PMCPA

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.

Daiichi Sankyo has breached the ABPI Code of Practice for the Pharmaceutical Industry and brought discredit upon, and reduced confidence in, the pharmaceutical industry.

Daiichi Sankyo – Case AUTH/3611/2/22

For failing to make immediately apparent to health professionals in promotional material which referred to the therapeutic use of Nilemdo (bempedoic acid) or Nustendi (bempedoic acid and ezetimibe) in combination with a statin that there was a contraindication regarding concomitant use with simvastatin >40mg daily, Daiichi Sankyo was ruled in breach of the following Clauses of the 2021 Code:

Clause 2 - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
Clause 5.1 - Failing to maintain high standards
Clause 6.1 - Misleading impression provided
Clause 6.2 - Misleading impression incapable of substantiation

Daiichi Sankyo– Case AUTH/3627/4/22

For the omission of safety information in relation to symptoms, which might not be readily recognised by the patient as signs of excessive bleeding, in two Lixiana (edoxaban) patient booklets, Daiichi Sankyo was ruled in breach of the following clauses of the 2021 Code:

Clause 2 - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
Clause 5.1 - Failing to maintain high standards
Clause 6.1 - Providing misleading information
Clause 6.2 - Misleading impression incapable of substantiation

Daiichi Sankyo – Case AUTH/3612/2/22

For failing to make the contraindication with simvastatin >40mg immediately apparent when presenting Nilemdo (bempedoic acid) and Nustendi (bempedoic acid and ezetimibe) indications which referred to their therapeutic use in combination with a statin; and for failing to display prescribing information for adequate time for each medicine during a live symposium, Daiichi Sankyo was ruled in breach of the following Clauses of the 2021 Code:

Clause 2 - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
Clause 5.1 - Failing to maintain high standards
Clause 12.5 - Failing to display prescribing information for sufficient duration so that it is easily readable

The case reports are available at www.pmcpa.org.uk.