the Code.

Ipsen stated that it strongly refuted the allegation that the LinkedIn post was ‘not responsible advertising’ on the grounds that the intention and content of both the LinkedIn post and the ENGAGE press release was non-promotional and scientific in nature. Therefore, it could not be considered an advertisement for Dysport. There was no brand name mentioned within the LinkedIn post or the URL itself, and the ENGAGE press release did not contain any promotional claims. Further to this, the PMCPA’s guidance on ‘Press releases and advertising’ stated that if a company, or its agent, controlled, or in any way paid for, the placement of an article about a product, then that article would be regarded as an advertisement for the product. Ipsen

confirmed that there was no payment of any sort to the UK or from the UK that related to the LinkedIn post.

Ipsen stated that it had a strong social media policy to guide employees on the appropriate use of social media and to maintain high standards in this regard, which was fully in line with Clauses 2 and 9.1 of the Code. The Ipsen Global Social Media Policy required, *inter alia*:

- 'Company-related information and announcements on press releases must be owned and managed by External Communications.'

In this case, the LinkedIn post was published on the account by a member of the Ipsen global external communications and digital team, based in the Ipsen Global organisation in Paris.

- 'LinkedIn and/or Twitter Ipsen corporate accounts may contain posts on: announcements of press-releases, including links to press releases related to significant research or regulatory milestones, results of a clinical study, regulatory approval of new Ipsen products or indications. The actual social media post itself may not reference the brand or molecule name, but the link (without visible product/molecule names) is acceptable.'

The LinkedIn post itself and the associated URL did not reference Dysport within it. The press release was newsworthy and related to significant research. The results of the ENGAGE study were shared amongst health professionals at the MDS congress in Paris around the same time as the LinkedIn post was published.

- 'The content must be reviewed and approved in accordance with the applicable Non-Promotional Materials [standard operating procedures] before it is placed on Social Media accounts.'

The post was reviewed and approved on Ipsen's compliance approvals platform by two Ipsen Global employees, and there was no involvement from the UK in the upload, review and approval of the post.

In summary, Ipsen strongly denied breaches of Clauses 2, 3.2, 9.1, 26.1 and 26.2 of the Code; it could not locate any evidence which supported the complainant's allegations. No reference or links had been made to the FDA press release, therefore the allegations made in that regard were unfounded.

Ipsen maintained that the LinkedIn post in question and the two links contained within it (ie the link to the International Parkinson and Movement Disorder Society and to the ENGAGE press release) fell outside the scope of the Code as they bore no relation to the UK affiliate.

Notwithstanding the above, the LinkedIn post itself and the ENGAGE press release were factual, balanced, non-promotional and in accordance with the Dysport marketing authorization. Therefore, the company had fully complied with the requirements of Clauses 3.2, 26.1 and 26.2 of the Code.

Ipsen stated that it took seriously its responsibility to ensure activities regarding social media were carried out in a manner that was not inconsistent with the Dysport marketing authorization, which protected and promoted patient safety; the company provided valuable medical education

to relevant health professionals, so as to improve patient care, and upheld the reputation of the UK pharmaceutical industry.

Ipsen considered that it had demonstrated that it had not behaved contrary to the Code in either letter or spirit and, therefore, it had maintained high standards in accordance with Clause 9. Further, Ipsen was confident that it brought discredit upon, or reduced confidence in the pharmaceutical industry, and thus it had not breached Clause 2.

PANEL RULING

The Panel noted that the LinkedIn post stated 'We're delighted to share the positive first results from the ENGAGE study in patients with upper and lower limb spastic hemiparesis'. The post included links to the International Parkinson and Movement Disorder Society website and to the ENGAGE press release regarding its first results. The ENGAGE study was an international, multicentre, prospective, single-arm study initiated by Ipsen Global, which investigated the simultaneous treatment of Dysport in upper and lower limb spasticity (within its product licence) in adults along with a Guided Self-Rehabilitation Contract (GSC) – a personalised, diary-based rehabilitation programme. The LinkedIn post also included a photograph of a global employee, (who was based in the UK), alongside a quotation taken from the ENGAGE press release which stated 'At Ipsen we are constantly searching for ways to improve disease management and comprehensive care with a patient-centered approach' and his/her name and global job title.

