

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 where companies were publicly reprimanded are highlighted below.

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

Britannia Pharmaceuticals Ltd – Case AUTH/3355/5/20

For paying health professionals for the preparation time when this was not warranted nor required as the same material or essentially the same material was reused by speakers, not having a contract for some of the engagements, not providing full information to the PMCPA about the arrangements for speakers at meetings outside the UK and arrangements for investigator led clinical trials which failed to consider patient safety and have the relevant approval processes in place, Britannia was ruled in breach of the following clauses of the 2019 Code:

- Clause 2** - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
- Clause 9.1** - Failing to maintain high standards
- Clause 13.4** - Failing to comply with the requirements for non-interventional studies
- Clause 18.1** - Paying health professionals fees which did not reflect fair market value
- Clause 23.1** - Engaging health professionals in other than genuine consultancy arrangements
- Clause 25.2** - Failure to approve and supervise non interventional studies

In addition the Code of Practice Appeal Board required Britannia to be audited

Sanofi – Case AUTH/3487/3/21

For a misleading email to existing customers about the reimbursement of its flu vaccine and another email to an NHS manager which disparaged the opinion of health professionals and appeared to call into question official NHS guidance, Sanofi was ruled in breach of the following clauses of the 2019 Code:

- Clause 2** - Bringing discredit upon the pharmaceutical industry
- Clause 8.2** - Disparaging the professional opinion of health professionals
- Clause 9.1** - Failing to maintain high standards
- Clause 9.2** - Failing to recognise the professional standing of the audience
- Clause 15.2** - Employee failing to maintain a high standard of ethical conduct

GlaxoSmithKline UK Limited – Case AUTH/3432/12/20

GlaxoSmithKline was ruled in breach of the following clauses of the 2019 Code in relation to the promotion of its respiratory medicines, Trelegy (fluticasone/umeclidinium/vilanterol), Anoro (umeclidinium/vilanterol), Incruse (umeclidinium) and Relvar (fluticasone/vilanterol):

- Clause 2** - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
- Clause 3.2** - Promotion inconsistent with the summary of product characteristics
- Clause 4.3** - Failing to include the non-proprietary names next to the most prominent display of the brand name
- Clause 4.9** - Failing to include information about how to report adverse events
- Clause 4.10** - Failing to include an inverted black triangle for relevant products
- Clause 9.1** - Failing to maintain high standards
- Clause 14.1** - Failing to certify the final form of promotional material
- Clause 26.3** - Failing to include information about how to report adverse events on material for patients

GlaxoSmithKline UK Limited – Case AUTH/3515/5/21

For referring to three medicines (Trelegy (fluticasone/vilanterol/umeclidinium), Anoro (vilanterol/umeclidinium) and Incruse (umeclidinium)) licensed for chronic obstructive pulmonary disease (COPD) but not asthma on a registration page for an asthma-focussed webinar, within a list of medicines which were indicated for use in asthma, which implied that the medicines could be used in asthma when their summaries of product characteristics stated that they should not be used in patients with asthma and was a matter of patient safety, GlaxoSmithKline 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 (SPC)
- Clause 9.1** - Failing to maintain high standards

The case reports and interim case report 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.