

Lundbeck, Otsuka Europe, Daiichi-Sankyo and Roche have breached the ABPI Code of Practice for the Pharmaceutical Industry and brought discredit upon, and reduced confidence in, the pharmaceutical industry.

Lundbeck – Case AUTH/3452/1/21

For an article which promoted Abilify Maintena (aripiprazole) in a manner which was not in accordance with its marketing authorisation, used inaccurate efficacy and safety claims which were not capable of substantiation, did not include prescribing information and other mandatory information and was considered to be disguised promotion, Lundbeck was ruled in breach of the following clauses of the 2019 Code:

- Clause 2** - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
- Clause 3.2** - Promotion inconsistent with the summary of product characteristics
- Clause 4.1** - Failing to include up-to-date prescribing information
- Clause 4.6** - Failing to include a clear, prominent statement as to where prescribing information could be found
- Clause 4.9** - Failing to include information about how to report adverse events
- Clause 7.2** - Making a misleading claim
- Clause 7.4** - Making an unsubstantiated claim
- Clause 7.9** - Making claims that did not reflect the available evidence regarding possible adverse reactions
- Clause 9.1** - Failing to maintain high standards
- Clause 12.1** - Disguising promotional material

Otsuka Europe – Case AUTH/3489/3/21

For voluntarily admitting a failure to promptly notify affiliates of changes to the summary of product characteristics for Samsca (tolvaptan) and to promptly provide the updated prescribing information which meant that it had breached the undertaking given in a previous case, Otsuka Europe was ruled in breach of the following clauses of the 2019 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

Daiichi-Sankyo – Case AUTH/3504/4/21

For using claims which misleadingly implied that Nilemdo (bempedoic acid) and Nustendi (bempedoic acid, ezetimibe) could be added to any existing oral lipid lowering treatments and were generally well tolerated when they were contraindicated with simvastatin >40mg daily (information in this regard was provided in a footnote in the material at issue) and Nustendi co-administered with a statin was contraindicated in patients with active liver disease or certain elevations in serum transaminases and were thus not capable of substantiation and had the potential to adversely affect safety in patients for which each medicine was contraindicated, for implying that both medicines could be taken at any time which was not so (information in this regard was provided in a footnote) and as the non-proprietary names were not readily readable, Daiichi-Sankyo was ruled in breach of the following clauses of the 2019 Code:

- Clause 2** - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
- Clause 4.3** - Legibility of generic names
- Clause 7.2** - Making a misleading claim
- Clause 7.4** - Making an unsubstantiated claim
- Clause 9.1** - Failing to maintain high standards

Roche – Case AUTH/3568/10/21

Roche voluntarily admitted a typographical dosing error in a Gazyvaro (obinutuzumab) leavepiece for nurses. As the dosing error could have led to patient safety issues, particularly as it related to the first dose of the medicine, Roche was ruled in breach of the following clauses of the 2021 Code:

- Clause 2** - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
- Clause 5.1** - Failing to maintain high standards
- Clause 6.1** - Including inaccurate and misleading information

The case reports are available at www.pmcpa.org.uk.

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 and other information, including details about ongoing cases, can be found on the PMCPA website: www.pmcpa.org.uk.