**CASE AUTH/3535/7/21**

# EMPLOYEE v SOBI

## Concerns about representative's activities, meetings and materials, and training

**A complainant who described him/herself as an employee of Sobi complained about three matters, field force activities, meetings and marketing material and representative's training.**

### 1 Haematology Field Force Activities

**The complainant stated that the Sobi UK commercial and medical field teams had responsibility for two products in the rare disease area of haemophilia, Elocta (efmoroctocog alfa) and Alprolix (eftrenonacog alfa). Prior to 2019 the focus was on patient outcomes however with the addition of a new competitor to the market place the focus had become heavily focused on activity.**

### 1.1 Alleged pressure to falsify calls and overcall on health professionals

**The complainant stated that there had been over the last year significant pressure to increase activity with no regard for the Code. Briefings regarding activity were predominantly done verbally and there were usually no briefing documents.**

**A 'WhatsApp' message sent by a manager in 2020 to the sales team before an international conference suggested that '[he/she] was on a call regarding activity the previous day and the consensus from the top was that if you 'smell' a customer at this meeting record it as a F2F' (face to face).**

**The complainant stated that the pressure for activity appeared to come from global. An activity report was run every Monday morning for all brands and field teams and there was a meeting with global looking at the weekly activity of all the affiliates across Europe including the UK which was attended by senior members of the UK Leadership Team.**

**In July 2020, the sales team was increased as there was going to be an additional product to promote and an additional group of customers to call on. This resulted in a smaller group of haemophilia customers. The complainant stated that he/she lost a third of his/her customers to a newly created territory. The complainant referred to an email he/she sent in November 2020 expressing concern regarding overcalling and the potential to breach the Code and did not receive a response.**

**The complainant stated that activity continued to be raised at the weekly cross functional team meeting. The call rate was almost doubled in November 2020on two thirds of the number of customers. The complainant stated that he/she raised his/her concerns in this regard which went unheeded.**

**A transcript and accompanying audio of the last ten minutes of meeting held in February 2021 with all the commercial sales team in attendance was provided. At that meeting a manager stated that there was discussion at the Leadership Team level the previous day about activity and that the UK performance was looking poor compared to the European teams. The manager explained that this was because the European affiliates had been creative with how they recorded their calls. The manager suggested that instead of recording one call for both products as normally done in the customer relationship management (CRM) system, they should create two calls instead- one for each product. The audio captured the sales force pushing back against this suggestion and that the employee made clear he/she had been asked to 'sound us out'.**

**The complainant provided the audio and transcript of the weekly cross functional meeting in March 2021 after the MSL was asked to leave which referenced that a senior leader and another employee had talked about how emails were being recorded. He/she then gave 'permission' to log an email that had 'moved the business forward' (no definition of this was given) as a phone call. This was significant because a phone call counted towards overall activity. The senior leader then continued to reference the pressure for activity. The complainant stated that he/she could be heard stating that he/she would be uncomfortable doing this and he/she did not action this direction. After this meeting members of the sales force started to follow this direction. This could be seen in the increased activity figures reported at subsequent cross functional weekly meetings.**

**All calls were recorded in the CRM system. The data from this pulled through to a series of dashboards which contained activity data, patient numbers per account, one dashboard compared the activity that had taken place in that account with the patient numbers. The dashboard also registered who had called on customers eg, the KAM/MSL and how the interaction was logged eg, phone call, email, virtual meeting. An area of major concern the complainant regularly raised was the contacting of customers by the UK and by the global teams and the significant overcalling on certain customers, including a named health professional during 2019.**

**1.2 Alleged concern that patient identifiers were shared with commercial/medical teams**

**The complainant stated that the dashboard also contained data from the homecare provider, which included patient identification numbers. The complainant raised this issue but inclusion of these identifiers had continued.**

**1.3 Alleged disguised market research/promotion (Take Control Survey)**

**The complainant stated that throughout the period of the pandemic Haemophilia patients had been less active. The impact of this was that they had used less factor as they were not bleeding as much, resulting in a reduction in the use of Elocta leading to lower revenues which concerned Sobi. In March 2021 two days before a webinar, a senior Sobi employee asked another employee to contact the Chair of a Sobi promotional webinar to ask for additional slides to be included. These slides were part of a global initiative, 'Take Control Survey', to ascertain what was driving the lower use of factor and whether there was an intention to increase it at any point soon. There was a visual briefing to the Sales and Medical field team, however no copy of the briefing was sent out. The survey**

**required the KAM/MSL to show a series of slides which included four questions which were recorded in the CRM system after recording a call for Elocta against a health professional. Verbally the sales team was advised that there would be a financial incentive to actioning the survey as the aim was to cover as many health professionals as possible. An email had been sent to senior employees outlining the required coverage and recording of the survey and how it would pull through to the relevant metric dashboards. The complainant raised concerns that this could be seen as disguised market research to his/her manager and another named employee which were ignored. It was apparent that there was now a second wave of this survey.**

**1.4 Sales manager contacting patients**

**The complainant stated that in April 2021 a sales manager sent an email and a publication to the commercial sales team. The email stated that he/she had been speaking with a named Haemophilia patient, who ran his/her own consultancy, to organise some training. Sobi's own internal policy known as iHIP stated that Patient Organisations should be dealt with by the Patient Access Team.**

