

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 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.

Vifor Pharma, Napp, Otsuka Europe and Otsuka UK have breached the ABPI Code of Practice for the Pharmaceutical Industry and brought discredit upon, and reduced confidence in, the pharmaceutical industry. In addition, Vifor Pharma was publicly reprimanded.

Vifor Pharma – Case AUTH/3199/5/19

For failing to comply with undertakings given in two previous cases in relation to the promotion of Ferinject (ferric carboxymaltose), including sending a promotional email without the prior consent of a recipient and the use of misleading claims which favourably differentiated its IV iron from a competitor on the grounds of tolerability, Vifor 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 29** - Failing to comply with an undertaking

Vifor Pharma – Case AUTH/3224/7/19

For making misleading and inaccurate claims which favourably differentiated Ferinject (ferric carboxymaltose) from a competitor on the grounds of tolerability, Vifor 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 7.2** - Making misleading and inaccurate claims
- Clause 7.3** - Making misleading comparisons
- Clause 8.1** - Disparaging a competitor product
- Clause 9.1** - Failing to maintain high standards

In both cases Vifor Pharma was reported to the Code of Practice Appeal Board which was very concerned that the initial responses from Vifor could be described as obstructive, defensive, aggressive, dissembling and untrue. The Appeal Board noted Vifor's subsequent responses to the PMCPA and its admission of errors and that it accepted responsibility for the breaches of the Code. Although Vifor submitted that there had been consequential changes in its senior management and the

company was committed to change how it promoted its medicines, the Appeal Board publicly reprimanded Vifor for its failure to provide accurate and truthful information to the Code of Practice Panel and its disingenuous approach to responding to the complaints. The Appeal Board also required an audit of Vifor's procedures in relation to the Code.

Napp – Case AUTH/3200/5/19

For the provision of excessive hospitality and entertainment at a five-day promotional meeting for pain specialists, held in New York in the early 2000s, Napp was ruled in breach of the following clauses of the 2001 Code:

- Clause 2** - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
- Clause 9.1** - Failing to maintain high standards
- Clause 18.1** - Providing a gift in connection with the promotion of medicines
- Clause 19.1** - Providing excessive hospitality

Otsuka Europe and Otsuka UK – Cases AUTH/3219/6/19 and AUTH/3220/6/19

Otsuka Europe and Otsuka UK voluntarily admitted omissions and errors in the prescribing information for four of its medicines and breaches of undertakings given in relation to previous cases and were ruled in breach of the following clauses of the Code in relation to Samsca (tolvaptan):

- Clause 2** - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
- Clause 4.1** - Failing to have up-to-date prescribing information
- Clause 9.1** - Failing to maintain high standards
- Clause 29** - Failing to comply with an undertaking

**The interim case reports or full case reports are available at www.pmcpa.org.uk.
The public reprimands appear under publications on the website.**

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.

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Teva UK, Bayer, Janssen and Merck Serono have breached the ABPI Code of Practice for the Pharmaceutical Industry and brought discredit upon, and reduced confidence in, the pharmaceutical industry.

Teva – Case AUTH/3226/7/19

For placing an advertisement for DuoResp Spiromax (budesonide/formoterol fumarate) that was misleading and inconsistent with the summary of product characteristics, Teva 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** - Promoting a medicine in a manner which was inconsistent with the particulars listed in its summary of product characteristics
- Clause 7.2** - Making misleading claims
- Clause 9.1** - Failing to maintain high standards

Bayer – Case AUTH/3242/9/19

For its global affiliate providing a UK health professional with inappropriate hospitality during the course of an international congress in France, Bayer UK was held responsible under the Code and ruled in breach of the following clauses:

- Clause 2** - Bringing discredit upon the pharmaceutical industry
- Clause 9.1** - Failing to maintain high standards
- Clause 22.1** - Providing inappropriate hospitality

Janssen – Case AUTH/3250/10/19

For promoting Tremfya (guselkumab) for an unlicensed indication and failing to comply with its previous undertaking, Janssen 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** - Promoting a medicine for an unlicensed indication
- Clause 9.1** - Failing to maintain high standards
- Clause 29** - Failing to comply with an undertaking

Merck Serono – Case AUTH/3268/10/19

For promoting a homecare delivery service for Mavenclad (cladribine) but not interacting with those with direct responsibility for such services within the NHS, and for not being clear about the company's relationship with the service provider, Merck Serono 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 9.10** - Failing to clearly indicate its sponsorship of material
- Clause 15.2** - Representative failing to maintain a high standard of ethical conduct
- Clause 15.4** - Representative failing to observe the arrangements in place at a particular establishment

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Britannia, Novo Nordisk, Rayner and Shionogi Europe have breached the ABPI Code of Practice for the Pharmaceutical Industry and brought discredit upon, and reduced confidence in, the pharmaceutical industry.

Britannia – Case AUTH/3297/1/20

Following the attendance of a member of the public at a Britannia symposium where Apo-Go (apomorphine for injection or infusion) was promoted, Britannia 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 26.1** - Promoting a prescription only medicine to the public

Novo Nordisk – Case AUTH/3299/1/20

For promoting Saxenda (liraglutide) at a fertility conference without ensuring that materials for health professionals (in addition to references in the prescribing information) and patients made available on a Novo Nordisk exhibition stand made it clear that Saxenda was not to be used in pregnancy, those wishing to become pregnant and those breast feeding, and for failing to be able to show that representatives were trained and their briefing was certified, Novo Nordisk 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** - Failing to reflect the current warnings and potential risks set out in the summary of product characteristics with respect to the safety of the medicine in pregnancy, those wishing to become pregnant and those breast feeding
- Clause 9.1** - Failing to maintain high standards
- Clause 15.1** - Failure to be able to show that representatives had been adequately trained to promote Saxenda within the fertility area
- Clause 15.9** - Failure to certify a verbal briefing given to representatives
- Clause 26.2** - Providing misleading information for patients

Rayner Ltd – Case AUTH/3334/4/20

For an apparent lack of care and attention to detail in placing a journal advertisement for Ilube (acetylcysteine eye drops), a prescription only medicine, which was visible to the public when the journal was sent through the post, Rayner 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 9.8** - Advertising on a mailing exposed to the public
- Clause 26.1** - Advertising a prescription only medicine to the public

Shionogi Europe – Case AUTH/3343/5/20

For promoting Fetcroja (cefiderocol), both before and after it received its marketing authorization, on LinkedIn, Shionogi Europe 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 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

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