

Case AUTH/3362/6/20

VOLUNTARY ADMISSION BY ROCHE

Promotional email sent to the public

Roche voluntarily admitted that a promotional email for Tecentriq (atezolizumab) had inadvertently been sent, by its third-party agency, to members of the public. In addition to being sent to health professionals as intended, the email was also sent to a small number of people in the pharmaceutical industry, including two Roche employees who were otherwise members of the public. Tecentriq was an antineoplastic agent indicated for the treatment of certain advanced cancers.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Roche.

The Panel noted that a promotional email had been received by members of the public due to the agency, working on Roche's behalf, inadvertently sending it to people who were on a mailing list of those in the pharmaceutical industry with an interest in oncology; not all of those people would have been health professionals.

The Panel considered that Roche had been let down by its agency in that a prescription only medicine had been promoted to the public and high standards had not been maintained. Breaches of the Code were ruled.

The Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2. No breach of Clause 2 was ruled.

Roche voluntarily admitted that a promotional email for Tecentriq (atezolizumab) had inadvertently been sent to members of the public. Tecentriq was an antineoplastic agent indicated for the treatment of certain advanced cancers.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Roche.

VOLUNTARY ADMISSION

Roche noted that in June 2020, it found out that a promotional email for Tecentriq had inadvertently been sent, by its third-party agency, to 35 pharmaceutical industry professionals, in addition to the intended health professionals. This was highlighted by two Roche employees (in this instance members of the public) who received the email into their work and/or personal email accounts.

Roche noted that Clause 26.1 stated that prescription only medicines must not be advertised to the public.

Roche stated that it was committed to the appropriate use of medicines, protecting the safety of patients and that it strove to maintain high standards in the ethical promotion of its medicines. Roche submitted that as soon as the matter was identified the issue was highlighted to the

compliance team and a full investigation was initiated, including of the agency which sent the email on Roche's behalf.

Summary of events

Roche explained that in February 2020, it contracted with an agency to provide third party support with the promotional email campaign in question. The contract between Roche and the media agency outlined the expectations with regards to Code compliance, including training and copy approval (details were provided).

As part of the agency onboarding there was also a telephone briefing which included background information of the disease area, overview of the marketing and communication strategy, Roche objectives including specific target audience (oncologist and oncologist nurses) who had given their consent to receive promotional material, frequency of communication, timelines and budget.

In February the media agency provided Roche with an overview of the proposed media plan with specific tactics including details of the email campaign and suggested subcontractors who would facilitate the mailing, which Roche agreed to. This proposal confirmed oncologists and nurse oncologists as the intended recipients of the mailing. On 4 June the content of the promotional email - NICE recommends TECENTRIQ (atezolizumab) + carbo/etop for the treatment of untreated extensive-stage small cell lung cancer (ES-SCLC) in adults - was certified and shared with the agency for distribution. The email was sent via the subcontracted mailing house to oncologists, nurse oncologists and, in error, 35 pharmaceutical industry professionals.

On receipt of the email a Roche employee promptly highlighted the potential issue and a full investigation was immediately launched.

Investigation

Roche initiated a thorough investigation with the agencies concerned to understand the extent and the root cause of the error. The investigation determined that the briefing between Roche and the media agency made it clear that the email campaign was targeted at health professionals and was limited to UK oncologists and nurse oncologists. The subsequent briefing between the media agency and its subcontracted agency again clearly stated the intended audience for the email campaign. However, the subcontracted agency admitted that, owing to human error, the email had been sent to two lists of email addresses; one with the email addresses of the health professionals and also a second email address list.

In 2019, the subcontracted agency had created a tag for email campaigns with a target audience comprising UK oncologists. It had also created another tag for email campaigns to people in the pharmaceutical industry who had an interest in oncology, and was usually used to send information about the subcontracted agency activity at up-and-coming oncology conferences. In order to send email campaign communications, the tags were selected manually by a member of the production team. When the email in question was sent out, the tag for pharmaceutical industry people, as well as the correct tag for UK oncologists, was mistakenly selected resulting in the email being sent to individuals who were related to the pharmaceutical industry but were not UK health professionals. The pharmaceutical industry email list consisted of 35 individuals two of whom were Roche employees. There were personal

email and pharmaceutical company email addressed used. As of 9 June, the email had been opened by 9 recipients, 2 of them, Roche employees.

Corrective and preventative actions

As a result of the investigation, the subcontracted agency removed the pharmaceutical industry tag from its database and moved the list to a separate system that did not interact with the email software. The subcontracted agency had committed to undertake a comprehensive audit of its database and to provide further training to all staff. Roche was working with both agencies to ensure full implementation of the necessary corrective and preventative actions.

Voluntary admission

Roche submitted that sending a promotional email to members of the public was in breach of the requirement that prescription only medicines must not be advertised to the public. Roche acknowledged overall responsibility for the actions of any third party acting on its behalf and therefore voluntarily admitted a breach of Clause 26.1.

Roche and its employees understood the strict requirements of UK medicines regulations and the Code, and as a result undertook full due diligence in contracting and briefing its agencies. It was regrettable that human error at the agency led to a promotional email being sent to members of the public, however Roche considered that under the circumstances, a ruling of a breach of Clause 2, a sign of particular censure, was not warranted in this case.

When writing to confirm that the matter would be taken up under the Code, The Authority asked Roche to provide any further comments it might have in relation to Clauses 2, 9.1 and 26.1.

RESPONSE

Roche had no further comments to add.

PANEL RULING

The Panel noted that a promotional email for Tecentriq had been received by members of the public due to an employee of a third party agency, working on Roche's behalf, inadvertently sending it to 35 people who were on a mailing list of people in the pharmaceutical industry with an interest in oncology; not all of those people would have been health professionals. The email should have only been sent to health professionals as agreed by Roche.

The Panel noted that it was an established principle under the Code that companies were responsible for the acts or omissions of any third party acting on their behalf. The Panel considered that Roche had been let down by its agency in that a prescription only medicine had been promoted to the public. A breach of Clause 26.1 was ruled. High standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and reserved for such. The Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2. No breach of Clause 2 was ruled.

Voluntary admission received 12 June 2020

Case completed

17 September 2020