CASE/0244/07/24

COMPLAINANT v GSK

Allegations regarding Omjjara prescribing information

CASE SUMMARY

This case was in relation to wording about the use of hormonal contraceptives in the prescribing information for Omjjara (momelotinib), which was contraindicated in pregnancy.

The outcome under the 2021 Code was:

Breach of Clause 2	**Bringing discredit upon, and reducing confidence in, the pharmaceutical industry**
Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 6.1	**Producing misleading information**

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 an anonymous, non-contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below:

> "To whom it may concern. There is a shocking error within the OMJJARA prescribing information for Great Britain PI-12711 and the OMJJARA prescribing information for Northern Ireland PI-12710. Both direct that 'Women using oral hormonal contraceptives should add a barrier method during treatment and for at least 1 week after the last dose of Omjjara', yet common sense and reasoning suggests any non-oral hormone contraception will raise the same concern. I query the ability of GSK to accurately produce prescribing information and query whether sufficient checks have been made to these items prior to release. Safety risks should be given the utmost focus. I would be grateful for consideration of breaches for 2 + 5.1 + 6.1 in both. PIs are online [URL provided]."

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

GSK'S RESPONSE

The response from GSK is reproduced below:

> "GSK was extremely disappointed to have received a letter dated 24th July 2024 from the PMCPA informing us of a complaint from an uncontactable individual describing themselves as an anonymous healthcare professional regarding the above. The PMCPA has asked us to bear in mind the requirements of Clauses 2, 5.1 and 6.1 of the 2021 ABPI Code of Practice (the Code).
>
> The complainant alleged 'a shocking error within the OMJJARA▼ prescribing information for Great Britain PI-12711 and the OMJJARA prescribing information for Northern Ireland PI-12710. Both direct that 'Women using oral hormonal contraceptives should add a barrier method during treatment and for at least 1 week after the last dose of Omjjara', yet common sense and reasoning suggests any non-oral hormone contraception will raise the same concern' The complainant went on to 'query the ability of GSK to accurately produce prescribing information and query whether sufficient checks have been made to these items prior to release.' The complainant further remarked, 'Safety risks should be given the utmost focus' and asked the PMCPA 'for consideration of breaches for 2 + 5.1 + 6.1 in both'. The complainant had found the Prescribing Information (PI) online at the GSK Pro website for UK Healthcare Professionals [ULR provided].
>
> GSK takes its responsibilities 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 reviewed the Omjjara Great Britain (GB) and Northern Ireland (NI) PI in question, as well as our internal ways of working. We withdrew the PI and all materials containing the PI pending a thorough investigation and undertook a detailed comparison of the materials in question. GSK confirmed that the PI adhered to the specific PI elements required and listed as i–viii in Clause 12.2 of the Code, in addition to including the legal classification of the product, the cost (exc. VAT) and the name of the medicine. Consequently, we disagree with the allegations that the referenced PIs are in breach of Clauses 2, 5.1 and 6.1 of the 2021 Code, as alleged by the complainant.
>
> GSK has laid out the specific responses to the individual clauses the PMCPA has asked us to bear in mind in detail below.
>
> **<u>Website background</u>**
>
> The Omjjara webpages referred to in the complaint are part of a more extensive promotional website called GSKPro, for UK Healthcare Professionals (HCPs) only. 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 Omjjara.
>
> The Omjjara website can be accessed by three methods:
>
> - Direct access by HCPs via a search engine, such as Google, that requires confirmation via a pop up that they are a HCP, as opposed to a member of the public for whom there is a link to a separate part of the website with relevant content.

- Via third party emails sent by [named third parties] to HCPs with an interest in Haematology and who had consented to receive promotional emails from pharmaceutical companies via these platforms.
- Via a single click through link from the meeting page for an Omjjara promotional webinar held on 21.05.2024. This meeting page was only accessible to relevant, validated UK HCPs who were invited to the webinar.

