

The ABPI Code of Practice for the Pharmaceutical Industry sets standards for the promotion of medicines for prescribing to health professionals and the provision of information to the public about prescription only medicines. Publicity is the main sanction when breaches of the Code are ruled. The latest cases ruled in breach of Clause 2 of the Code (a sign of particular censure) are highlighted below.

Novartis, Camurus, Pfizer and Boehringer Ingelheim 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/3400/10/20

For promoting inclisiran (Leqvio) prior to the grant of the 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
- Clause 9.10** - Failing to be sufficiently clear as to the company's role and involvement
- Clause 12.1** - Disguising promotional material
- Clause 14.1** - Failing to certify promotional material
- Clause 28.1** - Failing to comply with all relevant requirements of the Code

Camurus – Case AUTH/3404/10/20

For failing to include obligatory information and certify promotional materials for Buvidal (buprenorphine) and for failing to fairly reflect Camurus' role and responsibility in relation to two promotional webinars which were, in addition, not restricted to health professionals and other relevant decision makers and were thus considered to be promoting Buvidal to the public, Camurus was ruled in breach of the following clauses of the Code:

- Clause 2** - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
- 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 4.9** - Failing to include information about how to report adverse events
- Clause 9.1** - Failing to maintain high standards
- Clause 9.10** - Failing to clearly indicate its role and responsibility in relation to two promotional webinars
- Clause 12.1** - Disguising promotional material
- Clause 14.1** - Failing to certify promotional material
- Clause 26.1** - Promoting a prescription only medicine to the public
- Clause 26.2** - Encouraging members of the public to ask for a specific prescription only medicine
- Clause 28.1** - Failing to restrict access to promotional material to health professionals and other relevant decision makers

Pfizer – Case AUTH/3437/12/20

For a senior employee placing an uncertified promotional post on his/her personal LinkedIn account which linked to an article about the company's vaccine prior to the grant of its marketing authorisation which was 'liked' by another employee, Pfizer 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

Pfizer – Case AUTH/3438/12/20

For a senior employee placing an uncertified promotional post on his/her personal LinkedIn account about the Pfizer/BioNTech vaccine on LinkedIn which linked to an article about the vaccine which described the vaccine as being judged as safe for use in the UK without qualification, prior to the grant of its marketing authorisation, Pfizer was ruled in breach of the following clauses of the Code:

- Clause 2** - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
- Clause 7.9** - Using the word 'safe' without qualification
- Clause 9.1** - Failing to maintain high standards

Boehringer Ingelheim – Case AUTH/3462/1/21

For providing a flow diagram for Pradaxa (dabigatran) which directed health professionals to select the most appropriate dose for their patient, taking into account age, concomitant verapamil and bleeding risk, without clearly bringing to their attention that Pradaxa was contraindicated in severe renal impairment, which put patient safety at risk, Boehringer Ingelheim 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** - Providing a misleading diagram
- Clause 9.1** - Failing to maintain high standards

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.