

Teva and Daiichi Sankyo have breached the ABPI Code of Practice for the Pharmaceutical Industry and brought discredit upon, and reduced confidence in, the pharmaceutical industry.

Teva – Case AUTH/3656/6/22

Teva was ruled in breach of the following clauses of the 2019 Code for failing to include the black triangle for Ajovy in an article which, in the Panel's view, Teva was responsible for and was promotional, which was compounded by a failure to include an adverse event reporting statement; for failing to include prescribing information for Ajovy and Copaxone; for failing to certify the article; for describing Copaxone as 'new' when it had been available for more than 12 months in the UK, and including a statement in the article which implied that Copaxone was licensed for all types of multiple sclerosis which was not so:

- Clause 2** – Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
- Clause 3.2** – Promoting a medicine in a manner that was inconsistent with the particulars listed in its summary of product characteristics
- Clause 4.1** – Failing to include prescribing information
- Clause 4.9** – Failing to include the prominent adverse event reporting statement
- Clause 4.10** – Failing to include a black triangle
- Clause 7.11** – Referring to a product as 'new' when it has generally been available for more than 12 months in the UK
- Clause 9.1** – Failing to maintain high standards
- Clause 14.1** – Failing to certify promotional material

Daiichi Sankyo – Case AUTH/3673/7/22

For using a claim which misleadingly implied that Nilemdo (bempedoic acid) could be used therapeutically in combination with any oral lipid lowering treatment without making the contraindication with simvastatin >40mg daily immediately apparent which might prejudice patient safety and was such

as to reduce confidence in, and bring discredit upon, the pharmaceutical industry Daiichi Sankyo was ruled in breach of the following clauses of the Code:

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

Daiichi Sankyo – Case AUTH/3677/7/22

In referring to the therapeutic use of Nilemdo (bempedoic acid) and Nustendi (bempedoic acid and ezetimibe) in combination with a statin/other lipid lowering therapies, without sufficiently mentioning that they were contraindicated with simvastatin >40mg in two sales aids, two leavepieces and two briefing materials for representatives, particularly given that simvastatin was a commonly prescribed statin, meant that there was a risk that some patients on simvastatin >40mg daily might be inappropriately treated with Nilemdo or Nustendi and for the repeated failure to comply with the Code on this matter which was particularly serious and might prejudice patient safety Daiichi Sankyo 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** – Misleading impression provided
- Clause 6.2** – Misleading impression incapable of substantiation

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 2nd Floor, Goldings House, Hay's Galleria, 2 Hay's Lane, London, SE1 2HB 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.