

## **COMPLAINANT v JAZZ PHARMACEUTICALS UK**

### **Allegation about disclosure of company involvement**

#### **CASE SUMMARY**

This case was in relation to a named patient organisation website not including Jazz's involvement at the outset and three patient information booklets not including Jazz's involvement at all.

The outcome under the 2021 Code was:

<b>Breach of Clause 5.1</b>	<b>Failing to maintain high standards</b>
<b>Breach of Clause 23.2 (x4)</b>	<b>Failing to ensure that company involvement was made clear for donations and grants to the extent possible</b>
<b>Breach of Clause 25.3 (x4)</b>	<b>Failing to ensure that all sponsorship is clearly acknowledged from the outset</b>
<b>No Breach of Clause 2</b>	<b>Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry</b>
<b>No Breach of Clause 5.1</b>	<b>Requirement to maintain high standards</b>

**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 who described themselves as a health professional about Jazz Pharmaceuticals UK.

The complainant later became non-contactable.

#### **COMPLAINT**

The complaint wording is reproduced below:

"To director of PMCPA; [named patient organisation] are provided funding by Jazz Pharmaceuticals towards production of health information. The type of funding provided and the influence of Jazz was not provided from the outset. The only discussion of Jazz involvement was provided at the end and the type of funding was not clear. [link provided] The booklets about different types of cancer that had been

produced did not contain Jazz involvement declarations. [link provided] The clauses that are relevant to this complaint are: - 23.2 - 25.3, - 5.1 – 2.”

### Further information from the complainant

“As a follow up to your query, the materials where the declaration is missing is as follows. 1. [link provided] 2. [link provided] 3. [link provided] As Jazz pharma had provided funding to [named patient organisation] for health information, the declaration of involvement should be on the booklets from the outset. It is noted at the bottom of the following page regarding the booklets that Jazz pharma have provided funding towards the booklets and therefore each booklet should have its own funding declaration at the outset. [link provided].”

When writing to Jazz, the PMCPA asked it to consider the requirements of Clauses 25.3, 23.2, 5.1 and 2 of the 2021 Code.

### JAZZ’S RESPONSE

The response from Jazz is reproduced below:

“We have received a complaint letter dated 27 June 2024. The letter notifies us that a healthcare professional has made allegations about funding provided by Jazz Pharmaceuticals’ (Jazz) to [named patient organisation] webpage. The allegations are as follows:

- 1) the type of funding and influence of Jazz *‘was not provided from the outset’*, *‘was only provided at the end’* and *‘the type of funding was not clear’*; and
- 2) *‘the booklets about different types of cancer did not contain Jazz involvement declarations’*.

The complainant provided, as initial evidence for the allegation, a link to the [named patient organisation] webpage\*, which included many areas of information and access to support resources for people affected by [medical condition]. When requested by the PMCPA to provide more details, the complainant provided links to three [medical condition] booklets found on the ‘booklets’ section of the aforementioned webpage. Jazz was requested to respond to this matter with consideration to the clause requirements of 23.2, 25.3, 5.1 and 2 of the ABPI Code version 2021 (the ‘Code’), as cited by the complainant.

A thorough investigation has been conducted into the matters alleged in this complaint. Jazz provided an unrestricted grant to [named patient organisation] to support the activities required for the transformation of their health information portfolio. [Named patient organisation] requested funding for the implementation of their project, which was needed for patients, based on research they had carried out. Jazz agreed to provide an amount equivalent to approximately 5% of the total project cost. The agreement clearly required that [named patient organisation] include a prominent disclosure and acknowledgement of Jazz’s involvement.

We note that the requirements to make clear the financial arrangements for grants and donations in clause 23.2 is different from the obligations for sponsorships in clause 25.3. Clause 23.2, pertaining to donations and grants to HCO and Patient

Organisations, requires that *'Company involvement should be made clear for donations and grants to the extent possible.'* whereas Clause 25.3, pertaining to sponsorship with HCP, HCO, ORDM and Patient Organisations, requires that *'Companies must ensure that all sponsorship is clearly acknowledged from the outset. The wording of the declaration of sponsorship must be unambiguous and accurately reflect the extent of the company's involvement and influence over the material'*.

The complainant alleges breach of clauses 23.2 and 25.3 however the funding provided by Jazz to support this initiative, was given in the form of a grant, with no consequent obligation of the recipient organisation to provide goods or services to the benefit of Jazz in return. It is clear from the grant agreement and the declaration on the [named patient organisation] webpage\* that the funding provided was an unrestricted grant towards the transformation project undertaken by the organization. Jazz did not provide funding for the three information booklets as alleged by the complainant but instead provided an unrestricted grant for the whole project.

Since this was a grant and not a sponsorship, we believe that clause 25.3 does not apply and as such there cannot be a breach of clause 25.3. The complainant's assertion that each of the three booklets complained about required that *'each booklet should have its own funding declaration from the outset'* is incorrect, as Jazz did not provide funding for these three booklets.

