

# EMPLOYEE v OTSUKA

## Use of LinkedIn to promote medicines

An anonymous, contactable complainant who described themselves as an employee of Otsuka Pharmaceuticals (UK), complained about a medical science liaison (MSL) employee's use of LinkedIn.

The complainant referred to the unethical activity and attitude of the MSL employee. The complainant stated that for the last six months, the employee had promoted unlicensed medicines. The complainant provided examples including in relation to Equelle (s-equol and soy isoflavones).

The complainant noted that the individual had over 300 followers on LinkedIn nearly all of whom were UK based.

The complainant alleged that a LinkedIn message, posted by the employee in May 2017 promoted tolvaptan, a prescription only medicine to the public and included a link which sent the reader to an article containing favourable data for tolvaptan (Jinarc) on a website called '4 traders'.

The complainant alleged that the senior member of staff with oversight of MSLs should not have posted promotional material to members of the public.

The complainant submitted that the posting of tolvaptan data raised two issues. Firstly, that posting favourable study results from Phase 3 data of a licensed prescription only medicine was in breach of the Code and secondly, the linked clinical study stated that 'trial enrollees were adults aged 18 to 65 with ADPKD-induced chronic kidney disease between late stage 2 to early stage 4'. In that regard, the complainant noted that two matters arose from the Jinarc summary of product characteristics (SPC) which related to the serious situation of promoting the unlicensed use and indication to members of the public.

Firstly, that the SPC stated that 'the safety and effectiveness of tolvaptan in ADPKD patients aged over 50 years has not yet been established' and secondly, the study included patients that were at the enhanced stage of CKD 4. Otsuka was thus promoting an unlicensed medicine to the public. The indication was limited to use in adults with chronic kidney disease stages 1 to 3.

In addition, the complainant submitted that the employee promoted brexpiprazole on LinkedIn by sending readers to an article which noted that the medicine had been accepted for review by the European Medicines Agency (EMA) for use in adults with schizophrenia. The article informed the reader that the medicine was licensed in a number of countries (US, Canada, under different named brands) and that if approved, the brand name in the EU would be Rxulti. The complainant alleged that

this pre-licence advertising clearly breached the Code.

Finally, the complainant noted that the employee advertised Equelle, a non-hormonal supplement that purported to manage menopause symptoms, on LinkedIn. The article promoted to both patients and health professionals and stated 'Equelle is the product of fermentation of whole, non-GMO soy germ using a patented and proprietary process by the Otsuka Pharmaceutical Co., Ltd. The process results in the conversion of the daidzein to S-equol. Equelle tablets, created under current Good Manufacturing Practices, are clear coated and free of gluten, dairy, magnesium stearate and talc. Suggested patient use is two Equelle tablets daily, one tablet taken in the morning and one tablet at night, which provide the standardized dose of 10 mg of S-equol. Clinicians interested in ordering Equelle were invited to do so ...' and contact details were provided.

The complainant alleged that the employee had brought the industry into disrepute in breach of Clause 2.

The detailed response from Otsuka is given below.

The Panel noted that the complaint concerned postings made by an employee on his/her personal LinkedIn account which Otsuka stated were made without its knowledge or approval.

The Panel noted that the individual in question had over 300 followers and at least some of these were members of the public. The Panel noted the company's submission that none of the articles had been provided to the employee by Otsuka. The employee had sourced the material and proactively shared it. The Panel noted however that this implied that the source material for the postings were entirely independent of Otsuka and that was not so. It appeared to the Panel that the tolvaptan and brexpiprazole articles reproduced Otsuka global press releases. Nonetheless, there was no evidence before the Panel that the company had encouraged their dissemination or that the UK company had any role in their creation. The Panel noted that the LinkedIn postings by a company employee each highlighted positive and newsworthy material about the company's products and thus the LinkedIn postings came within the scope of the Code.

