

LEO Pharma, Norgine, 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.

LEO Pharma – Case AUTH/3311/2/20

For a media advisory board for Kyntheum (brodalumab) which did not meet the Code requirements and was thus considered to be promotional, LEO Pharma was ruled in breach of the following clauses of the Code:

- Clause 2** - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
- Clause 3.1** - Promoting an unlicensed medicine
- Clause 9.1** - Failing to maintain high standards.

Norgine – Case AUTH/3365/7/20

For an email comparing Feraccru capsules (ferric maltol) with intravenous iron, which did not have sufficient information for the reader to understand the basis and significance of the data and encouraging the use of Feraccru in all inflammatory bowel disease (IBD) patients when not all of those patients would be suitable for such therapy, Norgine was ruled in breach of the following clauses of the Code:

- Clause 2** - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
- Clause 7.2** - Making misleading claims
- Clause 7.3** - Making misleading comparisons
- Clause 7.4** - Making unsubstantiated claims
- Clause 9.1** - Failing to maintain high standards

Daiichi-Sankyo – Case AUTH/3375/8/20

For failing to publicly disclose transfers of value to healthcare organisations for three years in relation to therapy reviews, and in that regard breaching its undertaking given in Case AUTH/3285/12/19, 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 9.1** - Failing to maintain high standards
- Clause 24.1** - Failing to document and publicly disclose certain transfers of value to healthcare organisations

- Clause 24.4** - Failing to disclose transfers of value annually within the first six months after the end of the calendar year in which the transfers of value were made
- Clause 29** - Failing to comply with an undertaking

Daiichi-Sankyo – Case AUTH/3409/10/20

For a Lixiana (edoxaban) promotional campaign directed to UK health professionals, conducted by Daiichi-Sankyo Europe without the UK's involvement, which, *inter alia*, did not include the adverse events reporting statement and referred to an unlicensed dose for Lixiana (edoxaban), Daiichi-Sankyo UK Limited was ruled in breach of the following clauses of the 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 prescribing information
- Clause 4.3** - Failing to include the non-proprietary name immediately adjacent to the most prominent display of the brand name
- Clause 4.4** - Failing to provide prescribing information on digital material
- Clause 4.5** - Failing to provide prescribing information on audio visual material
- Clause 4.8** - Failing to state when the material was drawn up or last revised
- Clause 4.9** - Failing to include information about how to report adverse events
- Clause 7.2** - Making a misleading claim
- Clause 7.3** - Making misleading comparisons
- Clause 7.4** - Making an unsubstantiated claim
- Clause 7.10** - Making an exaggerated claim
- Clause 9.1** - Failing to maintain high standards
- Clause 14.1** - Failing to certify promotional material

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.

Novartis, Sanofi, Consilient and Pharmasure have breached the ABPI Code of Practice for the Pharmaceutical Industry and brought discredit upon, and reduced confidence in, the pharmaceutical industry.

Novartis – Case AUTH/3399/10/20

Novartis voluntarily admitted that one of its representatives had failed to maintain high standards with regard to discussions about the recommendation for use of Piqray (alpelisib) with two clinicians held before the medicine had been granted a marketing authorisation. Novartis was ruled in breach of the following clauses of the Code:

- Clause 2** - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
- Clause 3.1** - Promoting an unlicensed medicine
- Clause 9.1** - Failing to maintain high standards.

Sanofi – Case AUTH/3402/10/20

For a product website which contained inaccurate information about, and out of date prescribing information for Dupixent (dupilumab), Sanofi was ruled in breach of the following clauses of the 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 7.2** - Making a misleading statement
- Clause 9.1** - Failing to maintain high standards

Consilient – Case AUTH/3403/10/20

For allowing members of the public to view, within an app store, promotional information for InVita D3 (colecalciferol) on an app which was intended for health professionals, and for not re-certifying promotional material within two years, Consilient 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 14.5** - Using material for more than two years without re-certification
- Clause 26.1** - Advertising a prescription only medicine to the public

Pharmasure – Case AUTH/3407/10/20

For failing to comply with a previous undertaking and continuing to use claims for Meriofert (menotrophin) which had previously been ruled to be in breach of the Code, Pharmasure acknowledged the further following breaches of the Code:

- Clause 2** - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
- Clause 29** - Failing to comply with an undertaking

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