

## **COMPLAINANT v SOBI**

### **Allegations about a corporate article**

#### **CASE SUMMARY**

This case was in relation to an article sponsored by SOBI (Swedish Orphan Biovitrum Ltd) and published in the print and online versions of The Guardian.

The Panel ruled no breach of the following Clauses of the 2021 Code because:

- it did not consider that the complainant had established that the article advertised prescription only medicines to the public or that the article was disguised promotion
- it considered that the context of the phrase ‘without compromise’ was sufficiently clear in the heading ‘Taking steps to support people with haemophilia live life without compromise’ and the complainant had not provided any reasons to support the allegation that the phrase in question was ‘ludicrous’ and therefore had not established that it was either misleading or incapable of substantiation
- the complainant had not provided any detailed reasons to support their assertion that the statement in the article that Sobi was in “a unique position” because it was a small company was not a unique feature. The Panel considered that the statement in question primarily linked the company’s ‘unique position’ to its dedicated focus on rarer diseases, rather than its size and the complainant had not established that the claim at issue was misleading on the ground alleged
- it did not consider that mention of a tool called ‘liberation maps’ implied that patients would be liberated from haemophilia; the purpose of the tool appeared to be clear in the article and there was no evidence to support the complainant’s allegation that Sobi had mislead the reader by using the phrase ‘liberation maps’ or that there was a misleading implication that could not be substantiated
- in its view the statement regarding higher mortality rates in haemophilia referred to great strides having been made to improve therapies over the past 30 or 40 years, people with haemophilia having previously suffered from higher mortality and severe disabilities, it referred to an improvement in mortality rates over time and was not unqualified as alleged
- it did not consider that Sobi had linked the reference to sponsorships and grants to any Sobi medicines, either directly or indirectly such that the article was contrary to Clause 23.2 as alleged
- it noted that reference to wraparound services in the article in question referred to the fact that the condition was not just treated by the clinician but by a whole set of wraparound services, among other things and considered that the statement at issue appeared to be reasonably clear and the complainant had not established why failure to identify the services or explain the patient benefit rendered the statement in breach of the Code the complainant made very broad allegations in relation to ‘indirect attempts pharma companies made to indirectly promote drugs

through advocacy group pressure' but provided no evidence to support them it did not consider Sobi had failed to maintain high standards in relation to those matters within the scope of the complaint

<b>No Breach of Clause 3.6</b>	<b>Requirement that materials and activities must not be disguised promotion</b>
<b>No Breach of Clause 6.1</b>	<b>Requirement that information must not be misleading</b>
<b>No Breach of Clause 6.2</b>	<b>Requirement that claims/information/comparisons must be capable of substantiation</b>
<b>No Breach of Clause 23.2</b>	<b>Requirement that grants and donations to healthcare organisations, patient organisations or other organisations do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines</b>
<b>No Breach of Clause 26.1</b>	<b>Requirement not to advertise prescription only medicines to the public</b>
<b>No Breach of Clause 27.1</b>	<b>Requirement that when pharmaceutical companies interact with patient organisations or any user organisation, companies must not promote or request the promotion of a particular prescription only medicine</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, non-contactable complainant about an article sponsored by Sobi (Swedish Orphan Biovitrum Ltd) and published in the print and online versions of The Guardian.

## **COMPLAINT**

The complainant alleged this was an utter garbage article with absolutely no purpose other than for a commercial director to indirectly promote. The title was utter rubbish in context. Sobi offered patients to 'live a life without compromise' which was ludicrous, 'a unique position' because it was a small company when this was not a unique feature, a tool called 'liberation maps' for patients who would absolutely not be liberated, unqualified statements regarding 'higher mortality rates in 'Hae' [haemophilia] compared to other therapy areas', no medical insights for patients or groups as this was about a brand manager soliciting to get closer to health professionals, claims that its tools would 'empower patients to take a firm grip' on 'Hae', promotion of sponsorships and grants available to patient groups, claims of 'a whole set of wraparound services' without saying what these were or how they would benefit patients. The whole article was a commercial spin from a company that disrespected medical approvers. [Director of PMCPA], really needed to clean up this type of media hype from pharma. Just

because a company promoted a product the 'around the houses' approach also really must be stopped. Patients and health professionals were not fooled with the indirect attempts pharma companies made to indirectly promote medicines through advocacy group pressure. Yes, Sobi had dropped sufficient clues in the advertisement that they were selling medicines in the therapy area, or they would not have gotten involved in the first place.

