ANONYMOUS CLINICIAN v ViiV HEALTHCARE

Alleged promotion to the public

An anonymous non contactable clinician complained about the ViiV Healthcare International Aids Society (IAS) Webinar. The complainant appeared to be a pharmacist.

ViiV's product Tivicay (dolutegrivir) was indicated in combination with other anti retroviral medicines for the treatment of Human Immunodeficienty Virus (HIV).

The complainant stated that he/she took part in Viiv's live 'online' meeting which was mostly about dolutegrivir. The complainant was surprised to see an HIV patient on the stage with the ViiV doctors whilst they discussed their prescription products. The patient appeared to be giving a silent blessing for dolutegrivir. Further, the prescribing information for dolutegrivir was not easily available via a single click.

The complainant stated that ViiV did not appear to know the requirements of the Code which was not good for the industry profile, reputation or regulation. The complainant alleged that ViiV's standards were not high enough. Having the patient on stage looked like the thumbs up for ViiV's medicines which was not good for trust and the confidence in the industry. The complainant referred to Clause 2.

The detailed response from ViiV is given below.

The Panel noted that the meeting invitation clearly stated that two speakers from ViiV would present data on dolutegravir and a third speaker would present the results of a patient survey. The survey highlighted key global trends about the emotional support people living with HIV received.

According to the transcript the speaker did not mention ViiV's product or indeed any other product but he/she was presenting at a meeting where data on Tivicay was discussed in detail.

The Panel considered that in the particular circumstances of this case, contracting the expert to discuss his/her research into the impact of HIV on patients at a meeting where medicines were promoted, did not mean that a prescription only medicine had been promoted to the public. This speaker's expertise would be of interest and in this situation he/she was not a member of the public *per se*. In that regard, the Panel ruled no breach of the Code.

The Panel noted ViiV's submission that the prescribing information was included in the invitation, available on demand during the Webinar via four clicks as well as being shown on the slides for nearly four minutes during the Q&A session. The prescribing information was supplied and thus the Panel ruled no breach of the Code.

Given its rulings above the Panel did not consider that ViiV had failed to maintain high standards as alleged nor had it brought discredit upon or reduced confidence in the pharmaceutical industry. The Panel ruled no breach including of Clause 2.

An anonymous non contactable clinician complained about the ViiV Healthcare International Aids Society (IAS) Webinar filmed live in Paris on 27 July 2017. The complainant appeared to be a pharmacist.

ViiV's product Tivicay (dolutegrivir) was indicated in combination with other anti retroviral medicines for the treatment of Human Immunodeficienty Virus (HIV).

COMPLAINT

The complainant stated that he/she was an HIV positive clinician working with NHS patients who also had HIV. The complainant was also in a company doing research into medicines for very difficult infections.

The complainant stated that he/she took part in a meeting with colleagues at lunch time before busy clinics. The meeting was live 'online' by ViiV from the IAS conference in Paris. It was mostly about dolutegrivir [ViiV Healthcare's product Tivicay] to treat HIV/AIDS. The complainant was surprised to see an HIV patient on the stage with the ViiV doctors whilst they discussed their prescription products. The patient appeared to be giving a silent blessing for dolutegrivir. In the complainant's view the patient did not have to be there all the time and should have talked first and then left or come in at the end to discuss her patient project. It did not look right for him/her to sit there all the time. The complainant knew that companies were not to talk to patients about prescription medicines but it happened here. The complainant stated that he/she and his/her colleagues discussed the matter and many were unhappy that the patient had been continually present and in that regard he/she referred to Clause 26.1.

The complainant stated that in his/her company he/she was learning to give UK medicines information too, including digitally. In that regard the complainant noted that Clause 4.4 stated that prescribing information had to be accesible via a single click for easy access. Buttons onscreens for ViiV's medicines did not work in a click away so it was very difficult with colleagues getting annoyed when clicking continued. The prescribing information for dolutegrivir was not easily available. The complainant referred to Clause 4.1.

The complainant stated that ViiV did not appear to know the requirements of the Code which was not good for the industry profile, reputation or regulation. The complainant alleged that ViiV's standards were not high enough and referred to Clause 9.1 The patient on stage looked like the thumbs up for ViiV's medicines. This was not good for trust and the confidence in the industry. Companies needed the credit so that people, even the pharmacist with HIV could be sure of their safety in them. The complainant referred to Clause 2.

RESPONSE

ViiV stated that it took its responsibilities under the Code very seriously, and was concerned that a health professional considered that it might have breached the Code by promoting to the public and not providing prescribing information correctly. The company refuted the allegations.

In response to the individual being present during the webinar, ViiV provided copies of contractual documents outlining the panellist's professional role on the panel. The panel member was employed as an expert and author on the research he/she was presenting and did not discuss or endorse dolutegravir at any point; he/she also formed part of the panel to answer questions from the audience and ViiV panellists at the end of the webinar. The questions asked related to the presented paper in light of his/her specific experience and expertise and were contained to these parameters.

