CASE AUTH/3601/1/22

COMPLAINANT v BOEHRINGER INGELHEIM

Advertisement for Trajenta

CASE SUMMARY

This case was in relation to the use of the word 'unique' in the claim 'Unique convenience through always one dose, once daily' within a dynamic digital banner advertisement for Trajenta (linagliptin) issued by Boehringer Ingelheim Limited.

The Panel ruled no breach of the following Clause(s) of the 2021 Code, as it did not consider that the complainant had established that the claim 'Unique convenience through always one dose, once daily' in relation to Trajenta, within the context of type 2 diabetes mellitus, implied a special merit that could not be substantiated:

No Breach of Clause 14.4	**Requirement that claims should not imply that a medicine or an active ingredient has some special merit, quality or property unless this can be substantiated.**

This summary is not intended to be read in isolation.

For full details, please see the full case report below.

FULL CASE REPORT

A complainant who described themselves as a concerned health professional complained about a dynamic digital banner advertisement for Trajenta (linagliptin) issued by Boehringer Ingelheim Limited.

Trajenta was indicated for adults with type 2 diabetes mellitus (T2DM) as an adjunct to diet and exercise to improve glycaemic control in certain instances.

COMPLAINT

The complainant was surprised to see that the advertisement used the word 'unique' within the claim 'Unique convenience through always one dose, once daily'.

The complainant stated that the special attribute that this appeared to be referring to was that it was always one dose, once daily. The complainant noted that in no way was this 'unique convenience' qualified to any particular disease or type of therapy.

The complainant queried whether Trajenta was truly the only medicine that was one dose and once daily and stated of course not. Many tablets had one dose, once daily such as Cerazette, where one tablet was taken daily and there was only one dose. The complainant was sure

there were others in the entirety of medicine, but only one example was required to disprove an absolute.

When writing to Boehringer Ingelheim, the Authority asked it to consider the requirements of Clause 14.4 of the Code.

RESPONSE

Boehringer Ingelheim Limited stated that it took compliance with the Code very seriously and it had steps in place to ensure robust procedures continued to underpin its activities and the company embraced a compliance culture that was fully embedded into the business with the support of the Ethics & Compliance department.

As per the requirements of the Code, Boehringer Ingelheim UK had a standing operating procedure (SOP) in place for materials approval, which ensured that all materials were reviewed and certified for accuracy and compliance with Code requirements prior to being made available. Boehringer Ingelheim also ensured that all relevant staff completed SOP training, and that training also included emphasis on the requirements for digital materials. In addition, other relevant training, such as quarterly Code case training, was expected for all staff involved in materials development and approval.

Boehringer Ingelheim explained how the phrase 'unique convenience' met the requirements of Clause 14.4 of the Code. The complainant raised an objection that there might be other medications, such as Cerazette that qualified for this claim and, therefore, the existence of one more medication taken once daily would disprove the absolute.

Boehringer Ingelheim drew attention to the similarity between this complaint and Case AUTH/3381/9/20 in relation to the allegation about using the phrase 'Unique convenience through always one dose, once daily for Trajenta in adults with type 2 diabetes' and referred to the Panel's ruling of no breach with respect to this same claim.

Background

Boehringer Ingelheim noted that the complaint referred to a dynamic digital banner (animated banner) advertisement for Trajenta (job bag number PC-GB-103556 V1), that appeared on several online platforms between 15 April and 30 September 2021. These were British Medical Journal (BMJ), Guidelines in Practice (GIP), Practice Nurse, Independent Nurse and Pulse. These advertisements had not therefore been available for UK health professionals to view on any of these platforms since 30 September 2021. Boehringer Ingelheim acknowledged this complaint was raised in January 2022 several months after any of these advertisements last appeared.

Boehringer Ingelheim submitted that the item was certified in March 2021 as per the requirements of Clause 8 of the 2021 Code by a medical signatory.