The obligations of the Code require that company involvement in grants is declared 'to the extent possible'. The grant agreement clearly requires that [named patient organisation] discloses its financial relationship with Jazz by way of a *prominent mention of the financial support provided*. The [named patient organisation] webpage\* has a clear statement that the organization *'...has been transforming its health information. This project was made possible by generous funding from [nine] partners, trusts and foundations including ...Jazz Pharmaceuticals... These organisations provided funding but had no further input'*. The complainant themselves has evidenced that they were aware of Jazz's involvement from the webpage\* before engaging with other materials. Jazz therefore refutes the following allegations: that the type of funding and Jazz' involvement *'was not provided from the outset'*, *'was only provided at the end'* and *'the type of funding was not clear'*. We believe that the company involvement was made clear, to the extent possible and thereby maintain the declaration of funding for this project met the requirements of clause 23.2.

Jazz recognises the importance of maintaining the independence of patient organisations in accordance with the principles of the code. This is also echoed by [named patient organisation] in their policy when working with the pharmaceutical industry, where they seek to maintain their independence and influence from the industry when they receive funding. This too, aligns with the principles of the ABPI and the work that is ongoing to strengthen relationships and increase transparency when the industry works with patient organisations.

The complainant has alleged a breach of clause 5.1 and clause 2. Clause 5.1 requires that high standards must be maintained at all times and Clause 2 states that activities or materials must never be such as to bring discredit upon or reduce confidence in the pharmaceutical industry. The funding that Jazz provided to [named patient organisation] (in the form of a grant) is a legitimate activity and has been conducted in

line with the principles and rules of the ABPI Code. Therefore, we believe that high standards have been maintained at all times. Further, the complainant has not provided any evidence that high standards have not been maintained or that discredit has been brought upon or that there has been reduced confidence in the Pharmaceutical Industry. Therefore, Jazz refutes the allegations of breaches of clause 5.1 and clause 2.

I close this letter by reiterating Jazz's strong commitment to the rules and principles of the Code and look forward to hearing from you in due course."

## **PANEL RULING**

A complaint was received about a patient organisation's webpage, which allegedly did not provide Jazz Pharmaceuticals' involvement at the outset. It was further alleged that three patient information booklets produced by the patient organisation did not contain Jazz's involvement at all.

Jazz submitted that they had received a request from the patient organisation in April 2021 to provide an unrestricted grant of £10,000 in order for them to undertake a transformation of their health information portfolio and implement a new suite of health information resources. The patient organisation identified that the new health information would develop new resources specifically tailored to the needs of the patient community and health professionals to ensure patient community needs were being met.

The Panel considered the objectives of the patient organisation in receiving the unrestricted grant and noted that these included:

- Redesigning resources presented at diagnosis to address emotional and psychological needs of patients,
- Developing new concise content with language and tone addressed to ensure materials are representative for all backgrounds and levels of understanding,
- Resources will contain key information to support understanding a diagnosis and provide a gateway to other support pathways for the medical condition,
- The resources will be designed to be a "one-stop-shop", to prevent patients searching for other complicated information which could lead to increased anxiety,
- Developing a new tailored set of resources focused on family and friends to support them when a loved one is diagnosed with the medical condition,
- Creating a new suite of resources to help patients understand and cope with possible side effects of treatment, and
- Ensure all materials are inclusive and representative of the whole medical condition community.

Whilst the objectives and purpose of the funding was outlined, the Panel considered that neither the grant application nor the grant agreement identified specific materials. It was however clear

that the purpose was to improve patient materials which would be provided to and/or accessed by both patients and health professionals.

### **The Webpage**

The Panel considered the allegation that the type of funding and influence of Jazz was not provided at the outset but at the end of the webpage a link to which was provided by the complainant. The Panel considered the complaint on the basis of the screenshots taken by the Case Preparation Manager and provided to Jazz Pharmaceuticals.

The Panel noted that the webpage in question was headed "[name of patient organisation] health information"; the first section introduced a new booklet for people newly diagnosed with blood cancer alongside a picture of the booklet and details of how to order copies; the second section was headed "Types of blood cancer" and introduced booklets for specific types of blood cancer alongside pictures of several booklets with a link to "browse all booklets". At the bottom of what appeared to be a continuously scrolling webpage appeared the statement: "Throughout 2022-2024 [named patient organisation] has been transforming its health information. This project was made possible by generous funding from partners, trusts and foundations including [named companies and organisations]...Jazz Pharmaceuticals...These organisations provided funding but had no further input."

The Panel was provided with a copy of the grant agreement, which contained the following wording at paragraph 4(a), which stated, amongst other things:

"Jazz Pharmaceuticals shall be prominently mentioned as a sponsor of the Purpose on any publications to ensure that readers of the publications are aware of the financial support to the Purpose by Jazz Pharmaceuticals."