In relation to the posting headed 'Otsuka: Announces Results of Phase 3 Data on Tolvaptan Under Development for ADPKD in US', linked to an article which bore the same title published on a financial website the Panel noted that the article bore the post script 'Otsuka Holdings Co Ltd published this content on 22 May 2017 and is

solely responsible for the information contained therein'. The article appeared to be a reproduction of an Otsuka global press release. The article discussed positive study results. The Panel noted Otsuka's submission that there was a significant possibility that some of the followers were not health professionals. The Panel considered that the proactive dissemination of the article to the employee's followers on LinkedIn constituted promotion of a prescription only medicine to the public. A breach of the Code was ruled as acknowledged by Otsuka.

The Panel noted Section 4.2 of the Jinarc SPC stated that the safety and effectiveness of tolvaptan in ADPKD patients over 50 years has not been established and that it was indicated for use in adults with ADPKD patients with CKD stage 1 to 3 at initiation of treatment. The Panel noted that study patients referred to in the article were 18 to 65 years of age with ADPKD- induced chronic kidney disease between late stage 2 to early stage 4. The Panel noted the promotional use of the article and considered that the article was inconsistent with the SPC on each of these points and a breach of the Code was ruled. The Panel considered that for the same reason the article was misleading and in breach of the Code.

The Panel considered that the promotional dissemination of the article by posting a link to it was such that the certification requirements were triggered as accepted by Otsuka. The LinkedIn posting including the article had not been certified and a breach of the Code was ruled. Similarly, the required prescribing information was not provided and a breach of the Code was ruled.

The Panel considered that the proactive dissemination of positive study results by an employee to all his/her LinkedIn followers was clearly promotional and did not consider that it was in any way a disguised promotional act. No breach of the Code was ruled.

The Panel considered there was no evidence that Otsuka had arranged or paid for the article to be published on the independent financial website such that the article was similar to sponsored material. The complainant had not established that a declaration of sponsorship ought to be on the original article and no breach of the Code was ruled.

The Panel noted its rulings above and considered that high standards had not been maintained; a breach of the Code was ruled.

The Panel ruled no breach of the Code as the complainant had not raised a matter which related to meetings, hospitality and associated sponsorship. In relation to the complainants' allegation that the activities breached the definition of promotion. It was not capable of being breached *per se*. The Panel ruled no breach of the Code.

The Panel noted that the LinkedIn post was done by an individual employee using their own account and without the knowledge or authority of Otsuka. The Panel considered that Otsuka had been badly

let down by its employee. Nonetheless, the Panel did not consider that this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such use. The company had the requisite policies in place and the employee had been trained. No breach of Clause 2 was ruled.

The Panel noted that the employee had also posted a link to an article published on an external financial website headed 'H Lundbeck A/S: Lundbeck and Otsuka's brexpiprazole for adult patients with schizophrenia accepted for review by the EMA'. The Panel noted that the article referred to the fact that the EMA was expected to complete its review in the second quarter of 2018, and that it was already approved in the US and Canada. The article referred briefly to positive clinical data. The Panel noted its comments above about the conduct of the employee and Otsuka's responsibilities. The Panel considered that the proactive dissemination of the article to the employee's followers on LinkedIn constituted promotion of a prescription only medicine to the public. A breach of the Code was ruled. The Panel noted that brexpiprazole had been promoted prior to the grant of its licence and a breach of the Code was ruled. The Panel considered that the complaint on this point did not raise a matter, which related to meetings, hospitality and associated sponsorship, no breach of the Code was ruled.

The complainant also raised concerns about a link posted by the employee to an article published on a news wire headed 'NEW to the United States: Equelle, a non hormonal supplement clinically shown to help ease menopause symptoms' which discussed the availability of the product in the US and clinical data. The Panel noted Otsuka's submission that Equelle was not a prescription only medicine and therefore ruled no breach of the Code.

An anonymous, contactable complainant who described themselves as an employee of Otsuka Pharmaceuticals (UK) Ltd, complained about a named medical science liaison (MSL) employee's use of LinkedIn.

