CASE AUTH/3906/5/24

COMPLAINANT v BOEHRINGER INGELHEIM

Allegations regarding a Jardiance Slide Deck

CASE SUMMARY

This case was in relation to a Jardiance case study presentation on a Boehringer promotional website which the complainant alleged had not been re-certified in the requisite 2-year period, did not include prescribing information or a direct, single click link to it, and contained reviewer comments. The complainant also alleged that a slide comparing the impact of different diabetes medications on weight lacked adequate context to interpret the information in a meaningful way.

The outcome under the 2021 Code was:

Breach of Clause 5.1(x2)	**Failing to maintain high standards**
Breach of Clause 8.5	**Using material for more than two years without re-certification**
Breach of Clause 12.1	**Failing to include up-to-date prescribing information**
Breach of Clause 12.4	**Failing to include prescribing information within the digital material or via a direct, single click link**

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry.**
No Breach of Clause 6.1	**Requirement that information must be accurate, up-to-date and not misleading**
No Breach of Clause 6.2	**Requirement that information must be capable of substantiation**
No Breach of Clause 8.1	**Requirement to certify promotional material**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint was received from an anonymous, contactable complainant about Boehringer Ingelheim Limited.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

"Dear PMCPA,

The attached slide deck is available from the follow [URL provided]

On slide 1, the slides appear to have been prepared in January 2021, which is well over the 2 years required and this does not appear to have been updated.

The link to the Prescribing Information [URL provided] in fact appears to link through to [link to company website provided], so the PI is neither included in the item nor is one click away. This would add further weight that there have been changes since 2021 which have not been checked.

Slide 17 has several slides in a table in extremely small letters in the footnote it states that the trials should not be compared - which appears to be the entire point of the table. No attempt has been made to state the primary endpoint, the study design or any other facet of the studies that would enable the data to be viewed in a meaningful context. So, why mention any facet of the studies if they have no meaning in the context provided?

Several slides also have comments such as "note to reviewers". This raises questions whether these slides have truly been finalised or are a draft, and not for public consumption."

When writing to Boehringer Ingelheim, the PMCPA asked it to consider the requirements of Clauses 6.1, 6.2, 8.1, 8.5, 12.1, 12.4, 5.1 and 2 of the Code.

BOEHRINGER INGELHEIM'S RESPONSE

The response from Boehringer Ingelheim is reproduced below:

"Boehringer Ingelheim Limited ("Boehringer") takes compliance with the ABPI Code of Practice (the "Code") very seriously. We have steps in place to ensure robust procedures continue to underpin all our activities and we embrace a compliance culture that is fully embedded into the business with the support of senior leadership and the Compliance and Integrity Department.

As per the requirements of the Code, Boehringer has Standing Operating Procedures ("SOP") in place for Materials Approval and Materials Withdrawal, which ensures that all materials are reviewed and certified for accuracy and compliance with Code requirements prior to being made available, and are withdrawn to maintain Code compliance. We also ensure that all relevant staff complete SOP training, and that training emphasises the requirements for digital materials; in addition, attendance at other relevant training such as quarterly Code case review is expected for all staff involved in materials development, approval and withdrawal.

We thank the PMCPA for the agreed extension to our response. The internal investigation required more time because the asset in question is several years old, employees who were involved with the asset are no longer with Boehringer, global systems to house digital assets have changed since then, and additional time was needed to find when and where the URL was housed at that time.

The asset in question: Case Study presentation, “Weight and Type 2 diabetes” available via the link supplied by the complainant was reviewed and approved as a promotional item in Veeva Vault on the 27th Jan 2021, and was retired on the 1st July 2021. The signatories were [first named signatory] and [second named signatory] both of which were signatories previously notified to the PMCPA and MHRA. We have provided the certificate and quality colour copy of the asset [at issue] plus the Jardiance SmPC (both for UK and IE) as requested in your letter of 17 May 2024.