ViiV submitted that in this capacity, he/she was not a patient, or a member of the public, but was a *bona fide* panellist in his/her own right as an author and steering committee member of the study with significant expertise and experience. Details were provided. ViiV thus considered that this vast experience in HIV made him/her an expert in that area and an appropriate panel member.

As such, the panellist concerned was contracted as an expert and was at the presentation in that capacity rather than as a patient, or a member of the public.

With regard to Clause 4.1, ViiV submitted that the UK prescribing information was available via 3 routes, the first of which alone the company considered satisfied Clause 4.1:

1 The prescribing information was integral and included in the presentation, shown for 3 minutes and 53 seconds during the question and answer section at the conclusion of the webinar;
2 The prescribing information was embedded and included in email and print invitations, (copies provided);
3 On-demand prescribing information was available for the entire webinar via 4 clicks: one to scroll, one to select prescribing information, one to press the download button in Adobe and one to click the 'click to download' (screen shots were provided).

ViiV recognized 4-click-access might cause frustration and it was working to reduce the number of clicks.

ViiV referred to Case AUTH/2931/1/17 in which the Panel noted that in relation to presentations delivered at a meeting:

> 'It was an established principle that prescribing information for a presentation should either be part of it or be otherwise available to each delegate, a leave piece provided to each delegate would suffice in this regards. If prescribing information formed part of the presentation in the absence of alternative formats, it should be displayed such that the audience had sufficient time to consider it ….'

With the above in mind, ViiV did not consider that it had breached Clauses 4.1 or 26.1 and therefore it was not in breach of Clauses 9.1 or 2 for failing to meet high standards or for reducing confidence in the industry.

ViiV stated that invitations to the meeting were sent by email and in print via the local ViiV representative and also hosted on the ViiV exchange website. One external UK health professionals watched the meeting online and no health professionals attended the meeting in person. Each attendee was verified as a health professional. The meeting was not available to view online after the event.

ViiV Healthcare UK was closely involved in the organization of the webinar and was aware of the speakers and the subject of the presentation from the initial meetings with its global colleagues. The UK attended calls every two weeks in the run up to the webinar, and provided the up-to-date prescribing information that was displayed on the slides and in the link during the webinar. The UK also certified the print and email invitations. The slides were certified by the global team who were ABPI signatories, but had been reviewed by a UK ABPI signatory via email before final certification.

ViiV submitted that the panellist in question was briefed twice before the webinar. Briefings were face-to-face with the medical team, and included a slide by slide run-through on what he/she would say and which questions would likely be directed to him/her at the end. These questions would be those related to his/her presented paper.

ViiV provided a video link to the webinar together with a transcript of what was said.

PANEL RULING

The Panel noted that the invitation clearly stated that two speakers from ViiV would present data on dolutegravir. A third speaker would present the results of a patient survey. The survey highlighted key global trends about the emotional support people living with HIV received.

The Panel considered that it was not necessarily unacceptable under the Code for pharmaceutical companies to include patients or members of the public as speakers at meetings where medicines were discussed. Much would depend on the circumstances.

The Panel noted that the speaker in question was presenting data from a patient survey and was a member of the study's steering committee. In addition the speaker had broad experience in HIV. According to the transcript this speaker did not mention ViiV's product or indeed any other product but he/she was presenting at a meeting where data on Tivicay was discussed in detail.

The Panel considered that in the particular circumstances of this case, contracting the expert to discuss his/her research into the impact of HIV on patients at a meeting where medicines were promoted, did not mean that a prescription only medicine had been promoted to the public. This speaker's expertise would be of interest and in this situation he/she was not a member of the public *per se*. In that regard, the Panel ruled no breach of Clause 26.1.

The Panel noted ViiV's submission that the prescribing information was included in the invitation, available on demand during the Webinar via four clicks as well as being shown on the slides for nearly four minutes during the Q&A session.

The Panel noted that the meeting was a Webinar and in that regard it queried whether the provision of prescribing information was covered by Clause 4.4 or Clause 4.5 of the Code. Neither clause specifically referred to Webinars. Clause 4.4 referred to advertisements in electronic journals, emails, electronic detail aids and such like whereas Clause 4.5 referred to audio visual materials such as films, DVDs, interactive data systems.

The Panel considered that it would be preferable if the prescribing information was supplied via a single click rather than four clicks. However given that the company had shown the prescribing information on the screen for nearly four minutes the Panel considered that ViiV had met the requirements of Clause 4.5. The invitation met the requirements of Clause 4.4. The prescribing information was supplied and thus the Panel ruled no breach of Clause 4.1 of the Code.

Given its rulings above the Panel did not consider that ViiV had failed to maintain high standards as alleged nor had it brought discredit upon or reduced confidence in the pharmaceutical industry. The Panel ruled no breach of Clauses 9.1 and 2.

Complaint received **7 September 2017**

Case completed **14 November 2017**