When writing to Sobi, the Authority asked it to consider the requirements of Clauses 3.6, 5.1, 6.1, 6.2, 23.2, 26.1 and 27.1 of the Code.

## **RESPONSE**

Sobi stated that it was fully committed to strict adherence to the Code and all applicable laws and regulations. As a member of the ABPI, Sobi was dedicated to applying high standards at all times across all areas of its business and, similarly to the PMCPA, it stated that it took any and all complaints seriously.

Sobi respectfully rejected all the allegations in the complainant's letter.

Sobi stated that it recognised that perspectives might differ and the company strove to ensure that all of its activities were aligned with the requirements of the Code. Sobi believed it had achieved that in this instance.

## **Background**

Sobi stated that it worked in partnership with The Guardian newspaper to generate an article that explained the company's commitment to haemophilia and that the article was sponsored by Sobi. The article was certified by its Medical Director and went live on the website on Tuesday 11 October. It seemed that the PMCPA was contacted shortly after the article went live. A print version was also distributed with that day's newspapers.

Sobi stated that it was important to note that the article did not identify any Sobi product. It was an established principle that pharmaceutical companies could raise their corporate profile and the profile of their corporate activities in a compliant manner, aligned with the Code. Sobi also submitted for context, it might also be relevant to note that the Sobi article was one element of a series placed by other pharmaceutical companies in the same document, covering a wide range of medical conditions. A copy was provided for reference.

Sobi noted that the case preparation manager had listed several clauses of the Code through inference of the complainant's letter, and it addressed each in turn.

## **Clauses raised by the PMCPA and associated concerns raised by complainant (2021 Code)**

### **3.6 Materials and activities must not be disguised promotion**

Sobi submitted that there were at least 20 licensed treatments for haemophilia in the UK, only a small number marketed by Sobi. It was not possible to identify the name of any individual Sobi medicine from the content of the article. In fact, nothing in the article even hinted that it had a product either in the market or in development. Sobi stated that it was not going to name the

product in the response letter because as the name was not identifiable from the article, readers of the response letter would need to make a deliberate and conscious effort to look it up. Therefore, in accordance with Clause 1.17, Sobi submitted that as it had not identified a medicine, there could not have been any promotion, disguised or otherwise.

Sobi denied a breach of Clause 3.6.

**6.1 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.**

Sobi stated that it was a little difficult to identify the specific elements that the complainant believed were of concern, but it interpreted that they focused on the fact that the company was 'offering patients a life without compromise'. Sobi rejected the complainant's allegations that it had acted inappropriately.

Sobi submitted that a life without compromise was the ultimate aspiration of all medical care; in that regard, haemophilia was no different. Huge strides had been made in the care of patients with haemophilia in recent years, such that patients could actively participate in contact sport without fear. In this context, Sobi's statements were made in the context of an '*up to date evaluation of all the evidence*'; they '*reflect that evidence fairly*'.

Sobi stated that in fact, other sources supported the progression in the management of Haemophilia. These included a charity-funded article in the Guardian (<https://www.theguardian.com/global-development/commentisfree/2022/jun/14/haemophiliacs-the-world-still-in-dark-ages-acc>); and the World Federation of Haemophilia guidelines (WFH Guidelines for the Management of Hemophilia, 3rd edition ([haemophilia.org.uk](http://haemophilia.org.uk))), which stated that:

*'Over the past five years, unprecedented progress has been made not only in the development of newer therapeutics for hemophilia, but major paradigm shifts have also occurred in many of the principles governing the planning and philosophy of hemophilia treatment'*

*'People with hemophilia ... are now able to participate in many more activities than ever before without fear of bleeding'*

Sobi noted that the very first page of a respected patient organisation, declared on its website:

*'Because a bleeding disorder shouldn't define who we are, what we do or how we feel. Through our community, we find the freedom, opportunity and fun in life after diagnosis.'*

Sobi submitted that a check in various dictionaries made it clear that 'Compromise' (used as a noun and a verb) did not mean banishment of all aspects of a condition (medical or otherwise), but the achievement of acceptable standards that were agreeable by all.