## COMPLAINT

The complainant referred to the unethical activity and attitude of the MSL employee in question and the Authority's guidance on digital communications. The complainant stated that for the last six months, the employee in question had continued to promote medicines marketed by Otsuka Pharmaceuticals but unlicensed in the UK. The complainant was unable to prove the verbal messaging and instructions the employee had given to others in communicating this unlicensed information but provided three examples with evidence, of the employee's thinly veiled promotional activity to the public, in breach of the letter and spirit of the Code. The complainant particularly identified his/her example below in relation to Equelle (s-equol and soy isoflavones) as an action against the spirit of the Code.

The complainant noted that the employee currently had over 300 followers on LinkedIn nearly all of whom were UK based.

The first example provided by the complainant was a LinkedIn message, posted by the employee in May 2017. The post promoted tolvaptan (Jinarc), a prescription only medicine to the public and included a link which sent the reader to an article containing favourable data for tolvaptan on a financial website.

The complainant noted that in his/her LinkedIn profile, the employee stated that he/she undertook the day-to-day strategic and operational oversight of a team of people across various therapeutic areas and was responsible for, *inter alia*, the medical strategy planning by identifying key areas of focus and ensuring that this focus was undertaken in an efficient, strategic and highly scientific and compliant manner. The employee also claimed accountability for continuous development as well as training, leading, coaching and managing the team in collaboration with medical leadership. The complainant alleged that the senior member of staff in charge of actual operational oversight of MSLs should have been aware of the correctness of not posting promotional positive data to members of the public via LinkedIn.

The complainant stated that the posting of tolvaptan data raised two issues. Firstly, that posting favourable study results from Phase 3 data of a licensed prescription only medicine was in breach of the Code and secondly, the linked clinical study stated that 'trial enrollees were adults aged 18 to 65 with ADPKD-induced chronic kidney disease between late stage 2 to early stage 4'. In that regard, the complainant noted that two matters arose from the Jinarc (tolvaptan) summary of product characteristics (SPC) which related to the serious situation of promoting the unlicensed use and indication to members of the public.

The complainant's first concern was that the SPC stated that 'the safety and effectiveness of tolvaptan in ADPKD patients aged over 50 years has not yet been established' and secondly that the SPC stated that the product was for use in CKD 1 to 3 only whereas the study included patients that were at the enhanced stage of CKD 4. Otsuka was thus promoting an unlicensed medicine to the public. The indication was limited to use in adults with chronic kidney disease stages 1 to 3.

The complainant alleged breaches of Clauses 1.2, 2, 3, 4, 7, 9.1, 9.10, 12, 14, 22 and 26 of the Code.

In addition to the above, the complainant set out what he/she described as less detailed examples of breaches of the letter and spirit of the Code below. The complainant submitted that the employee promoted brexpiprazole on LinkedIn by sending readers to an article which noted that the medicine had been accepted for review by the European Medicines Agency (EMA) for use in adults with schizophrenia. The article informed the reader that the medicine was licensed in a number of countries (US, Canada, under different named brands) and that if the EMA approved the licence the brand name in the EU would be Rxulti. The complainant alleged that this pre-licence advertising by the employee clearly breached Clauses 3, 22 and 26 of the Code.

Finally, the complainant noted that in October the employee advertised Equelle on LinkedIn, a non-hormonal supplement that purported to manage menopause symptoms. The article posted on LinkedIn promoted to both patients and health professionals; the article stated 'Equelle is the product of fermentation of whole, non-GMO soy germ using a patented and proprietary process by the Otsuka Pharmaceutical Co., Ltd. The process results in the conversion of the daidzein to S-equol. Equelle tablets, created under current Good Manufacturing Practices, are clear coated and free of gluten, dairy, magnesium stearate and talc. Suggested patient use is two Equelle tablets daily, one tablet taken in the morning and one tablet at night, which provide the standardized dose of 10 mg of S-equol. Clinicians interested in ordering Equelle were invited to do so via [a named website]'.

