

Bayer plc, Astellas UK Limited, Astellas Pharma Europe Limited and A Menarini Pharma UK SRL have breached the ABPI Code of Practice for the Pharmaceutical Industry and brought discredit upon, and reduced confidence in, the pharmaceutical industry.

Bayer – Case AUTH/2943/3/17

For producing representatives' training and briefing material which suggested an unlicensed use for Xarelto (rivaroxaban), Bayer 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 15.9** - Producing representatives' briefing material that advocated a course of action likely to lead to a breach of the Code.

Astellas UK - Case AUTH/2957/5/17

Astellas UK voluntarily admitted that, over a long period of time, a large number of its promotional materials which referred to two medicines failed to include the prescribing information for both of those medicines. Prescribing information was omitted for Vesicare (solifenacin) and Prograf (tacrolimus). The company further admitted that it did not act immediately once the problem was discovered and it was ruled in breach of the following clauses of the Code:

- Clause 2** - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry.
- Clause 4.1** - Providing incomplete prescribing information.
- Clause 9.1** - Failing to maintain high standards.

Astellas Pharma Europe - Case AUTH/2958/5/17

Astellas Pharma Europe voluntarily admitted that an electronic advertisement for Xtandi (enzalutamide), which incorrectly referred to an indication and a publication as new, had not been certified; additionally the company had not followed its withdrawal process and it was ruled in breach of the following clauses of the Code:

- Clause 2** - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry.
- Clause 7.11** - Referring to an indication approved more than 12 months ago as new.
- Clause 9.1** - Failing to maintain high standards.
- Clause 14.1** - Failing to certify promotional material.

A Menarini – Case AUTH/2960/6/17

For failing to initially certify and subsequently recertify its website which provided information to the public and to patients and for failing to act quickly when a link to an adverse event reporting site was missing, A Menarini 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 14.3** - Failing to certify material for the public or patients.
- Clause 14.5** - Failing to recertify in-use material at an interval of not more than 2 years.
- Clause 14.6** - Failing to preserve certificates.

The full case reports were published in the PMCPA November 2017 Code of Practice Review and 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.