

## Novartis and Roche have breached the ABPI Code of Practice for the Pharmaceutical Industry and brought discredit upon, and reduced confidence in, the pharmaceutical industry.

### Novartis – Case AUTH/3633/4/22

For providing some, but not all, the relevant information in relation to renal and hepatic impairment in the body of a webpage which was intended to advise health professionals on considerations when using Entresto (sacubitril/valsartan) which was misleading, Novartis 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

### Novartis – Case AUTH/3635/4/22

For use of a claim in an Entresto (sacubitril/valsartan) podcast, in the absence of any qualification, which downplayed the importance of renal function and was thereby misleading and incapable of substantiation Novartis 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** - Making a claim incapable of substantiation
- Clause 14.4** - Implying that a medicine has some special merit, quality or property

### Novartis – Case AUTH/3655/6/22

For referring to Mayzent initiation in patients with a history of myocardial infarction and heart failure without making apparent the absolute contra-indication in patients with a history of myocardial infarction or heart failure in the previous 6 months, except on a separate webpage and within the prescribing information which, in the Panel's view, was insufficient to negate this immediate misleading impression, Novartis 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

### Roche – Case AUTH/3639/4/22

For providing some, but not all, of the important information in relation to the administration of Polivy (polatuzumab vedotin), within a section of the promotional website that was intended to advise health professionals on the appropriate administration of the medicine and for not highlighting to the reader, on the dosing webpage, that additional important information in relation to dose modifications was within the safety webpage of the website, Roche 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

### Roche – Case AUTH/3646/5/22

For omitting important safety information from the dosing webpage of the Rozlytrek (entrectinib) promotional website that a health professional would expect to have been made aware of on such a webpage, Roche 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

The case reports are available at [www.pmcpa.org.uk](http://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 2nd Floor, Goldings House, Hay's Galleria, 2 Hay's Lane, London, SE1 2HB or email: [complaints@pmcpa.org.uk](mailto: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](http://www.pmcpa.org.uk).