The complainant stated that he/she had also shown another Otsuka (Japan) piece which the employee highlighted to Otsuka UK staff.

The complainant alleged that the employee's blatant promotion to patients and clinicians was against the spirit of the Code. The complainant noted that the employee referred, in LinkedIn, to having passed the ABPI Medical Representatives Examination. The complainant alleged that the employee boasted about his/her knowledge of the Code but that he/she had clearly shown no respect for it and had brought the industry into disrepute in breach of Clause 2.

## RESPONSE

Otsuka stated that it expected the highest standards of ethical and professional behaviour, and compliance with the Code from all of its employees. It therefore took this complaint extremely seriously; it was disappointed that the complainant was a current employee given that the company promoted an open and transparent culture in which employees were encouraged to speak-up about compliance concerns either through internal channels or through an external speak-up facility. This was an area the company was committed to working on further in light of this complaint.

Otsuka submitted that following receipt of the complaint and appreciating the extremely serious nature of it, the morning after the complaint was received:

- the highlighted posts were removed from the personal LinkedIn account
- assurances were obtained from the employee that there were no other such posts on any other social media platforms
- other actions were taken pursuant to Otsuka's policies
- Otsuka's social media policies were re-circulated to all UK employees with online retraining for all to be undertaken by 16 November. That training would include a test that required a 100% pass rate with scenarios such as posting company information on social media

In addition to the above:

- a company meeting was conducted on 15 November to retrain staff on the social media policy and to highlight the external speak-up facility
- there would be face-to-face training in December where staff would be further retrained on the Otsuka social media policies as well as the PMCPA guidance on digital communications. This training would also highlight the external speak-up facility and employees would be encouraged to use this facility if they were concerned about compliance within the organisation
- Code training materials would also be updated to include a specific section on social media.

Otsuka submitted that it was committed to ensuring compliance with both the spirit and letter of the Code. The company had a comprehensive set of policies and standard operating procedures (SOPs) which reflected the requirements of the Code and all employees were promptly trained on the policies relevant to their role and responsibilities when first employed by Otsuka and at regular intervals thereafter. Social media was recognised as an area that needed specific attention in order to ensure compliance and all UK employees were trained on a specific European policy.

Otsuka noted that the employee in question joined the company in early 2017; he/she currently had a small number of direct reports. The employee was up-to-date on all training including the Code, business ethics and compliance, social media and the policy relating specifically to his/her role. Details of the training courses undertaken by the employee were provided.

Otsuka provided copies of its Group Global Policy for Use of Social Media (version 4) and European Policy EU-POL-ALL-004 'Social Media Policy' (version 3) and the associated test. The test required a good understanding of the principles behind ensuring compliance when using social media. Otsuka noted that the employee completed training on the most recent version of this policy in September 2017 and had passed the associated mandatory test. Section 3.2 'General Principles Regarding Producing and Sharing Information Online' of the European policy clearly stated 'Region Europe employees must not comment on or post information via personal social media channels that relate or refer to medicines or devices provided by Otsuka'. It also stated 'All social media activities initiated by Region Europe employees via professional social media channels must not link or refer to any pharmaceutical product or medical device, pre- or post-launch'.

Otsuka also provided a European policy document relevant to the employee's role which clearly stated that 'Discussions and activities must be conducted in the spirit of contributing to the practice of medicine, maintaining trusted peer-to-peer relationships and enhancing patient best care. They must therefore be non-promotional in content and tone nor seek to promote the administration, consumption, prescription, purchase, recommendation, sale,

supply or use of Otsuka medicines ...'. Section 3.5.4 stated that relevant staff were prohibited from engaging in off-label discussions with health professionals except in response to unsolicited requests in one-to-one situations or in discussions relating to investigator sponsored studies.

With regard to the materials posted by the employee, Otsuka noted that they had all been taken from external websites. Otsuka submitted that Equelle was not a prescription only medicine. With the Equelle posting there was a further screen shot from the Otsuka Japan website. However, none of the material was provided to the employee by Otsuka. The materials had been sourced externally by him/her and proactively shared on his/her LinkedIn profile in clear contravention of Otsuka's social media policies.