The complainant's allegation relates only to the NI and GB PI pages of the GSKPro website. The PI can be accessed by HCPs from digital materials, including the GSKPro website, via a clear, prominent, direct, single click link. PI is required *inter alia,* to consist of *'a succinct statement of the information in the summary of product characteristics relating to the dosage and method of use relevant to the indications quoted in the advertisement and where not otherwise obvious the route of administration'.* Furthermore, the PI is required to contain '*a succinct statement of the common adverse reactions likely to be encountered in clinical practice, serious adverse reactions and precautions and contra-indications relevant to the indications in the advertisement'.*

The Code is clear that the aim of the PI is to give *'in an abbreviated form, the substance of the relevant information in the summary of the product characteristics'.* Of particular note is the requirement to include a statement that*, 'prescribers should consult the summary of product characteristics in relation to other adverse reactions'.*

GSK processes and structure

GSK has robust processes and structures for material approval to ensure compliance with the Code, GSK's own code, and UK regulations. All employees involved in copy approval must complete mandatory GSK copy approval SOP training. Each brand team holds a regular forum for discussion and approval (FDA), involving medical and commercial teams, to discuss and align on materials requiring copy approval, and to ensure all materials and content generated are fully compliant with the Code. Should views differ, for example over specific claims, there is a clear and well-established route of escalation for resolution.

To maintain ongoing Code knowledge, GSK conducts a monthly Code Forum meeting in which Code cases are presented and discussed as well as any other compliance/governance issues which merit awareness. While the meeting is intended principally for all medical signatories, commercial reviewers, and content owners, other staff interested to attend for their own learning and development may do so. Attendance is consistently strong, and materials discussed are stored on GSK's internal governance platform, accessible to all UK employees.

Additionally, GSK holds Governance meetings once a month for medical signatories and medical reviewers. Attendees raise Code-related agenda items for discussion, with a view to reaching consensus within the group, under the guidance of experienced senior signatories.

Furthermore, GSK has a fair and objective process for assessing and validating not only medical signatories, but also commercial reviewers. The role of the commercial reviewer is to provide commercial overview of all promotional and relevant non-

promotional materials for appropriateness, including fundamental aspects and principles of the Code, as well as content suitability and strategic alignment. These assessments involve one, or more often two assessors, objectively questioning the candidate on case examples, covering multiple aspects of the Code. In addition, the appraisee must have completed a set of mandatory training requirements. In the case of medical signatories, the appraisee must have been mentored for a period by another experienced medical signatory, until the mentor deems the appraisee ready to take the assessment to become a final medical signatory.

Of relevance to this specific complaint, GSK has the following process in place to create and certify PI following initial grant of Marketing Authorisations.

- The regulatory team notifies the medical team that a GSK medicine has been granted Marketing Authorisations and provides copies of the SmPC approved by the respective Competent Authorities.

- Following receipt of the approved SmPC, the medical team carefully evaluates the SmPC and carefully derives abridged PI from the SmPC.

- The Medical team consults with cross-functional stakeholders and assiduously maintains documentation for audit purposes.

- The PI thus generated is aligned to the requirements of the MHRA Blue Guide and to Clause 12 of the Code.

- The responsible medical advisor or named signatory on the GSK product responsibility list approves the PI having ensured that it reflects the relevant information from the SmPC.

- Once approved, the PI is then Certified in line with the requirements of the Code and GSK process.

- Following EMA and MHRA Marketing Authorisation of Omjjara, the NI Omjjara PI was developed [29/1/2024-9/2/2024], certified and final form examined on 12th February 2024; the GB Omjjara PI was developed [7/2/2024-13/2/2024], certified and final form examined on 13th February 2024.

- Following certification and final form examination of the Omjjara PI, promotional materials requiring PI were certified for use with the newly developed PI.

Given the robust process followed, GSK remains firm in its view that the Omjjara PI is consistent with Clause 12.2 of the Code in providing the required elements of the SmPC.

The complainant commented '*I query the ability of GSK to accurately produce PI and query whether sufficient checks have been made to these items prior to release*'. The complainant provided no grounds or evidence to support their unfounded assertions.

As detailed above, the GB and NI PI were reviewed, certified and the final form examined by an experienced ABPI signatory UK pharmacist in line with the requirements of the Code and GSK processes.

Clause 6.1

Clause 6.1 states that information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly; they must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis.

As advised previously, the complainant alleges '*a shocking error within the Omjjara PI*' and therefore a breach of Clause 6.1. GSK contends that the Omjjara PI is accurate as it was taken, verbatim, from the Omjjara SmPC Section 4.4 Special warnings and precautions for use. Furthermore, the PI aligns fully with the Patient Information Leaflet, also reviewed and approved by the relevant Competent Authorities.

