

# EX-EMPLOYEE/DIRECTOR v GEDEON RICHTER

## Breach of undertaking

An ex-employee alleged that a meeting invitation, which was available (22 May) on an events company's website, breached the undertaking given by Gedeon Richter (15 April) in Case AUTH/2580/2/13. When the complaint was submitted the complainant's appeal in Case AUTH/2580/2/13 had yet to be heard.

As the complaint concerned an alleged breach of undertaking it was taken up by the Director as the Authority was responsible for ensuring compliance with undertakings.

The detailed response from Gedeon Richter is given below.

The Panel noted that a form of undertaking and assurance was an important document. Companies had to give an undertaking that the material in question and any similar material, if not already discontinued or no longer in use, would cease forthwith and give an assurance that all possible steps would be taken to avoid similar breaches of the Code in future. It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted that Gedeon Richter had accepted the ruling of a breach of the Code in Case AUTH/2580/2/13; the company's undertaking was signed on 15 April and it was stated that 6 March was the last date the material was used or appeared. Although the complainant had appealed the Panel's rulings of no breach in that case, the Panel did not understand why Gedeon Richter believed that its undertaking would not be in force until the final ruling was made. There was nothing in any of the correspondence from the PMCPA to give that impression. The guidelines on company procedures relating to the Code referred to material in breach of the Code being 'quickly and entirely withdrawn from use'.

The Panel considered that as the invitation at issue, which was available on the event company's website after Gedeon Richter had given its undertaking, did not include prescribing information, Gedeon Richter had failed to comply with its undertaking given in the previous case. The Panel ruled a breach of the Code. High standards had not been maintained and a further breach of the Code was ruled.

The Panel noted the importance of complying with undertakings and considered that Gedeon Richter's failure to enforce its undertaking brought discredit upon and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

An ex-employee of Preglem UK (a wholly owned subsidiary of Gedeon Richter) alleged that the company had failed to comply with the undertaking given in Case AUTH/2580/2/13 in relation to a meeting invitation and a breach of Clause 4.1. When the present complaint (Case AUTH/2601/5/13) was submitted certain other rulings in Case AUTH/2580/2/13 were the subject of an appeal from the complainant which had not yet been heard by the Code of Practice Appeal Board.

As the complaint concerned an alleged breach of undertaking it was taken up by the Authority in the name of the Director as the Authority was responsible for ensuring compliance with undertakings.

## COMPLAINT

The complainant referred to the Panel's ruling of a breach of Clause 4.1 in Case AUTH/2580/2/13 and Gedeon Richter's undertaking which the complainant understood was effective from 15 April 2013.

In Case AUTH/2580/2/13 the Panel had noted that the front page of a meeting invitation featured the brand imagery associated with Esmya (ulipristal acetate). In this regard the Panel considered that the recipients would immediately associate the meeting with Esmya. That invitation was considered promotional and prescribing information should have been included.

In the present case the complainant referred to a very similar invitation currently available (22 May) on the website of Gedeon Richter's events company. A link to the website and a copy of the invitation was provided.

The complainant stated that the invitation (ref GRADV 13/0034) now at issue featured brand imagery which was the same as that at issue in Case AUTH/2580/2/13 and the meeting was similar but the invitation did not contain prescribing information. The brand imagery would be associated with Esmya and the meeting should be expected to be promotional. The complainant alleged a breach of undertaking.

When writing to Gedeon Richter, the Authority asked it to respond in relation to Clauses 25, 9.1 and 2.

## RESPONSE

Gedeon Richter noted that the allegation related to an invitation to a meeting which was to take place on 14 May, which could be found on the events company's website. The complainant alleged that as the invitation did not contain the prescribing

information for Esmya the company had breached its undertaking.

Following the Panel's ruling in Case AUTH/2580/2/13, Gedeon Richter informed the Panel that it was satisfied with the Panel's conclusion and submitted its notice of undertaking based on this conclusion. However, the complainant appealed the Panel's ruling. Gedeon Richter thus believed that the case was still open and that its undertaking would not be in force until the final ruling was reached. It was still its firm intent to adhere to the spirit and word of the undertaking in relation to Case AUTH/2580/2/13 and it had begun to take steps to ensure that the prescribing information was on all promotional material that it produced, including meeting invitations. It had contacted the events company to ensure that the prescribing information was included on Gedeon Richter meeting invitations but unfortunately this had not been done when the complainant reviewed the website.

Gedeon Richter was undertaking a comprehensive update of its promotional practices including the introduction of standard operating procedures (SOPs) relating to matters such as meetings and events, medical and educational goods and services, consultancy agreements and many others. The company had also introduced an electronic review and approval tool to allow it to better control its processes and as it believed that the undertaking had not yet come into force it intended to update all materials, including those on the events company's website, in line with its new SOPs and review tool. The company never intended to breach its undertaking and it believed that it would be unfair for it to be found in breach of the Code due to a potential lack of clarity in the process.

In order to avoid any further concern or confusion the company had requested that all of its material be removed from the events company's website until it had received the full and final ruling in Case AUTH/2580/2/13 from the Appeal Board. In the meantime it would be grateful for guidance from the Panel as to the timing of its undertaking and when it could be considered to be in force, particularly as the case to which it related had yet to be concluded.

In summary Gedeon Richter did not believe it had breached Clauses 25, 9.1 or 2 of the Code.

## **PANEL RULING**

The Panel noted that a form of undertaking and assurance was an important document. Companies had to give an undertaking that the material in question and any similar material, if not already discontinued or no longer in use would cease

forthwith and give an assurance that all possible steps would be taken to avoid similar breaches of the Code in future. (Paragraph 7.1 of the Constitution and Procedure refers.) It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted that Gedeon Richter had accepted the ruling of a breach of Clause 4.1 in Case AUTH/2580/2/13; the company's undertaking was signed on 15 April 2013 and it was stated that 6 March was the last date the material was used or appeared. The fact that the complainant had appealed the Panel's rulings of no breach was irrelevant to the status of the undertaking. It was clear from the form that once a company accepted a breach of the Code material had to be withdrawn forthwith; there was no reference to such action being subject to the outcome of a possible appeal of other rulings by the complainant. If a complainant appeal were successful then a respondent company would have to give a further undertaking in relation to the Appeal Board's ruling of a breach.

The letter informing Gedeon Richter that the complainant had appealed did not refer to the undertaking, other than it had been received. The Panel did not understand why Gedeon Richter believed that its undertaking would not be in force until the final ruling was made. There was nothing in any of the correspondence from the PMCPA to give that impression. The guidelines on company procedures relating to the Code referred to material in breach of the Code being 'quickly and entirely withdrawn from use'. The Panel did not accept that there was a lack of clarity in the process. A company could always contact the PMCPA if it was unsure as to what action was required.

The Panel considered that as the invitation for the meeting of 14 May, which was available on the events company's website after Gedeon Richter had given its undertaking, did not include prescribing information, Gedeon Richter had failed to comply with its undertaking given in the previous case. Thus the Panel ruled a breach of Clause 25. High standards had not been maintained and a breach of Clause 9.1 was also ruled.

The Panel noted the importance of complying with undertakings and considered that Gedeon Richter's failure to enforce its undertaking brought discredit upon and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

**Complaint received**                      **2 May 2013**

**Case completed**                         **6 June 2013**