Otsuka stated that as part of ongoing internal investigation, the employee had categorically confirmed that she did not give any instructions to his/her team about the materials which were the subject of this complaint.

There was no certificate approving the materials as these had not been provided to the employee by Otsuka.

Otsuka stated that as noted above, it had clear guidance and training about the use of social media. The activities in question were not conducted on the instructions of Otsuka; the materials posted by the employee on his/her LinkedIn profile had not been provided by Otsuka. The employee's activities clearly contravened the relevant Otsuka policies as well as the Otsuka Group Global Code of Business Ethics.

In relation to the specific clauses cited in the complaint, Otsuka acknowledged:

**Clause 1.2:** The activities of the employee unintentionally, but, in effect, promoted three Otsuka products to his/her LinkedIn followers; it was possible that many of these were not health professionals.

**Clause 3:** Two of the LinkedIn posts in question mentioned either an unlicensed medicine (brexpiprazole) or highlighted data not in accordance with the EU marketing authorisation (Jinarc (tolvaptan)).

**Clause 4:** Prescribing information was not provided for what was in effect, although unintended, promotional material. There was also no adverse event statement included with the material.

**Clause 7:** As set out above, the employee's activities unintentionally but, in effect, promoted three Otsuka products to his/her LinkedIn followers. There was the possibility that many of these were not health professionals. Otsuka acknowledged that the LinkedIn posts did not meet the quality standards of Clause 7.

**Clause 9.1:** The employee's activities clearly failed to maintain high standards.

**Clause 26:** These activities were unintended as, but in effect, promoted prescription only medicines to the employee's LinkedIn followers. There was a significant possibility that some of these followers were not health professionals, therefore there was a significant chance that prescription only medicines were advertised to the public.

Otsuka noted, however, that in respect of each of the above clauses, whilst the individual was an Otsuka employee, his/her activities in question were not initiated, sanctioned or authorised by the company; indeed, they were in direct contravention of Otsuka's SOPs and policies. As soon as these activities were highlighted, the posts were removed from LinkedIn, assurances were received that no other such posts existed, other action was taken and the social media policies were recirculated to all Otsuka employees. A company meeting had been held to retrain staff on the social media policy and to highlight the external speak-up facility. All employees would also be further retrained on the Otsuka social media policies as well as the PMCPA guidance on digital communications at a face-to-face meeting in December. This training would reiterate the external speak-up facility and employees would be encouraged to use this facility if they had compliance concerns within the organisation. Code training materials would also be updated to include a specific section on social media.

**Clause 9.10:** Otsuka did not consider that there had been any breach of Clause 9.10 (Declaration of Sponsorship). These activities were not conducted at the request of Otsuka.

**Clause 12:** As set out above, the employee's activities were not conducted at the request of Otsuka and were in direct contravention of company policies and SOPs. The employee shared data about Otsuka's products from external websites without realising that this, in effect, promoted those products. However, Otsuka considered that this material, whilst in effect promotional, was not disguised.

**Clause 14:** Whilst Otsuka acknowledged that the employee's activities had, in effect, promoted three of the company's products, the majority of the materials posted were from external websites and all were shared on the employee's own LinkedIn profile without the authority or knowledge of Otsuka and indeed, in direct contravention of company policies and SOPs. As such, this material was not, and would not be, certified by and on behalf of Otsuka.

**Clause 22:** Otsuka noted that Clause 22 concerned 'Meetings, Hospitality and Sponsorship'. As there was no meeting, hospitality or sponsorship in connection with this complaint, the company did not consider that Clause 22 was relevant.

**Clause 2:** Otsuka recognized that a breach of Clause 2 required particular censure, ie when activities or materials associated with promotion brought discredit upon, or reduced confidence in, the pharmaceutical industry. However, the company hoped that in light of the circumstances of this

complaint, as summarised below, the Panel would conclude that there had not been a breach of Clause 2.

