

COMPLAINANT v CONSILIENT

Promotion of InVita D3 via an app

A complainant who described him/herself as a member of the public, alleged that within its app, Vitamin D Vitality, Consilient Health Ltd promoted InVita D3. The complainant noted that the app, which he/she had found on the Google Play Store, referred to InVita, had branded materials for everyone to see, even if the app was not downloaded, as well as prescribing information in the preview images (screenshots were provided). The complainant did not think that pharmaceutical companies were able to promote to members of the public. The last time Consilient seemed to have reviewed its content was three years ago, which seemed like a long time.

Consilient marketed Invita D3 (colecalciferol) for vitamin D deficiency.

The detailed response from Consilient is given below.

The Panel noted Consilient's submission that the Vitamin D Vitality app was not registered as a medical device; it was developed by Consilient to help health professionals who had already decided to prescribe InVita D3 to identify the most appropriate product and dose. According to Consilient, by answering questions such as age of the patient, whether prophylaxis or treatment was required, frequency of dose etc, the app would guide the user to the most appropriate medicine with information about dose and frequency.

The Panel noted from the complainant's screenshots that the app was categorised under 'Health and Fitness' by the developers rather than 'Medical' which might imply that it was suitable for members of the public rather than for a more specialist medical audience. In the Panel's view, Consilient was responsible for the categorisation of the app. The Panel further noted that whilst beneath the heading 'About this app' within the Google Play Store it stated: 'To help HCPs who have decided to prescribe InVita D3 select the appropriate dose', it appeared that content from the app was visible before the app was downloaded including a reference to InVita D3 and its use in vitamin D deficiency and part of the prescribing information.

The Panel noted that whilst the Code did not specifically refer to apps, it did refer to the requirements for promotional material which was provided on the Internet and the Panel considered that those principles were relevant to promotional material on the Google Play Store and which could be downloaded from the Google Play Store such as an app.

In the Panel's view, despite the statement which could be seen before downloading the app from the Google Play Store, ie that the app in question was 'To help HCPs who have decided to prescribe InVita D3 select the appropriate dose', the information that could be

seen before downloading the app meant that a prescription only medicine had been advertised to the public and a breach of the Code was ruled.

In relation to the allegation that the content was last reviewed three years ago, the Panel noted Consilient's submission that the prescribing information provided in the app was current and that the 2019 update to the summary of product characteristics had had no impact on the prescribing information. On the evidence before it the Panel ruled no breach of the Code.

The Panel noted that the app was first certified on 12 September 2017 and re-certified on 17 September 2019. The Panel noted therefore that the delay in re-certification meant that the requirements of the Code had not been met and a breach was ruled.

The Panel noted its comments and rulings above and considered that Consilient had failed to maintain high standards and a breach of the Code was ruled.

The Panel did not consider that the inclusion of the statement that the app was 'To help HCPs who have decided to prescribe InVita D3 select the appropriate dose' negated the fact that information which promoted InVita D3 was available to the public without having to download the app. In the Panel's view this demonstrated a lack of care and awareness of the Code on matters that reflected UK law and Consilient had thus brought discredit upon, and reduced confidence in, the industry. A breach of Clause 2 was ruled.

A complainant who described him/herself as a member of the public, complained that the Consilient Health Ltd app, Vitamin D Vitality, was promotional. The complainant had looked for an app so that he/she could record vitamin D intake and get more information and had found the app in question on the Google Play Store when he/she had searched for vitamin D.

Consilient marketed InVita D3 (colecalciferol) for vitamin D deficiency.

COMPLAINT

The complainant noted that Consilient's app referred to InVita, had branded materials for everyone to see, even if the app was not downloaded, as well as prescribing information in the preview images (screenshots were provided). The complainant stated that he/she did not think that pharmaceutical companies were able to promote to members of the public. The last time Consilient seemed to have reviewed its content was also three years ago, which seemed like a long time. The complainant stated that Consilient had over 500 downloads on the play store and he/she was sure more on the Apple one. This seemed like gross misconduct.

When writing to Consilient, the Authority asked it to consider the requirements of Clauses 2, 4.1, 9.1, 14.5 and 26.1 of the Code.

