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.

Grünenthal Ltd, Boehringer Ingelheim Limited, Eli Lilly and Company Limited, AstraZeneca UK Limited and Janssen-Cilag Ltd have breached the ABPI Code of Practice for the Pharmaceutical Industry and brought discredit upon, and reduced confidence in, the pharmaceutical industry. Boehringer Ingelheim and Eli Lilly and Company were required to issue a corrective statement.

Grünenthal – Case AUTH/2823/2/16

For failing to comply with its previous undertaking, failing to brief its representatives correctly regarding call rates and failing to agree written contracts in advance of engaging health professionals, Grünenthal was ruled in breach of the following clauses of various editions of the Code:

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

Clause 9.1 - Failing to maintain high standards.

Clause 15.4 - Failing to be sufficiently clear to representatives about the differences between call and contact rates.

Clause 15.9 - Producing representatives' briefing material that was likely to lead to them breaching the Code.

Clause 20.1 - Engaging health professionals in consultancy arrangements without agreeing a written contract in advance. (2015 Code)

Clause 23.1 - Engaging health professionals in consultancy arrangements without agreeing a written contract in advance. (2016 Code)

Clause 29 - Failing to comply with an undertaking.

The full case report was published in the PMCPA November 2016 Code of Practice Review and it is available at **www.pmcpa.org.uk**.

Boehringer Ingelheim and Lilly – Cases AUTH/2825/3/16 and AUTH/2826/3/16

For distributing a letter regarding Jardiance (empagliflozin) that prepared the market for an anticipated licence extension, Boehringer Ingelheim and Lilly were 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 - Using material that was inconsistent with the summary of product characteristics and promoted an unlicensed indication.

Clause 9.1 - Failing to maintain high standards.

Clause 12.1 - Disguising promotional materials.

The Code of Practice Panel reported Boehringer Ingelheim and Lilly to the Code of Practice Appeal Board which subsequently required both companies to issue a corrective statement to recipients of the item at issue.

The interim case report which includes the wording of the corrective statement is available at **www.pmcpa.org.uk**.

AstraZeneca – Case AUTH/2842/4/16

For facilitating the use by independent speakers of uncertified presentations which were misleading as to the licensed indication for Duaklir Genuair (formoterol/aclidinium), AstraZeneca 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 - Implying a use for a medicine which was inconsistent with its summary of product characteristics.

Clause 7.2 - Being misleading as to the licensed indications of medicines.

Clause 9.1 - Failing to maintain high standards.

The full case report was published in the PMCPA November 2016 Code of Practice Review and it is available at **www.pmcpa.org.uk**.

Lilly – Case AUTH/2849/6/16

For distributing a publication which included an error regarding the dose of Vitamin B12 which must be given with Alimta (pemetrexed), Lilly was ruled in breach of the following clauses of the Code:

Clause 2 - Reducing confidence in the pharmaceutical industry.

Clause 7.2 - Giving inaccurate and misleading information.

Clause 7.4 - Using unsubstantiated information.

Clause 9.1 - Failing to maintain high standards.

The full case report was published in the PMCPA November 2016 Code of Practice Review and is available at **www.pmcpa.org.uk**.

Janssen – Case AUTH/2871/8/16

For material sent by Janssen Europe to UK health professionals that promoted Stelara (ustekinumab) for an unlicensed indication and failing to certify such material, Janssen voluntarily admitted breaches of the following clauses of the Code:

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

Clause 3.2 - Promoting a medicine in a manner inconsistent with its summary of product characteristics.

Clause 9.1 - Failing to maintain high standards.

Clause 14.1 - Failing to certify promotional material.

The full case report was published in the PMCPA November 2016 Code of Practice Review and it is 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**