## Conclusion

Otsuka acknowledged that the employee's activities, and the materials posted by him/her on LinkedIn had breached a number of clauses of the Code and included, in effect, promotion of an unlicensed medicine or indication, and to members of the public, which were significant breaches of the Code.

However, Otsuka again noted that it took ethics and compliance extremely seriously and had put in place comprehensive and robust policies and SOPs upon which all employees were regularly trained.

In this instance, despite comprehensive training, including a test with a similar scenario to this instance, a single employee, who was relatively new to Otsuka, had acted independently in a way that was in breach of both the Code and Otsuka's own policies and SOPs by three times sharing material from external websites with his/her followers on LinkedIn. These issues were not initiated, sanctioned or authorised by Otsuka.

Once notified of this complaint, Otsuka acted swiftly to ensure that the materials in question were immediately removed from LinkedIn and obtained assurances that they were not available on any other social media sites. Other action had been taken. Otsuka had also reissued its social media policies to all employees with all employees having already undertaken further training on the policies at a company meeting in November 2017. Face-to-face training would also be conducted in December 2017 on social media policies and the PMCPA guidance on digital communications. Employees would also be reminded about the external speak-up facility in case of compliance concerns. Code training would also be updated to include a specific section on social media.

Otsuka noted that while it acknowledged that the employee's activities were in breach of the Code which it deeply regretted, this was without the authorisation of Otsuka. Otsuka had taken, and continued to take, all reasonable measures to ensure that employees were appropriately trained in the use and management of social media to prevent such instances occurring and had acted quickly to remove the materials and take appropriate measures once it had been notified of the complaint.

Otsuka stated that it had alerted all Otsuka employees to the fact that it had received a complaint about the use of social media. The company had mandated that all employees promptly confirm in writing that none of their personal social media accounts contained posts about Otsuka products.

Otsuka submitted that it was not possible for it or any other pharmaceutical company to actively and comprehensively monitor its employees'

social media accounts. The training that Otsuka provided on compliance with the Code and the Otsuka social media policy was extensive and set out very clear guidance around acceptable use of personal social media accounts. This complaint concerned one employee who, despite being made aware of the requirements of Otsuka's policies and being trained on them, contravened clear and strict internal policies and various clauses of the Code. This was being dealt with appropriately through an internal investigation. The immediate re-training of all Otsuka UK employees was part of a series of steps that would be taken to avoid this happening again in the future. This would be reinforced by a face-to-face meeting in December 2017 for all Otsuka Pharmaceuticals UK Ltd employees where there would be comprehensive training on social media, the Code, PMCPA guidance on digital communications and the Otsuka policy and SOPs.

## PANEL RULING

The Panel noted that the complaint concerned postings made by an employee on his/her personal LinkedIn account which Otsuka stated were made without its knowledge or approval.

The Panel noted that LinkedIn 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. In the pharmaceutical industry the Panel noted that an individual's followers on LinkedIn might, albeit not exclusively, be directly or indirectly associated with the healthcare industry. In the Panel's view it was of course not unacceptable for company employees to use personal LinkedIn accounts. The Code would not automatically apply to postings on a personal account however such postings might potentially be covered by the Code and the company be found responsible for postings by an employee. Whether the Code applied to such a posting should be decided on a case by case basis taking into account all of the circumstances including the nature of the material disseminated, any product references, the company's role if any in relation to the creation or availability of the material posted, whether such posting was directed, encouraged or otherwise acquiesced to by the company. The status and role of the employee might also be relevant.

The Panel noted that Clause 26.1 prohibited the promotion of prescription only medicines to the public. Clause 26.2 permitted information about prescription only medicines to be supplied directly or indirectly to the public but such information must be factual and presented in a balanced way. The quality standards in Clause 7 also applied to information provided to the public.

The Panel noted that in particular junior employees were often keen to link to senior employees and thus all employees should be mindful of the impression given about the acceptability of matters posted. In the Panel's view companies should give unambiguous guidance to help ensure that such

forums were not used by employees in a way that was potentially within the scope of and inconsistent with the Code, particularly Clause 26.