RESPONSE

Consilient stated that it had developed the app in question to help health professionals who had already decided to prescribe InVita D3 to identify the most appropriate product from the company's vitamin D range (8 products with multiple indications and posologies). By answering a few simple questions such as age of the patient, prophylaxis or treatment, frequency of dose etc, the app would guide them to the most appropriate product (based on the licensed

indications for each product) with information about the appropriate dose and frequency. The full pathway algorithm for this was mapped out before the app was built and was included with the supplementary information. Consilient provided links for the app in Apple and the Google Play Store.

Consilient stated that it did not believe that it had promoted any medicine to the general public and would demonstrate that the content was up to date.

With regard to Clause 4.1, Consilient stated that the prescribing information provided in the app was current and was certified for use. Regarding the prescribing information [dated May 2017] and the update to the InVita D3 5,600 IU soft capsule summary of product characteristics (SPC) dated 28 November 2019, Consilient stated that that update related to Section 6.5 of the SPC, Nature and Content of the Container, and so had no impact on the prescribing information.

In relation to Clause 14.5, Consilient stated that all content in the app, app descriptors and prescribing information, was certified for use in accordance with internal standard operating procedures (SOPs) and as per Code requirements. The job bags for the app (ref UK/INV/1116/0038) and 'app descriptors' (ref UK-INV-183 recertification of job bag UK/INV/1116/0038a) had been recertified for use after 2 years as required. There was a short delay after the initial 2-year approval period had passed before the job bags were recertified due to the implementation of a new online approval system to replace the previous system which was withdrawn by the supplier. A deviation was raised in response and steps were taken to improve the system by the supplier. The prescribing information was also recertified shortly after the initial 2-year approval period had passed. This was historic and related to the online approval system that was in use at the time, and Consilient had completed an internal investigation and had taken corrective action.

Consilient submitted that the app and associated material had been certified/re-certified for use and were not in breach of Clause 14.5.

Consilient denied that it had advertised prescription only medicines to the public and explained that the Vitamin D Vitality app was available to download from both the App (Apple) Store and Google Play Store. The descriptor text, clearly visible without downloading the app, stated 'You have decided to prescribe InVita D3'. It was thus absolutely implicit that the app was intended for prescribers ie health professionals and not for members of the public. In downloading the app the user was, in effect, agreeing that he/she was a UK prescriber (health professional). The Code was silent on the issue of apps specifically for health professionals and therefore, in the absence of specific guidance, Consilient had applied the spirit of the Code in making it clear that the app was for health professionals, using the same principles that were applied to websites. It was acknowledged that any member of the public could of course access the content, but it was clear that the content was intended for health professionals.

Consilient also noted that a search for the term 'vitamin D' on the Google Play Store returned 248 app results and the same search on the App Store returned >200 results; this demonstrated that there was plenty of information available that was suitable for, and aimed at, members of the public which offered valid alternatives to the health professional app provided by Consilient.

Consilient stated that it had not actively attempted to increase the positioning of its app on the respective app stores ie there had been no search engine optimisation and Consilient understood that the positioning in the listing was based on the number of downloads and user

rating. The company also understood that in the approximately 3 years that its app had been available, there had only been around 500 downloads, so this was not a widely used or sought after offering.

Consilient submitted that health professionals were made aware of the app through promotion by the sales team using materials such as web cards, sales aids and slide sets (copies provided) where health professionals were directed to search for 'Vitamin D Vitality' in the respective app stores or were provided with a QR code to take them directly to the app for download. This activity was solely directed towards health professionals and in that regard, in the last 6 months the app had been downloaded 105 times of which 78 (74%) happened on one of 3 days on which online meetings to promote the app to health professionals had taken place.

Consilient submitted therefore, that using existing principles set out in the Code, it had not advertised prescription medicines to the public and this activity was not in breach of Clause 26.1.

Consilient submitted that, for those health professionals who chose to prescribe a Consilient brand of vitamin D, the Vitamin D Vitality app provided useful information, in an easily accessible format. All elements of the app and associated materials had been reviewed and certified as required by the Code and high standards had been maintained. Consilient denied a breach of Clause 9.1.

In summary, Consilient submitted that the app and all associated materials fully complied with the Code. Consilient did not consider that any of the concerns that the company had been asked to consider would constitute a breach of Clause 2 which the company recognised as being a sign of particular censure.

In response to a request for further information, Consilient submitted that the app developers chose the category 'Health and Fitness' within the Google Play Store and that this categorisation did not affect its accessibility. The company did not categorise the app in question in any way within the App (Apple) Store.

