CASE AUTH/3901/5/24 ***NO BREACH OF THE CODE***

COMPLAINANT v GSK

Allegations about Jemperli website

CASE SUMMARY

This case was in relation to webpages of a GSK promotional website aimed at UK health professionals. The complainant alleged that four webpages had not been certified for use on a mobile phone, due to the differences between the mobile and desktop versions, and that the two versions should have been certified separately. The complainant also alleged that a claim on the home page, which included the wording "manageable safety profile", was misleading and unqualified.

The outcome under the 2021 Code was:

No Breach of Clause 2 (x2)	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1 (x2)	**Requirement to maintain high standards at all times**
No Breach of Clause 6.1	**Requirement that information/ claims/ comparisons must not be misleading**
No Breach of Clause 6.2	**Requirement that information/ claims/ comparisons 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 about GSK UK Limited was received from a contactable complainant who described themselves as a health professional.

COMPLAINT

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

> "Subject - Jemperli promotional website for GB HCPs in breach of compliance standards. The Jemperli promotional website (FOR GB HCPs) had not been certified for use on a mobile phone. Below are issues around certification changes that had been made on the mobile phone version in contrast to the desktop version and also a misleading safety claim. 1) [Link 1 provided] On this home page desktop version at the start of the page, there is an image of a lady in a bulb with the text new licence for Great Britain written in a white colour font adjacent to the image of the lady along with

the indication text also in white colour font. However, on the mobile phone version, the new licence for Great Britain text and the indication text is below the image and written in blank colour font. This is a clear and obvious difference in final form on the mobile phone version in comparison to the desktop version. Clauses 8.1, 5.1 and 2 have been breached. 2) [Link 1 provided] On the home page, just above the explore the resource library section, there is a claim on safety which is written as - Jemperli + CP offers a manageable safety profile consistent with known profiles of individual components after 2 years of follow up. This claim is inaccurate as Jemperli + CP could cause a number of serious side effects, which require withdrawal of the drug as opposed to management of the serious adverse effects. Infusion related reactions severity 3 or 4, nephritis 3 or 4, myocarditis 3 or 4 require permanent discontinuation, as described in table 3 of the SPC. Such a misleading standalone unqualified claim that the combination offers a manageable safety profile is very concerning considering the drug is a black triangle product. This claim is in breach of clauses 6.1, 6.2, 5.2 and clause 2 for patient safety reasons. 3) [Link 2 provided] On this ruby trial page, at the start of the page there is an image of 2 ladies with directly adjacent text in white colour font stating The RUBY trial: part 1. Discover efficacy and safety outcomes. On the mobile phone version of the same page, the same text drops to below the image and is in black colour font. Clauses 8.1, 5.1 and 2 have been breached. 4) [Link 3 provided] At the start of this page, there is an image of 2 ladies with adjacent white text written as dosing and treatment management. On the mobile phone version, the text appears in black coloured font directly below the image. Clauses 8.1, 5.1 and 2 have been breached. 5) [Link 4 provided] On the desktop version of this page, at the beginning of the page there is an image of a lady in a light bulb with adjacent white coloured text stating Resource library. On the mobile phone version of this page, the exact resource library text is below the image and in black colour font. Clauses 8.1, 5.1 and 2 have been breached. 6) Extra Product tab wording on mobile. On all of the pages mentioned in points 1-5 above, there is a red tab at the top of the desktop pages with 5 titled tabs - home, ruby trial, dosing and treatment management, resource library, get in touch. However on the mobile phone version these 5 tabs condense into a drop down menu but there is an extra title for the drop down menu which is titled 'product menu'. This 'product menu' text is not present on the desktop version and is therefore a final form change on all of the pages of this product website when comparing desktop to mobile. Clauses 8.1, 5.1 and 2 have been breached. The differences between mobile and desktop versions of this website should have undergone separate certification as certification is critical to self-regulation."

When writing to GSK, the PMCPA asked it to consider the requirements of Clauses 8.1, 6.2, 6.1, 5.1 and 2 of the 2021 Code.