The Omjjara PI contains an underlined statement prominently positioned at the top of the page: 'Please consult the full Summary of Product Characteristics for Great Britain (SmPC GB) before prescribing Omjjara.' In addition, a link to the GB EMC webpage is listed at the bottom of the PI page so healthcare professionals can access the latest version of the SmPC '*Full SmPC available from GSK Limited or from* www.medicines.org.uk/emc*.'* The same applies to the NI version of the PI, with reference to the NI SmPC and link to the NI EMC webpage – www.emcmedicines.com/en-GB/northernireland/.

Sections relating to fertility, pregnancy and lactation within the GB and NI Omjjara PI are as follows:

> **Contraindications:** Pregnancy and breast-feeding.
> **Interactions:** Effect of Omjjara on other medicinal products: *Hormonal contraceptives:* The effectiveness of oral contraceptives co-administered with Omjjara may be reduced.
> **Fertility, pregnancy and lactation:** *Women of childbearing potential (WOCBP)/Contraception:* WOCBP should be advised to avoid becoming pregnant whilst receiving Omjjara. Women using oral hormonal contraceptives should add a barrier method during treatment and for at least 1 week after the last dose of Omjjara. *Pregnancy*: Omjjara is contraindicated during pregnancy. If used during pregnancy, or if the patient becomes pregnant while on treatment, the patient should discontinue treatment and be advised of the potential hazard to the foetus. *Breast-feeding:* Contraindicated during breast-feeding. *Fertility:* No clinical data on human male or female fertility.

PI is the essential information which must be provided in promotional material. As advised in the supplementary information to Clause 12.2, use of the Summary of Product Characteristics, 'The Code defines prescribing information to consist of three parts: the legal classification, the cost and other elements (listed as i–viii) in Clause 12.2.' GSK duly and diligently provided all the required elements listed as i–viii in Clause 12.2, together with the clear statement at the outset of the PI to consult the

SmPC for full PI. The relevant information regarding use of contraceptives from the GB and NI Omjjara SmPC incorporated by GSK into the PI included the following:

> **Section 4.3 Contraindications**
> Pregnancy and breast-feeding
>
> **Section 4.4 Special warnings and precautions for use**
> Women of childbearing potential
> Given uncertainties whether Omjjara may reduce the effectiveness of hormonal contraceptives, women using ***oral*** *hormonal contraceptives* (GSK-added emphasis/ italics) should add a barrier method during treatment and for at least 1 week after the last dose of Omjjara.
>
> **Section 4.5 Interaction with other medicinal products and other forms of interaction**
> Hormonal contraceptives
> Multiple doses of momelotinib had no influence on the exposure of midazolam, a sensitive CYP3A substrate. However, a risk for induction of other pregnane X receptor (PXR) regulated enzymes apart from CYP3A4 cannot be completely excluded and the effectiveness of concomitant administration of ***oral*** *contraceptives* (GSK-added emphasis/ italics) may be reduced.

Recommendations relating to the use of contraceptives within the GB and NI Omjjara Patient Information Leaflet, reviewed and approved by the EMA and MHRA, are as follows:

> **Omjjara GB and NI Patient Information Leaflet**
> If you are a woman who could become pregnant, you must use highly effective contraception while you are taking Omjjara and you must continue to use highly effective contraception for at least 1 week after taking your last dose. It is currently unknown if Omjjara could reduce the effectiveness of ***oral*** *contraceptives*, (GSK-added emphasis/italics) therefore it is recommended to add a barrier method during treatment and for at least 1 week after taking your last dose of Omjjara. Your doctor may ask you to take a pregnancy test before starting your treatment, to confirm that you are not pregnant.

Thus, the elements of Clause 12.2 required by the Code were identified from the SmPCs and incorporated into the Omjjara PI for GB and NI health professionals.

Additional Information: Section 5.2 of the Omjjara SmPC elaborates further on the effect of momelotinib on hormonal contraceptives, which are typically metabolised by CYP3A4. Omjjara has not been shown to be a significant inhibitor or inducer of this isoenzyme. The effect of momelotinib on a sensitive CYP3A substrate, midazolam, has been evaluated. Multiple doses of momelotinib did not alter the pharmacokinetics of midazolam (Ho YH, et al. 2024). While an *in vivo* drug-drug interaction study of momelotinib with hormonal contraceptives has not been conducted, the SmPC advises that ‘a risk for induction of other pregnane X receptor (PXR) regulated enzymes apart from CYP3A4 cannot be completely excluded and the effectiveness of concomitant administration of ***oral*** *contraceptives* (GSK-added italics) may be reduced.’ The

prescriber is also referred specifically to Sections 4.4 and 4.5 of the SmPC, as cited earlier.