There was no further detail in the grant agreement as to the wording or positioning of the declaration.

The Panel did not agree with Jazz's submission that the provision of funding to the patient organisation could not be both a grant and a sponsorship. The Panel bore in mind the broad definition of sponsorship at Clause 1.22 and the definition of donations and grants at Clause 1.5 and considered that the terms were not mutually exclusive. The Panel considered it clear from the wording of the definitions that funding could in certain circumstances be both sponsorship and a grant.

When engaging with patient organisations, the Panel considered that it was particularly important to ensure that the relevant requirements of Clauses 25 and 27 were borne in mind. In relation to donations and grants and declarations of involvement the Panel noted Clause 23.2 stated that such involvement should be made clear to the extent possible. The Panel considered that the qualification 'to the extent possible' reflected the fact that Clause 23 applied equally to donations and grants, and donations might include benefits in kind and services. Clause 25.3 which applied to, amongst other things, relationships with patient organisations, required companies to ensure that all sponsorship was clearly acknowledged at the outset. The Panel further considered that, whilst not at issue, it was important to bear in mind that Clause 27.2 set out the requirements for the mandatory written agreement with patient organisations for donations, grants and sponsorships and required the inclusion of a statement that 'all parties

are fully aware that the donation, grant or sponsorship must be clearly acknowledged and apparent from the start.'

The Panel therefore considered that a declaration of involvement for the patient organisation material at the bottom of what appeared to be a continuously scrolling webpage was inadequate and failed to satisfy the requirements of Clause 25.3 that the sponsorship should be clearly acknowledged from the outset. A **breach of Clause 25.3** was ruled.

The Panel noted the relevant requirements of Clause 23.2 that "company involvement should be made clear for donations and grants to the extent possible" and bearing in mind its comments and ruling above in relation to Clause 25.3 it followed that the declaration of involvement did not meet the requirements of **Clause 23.2 and ruled a breach** accordingly.

On balance the Panel decided that the circumstances did not warrant a breach of Clause 5.1 as the declaration of involvement was not absent from webpage in question. The Panel therefore ruled **no breach of Clause 5.1**.

### **The patient information booklets (x3)**

The Panel considered the allegation that three patient information booklets produced by the patient organisation did not include a declaration of involvement from Jazz. The Panel noted that the webpage at issue above referred to browsing the materials however it was clear from the linked webpages that they were downloadable and it appeared that printed copies of certain materials were available. The booklets at issue were titled:

- Could it be [medical condition] [downloadable from a page headed "[medical condition] symptoms guide and download"]
- [Medical condition 2]
- Your [medical condition] diagnosis: What happens now?

Jazz submitted that they "did not provide funding for the three information booklets as alleged by the complainant but instead provided an unrestricted grant for the whole project." The Panel noted that the grant agreement did not identify specific materials but it was clear that it was intended to be an unrestricted grant for a specific purpose; patient information including printed materials, rather than for the organisation's core funding. In the Panel's view and in accordance with the principle of transparency, the material produced for patients and their health professionals to provide to patients as a result of such funding ought to make the source of the funding clear. They were downloadable and available in printed form and had to stand alone in relation to the requirements of the Code. They could not take the benefit of a declaration on a linked webpage which in any event was inadequate and had been ruled in breach of the Code above.

The Panel noted its comments above in relation to the grants and sponsorships and the relevant requirements of Clauses 23 and 25 in relation to patient organisations and considered that they applied here. The Panel noted that none of the patient leaflets featured a declaration of involvement and therefore they each failed to satisfy the requirements of Clause 25.3 that the

sponsorship should be clearly acknowledged from the outset. A **breach of Clause 25.3** was ruled in relation to each booklet.

The Panel noted the relevant requirements of Clause 23.2 that “company involvement should be made clear for donations and grants to the extent possible” and bearing in mind its comments and ruling above in relation to Clause 25.3 it followed that the failure to include a declaration of involvement did not meet the requirements of **Clause 23.2 and ruled a breach** accordingly in relation to each booklet.

The Panel was particularly concerned that patient materials did not include a declaration of sponsorship given the specific requirements in the Code about arrangements with patient organisations including that the agreement should include a statement that the donation, grant or sponsorship must be clearly acknowledged and apparent from the start. The grant agreement required a declaration to be prominent but gave no further guidance about its location. There was no allegation about the agreement. The Panel was also concerned that Jazz’s response indicated that it did not consider that it had a responsibility to require that a declaration appear on the materials at issue. In these circumstances the Panel **ruled a breach of Clause 5.1** of the Code as high standards had not been maintained.

## **Clause 2**

The Panel considered that the complainant’s concerns were adequately covered by its rulings of breaches above. The Panel did not consider that the particular circumstances of this case warranted a breach of Clause 2 which was reserved to indicate particular censure; **no breach of Clause 2** was ruled.

**Complaint received**      **7 June 2024**

**Case completed**        **9 July 2025**