GSK'S RESPONSE

The response from GSK is reproduced below:

"GSK was extremely disappointed to have received a letter dated 17th May 2024 from the PMCPA informing us of a complaint from an individual describing themselves as an anonymous healthcare professional regarding the above. The PMCPA has asked us to consider clauses 6.1, 6.2, 8.1, 5.1 and 2 of the 2021 ABPI Code of Practice (the code).

The complainant alleges that the promotional webpages PM-GB-DST-WCNT-230013, PM-GB-DST-WCNT-230018, PM-GB-DST-WCNT-230020 and PM-GB-DST-WCNT-230025 have breached clauses 8.1, 5.1 and 2 of the code, as the mobile version of the web page has not been certified separately. The complainant also alleges that the safety profile claim on PM-GB-DST-WCNT-230013 is inaccurate and has breached clauses 6.1, 6.2, 5.1 and 2.

GSK takes its responsibility of abiding by the letter and the spirit of the code and all other relevant UK rules and regulations very seriously. Following the complaint, we have temporarily taken down all relevant webpages to review the materials in question, as well as review our internal ways of working. Following our review, GSK is comfortable that both our processes and the materials in question are of suitable quality and of a high standard and are therefore in line with the code as they are. Consequently, we deny breaches of clauses 6.1, 6.2, 8.1, 5.1 and 2 of the code.

GSK has laid out the specific responses to the individual clauses the PMCPA has asked us to consider in detail below.

Website background

The Jemperli (dostarlimab) webpages referred to in the complaint are part of a more extensive promotional website called GSKPro, which is aimed at UK Healthcare Professionals (HCPs). The website contains promotional information about all GSK products currently marketed in the UK. Within the website there is a section dedicated entirely to the product Jemperli. The complainant's allegations relate to only some of the pages from this section but not all.

The Jemperli website can be accessed by two methods:

- Direct access by HCPs via a search engine, such as Google, including confirmation that they are a HCP via a pop up, as opposed to a member of public for whom there is a link to a separate part of the website with relevant content.
- Via promotional banners on doctors.net.uk linking directly to the website, which are targeted at relevant HCPs with a specific interest in gynae-oncology.

GSK copy approval review and certification processes

GSK has robust and established processes and structures in place for the setup, review, and certification of all relevant materials, including promotional webpages and websites, which adhere to the code, GSK's internal code and relevant UK regulations. Our processes are regularly updated in line with new learnings from a variety of sources including internal management monitoring as well as PMCPA case precedent. Every individual involved in any aspect of copy approval has to undergo mandatory training on the GSK copy approval Global SOP as well as the associated UK Work Instruction.

Throughout the copy approval process for webpages, both desktop and mobile platform views are meticulously checked, reviewed, and approved as part of the same job, ensuring that all content, functionality, dynamic content, and links work correctly on

both views. We take this approach because when it comes to digital content such as webpages, there are multiple platforms on which content can be viewed. We therefore review and approve the two commonest platform views: desktop and mobile views. It is unrealistic and exceptionally inefficient to separately certify every possible iteration of the same content to cover all the possible platforms/devices available, with their subtle individual variations of formatting etc. To our knowledge, this is a similar approach to that taken by most UK pharmaceutical companies as the issue affects us all in the same way.

To ensure that the review and approval process for webpages on our copy approval system is as robust as possible, GSK requires both the desktop and mobile renditions to be visible throughout as part of the job. Furthermore, it is a mandatory requirement of the GSK process for the staging links for the final form webpages to be examined on both a desktop and a mobile phone. This is to ensure that the content and layout is consistent across both platforms, that there are no substantive content changes between the two and that the mobile version treats all options equally despite the different format. The process allows for formatting and functionality variations between the two views, ensuring that both platforms meet the code's requirements for legibility, optimal visibility, mandatory information, and user-friendliness for the HCP target audience. Before any webpages are released to an external HCP audience, GSK ensures that they are comprehensively reviewed, approved, and certified for use on both platforms. We contend that the code requirements for certification across both views are therefore met by this approach and they do not require separate certification.

Clause 6.1

The complainant alleges that in the webpage PM-GB-DST-WCNT-230013, the claim *'Jemperli + CP [carboplatin-paclitaxel] offers a manageable safety profile consistent with known profiles of individual components after 2 years of follow up' is inaccurate as (in their words) 'Jemperli + CP could cause a number of serious side effects, which require withdrawal of the drug as opposed to management of the serious adverse effects*'. They have therefore quoted a breach of clause 6.1.