The Panel noted that the employee in question had over 300 LinkedIn followers. Otsuka accepted that at least some of these were members of the public. The Panel noted the company's submission that none of the articles had been provided to the employee by Otsuka and all had been taken by the employee in question from external websites. The employee had sourced the material and proactively shared it. The Panel noted, however, that this implied that the source material for the postings were entirely independent of Otsuka and that was not so. It appeared to the Panel that the tollevantan and brexpiprazole articles reproduced Otsuka global press releases. Nonetheless, there was no evidence before the Panel that the company had encouraged their dissemination or that the UK company had any role in their creation. The Panel noted that the LinkedIn postings by a company employee each highlighted positive and newsworthy material about the company's products and thus the LinkedIn postings came within the scope of the Code.

In relation to the posting headed 'Otsuka: Announces Results of Phase 3 Data on Tolvaptan Under Development for ADPKD in US', linked to an article which bore the same title published on a financial website the Panel noted that the article bore the post script 'Otsuka Holdings Co Ltd published this content on 22 May 2017 and is solely responsible for the information contained therein'. The article appeared to be a reproduction of an Otsuka global press release. The article discussed positive study results. The Panel noted Otsuka's submission that there was a significant possibility that some of the followers were not health professionals. The Panel considered that the proactive dissemination of the article to the employee's followers on LinkedIn constituted promotion of a prescription only medicine to the public. A breach of Clause 26.1 was ruled as acknowledged by Otsuka.

The Panel noted Section 4.2 of the Jinarc SPC stated that the safety and effectiveness of tolvaptan in ADPKD patients over 50 years has not been established and that it was indicated for use in adults with ADPKD patients with CKD stage 1 to 3 at initiation of treatment. The Panel noted that study patients referred to in the article were 18 to 65 years of age with ADPKD-induced chronic kidney disease between late stage 2 to early stage 4. The Panel noted the promotional use of the article and considered that the article was inconsistent with the product's licence on each of these points and a breach of Clause 3.2 was ruled. The Panel considered that for the same reason the article was misleading and in breach of Clause 7.2.

The Panel noted that the article had not been certified. The Panel did not know whether the use of the original press release which appeared to have been issued by the global company came within the scope of the UK Code. It was not the subject of complaint. The Panel considered that the promotional dissemination of the article by posting a link to it was such that the certification requirements

were triggered as accepted by Otsuka. The LinkedIn posting including the article had not been certified in accordance with Clause 14.1 and a breach of that Clause was ruled. Similarly, the required prescribing information was not provided and a breach of Clause 4.1 was ruled.

In relation to Clause 12.1 the Panel considered that the proactive dissemination of positive study results by a company employee beyond the company to all his/her LinkedIn followers was clearly promotional and did not consider that it was in any way a disguised promotional act. No breach of Clause 12.1 was ruled.

The Panel noted that the complainant had not set out why the LinkedIn post including the article was in breach of Clause 9.10. The Panel considered that it was clear that the link to the article had been posted by an Otsuka employee. Whilst the article apparently reproduced a global press release that Otsuka global was responsible for there was no evidence that Otsuka had arranged or paid for the article to be published on the independent financial website such that the article was similar to sponsored material. Nonetheless, the Panel had decided that the company was responsible for the employee's decision to disseminate the article on LinkedIn. The complainant bore the burden of proof. The complainant had not established that a declaration of sponsorship ought to be on the original article and no breach of Clause 9.10 was ruled.

The Panel noted its rulings above of breaches of the Code and considered that high standards had not been maintained; a breach of Clause 9.1 was ruled.

The Panel ruled that there was no breach of Clause 22 which related to meetings, hospitality and associated sponsorship. In relation to the complainants' allegation that the activities breached Clause 1.2 the Panel noted that Clause 1.2 was a statement of principle and set out the definition of promotion. It was not capable of being breached *per se*. The Panel ruled no breach of Clause 1.2 as it considered that it was not applicable; no breach of that Clause was ruled.

