PMCPA | Prescription Medicines Code of Practice Authority

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) and/or where companies were required to issue a corrective statement are highlighted below.

Daiichi-Sankyo, GW Pharmaceuticals, Bayer plc and Proveca Ltd have breached the ABPI Code of Practice and brought discredit upon, and reduced confidence in, the pharmaceutical industry. In addition Daiichi-Sankyo has been required to issue a corrective statement.

Daiichi-Sankyo – Case AUTH/3010/1/18

For distributing two Lixiana (edoxaban) guides that were misleading in that they failed to highlight an important patient safety consideration and therefore did not encourage the rational use of the medicine, Daiichi-Sankyo was ruled in breach of the following clauses:

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

Clause 9.1 - Failing to maintain high standards.

Clause 7.2 - Providing misleading information.

Clause 7.10 - Not encouraging the rational use of a medicine.

The Code of Practice Appeal Board required Daiichi-Sankyo to issue a corrective statement to recipients of the items at issue.

GW Pharmaceuticals – Case AUTH/3014/1/18

For promoting Epidiolex (cannabidiol) before the grant of a marketing authorization which permits its sale or supply, GW Pharmaceuticals was ruled in breach of the following clauses:

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.

Bayer – Case AUTH/3035/4/18

For a misleading claim about Xarelto (rivaroxaban) which potentially put the safety of patients with severe renal impairment at risk, Bayer was ruled in breach of the following clauses:

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

Clause 7.2 - Making a misleading claim.

Clause 7.4 - Making an unsubstantiated claim.

Clause 9.1 - Failing to maintain high standards.

Proveca Ltd – Cases AUTH/3058/8/18 and AUTH/3060/8/18

For a letter sent to individual pharmacists about the supply of unlicensed and off-label glycopyrronium vs the use of its own product, Sialanar (glycopyrronium bromide), and which could be seen as threatening in tone, Proveca was ruled in breach of the following clauses:

Case AUTH/3058/8/18

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

Clause 8.2 - Disparaging the professional opinion of health professionals.

Clause 9.1 - Failing to maintain high standards.

Clause 9.5 - Including a reference to the MHRA when this was not specifically required.

Case AUTH/3060/8/18

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

Clause 9.1 - Failing to maintain high standards.

All cases are published in the May 2019 Code of Practice Review and on 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, full case reports, Code of Practice Reviews and other information, including details about ongoing cases, can be found at: **www.pmcpa.org.uk.**