This asset was uploaded and publicly visible during June and July 2021 on the “Resources/CardioRenalMetabolic/Learn” page of a Boehringer promotional website. The link when clicked, opened up the Case Study presentation “Weight and Type 2 diabetes”, which was housed in Boehringer’s Content Management System (CMS).

The complainant raised concerns around reviewer comments being visible in the asset. We acknowledge this is a technical error, as the comments should not have been visible and are not present in the final certified form.

At the end of July 2021 the webpage was taken down. The asset in question was updated as a result of an SmPC change in September 2021, the webpage was re-instated in December 2021 and that updated piece was retired in July 2022 , at which point the webpage was permanently decommissioned.

However, at that time the CMS system required manual withdrawal of assets once certification had expired. Due to human error, the asset that had retired in July 2021 was not manually withdrawn, and the revised asset approved in September 2021 was never uploaded into the CMS. For completeness we attach the certificate and quality copy of the approved updated asset.

Although the webpage was decommissioned on the 28th July 2022, the URL link to the asset in CMS was not deactivated and hence the URL remained accessible until we received the complaint, when we started our investigation and formally deactivated it on the 21st May 2024.

It is important to note however, that even though the page was decommissioned, the URL remained accessible until recently, but the asset could not have been accessed unless the complainant had stored the specific URL link as a bookmark, or potentially had knowledge of the specific Veeva code of the asset and was able to locate using a search engine.

We acknowledge unfortunately that the requirements for clauses 8.1 and 8.5 were breached for this asset.

The letter highlights concerns around the Prescribing Information hyperlink not working as accessed through the asset in question. We can confirm that the UK PI hyperlink did work correctly until July 2022, when the webpage was decommissioned. Since then, we have also changed the housing requirements for our UK Prescribing Information, explaining why the UK hyperlink did not work when the complainant clicked through. As explained above, the URL and asset was accessible, but not publicly visible since 2022. So we unfortunately also acknowledge that this material because of the circumstances is also in breach of clauses 12.1 and 12.4.

The letter raises concerns around the table in slides 17. The table in slide 17 (and slide 18) does not represent a comparison of individual clinical trials, as the complainant implies. The purpose of this table was to provide a summary of the expected impact of different diabetes medications on clinical outcomes, as per the Position Statement of the American Diabetes Association (ADA) and European Association of the study of Diabetes (EASD), followed immediately by slides 19 and 20 which provide the overview of when such medicines should be used. It would have been irrelevant and confusing to the reader if information on every study design and primary endpoint had been included. We submit that slide 17 (and 18) provide the opportunity to view the data in a meaningful context because the context is the ADA/EASD consensus – a highly regarded and well known guidance document for HCPs. We refute the allegations of clauses 6.1 and 6.2.

Since 2022, we have changed the way we manage digital materials hosted on our websites. For the majority of assets, we now rely on systems which have automated withdrawals in place once certification expires which means that we have more robust processes in place to mitigate risks such as this recurring. As a result of this complaint, we have now initiated a full and wide investigation into any continued use of the Content Management System by Boehringer Ingelheim UKIE in order to ensure that our assets remain compliant with relevant codes of practice. We intend also to review options for other ways of managing digital assets, and will be working with our global colleagues to ensure our processes are as robust as possible around digital asset management. On the basis of the steps we have taken since receiving this complaint, we believe we have maintained high standard and have not brought the industry into disrepute, and as such refute the allegations of breach of clauses 5.1 and 5.2 [sic]."

PANEL RULING

This case related to a presentation for Jardiance (empagliflozin) available on a Boehringer Ingelheim promotional website. The presentation, a case study titled "Weight and type 2 diabetes", was aimed at primary care health professionals.

The Panel understood the purpose of the presentation was to use a case study of a typical diabetic patient, firstly, to consider the relationship between obesity and type 2 diabetes and the importance of lifestyle modifications and, secondly, to consider the impact of diabetes medications on weight.