Sobi included the following:

**noun**

noun: compromise; plural noun: compromises

*an agreement or settlement of a dispute that is reached by each side making concessions.*

'eventually they reached a compromise'

Similar: agreement; understanding; settlement; terms; accommodation; deal; trade-off; bargain; balance; modus vivendi; give and take; concession; cooperation

*the expedient acceptance of standards that are lower than is desirable.* 'sexism should be tackled without compromise'

**verb**

verb: compromise; 3rd person present: compromises; past tense: compromised; past participle: compromised; gerund or present participle: compromising

*settle a dispute by mutual concession.*

"in the end we compromised and deferred the issue"

Similar:

meet each other halfway; find the middle ground; come to terms; come to an understanding; make a deal; make concessions; find a happy medium; strike a balance

*expediently accept standards that are lower than is desirable.*

'we were not prepared to compromise on safety'

Sobi stated that clearly, 'compromise' was not the same as 'perfection', or 'utopia' in the near-dismissal of the fact a medical condition existed, but achievement of sufficient normality that the medical condition became something that could be managed without it hindering the way an individual lived their life. SOBI firmly believed that haemophilia sufferers could and did live lives without compromise.

Sobi also noted that the ABPI itself used the phrase in the context of the welfare of animals undergoing medical testing:

*'You are in a position where you're advising people, and you may need to tell people things they may not want to hear, for example if a study is compromising the welfare of the animal you need to tell them to stop the study which might be crucial to the development of a new drug. That can be very difficult, but you are there to safeguard the welfare of the animals.'* (<https://www.abpi.org.uk/careers/job-case-studies/veterinary-surgeon/>)

Sobi stated that the title of the article was appropriate in context: **Taking Steps** to support people with haemophilia live a life without compromise (emphasis added). There was no claim

that Sobi, or the NHS or anyone could remove all compromise, but Sobi was proud of the efforts made by the entire medical community (including Sobi, NHS, patient organisations and the patients themselves) to achieve the aspiration of normality. Sobi believed that near-normality had already been achieved. The opening paragraph explained this aspirational community goal:

*'An innovative biopharmaceutical company is committed to working with the haemophilia community to improve patient quality of life is mobilising various initiatives to bring about greater collaboration.'*

Sobi added it, however, made no comments about its products helping achieve this; only of the aspiration and some examples of the steps taken towards it. The Patient Advisory Council was a group of patients who helped Sobi ensure that the projects undertaken were appropriate for the modern, diverse, patient community. The quote from Sobi's Director of Patient Access and Community Engagement (PACE) stated clearly that such initiatives

*'**help empower patients** to continue to take a grip on their condition and live a life without compromise'* (emphasis added).

Sobi stated that the clear focus was on assistance and empowerment; it was most definitely *not* a claim that Sobi was itself offering patients a life of perfection but striving towards a life without hindrance.

A senior commercial Sobi' member of staff was also quoted in the article. The staff member focused on some of the tools that Sobi had developed:

*'Through our patient-focused campaign, Liberate Life, we have created tools and resources to support people with haemophilia to live life without compromise.'*

The BUD also clearly referred to the **support** provided by Sobi; again there was no claim that haemophilia was a dismissible illness or that Sobi could offer a utopian ideal. The staff member merely stated that Sobi was assisting (providing support) to achieve life without compromise (hindrance).

Sobi submitted that the comments about the Liberation Maps tool were made in the context of the statement that women were diagnosed with haemophilia less frequently than men and so consequently faced different challenges to that usually experienced in the management of the condition.

*'A good example is Liberation Maps, an interactive, shared decision-making tool that we developed in collaboration with the patient advocacy community to support patients in their consultations with healthcare professionals to really get to the bottom of any difficulties or challenges they are facing.'*

By identifying the challenges so that health professionals and patients could discuss them openly, the hindrance could be removed and the patient would no longer need to compromise on that aspect of their life.

Sobi denied any breach of Clause 6.1.

### **6.2 Any information, claim or comparison must be capable of substantiation.**

Sobi noted that the complainant had not asked for substantiation, which it would have been happy to provide.