Boehringer Ingelheim submitted that as Trajenta had been licensed for more than 10 years, its brand name, active ingredients, and dosing regimen were generally well known amongst health professionals, in particular General Practitioners (GPs). UK usage and awareness data confirmed that over 70% of GPs regularly prescribed Trajenta and over 80% used the DPP4 inhibitor class of medicines monthly (IQVIA market data, December 2021). The purpose of the

dynamic digital banner advertisement was to remind health professionals of the characteristics of Trajenta including convenience of its dosing regimen.

In this job bag, different sizes of banner advertisements had been certified. The screenshot in the complainant's email referred to the double mid page unit (MPU) version.

Boehringer Ingelheim noted that the complainant had taken a screenshot of a single screen (frame 4) out of six screens from this dynamic Trajenta digital advertisement. The double MPU advertisement appeared on appropriate webpages on the specific websites detailed in the job bag including Pulse Today, BMJ, Practice Nurse, Independent Nurse and Guidelines. An example of how this would look on screen was provided.

Boehringer Ingelheim stated that in order to access the content, UK-based doctors, nurses and pharmacists would have had to register with the relevant digital platform. Therefore, only registered users who were confirmed by the platform owners as UK health professionals could have viewed the websites and the advertisement for Trajenta. The intended audience of these websites and digital publications was made clear on each of their webpages which stated 'This site is intended for UK healthcare professionals'. The intended audience was also made clear on the dynamic digital double MPU banner advertisement itself as it stated it was for 'Healthcare professionals only'.

Boehringer Ingelheim stated that this specific dynamic digital banner advertisement comprised 6 rotating frames which appeared in sequential order. The advertisement always started with the first frame and rotated continuously. Each frame was visible for 2.5 to 3 seconds, making the whole advertisement 15 seconds in duration, which allowed readers enough reading time for all screens. Should there be any issue with the rotation of the frames on any of the online platforms, or on any device on which they were viewed, frame 6 was stipulated as the 'static' frame which contained all the obligatory information and this would appear and remain on screen. Thus screen 6 was the only frame that could ever appear in isolation of the other 5 frames. The prescribing information and adverse event reporting link could be found at the bottom of the advertisement through a single direct link and remained static throughout the whole duration of the advertisement ie, always appeared on each of the frames of the digital banner advertisement.

The item was certified as a dynamic digital banner advertisement only, with the resolution of the digital advertisement (300 x 600 pixels) included in the job bag. The final form of the digital banner advertisement and the associated prescribing information was checked and was found to be legible and meeting the requirements of Clause 12.4 of the Code. In the description of the job bag in the meta-data, a test link was provided for each of the sizes/formats of the banner advertisements which showed the advertisement as it would appear in final form.

Response to the complaint received and consideration of the requirements of Clause 14.4 of the 2021 Code

Boehringer Ingelheim stated that the word 'unique' was used in the claim 'Unique convenience, through always one dose, once daily' in the context of Type 2 diabetes mellitus (T2DM) treatments. Trajenta 5mg dosing was referred to as 'unique' as only one dose, once daily was always needed in adult patients with T2DM, regardless of the level of renal or liver impairment or in the elderly population. Additionally, Trajenta also did not need a separate initiation dose, nor did it need dose adjusting according to patient needs. No other T2DM treatments currently

available in the UK (oral or injectables) had these combined dosing qualities. The claim was substantiated by the information in the Trajenta summary of product characteristics (SPC). Careful consideration of the word 'unique' had been used, and an extensive review of all marketed products in the UK for T2DM had been completed to ensure Boehringer Ingelheim met the requirements of Clause 14.4.

Boehringer Ingelheim stated that it would continue to review the range of available treatments for T2DM to ensure Boehringer Ingelheim continued to meet requirements of Clause 14.4 and would update its materials accordingly.

In the dynamic digital advertisement 'for your adult patients with type 2 diabetes' appeared on screen 3 of 6, immediately prior to the screen the complainant had taken a screenshot of (screen 4 of 6) – therefore Boehringer Ingelheim believed the 'unique' claim regarding one dose, once daily would be clearly understood to be in the context of adult type 2 diabetes patients. The banner ensured mention of Type 2 Diabetes Mellitus in other frames too which put the advertisement into context.