Omjjara is a specialist medicinal product and should be initiated and monitored by physicians experienced in the use of anti-cancer therapeutics. Haematologists who prescribe Omjjara and who may have been presented with the Omjjara PI in materials from GSK are well versed in the assessment and management of men and women diagnosed with myelofibrosis. It is worth noting that the median age at diagnosis of myelofibrosis patients in the UK is 69.7 years [Interquartile range 63.5-75.7 years] from the UK REALISM study (Mead A, et al. 2022). In an analysis of diagnoses between 2010 and 2019 by the Haematological Malignancy Research Network (HMRN), a collaborative research group led by the University of York and NHS clinicians from 14 UK hospitals, myelofibrosis occurs more frequently in males than females (sex rate ratio of 1.6), with median age at diagnosis of 73 years (The HMRN. Factsheets: Myelofibrosis 2022. [URL provided] (accessed Sept 2024)). Nonetheless, women of childbearing potential may be diagnosed with myelofibrosis and Omjjara considered by their treating physician. However, both the Omjjara GB and NI SmPC and PI provide important safety information relating to its contraindication during pregnancy and breast feeding, and guidance on its use in women of childbearing potential. As mentioned previously, the PI additionally directs prescribers to consult the full SmPC before prescribing Omjjara. Consequently, GSK is of the view that the information contained in the Omjjara PI for GB and NI specialist prescribers meets the requirements for Prescribing Information as defined by Clause 12.2 of the Code. In conjunction with the product's full SmPC, it enables recipients to form their own opinion of the therapeutic value of the medicine thereby ensuring its appropriate and rational use.

Following further review of the SmPCs and the PIs, we additionally sought referenced information on contraceptive use in the UK; a 2018 UK study identified oral contraceptives as the most common form of contraceptives prescribed in the UK compared to other types of hormonal contraception (Fig. 1–3; Pasvol TJ, et al. 2022). As described above, Omjjara has not been shown to be a significant inhibitor or inducer of CYP3A4, which is typically involved in the metabolism of hormonal contraceptives. This does present a theoretical risk of induction of other enzymes, apart from CYP3A4. Therefore, CHMP Rapporteurs included advice in Sections 4.4 and 4.5 of the SmPC relating to concomitant use of ***oral*** *hormonal contraceptives* only. Section 4.6 of the SmPC refers to concomitant use of systemically acting hormonal contraceptives where the prescriber is also referred specifically to Sections 4.4 and 4.5 of the SmPC once again.

As GSK recognises patients' safety is of the utmost importance, we have decided to incorporate Section 4.6 information, which is not normally included in the PI. GSK has therefore withdrawn the existing PI and all materials containing that PI, and to replace it with PI including wording from Section 4.6 of the SmPC. GSK maintains, nevertheless, that the Omjjara PI for GB health professionals PI-12711 and that for NI clinicians PI-12710 met all the technical requirements of Clause 12.2 of the Code. GSK disagrees with the complainant that there was a '*shocking error within the OMJJARA Prescribing Information'* and, therefore, a breach of Clause 6.1.

Clause 5.1

The complainant stated, '*I query the ability of GSK to accurately produce prescribing information and query whether sufficient checks have been made to these items prior to release*'. As discussed fully earlier, the Omjjara SmPCs for GB and NI were critically appraised following receipt of Market Authorisations, their respective PIs were subsequently carefully derived, and each PI approved. This followed reviews by GSK Medical and confirmation that the information was consistent with the requirements of Clause 12.2 of the Code. Subsequently, the PIs were certified, and their final forms examined by an experienced Medical Signatory in line with the requirements of the Code. Therefore, GSK is confident that the entire process was carried out with all due diligence, in accordance with the Code and in line with GSK SOP/processes.

As previously advised, GSK processes, training, governance, and management monitoring have been designed and implemented to embed the spirit as well as the letter of the Code. GSK's standards promote rigour when creating, reviewing, approving, and certifying materials. We remain confident in the quality of the cited materials, their accuracy, and their robustness. The alleged PI safety considerations brought into question by the complainant were subjected to further critical appraisal. While the Omjjara PI was confirmed to be technically accurate in relation to Clause 12.2 of the Code, safety and benefit/risk are of foremost importance to GSK. Given this, GSK decided to take action to withdraw the existing GB and NI PI and include additional information from Section 4.6 of the SmPC.