GSK contends that the SmPC for Jemperli is the best and most reliable source of the most up to date and robust safety information on the product. In section 4.2 of the Jemperli SmPC, under the heading 'Dose Modifications', the SmPC clearly states that: *'Recommended modifications to **manage** adverse reactions are provided in Table 3.'* Indeed, the complainant themselves makes a reference to table 3 but does not mention the text immediately preceding it. The table in question provides detailed information about the actions to take in the case of specific safety effects. This clearly includes the option to discontinue treatment where necessary. GSK strongly contends therefore, that discontinuation is a part of the management of side effects and does not require a specific mention in the context in which the claim is used on the webpage in question.

Additionally, GSK would like to highlight that the inclusion of treatment discontinuation within side effect management strategies is not unique to Jemperli. This approach is consistent with the management practices for other immunotherapy (IO)/ anti-PD-1 products used in oncology as documented in their SmPCs. Furthermore, the discontinuation of IO due to severe side effects is a recognised and documented

management strategy as described in European Society of Medical Oncology (ESMO) Clinical Practice Guidelines which UK HCPs refer to.

Furthermore, it is also important to note that the intended audience (doctors, nurses, and pharmacists), are oncology specialists who are familiar with chemotherapy as well as IO products' safety profiles when used separately as well as in combination as this is their practice. The safety profiles of Jemperli + CP is consistent with that of its' individual components, and adverse event management of patients on the combination does not differ from that of patients who are on either CP or Jemperli alone.

Jemperli is an anti-PD-1 antibody treatment. This class of medication, in combination with chemotherapy, has been regularly reported by Oncology HCPs to have a manageable safety profile, despite the occurrence of grade 3 to 5 adverse events. This is due to the nature of oncological treatments and diseases being treated, where the risk-benefit ratio is viewed differently compared to other medical specialties. This has previously also been acknowledged by the PMCPA in a previous code case of anonymous oncologist v Pierre Fabre (AUTH/2799/10/15), where the panel: '*...noted the highly specialised therapy area … In the Panel's view the audience would be familiar with the side effect profile of cytotoxic medicines generally*.' Oncology treatments that are life prolonging and/or reduce disease relapses are generally associated with severe adverse reactions. Consequently, what is deemed manageable within the oncology community differs from perspectives outside this specialty. Jemperli has been licensed since 2021, while anti-PD-1 treatments have been available for over a decade, and oncologists who prescribe them have extensive experience of their use.

GSK also contends that while the claim in question can stand alone, it is accompanied by a tab to 'explore the data', which directs the HCP to another webpage dedicated entirely to the detailed safety information for Jemperli. The bright red tab, which is visually striking and difficult to miss, is positioned immediately below the claim demonstrating that every effort has been made to point the reader to the additional detailed safety information as opposed to mislead them which the clause refers to.

GSK therefore disagrees strongly with the complainant's assertion that discontinuation of Jemperli is not part of the management strategy for dealing with side effects. As detailed above, according to European guidelines and the product SmPC, management encompasses a spectrum of actions tailored to the severity of side effects, which includes discontinuation. Therefore, stating that the drug has a 'manageable safety profile consistent with known profiles of individual components after 2 years of follow up' is consistent with the product SmPC, industry practices, and clinical consensus among a group of HCPs who are well-versed in the use of such treatments including dealing with their side effects.

GSK contends that the claim is accurate, balanced, fair, and reflects current evidence on adverse events for the product and for these reasons, we deny a breach of Clause 6.1.

Clause 6.2

The complainant has also referred to a breach of clause 6.2 with respect to the claim *'Jemperli + CP offers a manageable safety profile consistent with known profiles of*

individual components after 2 years of follow up' on PM-GB-DST-WCNT-230013 i.e., that the claim is incapable of substantiation. GSK strongly disagrees with this assertion.