Consilient submitted that the app was not registered as a device and did not have a UKCA or CE mark. The company stated that the app did not attempt to diagnose or recommend treatment; it was designed to ensure that once a prescriber diagnosed the patient and decided to treat them with InVita D3, he/she was able to filter which of Consilient's range of vitamin D doses and forms would be suitable.

PANEL RULING

The Panel noted that whilst the complainant referred to the Vitamin D Vitality app being available on the Apple Store, he/she had come across it on the Google Play Store when searching for vitamin D and had provided screenshots in that regard. The Panel therefore made its ruling in relation to the app as it appeared on the Google Play Store.

The Panel noted Consilient's submission that the Vitamin D Vitality app was not registered as a medical device; it was developed by Consilient to help health professionals who had already decided to prescribe InVita D3 to identify the most appropriate product and dose from the company's vitamin D range. According to Consilient, by answering questions such as age of the patient, whether prophylaxis or treatment was required, frequency of dose etc, the app

would guide the user to the most appropriate medicine with information about the appropriate dose and frequency.

The Panel noted from the complainant's screenshots that the app was categorised under 'Health and Fitness' by the developers rather than 'Medical' which might imply that it was suitable for members of the public rather than for a more specialist medical audience. It was a well-established principle that pharmaceutical companies were responsible for the acts and omissions of third parties acting on their behalf and, in the Panel's view, Consilient was responsible for the categorisation of the app. The Panel noted, however, Consilient's submission that the categorisation of the app in the Google Play Store would not have impacted its accessibility. The Panel further noted that whilst beneath the heading 'About this app' within the Google Play Store it stated 'To help HCPs who have decided to prescribe InVita D3 select the appropriate dose', it appeared that content from the app was visible before the app was downloaded, including reference to InVita D3 and its use in vitamin D deficiency and part of the prescribing information.

The Panel noted that whilst the Code did not specifically refer to apps, it did refer to the requirements for promotional material which was provided on the Internet and the Panel considered that those principles were relevant in relation to promotional material on the Google Play Store and which could be downloaded from the Google Play Store such as an app.

In the Panel's view, despite inclusion of the statement (which could be seen before downloading the app from the Google Play Store) that the app in question was 'To help HCPs who have decided to prescribe InVita D3 select the appropriate dose', the information that was available to members of the public before downloading the app meant that a prescription only medicine had been advertised to the public and a breach of Clause 26.1 was ruled.

In relation to the allegation that the content was last reviewed three years ago, the Panel noted Consilient's submission that the prescribing information provided in the app was current and that the update to the SPC in November 2019 had had no impact on the prescribing information. On the evidence before it the Panel therefore ruled no breach of Clause 4.1.

The Panel noted that Clause 14.5 stated that material which was still in use must be recertified at intervals of no more than two years to ensure that it continued to conform with the relevant regulations relating to advertising and the Code. The Panel noted Consilient's submission that the app in question and associated material had been certified and re-certified for use. The Panel noted Consilient's submission that there was a short delay after the initial 2-year approval period had passed before the job bags were recertified which arose following the implementation of a new online approval system. The Panel noted that Consilient did not provide certificates of initial certification or recertification of the app's associated material. However, the complaint appeared to be limited to the content of the app itself. The Panel noted that the job bag for the app in question (ref UK/INV/1116/0038) was first certified on 12 September 2017 and was re-certified on 17 September 2019. The Panel noted therefore that the delay in re-certifying the app meant that the requirements of Clause 14.5 had not been met and a breach of that clause was ruled.

The Panel noted its comments and rulings above and considered that Consilient had failed to maintain high standards in relation to the app in question on the Google Play Store. A breach of Clause 9.1 was ruled.

The Panel noted that it appeared that upon searching for Vitamin D within the Google Play Store, the complainant was presented with Consilient's Vitamin D Vitality app as a recommendation; the app was intended only for health professionals who had decided to prescribe InVita D3, but it appeared to be in the 'Health and Fitness' category rather than the 'Medical' category. The Panel did not consider that the inclusion of the statement that the app was 'To help HCPs who have decided to prescribe InVita D3 select the appropriate dose' negated the fact that information which promoted InVita D3 was available to the public without having to download the app. In the Panel's view this demonstrated a lack of care and awareness of the Code on matters that reflected UK law and Consilient had thus brought discredit upon, and reduced confidence in, the industry; a breach of Clause 2 was ruled.

Complaint received **21 October 2020**

Case completed **12 April 2021**