Sobi trusted from its discussion of the phrases related to “a life without compromise” above, that it had demonstrated that it had not misled readers; and that it could substantiate the statements it made in the article. Sobi stated that it was proud of its efforts to assist the community and believed its actions and descriptions of those actions were in line with the aspirations of the ABPI itself and of the wider industry.

Sobi denied any breach of Clause 6.2.

### **23.2 Donations and grants to healthcare organisations, patient organisations or other organisations are only allowed (under certain stated conditions)**

Sobi submitted that it believed the reason the PMCPA had highlighted Clause 23.2 was that the complainant mentioned the “*promotion of sponsorships and grants available to patient groups*”

The BUD did mention the availability of such Donations:

*“We are proud to work in partnership with haemophilia-focused advocacy groups across the UK and Ireland on a number of goals, both through collaborative projects and through the provision of sponsorship and grants”*

Sobi submitted that there was nothing in the Code that prevented companies from telling organisations that such support existed. In fact, Sobi was bound by the Code to ensure all such funding was fully and transparently disclosed, and it abided by this with the annual publication. Sobi believed it would be ludicrous if such a ban existed as the stakeholders would never know that funding and resources were secretly available! Sobi stated that it was much more appropriate that access to such resources was openly and transparently discussed and that proper procedures, as laid out in the Code and in Sobi’s SOPs, and a robust control process was in place to separate the provision of such support in isolation from commercial considerations about the recipient organisation.

Sobi denied any breach of Clause 23.2.

### **26.1 Prescription only medicines must not be advertised to the public.**

Sobi stated that it was not possible to tell from the content of the article what the name of its product in this therapy area was. In fact, nothing in the article even hinted that it had a product either in the market or in development. Sobi stated that it was not going to name the product in its response letter because as the name was not identifiable from the article, readers of this response letter would need to make a deliberate and conscious effort to look it up. Therefore, Sobi believed there could not have been any promotion.

Sobi denied any breach of Clause 26.1.

**27.1 When pharmaceutical companies interact with patient organisations or any user organisations such as disability organisations, carer or relative organisations and consumer organisations, companies must (meet certain conditions stated in the Code)**

Sobi stated that it believed the reason the PMCPA had included Clause 27.1 in the complaint was because of the phrase by the complainant:

*'indirect attempts pharma companies make to indirectly promote drugs through advocacy group'*

Sobi stated it could not identify any specific concerns raised by the complainant beyond this very general allegation. As such Sobi was unable to investigate any specific activities.

Sobi reassured the Panel that all activities undertaken with Patient Organisations underwent certification in accordance with the requirements of the Code. None of those activities promoted medicines to or through Patient Organisations. All interactions were declared openly on the Sobi website as required by the Code.

Sobi denied any breach of Clause 27.1.

**5.1 High standards must be maintained at all times**

Sobi stated it was proud of its activities to support the haemophilia community. Sobi operated to the highest standards and believed its actions to be fully in line with the requirements of the ABPI Code. Sobi's internal considerations of matters discussed above, provided ample evidence of the openness with which it debated and considered appropriate courses of action.

Sobi submitted that it denied all other alleged breaches in the complaint; and accordingly, denied breaching Clause 5.1.

**Additional Background: Internal investigation**

Sobi stated that it was also important that PMCPA was aware that it operated a robust internal procedure for identifying and addressing risk. Sobi made a detailed submission about a new compliance member of staff and compliance concerns about the article in question.

Without consulting either the General Manager (who was on annual leave) or the Medical Director, the new compliance employee acted independently and directed that the article should be withdrawn from The Guardian website until such time as further discussions could occur.

The article had, therefore, already been withdrawn by the end of the day it was first published. Sobi confirmed that the article was not currently live when responding to the complaint.

Sobi stated that internal discussions had since been held and the General Manager and Medical Director, along with the regional compliance function, and Sobi stood by the decision to certify



and release the article. This was in line with its internal processes and as outlined in its response, Sobi believed the content of the certified article was appropriate and substantiable. Accordingly, Sobi stated, it could have been republished on The Guardian website; but out of respect for the PMCPA and the anonymous complainant, it held back from doing so until such time as this case was resolved.

Sobi advised that since the complaint was raised, it had identified that the online and hardcopy versions of the article portrayed a different image in the introduction to the article. Owing to the digital format of the online version there was a slightly different structural layout. Sobi submitted that it had certified the final version of what it believed to be both the hardcopy and digital versions prior to issuance. Sobi did not believe the image used in the online variant in any way changed the context of the article or its formal response to this complaint.