The evidence to substantiate this claim is well established. In the RUBY study, immune-related adverse events (irAEs) were managed as per trial protocol specifications, using the joint American Society of Clinical Oncology (ASCO) and National Comprehensive Cancer Network (NCCN) guidelines, ensuring effective management of irAEs. Novak et al. (2023) observed that the irAE profile reported for the dostarlimab + CP arm in the Ruby study was similar to that reported for dostarlimab monotherapy, and the anti-PD-1 therapy class, showing that the combination with chemotherapy did not introduce new or worsened irAEs beyond those expected from dostarlimab alone. The study therefore demonstrated that Jemperli + CP has a manageable safety profile consistent with the known profiles of its individual components and GSK contends again that for this reason, the claim in question is capable of substantiation as per the requirements of the code.

The claim is also consistent with reported oncologist experience as shown in peer-reviewed presentations by oncology experts in the field at well-respected and reputable international oncology congresses such as:

- Presentation by Dr Mirza et al. at the Society of Gynaecologic Oncology (SGO) Annual Meeting, 2023 – *'Safety profile for dostarlimab + CP was **manageable** and **generally consistent with that of the individual drugs**'*
- Presentation by Dr Powell et al. at the American Society of Clinical Oncology (ASCO) Annual Conference, *2023 – 'Overall, efficacy assessments by both INV and BICR, along with a **manageable safety profile**, support a favourable benefit/risk profile for dostarlimab + CP in patients with primary advanced or recurrent EC'*

GSK contends that the claim aligns with trial study results and the clinical experience of oncology specialists to whom the webpage is directed. The claim in question has been presented with clear and obvious reference citations which GSK contends counter the allegation that it is not capable of being substantiated as per the code requirement.

GSK note that the complainant referred to clause 6.2 in general terms with regard to this claim. Although clause 6.2 also states that companies must provide substantiation following a request for it, to our knowledge, GSK have not received any such requests prior to receiving this complaint, and so we have not commented further on this aspect of clause 6.2

GSK therefore strongly denies a breach of clause 6.2.

Clause 8.1

Clause 8.1 states that promotional material must not be issued unless its final form, to which no subsequent amendments will be made has been certified by one person on behalf of the company. The complainant claims that the 'Jemperli promotional webpage (For GB HCPs) had not been certified for use on a mobile phone' and therefore clause 8.1 has been breached. GSK contends that this is incorrect because both the mobile and desktop versions of these materials have been reviewed, certified and final form examined in line with the requirements of the code as described above. The webpages were certified by a UK Pharmacist.

According to PMCPA's guidance on certification for different platform, '*Companies must ensure that the final form viewed is not distorted and the requirements of the Code are complied with, e.g., the legibility of the prescribing information.*' The differences in colour and text placement are intentional for the reasons laid out below and adhere precisely to the PMCPA guidance. The white text that appears next to the image on the desktop versions for PM-GB-DST-WCNT-230013, PM-GB-DST-WCNT-230018, PM-GB-DST-WCNT-230020 and PM-GB-DST-WCNT-230025 has been moved to sit beneath the image on the mobile versions in black font precisely to ensure legibility and appropriate sizing.

Both the certified mobile and desktop versions of the webpages at issue had their content appropriately formatted for the two devices without altering any of the actual content. It is important to note that the content visible to HCPs on both platforms is identical in terms of text, images, and overall message. The intentional differences pertain to colour and font sizes, which have been formatted to ensure readability and improved user experience on different devices. GSK contends that while the unique identifier job numbers are the same for both views, the job has been reviewed, certified and final form examined for use on both desktop and mobile as per the code requirements.

With respect to the extra 'Product' tab wording on mobile, this was a technical matter of webpage functionality and navigation for the same reasons as those stated above i.e., to ensure readability and improve user experience. The drop-down 'Product' menu is a necessity for the mobile version as, due to the size of the screen, the section headers on the webpage would not be clearly legible to HCPs had they been presented in the same format as the desktop view. It is important to note that during GSK's review and certification process, we ensure that the use of a drop-down menu on the mobile version does not obscure any critical information required for HCPs and as mandated by the code such as the Prescribing Information (PI), safety information, adverse event reporting information, etc.

GSK would also like to draw attention to the PMCPA case of Health professional v Roche (AUTH/3667/6/22) which bears some similarities to this complaint. In that case, '*the Panel noted the navigation reference, 'Resources > Congresses and Meetings > Future Positive Lite' appeared on the desktop version and not on the mobile version of the webpage, the Panel did not consider this necessarily required separate certification*'. In the Panel's view, '*this would be considered to be, on balance, a technical matter of webpage functionality and navigation as opposed to part of the substantive content of the webpage itself*.'