Firstly, the Panel had to decide whether the LinkedIn post in question and associated press release were subject to the Code. The Panel noted Ipsen's submission that the LinkedIn account in question was owned by the Ipsen Global organisation based in France and that the LinkedIn post in question contained a quotation from a global employee based in the UK. In that regard, the Panel thus considered that a UK based company (Ipsen Global based, at least in part, in Slough) had contributed to the LinkedIn post albeit that the post was placed on LinkedIn by the Ipsen Global digital communications team based in France; the Panel considered that global Ipsen employees based in France and the UK had co-operated with regard to the content of the LinkedIn post. The Panel did not have details of the degree of cooperation but noted that at the very least a statement from a senior medical UK based global employee, taken from the ENGAGE press release, was included in the post.

The Panel noted Ipsen's submission that Ipsen UK was not involved in the generation, approval or publication of the post on the LinkedIn account. In this regard, the Panel noted that it was a long standing principle under the Code that UK based global or other such companies were subject to the Code. If such entities were not members of the ABPI, or on the list on non-member companies that otherwise complied with the Code, the UK company had to take responsibility for their acts and omissions under the Code. Thus, in the Panel's view, Ipsen UK was responsible for acts and omissions by UK based Ipsen global which came within the scope of the Code regardless of whether the UK company had any role in such matters. To decide otherwise would allow UK based affiliates to circumvent the requirements of the UK Code. The issue therefore was whether the UK based global company's involvement was sufficient to bring the LinkedIn post within the scope of the UK Code.

The Panel noted that whether material came within the scope of the Code depended on a consideration of all the circumstances including the supplementary information to Clause 1.1, Applicability of Codes, and Clause 28. Clause 28 was particularly relevant to digital materials.

The Panel noted that Clause 28.2 stated that information or promotional material about medicines covered by Clause 28.1 which was placed on the Internet outside the UK would be regarded as coming within the scope of the Code, if: it was placed there by a UK company/with a UK company's authority; or it was placed there by an affiliate of a UK company, or with the authority of such a company and it made specific reference to the availability or use of the medicine in the UK. The Panel further noted that by 'company' the Code referred to any legal entity that organised or sponsored promotion which took place within Europe, whether such entity be a parent company, subsidiary or any other form of enterprise or organisation. In that regard, the Panel considered that that part of Ipsen Global, which operated from within the UK, was, for the purposes of the Code, a UK company.

The Panel noted that according to the online Cambridge dictionary the word authority meant, *inter alia*, permission. In Panel's view, it could be argued that collaboration by the provision of and allowing a statement by a senior UK based medical employee to be placed on a global LinkedIn post, in France the UK based global company had given permission and thereby authority for such use. The Panel considered that the LinkedIn post thus came within the scope of the UK Code.

The Panel noted that the ENGAGE press release detailed the positive results on the combination of the use of Dysport and a Guided Self-Rehabilitation Contract in adult patients with upper and lower limb spastic hemiparesis. Results from ENGAGE had been presented at the International Congress of Parkinson's Disease and Movement Disorders (MDS) in Nice, France, 22-26 September 2019 and were positive both with regard to degree of limb movement and time to re-injection.

The Panel considered that there was a difference between making a press release available only to the press, to be published or not, or linking it on a social media platform with the expectation that people would read it. With regard to the latter, the Panel considered that the press release effectively promoted Dysport to the public. A breach of Clause 26.1 was ruled. Given the positivity of the press release, the Panel considered that it would encourage members of the public to ask their health professional to prescribe Dysport. A breach of Clause 26.2 was ruled.

The Panel noted that the ENGAGE study used Dysport for the treatment of adults with upper and lower limb spastic hemiparesis and so, in that regard, it had been used in accordance with its licence. No breach of Clause 3.2 was ruled.

The Panel noted its comments above and considered that high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and reserved for such. The Panel considered that the particular circumstances of this case did not warrant a ruling of a breach of Clause 2 and no breach was ruled.

Complaint received **25 October 2019**

Case completed **28 August 2020**