The complaint alleged failings in respect of certification of the final form of the material and its re-certification within 2 years, accessibility of the prescribing information and a slide headed "What is the impact of diabetes medications on weight?" which, the complainant alleged, did not provide adequate context to interpret the information in a meaningful way.

The Panel noted the presentation provided by the complainant had been certified in January 2021, and according to Boehringer Ingelheim uploaded to the 'Resources/CardioRenal Metabolic/Learn' page of the website in June 2021. This webpage was taken down at the end of July 2021. Subsequently a new version of the presentation was created following an update to the SPC in September 2021 however, this updated presentation was never uploaded into Boehringer Ingelheim's content management system. In December 2021 the webpage was reinstated. The updated presentation was retired in July 2022 when the webpage was

permanently decommissioned. The Panel made its rulings on the presentation provided by the complainant.

The Panel made the following findings on the balance of probabilities having considered the submissions and evidence of the parties. These findings are limited to those that are relevant to the matters complained about, and necessary to explain the conclusions the Panel reached.

Slide content

The Panel interpreted the complaint to be that the slide at issue compared clinical trial findings without providing details of the study design or primary endpoints such that there was inadequate context to interpret the information in a meaningful way.

The Panel considered the impression created by the presentation as a whole. It noted the information was presented in the form of a case study; the first half focussed on the relationship between obesity and type 2 diabetes and the importance of lifestyle modification while the second half concerned the impact of different diabetes medications on weight, published guidance and Jardiance.

The slide at issue appeared midway in the presentation and marked the transition from the first to the second half. Under the heading was a table listing six medicines/classes together with their impact on weight, HbA1c reductions, and hypoglycaemia risk. Footnotes explaining annotations in the table appeared towards the bottom of the slide and stated, in bold font, “SGLT2 inhibitors are not indicated for weight loss” and “Hypoglycaemia risk increased if used in conjunction with insulin or sulfonylureas”. Underneath in non-bold text was the statement, “Direct comparison of trials is not valid due to differences in study design, populations and methodology”, and a list of references for the data provided. A banner containing “What do current guidelines recommend if there is a need to minimise weight gain or promote weight loss in a person with type 2 diabetes?” appeared as a build on the slide.

The Panel noted the subsequent slides discussed the Position Statement of the American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD) with regard to the choice of glucose-lowering medication after metformin if there is a need to minimise weight gain or promote weight loss. This was then considered in the context of the patient case study.

Having considered the purpose and flow of the presentation the Panel concluded the slide at issue was a summary of the expected impact of different diabetes medications on clinical outcomes, as submitted by Boehringer Ingelheim. In the Panel’s view, the slide did not compare clinical trials.

Clause 14.1 of the Code permits comparisons in promotional material provided they are accurate, balanced and fair and that the features compared are material, relevant, substantiable and representative. In the Panel’s view the clinical outcomes compared were material and relevant in the treatment of type 2 diabetic patients and thus the slide was consistent with Code requirements in this regard.

The Panel noted Boehringer Ingelheim had been asked to consider Clauses 6.1 and 6.2 which, among other things, require material to be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine and comparisons to be substantiable.

Noting the narrow nature of the allegation and its comments above the Panel considered the complainant had not, on the balance of probabilities, established that the omission of information regarding study design and primary endpoints meant that the slide at issue was not sufficiently complete such that it was misleading, or that the information could not be substantiated. The Panel ruled **no breach of Clause 6.1** and **no breach of Clause 6.2**.

Certification

The allegation comprised two issues; firstly that the material did not appear to have been re-certified within the requisite two-year period and secondly that the visibility of reviewer comments suggested that the material had not been "truly finalised" or was a "draft".

The Panel noted that Clause 8.1 required that promotional material must not be issued unless its final form had been certified and that Clause 8.5 required, among other things, material which is still in use to be recertified at intervals of no more than two years to ensure that it continues to conform with the relevant regulations relating to advertising and the Code. The Panel considered that a robust certification procedure underpinned self-regulation.