Sobi stated that it offered the information above in full and frank disclosure and thanked the PMCPA for bringing it to its attention.

Sobi stated that it wished to assure the Panel of its commitment to the Code, and of the General Manager's commitment personally.

## **PANEL RULING**

The Panel noted a complaint had been received from an anonymous, non-contactable complainant about an online article which appeared in the Guardian titled 'Taking steps to support people with haemophilia live life without compromise' and was paid for by Sobi. The Panel noted Sobi's submission that the article was developed in partnership with the Guardian newspaper with the intention of explaining the company's commitment to haemophilia.

The Panel noted the complainant raised concerns that the article was developed for 'no other purpose than for a commercial director to indirectly promote'. The complainant also raised concerns about the context of the article in that the title offered 'patients to live life without compromise'; that the term unique in relation to the size of the company was not a unique feature, that, a Sobi developed tool called liberation maps would not 'liberate patients' as claimed; that the article contained 'unqualified statements regarding higher mortality rates in Haemophilia compared to other therapy areas'; there were 'no medical insights for patients or groups' as the article was 'about a brand manager soliciting to get closer to HCP(s)' and that the article 'promoted sponsorships and grants available to patient groups'. The complainant alleged that the article constituted a 'commercial spin' and that the company 'disrespects medical approvers'. The complainant also alleged that Sobi had 'dropped sufficient clues in the advertisement that they are selling drugs in the therapy area'.

The Panel noted that the Constitution and Procedure stated that the complainant had the burden of proving their complaint on the balance of probabilities. All complaints were judged on the evidence provided by both parties. When ruling on this complaint, the Panel noted the broad nature of the allegations and noted that it was not for the Panel to infer what the complainant meant if this was not sufficiently clear on the face of the complaint. The complainant was non-contactable so it would not have been possible to ask them for further information.

The Panel noted that the imagery and layout of the article provided by the complainant differed from the certified article submitted by Sobi, however, there only appeared to be one certificate for both items (NP-23595, Date of Preparation September 2022). It appeared to the Panel that whilst the items looked different in terms of imagery and layout; the written content appeared to be the same. The Panel made its ruling based on the article from the link provided by the complainant.

The Panel noted Sobi accepted that it was responsible for the article.

The Panel noted that the complainant had raised a number of matters that potentially fell within Clauses 3.6 and 26.1 of the Code, the latter Clause prohibited the promotion of prescription only medicines to the public. The complainant alleged that 'this was an utter garbage article with absolutely no purpose other than for a commercial director to indirectly promote'. The complainant alleged that Sobi had 'promoted a product (via) the around the houses' approach and the 'indirect attempt pharma companies made to indirectly promote drugs through advocacy group pressure' did not fool health professionals. The complainant also alleged 'Sobi had dropped sufficient clues in the advertisement that they were selling medicines in the therapy area, or they would not have gotten involved in the first place'. The Panel noted that the complainant had made very broad allegations and had not provided any evidence to support their concerns of direct, indirect (or disguised) promotion. It was not for the Panel to infer what the complainant meant by their comments or which Clauses of the Code they believed had been breached. The Panel noted Sobi's response in relation to Clauses 3.6 and 26.1 on this matter and its submission that there were at least 20 licenced haemophilia treatments available in the UK and only a small number were marketed by Sobi and that the article neither included nor hinted at any Sobi medicines either directly or indirectly. Whilst the Panel had concerns about the article, in the Panel's view, it discussed corporate activities and did not appear to directly or indirectly identify medicines. Further whilst a reader might infer that the company had a commercial interest in the subject matter of such articles their publication was not unacceptable so long as they complied with the Code. Noting its comments above, the Panel did not consider that, in its view, the article at issue was promotional. The Panel did not consider that the complainant had established that the article advertised prescription only medicines to the public or that the article was disguised promotion and ruled **no breach of Clauses 26.1 and 3.6** accordingly.