The complainant alleged that the claim was not true, as other medications also had one dose, one daily, explicitly referring to the medicine 'Cerazette'. It was clear from the digital banner advertisement that the claim had been made in the context of T2DM treatments and not comparing to all or any medicines available in the UK market, which made the comparison with Cerazette not applicable. Therefore, Boehringer Ingelheim believed it had met the requirements of Clause 14.4.

Boehringer Ingelheim submitted that, based on above facts and the previous Panel decision, (Case AUTH/3381/9/20):

> 'Based on the evidence before it, the Panel did not consider that the complainant had shown that the claim "Unique convenience through always one dose, once daily" in relation to Trajenta for type 2 diabetes was misleading or incapable of substantiation and no breach of Clauses 7.2 and 7.4 were ruled'

it had met the requirements of Clause 14.4 in this instance.

PANEL RULING

The Panel noted Boehringer Ingelheim's submission that the complainant had taken a screenshot of a single screen (frame 4) of the dynamic Trajenta digital advertisement (PC-GB-103556 V1, date of preparation March 2021). The Panel noted Boehringer Ingelheim's submission that the advertisement always started with the first frame and rotated continuously through the six frames, each of which was visible for 2.5 to 3 seconds allowing readers enough reading time for each. The Panel noted that frame 3, which appeared immediately prior to the frame the complainant had provided a screenshot of, stated 'Thank you for continuing to Choose.Simplicity. for your adults with type 2 diabetes (T2D)' as submitted by Boehringer Ingelheim. The Panel noted Boehringer Ingelheim's submission that the banner ensured mention of Type 2 Diabetes Mellitus in other frames too and therefore the 'unique' claim regarding one dose, once daily would be clearly understood to be in the context of adult type 2 diabetes patients. In this regard, the Panel noted that the final frame (frame 6) stated 'proven efficacy vs placebo for your adult T2D patients'.

Clause 14.4 stated that promotion must encourage the rational use of a medicine by presenting it objectively and without exaggerating its properties. Exaggerated or all-embracing claims must not be made and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a medicine. Claims should not imply that a medicine or an active ingredient has some special merit, quality or property unless this can be substantiated. The supplementary information stated that care needed to be taken with the use of 'unique'.

With regard to the claim 'Unique convenience through always one dose, once daily', the Panel noted that the complainant stated that Trajenta was not the only medicine that was one dose, once daily and referred to Cerazette [desogestrel] as an example. The Panel noted that Cerazette was an oral contraceptive pill. In this regard, the Panel noted Boehringer Ingelheim's submission that the claim had been made in the context of T2DM treatments and not in relation to all or any medicines available in the UK market, which made the comparison with Cerazette not applicable.

The Panel further noted Boehringer Ingelheim's submission that 'unique' had been used in the context of treatments for type 2 diabetes mellitus and that Trajenta 5mg dosing was referred to as 'unique' as only one dose, once daily was always needed in adults with type 2 diabetes mellitus, regardless of the level of renal or liver impairment or in the elderly population. The Panel noted Boehringer Ingelheim's submission that Trajenta did not need a separate initiation dose, nor did it need dose adjustments according to patient needs and the claim was substantiated by the information in the Trajenta SPC. The Panel further noted Boehringer Ingelheim's submission that no other currently available treatments for type 2 type diabetes mellitus (oral or injectables) had those combined dosing qualities.

Based on the evidence before it, the Panel did not consider that the complainant had established that the claim 'Unique convenience through always one dose, once daily' in relation to Trajenta within the context of type 2 diabetes mellitus implied a special merit that could not be substantiated, and **no breach of Clause 14.4** was ruled.

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During its consideration of this case, the Panel was concerned to note Boehringer Ingelheim's submission that the adverse event reporting link could be found at the bottom of the advertisement through a single direct link. The Panel referred to its recent advice published in this regard which states that according to the requirements of the Code, the adverse event reporting statement should appear as an integral part of the banner advertisement as required by Clause 12.9; there is no exemption for it to be provided via an external link in the banner to a separate webpage or document and requested that Boehringer Ingelheim reviewed its materials in this regard.

Complaint received **20 January 2022**

Case completed **20 February 2023**