The Panel noted the chronology submitted by Boehringer Ingelheim; it accepted that the material was certified in January 2021, was first available on the webpage in June 2021 and that Boehringer Ingelheim intended the material to be retired in July that year. The Panel understood that due to a combination of human error and technical reasons the presentation remained available. Although the webpage had been taken down permanently in July 2022, the URL for the material was not deactivated and therefore it remained possible to access the presentation if the specific URL had been bookmarked, or through a search engine using the Veeva job code. The URL was eventually deactivated following receipt of the complaint in May 2024.

While recognising that Boehringer Ingelheim did not intend the material to be 'in-use' after July 2021, the Panel concluded the promotional presentation was available until May 2024 which was over a year beyond when it should have been recertified. The Panel ruled a **breach of Clause 8.5,** as acknowledged by Boehringer Ingelheim.

With regard to the allegation whether the slides at issue "have been truly finalised or are a draft", the Panel noted that the PowerPoint presentation downloaded by the case preparation manager from the link provided by the complainant contained reviewer comments which Boehringer Ingelheim submitted was due to a technical error, although it maintained the comments were not present in the final certified form. In the Panel's view, it was usual for reviewer comments to be resolved and removed prior to approval so that the certified material was a 'clean version'. The Panel noted that the slides at issue were certified, and the final form did not appear to include any reviewer comments. On balance, and on the narrow basis that the material at issue was certified, the Panel ruled **no breach of Clause 8.1**.

The Panel was, however, concerned that the slides at issue which had been uploaded to the Content Management System and made available to viewers included reviewers' comments, and acknowledged Boehringer Ingelheim's submission that this was a technical error, and the comments should not have been visible. In the Panel's view, Boehringer Ingelheim had failed to maintain high standards in this regard, and the Panel ruled a **breach of Clause 5.1** accordingly.

Prescribing information

Clause 12.1 required, amongst other things, that prescribing information must be provided in all promotional material; Clause 12.4 stated in digital material, the prescribing information "may be provided either:

- by inclusion in the digital material itself, or
- by way of a clear, and prominent, direct, single click link."

The Panel noted a clear and prominent link was included on the first slide of the promotional presentation, however when the complainant accessed the material, the prescribing information was neither integral in the presentation nor accessible via a direct, single click link as required by the Code. The Panel noted Boehringer Ingelheim's submission that the UK PI hyperlink did work correctly until July 2022, when the webpage was decommissioned, however, the company had since changed the housing requirements for UK prescribing information, explaining why the UK PI hyperlink did not work when the complainant clicked through. The Panel therefore ruled **breaches of Clauses 12.1 and 12.4**. as acknowledged by Boehringer Ingelheim.

High Standards

The Panel noted Boehringer Ingelheim's submission that it had standard operating procedures (SOP) in place for the approval and withdrawal of materials and that relevant staff were trained on these and received other training including quarterly Code case reviews. In addition, the company had incorporated an automated process for withdrawal of its digital materials from its website once certification expired.

The Panel accepted Boehringer Ingelheim's submission that in this instance, due to a human error, although the asset had been retired it had not been manually withdrawn from its content management system. In addition, when the webpage was decommissioned the URL for the material was not deactivated and thus remained available as evidenced by the complaint. While acknowledging the material was not readily accessible at the time of the complaint the Panel considered, on balance, the ongoing availability of the slide deck for nearly three years after its retirement indicated a failure to maintain high standards. The Panel ruled a **breach of clause 5.1** in this regard.

Clause 2

The Panel considered that the rulings of breaches adequately covered this matter and an additional ruling of a breach of Clause 2 would be disproportionate in the particular circumstances of this case. A ruling of a breach of Clause 2 was used as a sign of particular censure and reserved for such use. The Panel ruled **no breach of Clause 2**.

Complaint received **16 May 2024**

Case completed **6 June 2025**