The complainant alleged that 'the title was utter rubbish in context' and stated that Sobi offered patients to 'live a life without compromise which was ludicrous'. The Panel noted that the title read 'Taking steps to support people with haemophilia live life without compromise'. The Panel noted that the complainant had not explained why they considered the title to be ludicrous nor provided any evidence to support their allegation. It was not for the Panel to infer what the complainant meant by their statement. The Panel noted Sobi's response including that it did not believe it had acted inappropriately, and that 'a life without compromise' was aspirational in relation to all medical care including haemophilia. The Panel noted Sobi had responded to Clauses 6.1 and 6.2 of the Code in relation to this allegation and therefore made its ruling based upon those Clauses. The Panel noted that the phrase 'without compromise' in the heading was qualified by the preceding text which referred to taking steps to support people with haemophilia live life. In the Panel's view the qualifying text meant the heading overall appeared to be an aspirational statement, as submitted by Sobi. The Panel noted that the phrase 'without compromise' appeared a further 3 times within the article but noted that these were not the subject of complaint as the complainant had referred specifically to the title of the article. The Panel considered that the context of the phrase 'without compromise' was sufficiently clear in

the heading. The Panel noted its comments above and that the complainant had not provided any reasons to support the allegation that the phrase in question was 'ludicrous' and therefore considered that the complainant had not established that the phrase was either misleading or incapable of substantiation contrary to either **Clause 6.1 or Clause 6.2** and the Panel therefore **ruled no breach of each Clause** accordingly.

The complainant questioned the statement in the article that 'Sobi was in "a unique position" because it was a small company when this was not a unique feature'. The Panel noted that Sobi had reproduced the allegation in question when responding to Clause 6.1 and thus considered it under this clause. The Panel noted that the relevant text in the article at issue read: 'We are a smaller company, but because we have this dedicated focus on rarer diseases, we feel it uniquely positions us to get very close to our communities and listen to our patients and clinicians.' The Panel noted the complainant had not provided any detailed reasons to support their assertion. The Panel considered that the statement in question in the article primarily linked the company's 'unique position' to its dedicated focus on rarer diseases, rather than its size as implied by the complainant. The Panel therefore considered that the complainant had not established that the claim at issue was misleading on the ground alleged and **no breach of Clause 6.1 was ruled** in this regard.

The complainant also alleged that the article mentioned 'a tool called liberation maps for patients who would absolutely not be liberated'. The Panel noted the complainant had not provided any evidence to support the allegation that patients would not be liberated and further why they were concerned about this statement, it was not for the Panel to infer what the complainant meant. The Panel noted that Sobi responded to this matter in relation to Clauses 6.1 and 6.2 and the Panel thus considered the allegation under these Clauses. Sobi submitted that the comments about Liberation Maps were in the context of the differences of managing the condition between men and women which allowed health professionals and patients to discuss these challenges openly and 'patients would no longer need to compromise on that aspect of their life'. The Panel noted that the article referred to Liberation Maps as an example of a tool and resource it had created as part of Liberate Life to support people with haemophilia to live their lives without compromise and described it as an interactive shared decision-making tool to support patients in their consultations with health professionals. The relevant section of the article did not refer to differences in managing the condition in men and woman as inferred by Sobi. What were described as unique challenges faced by women were referred to in the preceding section, Challenging Inequity. The Panel did not consider that there was any implication in the article that Liberation Maps would liberate patients as alleged. There was no implication that patients would be liberated from haemophilia. The purpose of the tool appeared to be clear in the article. The Panel considered that there was no evidence to support the allegation that Sobi had mislead the reader by using the phrase 'liberation maps' or that there was a misleading implication that could not be substantiated and therefore ruled **no breach of Clause 6.1 and subsequently no breach of Clause 6.2**.

The complainant alleged that Sobi had made 'unqualified statements regarding higher mortality rates in Hae [haemophilia] compared to other areas'. The Panel noted the complainant had not provided any evidence to support why they were concerned about this statement, and it was not for the Panel to infer the complainant's concerns. The Panel noted that the statement in the article referred to great strides having been made to improve therapies over the past 30 or 40 years, people with haemophilia having previously suffered from higher mortality and severe disabilities. It was not an unqualified statement about current mortality rates as implied by the complainant. It was not clear what the complainant meant by the phrase 'other areas'. The

Panel also noted Sobi had not responded directly on this matter. The Panel considered it appropriate to consider the matter under Clause 6.1. In the Panel's view the statement in question was not unqualified as alleged, it referred to an improvement in mortality rates over time, and the Panel therefore ruled **no breach of Clause 6.1**.