GSK also contends that our approach is currently the standard UK pharma industry approach to certifying digital materials which can be viewed on different devices. In the rapidly expanding digital environment, any alteration to this approach risks having a significant impact on the entire UK pharma industry with massive implications for resource, time, and effort for no discernible benefit in return in terms of patient care and safety, raising standards or code compliance.

For the reasons above, GSK contends that the final form certification and examination of materials PM-GB-DST-WCNT-230013, PM-GB-DSTWCNT-230018, PM-GB-DST-WCNT-

230020 and PM-GB-DST-WCNT-230025 for both mobile and desktop meets the requirements of the code. GSK therefore denies a breach of clause 8.1.

Clause 5.1

The materials PM-GB-DST-WCNT-230013, PM-GB-DST-WCNT-230018, PM-GB-DST-WCNT-230020 and PM-GB-DST-WCNT-230025 have been created, reviewed, certified and final form examined for both mobile and desktop versions as described in detail above. GSK contends that the entire process was carried out in accordance with the code and in line with GSK SOP/processes. The complainant has alleged that the different views (mobile and desktop) should have been certified as separate jobs. GSK strongly contends that this is a subjective interpretation of the code on their part and therefore unnecessary for the reasons we have laid out above.

GSK contends that our process encapsulates entirely the spirit of the code with regards to the rationale for certification of all promotional materials. We also contend that the robustness of the certification process and the quality of the materials, including the safety claim raised by the complainant, are of the required standard with respect to the code. For these reasons, GSK maintains that high standards have been maintained and we deny a breach of clause 5.1.

Clause 2

The PMCPA has also asked GSK to consider clause 2. GSK contends that a breach of clause 2 is reserved for special sanction when significant failings have been identified, including a risk to patient safety.

As described in detail above, GSK contends that there is no evidence of significant failings in our systems and processes, which we believe are robust and the webpages in question have been reviewed, certified and final form examined to a suitably high standard and in line with the code.

Furthermore, GSK also contends that the claim at issue is fully supported, referenced and substantiable with clinical evidence as described above. The target audience of specialist oncology HCPs is experienced and knowledgeable in treating their patients with medicines such as Jemperli (with or without CP) due to the length of time these products have been available, as well as the existence of established guidelines for treatment that exist to support their treatment practices further. This experience and knowledge also extend to the management of the safety issues related to such treatments. GSK also contends that for the reasons detailed above, the use of the terminology ‘manageable safety profile’ is well recognised and commonly used by the HCPs in question and unlikely to cause any confusion. GSK therefore contends that patient safety has not been nor will be prejudiced by the materials or claim in question.

For these reasons, and those covered in detail further above, we contend that GSK’s activities and materials do not risk bringing discredit upon or reducing confidence in the pharmaceutical industry. GSK therefore denies a breach of clause 2.

Additional information

The signatories who reviewed, approved, and certified the material at issue in AUTH/3901/5/24 are as follows: The final form reviewer is a registered UK pharmacist with 1 years' signatory experience and was previously an oncology pharmacist with 10 years of NHS experience. The safety profile claim was reviewed and approved by an experience external/remote signatory with more than 6 years' experience.

Summary

GSK takes its responsibility of abiding by the letter and the spirit of the code extremely seriously. As laid out in our detailed response above, GSK denies breaches of clauses 8.1, 6.1, 6.2, 5.1 and 2 of the 2021 ABPI Code of Practice."

PANEL RULING

The complaint related to four webpages of a GSK promotional website aimed at UK healthcare professionals about its product Jemperli (dostarlimab). The complainant alleged that these four webpages had not been certified for use on a mobile phone, and that the differences between mobile and desktop versions of the website should have undergone separate certification. The complainant further alleged that one of the claims on the webpages which stated "Jemperli + CP [carboplatin-paclitaxel] offers a manageable safety profile" was misleading and unqualified. The Panel dealt with the certification allegation and the safety allegation separately.

