

Otsuka Pharmaceuticals Europe Ltd has received a further public reprimand. In addition, Otsuka Europe has breached the ABPI Code of Practice for the Pharmaceutical Industry and brought discredit upon, and reduced confidence in, the pharmaceutical industry in a number of cases.

Otsuka Europe – Cases AUTH/3041/6/18 and AUTH/3123/11/18

For failing to implement timely changes to summaries of product characteristics (SPCs) and make consequential changes to its promotional material, Otsuka Europe was publicly reprimanded by the Code of Practice Appeal Board, which considered that the company's failures had the potential to impact patient safety (see May 2019 Code of Practice Review). Otsuka Europe was also required to be audited. At the consideration of the audit reports the Appeal Board noted that Otsuka Europe had previously not provided it with accurate information. Self-regulation relied, *inter alia*, on the provision of accurate information. The Appeal Board subsequently publicly reprimanded Otsuka Europe for a second time and required a re-audit of its procedures in relation to the Code.

Otsuka Europe – Case AUTH/3151/1/19

For internal distribution of incorrect prescribing information which omitted important safety information and for a lack of oversight and process in relation to creation and revision of prescribing information for Jinarc (tolvaptan), Otsuka Europe was ruled in breach of the following clauses of the Code:

Clause 2 - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry.

Clause 9.1 - Failing to maintain high standards.

Otsuka Europe – Case AUTH/3153/1/19

For using and failing to certify an advertisement which had been withdrawn and for multiple errors in the certification of a large number of pieces of material used at, or in

relation to, a congress including the use of some material prior to certification, Otsuka Europe was ruled in breach of the following clauses of the Code:

Clause 2 - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry.

Clause 9.1 - Failing to maintain high standards.

Clause 14.1 - Failing to certify material.

Otsuka Europe – Case AUTH/3169/3/19

Otsuka Europe voluntarily admitted that it had failed to clearly communicate changes to the summaries of product characteristics (SPCs) for Jinarc (tolvaptan), consistently apply the company's process and comply with an undertaking given in a previous case and was ruled in breach of the following clauses of the Code:

Clause 2 - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry.

Clause 9.1 - Failing to maintain high standards.

Clause 29 - Failing to comply with an undertaking.

Otsuka Europe – Case AUTH/3174/3/19

For failing to correctly classify a meeting as promotion for Jinarc (tolvaptan) and for undermining the Code and self-regulation in relation to failing to encourage open dialogue about compliance, Otsuka Europe was ruled in breach of the following clauses of the Code:

Clause 2 - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry.

Clause 9.1 - Failing to maintain high standards.

Clause 12.1 - Disguising promotional material.

The interim case reports or full case reports are available at www.pmcpa.org.uk. The public reprimand appears on the front cover of the PMCPA May 2020 Code of Practice Review and under Publications on the website.

The Prescription Medicines Code of Practice Authority (PMCPA) was established by The Association of the British Pharmaceutical Industry (ABPI) to operate the ABPI Code of Practice for the Pharmaceutical Industry independently of the ABPI. The PMCPA is a division of the ABPI. The Code covers the promotion of medicines for prescribing to health professionals and the provision of information to the public about prescription only medicines.

If you have any concerns about the activities of pharmaceutical companies in this regard, please contact the PMCPA at 7th Floor, 105 Victoria St, London, SW1E 6QT or email: complaints@pmcpa.org.uk.

The Code, full case reports, Code of Practice Reviews and other information, including details about ongoing cases, can be found at: www.pmcpa.org.uk.