The complainant raised concerns about 'no medical insights for patients or groups as this was about a brand manager soliciting to get closer to HCPs'. The Panel considered that the nature of the concern was unclear, it did not appear to be an allegation of a breach of the Code. It was not for the Panel to infer what the complainant meant. In these circumstances the Panel decided that it did not have a bona fide allegation and was thus unable to rule on this matter.

The complainant also raised concerns that Sobi made claims that their tools would 'empower patients to take a firm grip on Hae [haemophilia]'. The Panel noted that the complainant had not stated why they were concerned about this statement. The allegation was unclear. The Panel noted that the article at issue referred to a patient advisory council developing educational initiatives and tools which the company hoped would help empower patients to, amongst other things, take a firm grip on their condition. The statement in question was not an unequivocal statement that the tools would empower patients as inferred by the complainant. Whilst the complainant had identified the statement they had not directly or indirectly stated why they considered that it was in breach of the Code. The Panel decided that it did not have a bona fide allegation and was thus unable to rule on this matter.

The complaint alleged Sobi had promoted 'sponsorships and grants available to patient groups'. The Panel noted that Clause 23.2 related to donations and grants to healthcare organisations, patient organisations and other organisations; and the Code did not prevent the provision of grants and donations to patient organisations as long as they met the requirements of Clause 23 and were not provided to individuals or linked directly to the promotion of medicines. The Panel did not consider that the article promoted sponsorships and grants as alleged, rather it stated that the company was proud to work in partnership with haemophilia advocacy groups on a number of goals, both through collaborative projects and through the provision of sponsorships and grants. The article in question referred to Sobi wanting to see the pharmaceutical industry work more closely with clinicians and patient organisations. The Panel did not consider that Sobi had linked the reference to sponsorships and grants to any Sobi medicines, either directly or indirectly such that the article was contrary to Clause 23.2 as alleged. The Panel therefore ruled **no breach of Clause 23.2**.

The complainant also expressed concerns about 'claims of a whole set of wraparound services without saying what these were or how they would benefit patients'. The Panel noted that the reference to wraparound services in the article in question referred to the fact that the condition was not just treated by the clinician but by a whole set of wraparound services, among other things. The Panel considered that the statement at issue appeared to be reasonably clear and that the complainant had not established why the failure to identify the services or explain the patient benefit rendered the statement in breach of the Code. The complainant had not provided any evidence to support their assertion and Sobi had not responded to this broad allegation directly. Noting its comments above the Panel ruled **no breach of Clause 6.1**.

The complainant was concerned that the whole article 'was a commercial spin and utter garbage from a company that disrespected medical approvers'. The Panel noted that the meaning of the allegation was unclear in relation to what it meant and whether it raised a Code matter. Little detail was provided. It was not for the Panel to infer meaning on the

complainant's behalf. The Panel noted the complainant had not provided any explanation or evidence to support why they were concerned about this matter. The Panel also noted Sobi had not responded directly to the matter. On this very broad allegation the Panel was therefore unable to make a ruling.

The Panel noted the case preparation manager (CPM) had also raised Clause 27.1 in relation to the responsibilities companies must consider when working with patient organisations and the like. Clause 27.1 stated, among other things, that when interacting with patient organisations companies must not promote or request the promotion of a particular prescription only medicine. The Panel noted the complainant's allegation in relation to 'indirect attempts pharma companies made to indirectly promote drugs through advocacy group pressure' and also noted Sobi's comments that the complainant had made very general allegations and that no evidence had been provided by the complainant to support these broad allegations. The Panel noted the complainant bore the responsibility of proving their complaint on the balance of probabilities and in this matter had not done so, therefore based on the very broad allegations made by the complainant and the lack of evidence to support them, the Panel ruled **no breach of Clause 27.1**.

The Panel had some concerns about the article but noted that these were not the subject of complaint. Given the above considerations and rulings, the Panel did not consider Sobi had failed to maintain high standards in relation to those matters within the scope of the complaint and therefore ruled **no breach of Clause 5.1**.

**Complaint received**      **11 October 2022**

**Case completed**        **27 July 2023**