

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.

Otsuka Europe and Otsuka UK have breached the ABPI Code of Practice and brought discredit upon, and reduced confidence in, the pharmaceutical industry. In addition both companies received a public reprimand.

Otsuka Europe – Cases AUTH/3041/6/18 and AUTH/3123/11/18, Otsuka UK – Case AUTH/3042/6/18

For failing to communicate changes to the summaries of product characteristics (SPCs) from 2017 for Jinarc (tolvaptan), Samsca (tolvaptan) and Abilify (aripiprazole), update prescribing information and relevant materials and withdraw materials in a timely manner (Otsuka UK); and for failing to communicate SPC changes or provide up-to-date prescribing information (Otsuka Europe) each company was ruled in breach of the following clauses:

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

The Code of Practice Appeal Board subsequently publicly reprimanded Otsuka Europe and Otsuka UK for failing to implement SPC changes and update materials in a timely manner which had the potential to impact patient safety. Both companies were required to be audited. The interim case report is available at www.pmcpa.org.uk. The public reprimand appears on the front cover of the PMCPA May 2019 Code of Practice Review.