The Panel noted that the LinkedIn post was done by an individual employee using their own account and without the knowledge or authority of Otsuka. The Panel considered that company employees ought to be cautious when using social media in areas which impinged on their professional role or the commercial interests of their company. As stated above companies should give clear and unambiguous guidance in this regard. The Panel noted that the Otsuka Group Global Policy for Use of Social Media stated that in using social media, Otsuka Group companies and their employees were required to observe local laws, regulations, code and the like. The policy applied to social media activities, regardless of whether such activities were done for personal reasons or on behalf of the company, during work time or personal time and whether inside or outside of the workplace. The Panel noted that the Europe Social Media Policy stated that employees must not comment on or

post information via personal social media channels that relate or refer to medicines or devices provided by Otsuka. The policy also stated that employees who engaged with Otsuka-related social media activities via personal social media accounts should only do so if, *inter alia*, the content did not mention or refer to medicines or products. The employee had completed training on this Policy (version 2) in February 2017 and (version 3) in September 2017, on each occasion passing the associated mandatory test. The company thus had a policy in place that should have prevented the employee from posting such material on LinkedIn. The complainant had stated that the posting in question was made in May 2017. The Panel noted that the employee in question had joined the company earlier that year. The Panel further noted that the Medical Science Liaison Policy also stated that MSLs were prohibited from engaging in off-label discussions with health professionals except in response to unsolicited requests and in discussions related to investigator initiated studies. The Panel considered that Otsuka had been badly let down by its employee. Nonetheless, the Panel did not consider that this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such use. The Company had the requisite policies in place and the employee had been trained. No breach of Clause 2 was ruled.

The Panel noted that the employee had also posted a link to an article published on an external financial website headed 'H Lundbeck A/S: Lundbeck and Otsuka's brexpiprazole for adult patients with schizophrenia accepted for review by the EMA' and alleged breaches of Clauses 3, 22 and 26. The Panel noted that the article referred to the fact that the EMA was expected to complete its review in the second quarter of 2018, and that it was already approved in the US and Canada. The article referred briefly to positive clinical data. The Panel noted its comments above about Clause 26, the conduct of the employee and Otsuka's responsibilities. The Panel considered that the proactive dissemination of the article to the employee's followers (over 300) on LinkedIn constituted promotion of a prescription only medicine to the public. A breach of Clause 26.1 was ruled. The Panel noted that brexpiprazole had been promoted prior to the grant of its licence and a breach of Clause 3.1 was ruled. The Panel considered that the complaint on this point did not raise a Clause 22 matter, which related to meetings, hospitality and associated sponsorship, no breach of that Clause was ruled.

The complainant also raised concerns about a link posted by the employee to an article published on a news wire headed 'NEW to the United States: Equelle, a non hormonal supplement clinically shown to help ease menopause symptoms' which discussed the availability of the product in the US and clinical data. At the end, after ordering details, and information about another company, information about Otsuka was provided and readers invited to visit its global website. The Panel noted that unlike the previous matters the complainant had not cited clauses of the Code specific to this link. The complainant did state that his/her concerns about promoting a prescription only medicine to the

public applied to all three matters and referred to the spirit of the Code in relation to Equelle. The Panel noted Otsuka's submission that Equelle was not a prescription only medicine and therefore ruled no breach of Clause 26.1.

The complainant also provided a copy of a page from Otsuka's global Japanese website about Equelle. The Panel noted that this page did not appear to have been posted on LinkedIn but noted the complainant's allegation that the employee had highlighted it to UK staff. The Panel noted that

the complainant bore the burden of proof and had not provided any evidence to show that this had occurred or explained why such activity would be in breach of the Code. Otsuka had not responded to this point. The Panel made no ruling as it did not consider that it had a valid complaint in this regard.

**Complaint received**      **31 October 2017**

**Case completed**      **31 January 2018**

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