Certification allegation

The complainant provided details of the four webpages and set out the differences between the desktop and mobile versions:

1. Home page – the text appeared in white font adjacent to an image of a woman, compared to the mobile version where the text appeared below the image in black font. The text at issue stated:

   "New License for Great Britain
   JEMPERLI is the first and only immunotherapy with platinum-containing chemotherapy licensed in adult patients with dMMR/MSI-H primary advanced or recurrent EC and who are candidates for systemic therapy"

2. Ruby Trial page - the text appeared in white font adjacent to an image of two women, compared to the mobile version where the text appeared below the image in black font. The text at issue stated:

   "The RUBY Trial: Part 1
   Discover efficacy and safety outcomes from the RUBY Trial"

3. Dosing and treatment management page - the text appeared in white font adjacent to an image of two women, compared to the mobile version where the text appeared below the image in black font. The text at issue, which was followed by the indications for monotherapy and combination therapy, stated:

   "Dosing and Treatment Management"

4. Resource library page - the text appeared in white font adjacent to an image of a woman, compared to the mobile version where the text appeared below the image in black font. The text at issue stated:

   "Resource Library
   Healthcare Professional Resources & Patient-Facing Resources"

The complainant also alleged that, on the desktop version, the webpages listed one to four above could be navigated through five individual tabs across a red banner at the top of the webpage (Home, RUBY Trial, Dosing and Treatment Management, Resource Library and Get in Touch) in comparison to the mobile version where the five tabs condensed into a drop-down menu, and contained an additional title, "Product menu". The complainant alleged that as the "Product menu" text was not present on the desktop version, this was therefore a final form change on all of the webpages of this product website compared with the mobile version.

Clause 8.1 stated that promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified.

Companies must ensure that the final form view is not distorted and the requirements of the Code are complied with e.g. the legibility of the prescribing information.

In the Panel's view, the Code did not necessarily require a website to be certified multiple times for each different device it might be viewed on. However, the Panel considered that the appearance of the material on different devices should be taken into consideration prior to certification to ensure that the content met the requirements of the Code when viewed on different commonly used types of electronic device.

GSK, in its response, set out its certification process, which required both the desktop and mobile versions to be visible throughout as part of the job. There was also a mandatory requirement for the staging links for the final form webpages to be examined on both a desktop and a mobile phone to ensure that the content and layout was consistent across both platforms, and that there were no substantive content changes between the two.

The Panel noted GSK's submission that both desktop and mobile versions of the webpages in question were approved as part of the same job and that the differences in colour and text placement between the two versions were intentional to account for legibility and readability on the two commonest platform views, desktop and mobile views. The content visible to health professionals on both platforms was identical in terms of text, images, and overall message.

The Panel noted that the red navigation banner with five tabs, "Home, RUBY Trial, Dosing and Treatment Management, Resource Library and Get in Touch" appeared on the desktop version and not on the mobile version of the webpages, whereas the mobile version condensed these five tabs into a single "Product menu". The Panel did not consider this necessarily required separate certification. The Panel considered this to be, on balance, a technical matter of webpage functionality and navigation as opposed to part of the substantive content of the webpage itself.

The Panel noted that the text at issue on each of the four webpages was identical on the desktop and mobile versions; there were no differences in the images, the font or emboldening.

The only differences were the font colour and the position of the text relative to the images, with the text being adjacent to the images in the desktop version, and beneath the images in the mobile version. In the Panel's view, the font colour was such that it aided readability in the two versions and did not appear to give prominence to the text in one version over the other.

In the Panel's view, in the particular circumstances of this case, noting that there were no substantive differences in the content between the desktop and mobile versions of the webpages, the Panel considered that the complainant had not established that the difference in final form between the desktop and mobile versions meant that the two versions should have been certified separately. The Panel therefore ruled **no breach of Clause 8.1** and consequently **no breach of Clause 5.1 and Clause 2**.

Safety claims allegation

A claim about the Jemperli safety profile appeared on the homepage of the website, near the bottom of the webpage. The central box of a row of three boxes included the heading "Jemperli Safety Profile" in bold followed by the text,

> "JEMPERLI + CP offers a manageable safety profile consistent with the known profiles of its individual components after 2 years of follow-up"

This was followed by a link in a prominent red box to "EXPLORE THE DATA". While the Panel did not have the content of the linked webpage before it, the Panel noted GSK's submission that this webpage was dedicated entirely to the detailed safety information for Jemperli.