High standards were maintained throughout the creation, approval, and Certification of the original Omjjara PIs. The additional action taken demonstrates GSK's commitment to put patient safety first and to adopt the highest standards possible. Consequently, GSK disagrees with the complainant that there is cause to consider a breach of Clause 5.1.

Clause 2

The PMCPA asked GSK to bear in mind the requirements of Clause 2, raised by the complainant for consideration alongside Clauses 5.1 and 6.1 of the Code. GSK notes that a ruling of a breach of Clause 2 is a sign of censure, reserved for circumstances that include prejudicing patient safety and/or public health. It is ruled when significant failings have been identified, that include *inter alia* a risk to patient safety.

In responding to the breaches alleged by the complainant, GSK has advanced strong arguments that the Omjjara GB and NI PIs adhered to the requirements of the Code. Neither did the process of their creation demonstrate any failure in the Company's systems or processes. GSK maintains that these are robust. The PIs in question were created diligently, in line with the relevant requirements of the Code. Each PI referred prescribers to the Omjjara SmPC for the full Prescribing Information on the medicinal product. The PIs were produced, certified and their final forms examined in the manner required and to the standards mandated by the Code and by GSK's own SOP. As noted above, GSK's further actions demonstrate a clear understanding of the importance of patient safety in all materials produced.

For these reasons, and all others detailed earlier, we contend that GSK's activities and materials do not risk bringing discredit upon or reduce confidence in the pharmaceutical industry. Consequently, GSK does not recognise that Clause 2 has been breached.

Additional information

The signatory who reviewed, approved, and certified the GB and NI Omjjara PI in Case AUTH/0244/07/24 is a registered UK pharmacist with more than 10 years' signatory experience.

Summary

GSK takes its responsibilities of abiding by the letter and the spirit of the Code extremely seriously. As laid out in our considered responses above, GSK denies breaches of Clauses 2, 5.1 and 6.1 of the 2021 ABPI Code of Practice."

PANEL RULING

The complainant alleged that there was an error in the Omjjara (momelotinib) prescribing information for Great Britain and for Northern Ireland relating to the wording around the use of hormonal contraceptives.

The Panel noted that there were no differences between the Great Britain and Northern Ireland versions of the prescribing information that were the subject of this complaint, apart from different MA numbers and MA holder details. In addition, the relevant sections of the summary of product characteristics (SPC) relied upon by the Panel below, were identical in the Great Britain and Northern Ireland versions of the SPC. The Panel's ruling therefore applied to both versions of the prescribing information.

The complainant's allegation related to the following wording in the prescribing information:

> *"Women using oral hormonal contraceptives should add a barrier method during treatment and for at least 1 week after the last dose of Omjjara."*

The complainant alleged that this instruction would also apply in relation to any non-oral hormonal contraception.

The Panel noted that, although prescribing information must be consistent with the particulars given in the SPC, the content of an SPC was approved by the licensing authority and was not within the scope of the Code.

GSK submitted that the prescribing information adhered to the specific requirements listed in Clause 12.2 of the Code. The Panel noted, however, that Clause 12.2 had not been raised in relation to this case and GSK had been asked to respond to the complaint in relation to the requirements of Clause 6.1. Clause 6.1 stated, among other things, that information must be accurate, unambiguous and must not mislead. GSK submitted that the prescribing information was accurate as it was taken verbatim from section 4.4 of the Omjjara SPC.

The relevant wording of the prescribing information and the SPC is presented in the following table, for ease of comparison:

