

MEMBER OF THE PUBLIC v ViiV HEALTHCARE

Use of an iPad in public

A member of the public complained that a representative's use of an iPad on a train was such that the outline sales strategy for, and clinical information about, Triumeq (dolutegravir/abacavir/lamivudine) was clearly visible. The complainant was concerned that an HIV patient could take the information back to his/her nurse or doctor and argue his/her current regime without fully understanding the overall treatment regime he/she was on.

The detailed response from ViiV is given below.

The Panel noted that the complainant had seen promotional material for Triumeq which an employee from a third party was working on whilst travelling by train. As no representative as defined by the Code was involved, no breach of the relevant clause of the Code was ruled.

The Panel considered that it was unfortunate that the complainant had seen the material and that the third party employee had not been more discrete. ViiV submitted that the train was not overcrowded; there was an empty seat between the third party employee and the next passenger. The Panel considered that there was a difference between proactively showing material to the public or making material readily available for them and a member of the public reading material over someone's shoulder. The material at issue had not been directed at fellow travellers or other members of the public. On balance, the Panel did not consider that in the particular circumstances of this case a prescription only medicine had been promoted to the public and thus ruled no breach of Code.

The Panel did not consider that there had been a failure to maintain high standards nor did the circumstances bring discredit upon, or reduced confidence in, the pharmaceutical industry. No breaches of the Code including Clause 2 were ruled.

A member of the public, complained about a representative using an iPad during a train journey such that information about Triumeq (dolutegravir/abacavir/lamivudine) was clearly visible. Triumeq was marketed by ViiV Healthcare and indicated for the treatment of Human Immunodeficiency Virus (HIV).

COMPLAINT

The complainant stated that he was saddened to see a representative using his iPad on a train such that he could clearly see the outline for Triumeq's sales strategy and the clinical data for flamingo/aria/step-2. The complainant stated that he actually enjoyed Chris's journey as detailed in the material and how he dealt with his HIV medicines.

The complainant stated that he did not think it right that this sort of information was visible on public transport and used in close quarters with the public like himself.

The complainant was concerned that an HIV patient could easily take the information back to his/her nurse or doctor and argue his/her current regime without full knowledge and understanding of the medicines and the overall treatment regime he/she was on.

The complainant briefly described the representative at issue and the journey details.

When writing to ViiV, the Authority asked it to consider the requirements of Clauses 2, 9.1, 15.2 and 26.1 of the Code.

RESPONSE

ViiV Healthcare stated that the individual in question was not a representative, he was employed by a third-party service supplier responsible for the technical development of promotional materials for use on iPads. This platform was used only by fully briefed and trained specialists to detail ViiV's medicines to health professionals treating HIV patients. Since no representative was involved the company denied a breach of Clause 15.2.

The third party employee confirmed that he opened the material on his company iPad for about 10 minutes while travelling on a train. He recalled that one or two passengers sat opposite him and one person next to him, with an empty seat between. The employee estimated to have swiped about 20 screens, to make a number of technical checks on interactive elements and functionality. The individual concerned believed that he was diligent and had made effective use of train-bound time. He did not engage the complainant or others in any communication (either verbally, by playing audio, making eye contact, or other); nor was he aware of anyone overlooking his work.

ViiV submitted that the material in question was written for hospital specialists, not in language likely to be readily understood by the public, with graphs of efficacy and tables listing side effects. The complainant had provided no detail of the promotional messages conveyed, and as the third party employee was not interested in reading the content, it was unlikely that any reader would have had the chance to digest much more than the name of the studies being displayed, as mentioned by the complainant. This information in itself was not promotional and was available to the public on the clinical trials register. As such, ViiV denied that it had

promoted a prescription only medicine to the public in breach of Clause 26.1.

In response to Clause 9.1, ViiV reviewed its internal governance processes relating to third party service providers, and submitted that appropriate agreements and training were in place. The written agreement between ViiV and the third party at issue stipulated that the third party must ensure compliance with the Code and decisions of the PMCPA and its staff must have the skill, expertise, and knowledge with respect to the products and services required of them, including for technical testing, which should be undertaken in a comprehensive, timely and professional manner. ViiV noted that the third party employee in question had been trained on the Code including a PMCPA familiarisation seminar in January 2015. The third party also regularly emailed the employee with updates about the Code, the latest email was sent in January 2017.

ViiV stated that although it acknowledged that the third party employee ought to have behaved with total discretion whilst on public transport, it considered that this was somewhat naïve and a wholly unintended error of judgement. As such, ViiV did not consider that it represented a failure to observe the standards set by the Code for the promotion of medicines and it thus denied a breach of Clause 9.1.

ViiV stated that it regretted the wholly unintended consequences arising from the conduct of the third party employee and had taken the following additional and immediate corrective actions to ensure that such incidents were not repeated:

- The third party had re-issued the Code and the ViiV Code of Practice to all staff and given them two days to acknowledge that they had read and understood the documentation
- Following the above, team meetings were scheduled over the coming weeks to ensure all third party staff fully understood the implications of their day-to-day activity in relation to the Code and were being reminded that they must not work on promotional materials for health professionals in public places
- The third party would provide refresher training on the Code to the individual involved in the incident and all other relevant staff working on the account within the coming month
- When there were updates to the Code, the third party would hold briefing sessions with all relevant team members in addition to continuing to circulate the changes over email
- As per its internal Third Party Oversight Process,

ViiV had notified the Critical and Sensitive Information Risk team, which was currently undertaking a security assessment of the vendor

- ViiV had reminded all global ViiV suppliers that they must familiarise themselves with, and adhere to at all times, the laws and codes of practice in the country in which they were based

In response to Clause 2, although ViiV was sincerely disappointed by this isolated incident, it did not consider that the unintended actions of a technical third party provider brought discredit to, or reduced confidence in, the industry. Neither patient safety, nor public health, had been compromised or prejudiced.

PANEL RULING

The Panel noted that the complainant had seen material promoting Triumeq to hospital specialists which an employee from a third party was working on whilst travelling by train. The Panel accepted that no representative as defined by the Code was involved and thus ruled no breach of Clause 15.2.

The Panel considered that it was most unfortunate that the complainant had seen the material and that the third party employee had not been more discreet so that people sitting nearby could not see the material. The Panel noted that the part of the train where the third party employee was sitting did not appear to be overcrowded. There was an empty seat between the third party employee and the next passenger. The Panel considered that there was a difference between proactively showing material to the public or making material readily available for them and a member of the public reading material over someone's shoulder. The material at issue had not been directed at fellow travellers or other members of the public. On balance, the Panel did not consider that in the particular circumstances of this case a prescription only medicine had been promoted to the public and thus ruled no breach of Clause 26.1.

The Panel did not consider that there had been a failure to maintain high standards and no breach of Clause 9.1 was ruled. Clause 2 was a sign of particular censure and reserved for such use. The Panel did not consider the circumstances brought discredit upon, or reduced confidence in, the pharmaceutical industry and ruled no breach of Clause 2.

Complaint received **26 September 2017**

Case completed **23 November 2017**