

PMCPAPrescription 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) are highlighted below.

Shire Pharmaceuticals Ltd and Roche Products Limited have each breached the ABPI Code of Practice for the Pharmaceutical Industry and brought discredit upon, and reduced confidence in, the pharmaceutical industry.

Shire – Case AUTH/2528/8/12

For issuing a press release for VPRIV (velaglucerase alfa) (a prescription only medicine) that was misleading, inaccurate, disparaging, implied statistical and clinical significance from exploratory data and effectively promoted the medicine and encouraged patients to ask their health professionals to prescribe it, Shire was ruled in breach of the following clauses of the Code:

- Clause 1.8** - Failing to comply with the Code.
- Clause 2** - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry.
- Clause 4.1** - Failing to include prescribing information in promotional material.
- Clause 7.2** - Making misleading claims.
- Clause 7.3** - Making a misleading comparison.
- Clause 8.1** - Making disparaging claims.
- Clause 14.1** - Failing to certify promotional material before issue.
- Clause 14.5** - Failing to certify promotional material before issue.
- Clause 22.1** - Promoting a prescription only medicine to the public.
- Clause 22.2** - Encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine.

Voluntary admission by Roche – Case AUTH/2582/2/13

Roche made a voluntary admission in relation to the distribution of an uncertified, promotional mailing for an unlicensed medicine. Roche 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 a medicine prior to the grant of a marketing authorization.
- Clause 9.1** - Failing to maintain high standards.
- Clause 14.1** - Failing to certify promotional material before issue.

The full case reports were published in the PMCPA May Code of Practice Review and are also available at www.pmcpa.org.uk

The Prescription Medicines Code of Practice Authority (PMCPA) administers The Association of the British Pharmaceutical Industry's (ABPI) Code of Practice for the Pharmaceutical Industry at arm's length from the Association itself. 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 complaints@pmcpa.org.uk.

The Code and other information, including details about ongoing cases, can be found on the PMCPA website.