Summary of product characteristics	Prescribing information
4.3 Contraindications Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Pregnancy and breast-feeding (see section 4.6).	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients; see SmPC for full details. Pregnancy and breast-feeding.
4.4 Special warnings and precautions for use Women of childbearing potential Given uncertainties whether Omjjara may reduce the effectiveness of hormonal contraceptives, women using oral hormonal contraceptives should add a barrier method during treatment and for at least 1 week after the last dose of Omjjara (see sections 4.5 and 4.6).	
4.5 Interaction with other medicinal products and other forms of interaction Effect of momelotinib on other medicinal products *Hormonal contraceptives* Multiple doses of momelotinib had no influence on the exposure of midazolam, a sensitive CYP3A substrate. However, a risk for induction of other pregnane X receptor (PXR) regulated enzymes apart from CYP3A cannot be completely excluded and the effectiveness of concomitant administration of oral contraceptives may be reduced (see sections 4.4 and 5.2).	**Interactions:** Effect of Omjjara on other medicinal products: … *Hormonal contraceptives:* The effectiveness of oral contraceptives co-administered with Omjjara may be reduced.
4.6 Fertility, pregnancy and lactation Women of childbearing potential/Contraception Women of childbearing potential should be advised to avoid becoming pregnant whilst receiving Omjjara. It is currently unknown whether Omjjara may reduce the effectiveness of systemically acting hormonal contraceptives, therefore women using systemically acting hormonal contraceptives should add a barrier method during treatment and for at least 1 week after the last dose of Omjjara (see sections 4.4 and 4.5).	**Fertility, pregnancy and lactation:** *Women of childbearing potential (WOCBP)/Contraception:* WOCBP should be advised to avoid becoming pregnant whilst receiving Omjjara. Women using oral hormonal contraceptives should add a barrier method during treatment and for at least 1 week after the last dose of Omjjara.

The Panel noted that sections 4.4 and 4.5 of the SPC referred only to oral hormonal contraceptives, while section 4.6 referred to “systemically acting hormonal contraceptives”.

In the Panel's view, there was an important difference between "systemically acting hormonal contraceptives" and "oral hormonal contraceptives". The phrase "oral hormonal contraceptives" did not include hormonal contraceptives such as an intrauterine device, injection or implant.

The Panel took account particularly of the wording in the "Fertility, pregnancy and lactation" section of the prescribing information (as cited by the complainant). The Panel considered that, given the header of this section of the prescribing information, a health professional would expect it to fairly reflect the substance of the corresponding section of the SPC (section 4.6 Fertility, pregnancy and lactation).

The "Fertility, pregnancy and lactation" section of the prescribing information stated:

> *"WOCBP should be advised to avoid becoming pregnant whilst receiving Omjjara. Women using oral hormonal contraceptives should add a barrier method during treatment and for at least 1 week after the last dose of Omjjara."*

The Panel concluded that this wording was misleading because it implied that, while all women of childbearing potential should be advised to avoid becoming pregnant, only those women using specifically oral hormonal contraceptives would need to add a barrier method. This was not consistent with the information in SPC section 4.6, which referred to "systemically acting hormonal contraceptives".

The Panel acknowledged that sections 4.4 and 4.5 of the SPC referred only to oral contraceptives. However, there was cross-referencing within these sections of the SPC that ultimately directed the reader to refer to section 4.6 and the related safety provisions, the wording of which referred to "systemically acting hormonal contraceptives".

In the Panel's view, the statement at the top of the prescribing information that the reader should "Please consult the full Summary of Product Characteristics … before prescribing Omjjara" was insufficient to counter the misleading wording regarding the action required by women using hormonal contraceptives. The prescribing information and the SPC, at first glance, appeared to be similar to each other, but there was an important safety component missing from the prescribing information which the Panel considered to be misleading. The Panel therefore ruled a **breach of Clause 6.1**.

As part of their complaint, the complainant had also queried GSK's ability to accurately produce prescribing information. The Panel noted GSK's submission which outlined their process for creating and certifying prescribing information, including an approval that it reflected the relevant information from the SPC. The Panel considered that, in this instance, prescribing information missing an important safety component had been produced despite this process being followed and the prescribing information being approved and certified. The Panel noted that Omjjara, a black triangle product, was contraindicated in pregnancy. The Panel considered that the production of prescribing information that was misleading regarding the need for women using hormonal contraceptives to take additional precautions to avoid pregnancy was such that high standards had not been maintained in this case. The Panel ruled a **breach of Clause 5.1**.

The Panel noted that GSK had withdrawn the prescribing information at issue to update it with wording from section 4.6 of the SPC. Nevertheless, the Panel considered that patient safety was of the utmost importance. As set out in the supplementary information to Clause 2, examples of activities likely to lead to a breach of Clause 2 included prejudicing patient safety.

Given that Omjjara was a black triangle medicinal product subject to additional monitoring which was contraindicated in pregnancy as it may cause foetal harm, and that important safety information with respect to preventing pregnancy had been presented in a misleading manner, the Panel considered that GSK had brought discredit upon and reduced confidence in the pharmaceutical industry. The Panel ruled a **breach of Clause 2**.

Complaint received **23 July 2024**

Case completed **12 March 2025**