The complainant alleged that the "manageable safety profile" claim was inaccurate because Jemperli + CP could cause a number of serious side effects which required withdrawal of the drug as opposed to management of the side effects. The complainant also alleged that the claim was misleading, unqualified and of concern considering the drug was a black triangle product.

The Panel noted that Jemperli was an anti-PD-1 (anti-programmed cell death protein) antibody used as a treatment option in oncology. Jemperli was indicated as monotherapy or in combination with platinum-containing chemotherapy for the treatment of adult patients with certain types of recurrent or advanced endometrial cancer.

The Panel noted the following in the Jemperli SPC:

Section 4.2 Posology and method of administration, Dose modifications, stated:

> "Dose reduction is not recommended. Dosing delay or discontinuation may be required based on individual safety and tolerability. Recommended modifications to manage adverse reactions are provided in Table 3".

Table 3 set out a number of immune-related adverse reactions and infusion-related reactions, with their severity grade and dosage modifications to make in respect of each. The Panel noted that eleven out of thirteen listed adverse reactions required permanent treatment discontinuation at varying grades of severity.

The Panel noted GSK's submission that discontinuation of treatment to manage side effects was consistent with practice for other immunotherapy / anti-PD-1 products used in oncology, and the discontinuation of immunotherapy due to severe side effects was a recognised and documented management strategy as described in the European Society of Medical Oncology (ESMO) Clinical Practice Guideline. The Panel noted that the management escalation pathways for immunotherapy-related toxicities in the ESMO guideline included discontinuation in certain cases of myocarditis and nephritis, among others.

The Panel noted GSK's submission that Jemperli was an anti-PD-1 antibody treatment, and this class of medication, in combination with chemotherapy, had been regularly reported by oncology health professionals to have a manageable safety profile, despite the occurrence of grade 3 to 5 adverse events. In this regard, the Panel noted that Lipson E J *et al* (2015) stated that the manageable safety profile of PD-1/PD-L1 blocking drugs identified them as suitable for outpatient administration and the development of combinatorial therapies. In a Phase I trial involving another anti-PD-1 drug in non-small-cell lung cancer, drug-related grade 3 to 4 adverse events occurred in 14% of patients primarily related to immune activation, and were generally manageable. The authors concluded that the generally manageable safety profile of anti-PD-1/PD-L1 drugs supported the development of combinatorial therapies, which were predicted by preclinical models to be able to increase the efficacy of PD-1 pathway antagonists.

The Panel noted GSK's submission that Novak Z *et al* (2023) observed that the irAE (immune-related adverse event) profile reported for the dostarlimab + CP arm in the RUBY trial was similar to that reported for dostarlimab monotherapy, and the anti-PD-1 therapy class, showing that the combination with chemotherapy did not introduce new or worsened irAEs beyond those expected from dostarlimab alone. The authors stated that the majority of treatment-emergent irAEs resolved during the course of treatment and few patients discontinued dostarlimab because of irAEs. The authors further stated that with over two years of follow-up, these results supported the favourable benefit-risk profile of dostarlimab + CP and supported its use as a standard of care in patients with primary advanced or recurrent endometrial cancer.

The claim at issue was further supported by reported oncologist experience stating that the safety profile for dostarlimab + CP was manageable and generally consistent with that of the individual drugs, supporting a favourable benefit/risk profile for dostarlimab + CP in patients with primary advanced or recurrent endometrial cancer.

The Panel therefore considered that the complainant had not established that the claim "JEMPERLI + CP offers a manageable safety profile consistent with the known profiles of its individual components after 2 years of follow-up" was inaccurate, misleading or unqualified, and the Panel ruled **no breach of Clauses 6.1 and 6.2** accordingly.

The Panel concluded that GSK had therefore not failed to maintain high standards, nor had it brought discredit upon, or reduced confidence in, the pharmaceutical industry. The Panel ruled **no breach of Clause 5.1 and Clause 2**.

Complaint received **12 May 2024**

Case completed **30 April 2025**