**2 <u>Meetings and Marketing Material</u>**

**2.1 Health professional contracts**

**The complainant stated that a health professional raised a complaint regarding a virtual meeting at which he/she had been asked to present. The meeting had been cancelled and the health professional had completed the slide presentation at the request of the complainant's commercial colleague, who was organising the meeting. A haemophilia team had approached a named Sobi employee and asked if he/she could organise a speaker on 'Acquired Haemophilia'.**

**The complainant stated that the problem with the meeting was twofold- acquired haemophilia was off label for Elocta and at the point the speaker complained, he/she had completed and sent the presentation but there was no speaker contract in place.**

**The complainant stated that a second webinar took place in April 2021, this time utilising health professionals from a named area. The slide rehearsal for the health professionals was the week commencing 2 April and the complainant was advised by a colleague that the contracts were only signed on the evening of the rehearsal and the work by all three health professionals had been completed by that point.**

**2.2 Certification and Review**

**The complainant referred to an email from a medical employee who in response to the complainant's questions regarding a slide deck advised that the complainant could send a customer a non-approved, medical slide deck that had expired. The complainant did not send the deck and raised his/her concerns with his/her manager who did not appear to have taken any action. The slide deck should not have been made available for a commercial colleague and should have been approved prior to such use.**

**The complainant referred to an email from a medical employee to an external agency responsible for the Sobi webinar series logistics. The slides that he/she was sending to**

**the agency were meant to be the final, approved version for the webinar taking place that evening (25 March 2021). The email highlighted that the name of one of the health professionals was inaccurate and had been amended on the slide deck being sent to the agency. He/she then asked a member of the marketing team to amend the name in the review system. The complainant alleged that the final deck was not reapproved with these changes.**

**2.3 Marketing activities**

**The complainant referred to an invitation to a webinar taking place on 25 March 2021 and where the wrong link had been sent and that the 'briefing document had the wrong job bag code'. A further email withdrawing that link was provided. The complainant stated that he/she told the sender that he/she needed to withdraw the link sent out on 26 February and this was not actioned until 3 March.**

**Training material sent out to the commercial field team for training purposes in September 2020 with job bag code ITM-0995 was missing a black triangle.**

**3 Training**

**The complainant alleged that there was no formal product training for Haematology within Sobi. New permanent staff received a series of online modules which were assigned through Sobi's online platform, via Global training. The online platform also included training which related to policies, procedures, and compliance. The complainant alleged that the material contained within the online platform was not reapproved by the UK approval system, and it was not always checked as to whether the correct modules had been included. Haematology team members would then attend three days induction as led by Global although this appeared to be only for permanent staff as two named contractors did not attend this ITC.**

**The complainant alleged that no formal curriculum had been developed as to what was the minimum standard for new commercial sales representatives. In addition it appeared that new commercial staff did not go through classroom training with medical. The complainant did not know of any product training completed by one of the named contractors. There seemed to be no storage of validations or training that had taken place. There was normally no follow up if people had missed the training. The complainant stated that he/she did not receive any training on the 'Take Control' survey slides.**

**3.1 Onboarding of new haematology sales representatives**

**The complainant stated that in July 2020 Haematology was restructured and three new positions were created. It became apparent that one of the employee's online system was missing crucial training courses which was raised by the employee with a training employee and his/her manager but no action was taken.**

**There had been a training session where a representative raised that he/she had been sent the wrong summary of product characteristics (SPC). The representative confirmed that he/she had not shared the SPC. The complainant stated that despite raising this with his/her manager, the training employee and a medical employee being aware of this,**

**the SPC was not formally withdrawn. Not all new field commercial staff had had final written product validations and for those who did they were not stored anywhere.**

**Reference was made to another new starter who had experienced the same problems regarding training modules. In fact, all four new starters experienced the same problem and lack of defined curriculum and training. The complainant stated that he/she believed it was this that had contributed to the meeting that another named employee attempted to organise on acquired haemophilia. He/she had not been adequately trained on either the therapy area or the process required for organising meetings.**

**3.2 Training Records**

**The complainant referred to training that employees were to attend and complete a quiz and that he/she received no information as to whether he/she had passed or failed the quiz. There was no record of the training validation kept in a central point; there was no accurate record of any training received since the complainant had been with Sobi.**

**The complainant referred to an email from the training employee to the UK organisation outlining that action would now be taken to follow up on any SOP training not completed. The complainant believed this was in response to concerns raised by him/her. The complainant did not know if this had been actioned however prior to this no action was ever taken.**

**The detailed response from Sobi is given below.**

**1 <u>Haematology Field Force Activities</u>**

**1.1 Alleged pressure to falsify calls and overcall on health professionals**

**The Panel noted that Sobi rejected the allegation that briefings regarding activity were predominantly done verbally and that there were usually no written briefing documents. The Panel noted that the complainant bore the burden of proof and did not consider that he/she had established his/her case on the balance of probabilities in relation to this allegation and no breach of the Code was ruled in this regard.**

**The Panel noted Sobi's acknowledgement that the unique circumstances of the 18 months prior to the complaint had been difficult and stressful for its key account managers who might have found it challenging to maintain the expected activity levels. Nonetheless, Sobi refuted any suggestion that it had encouraged or pressured its representatives to falsify records or conduct unsolicited calls on health professionals in excess of the maximum permitted under the Code.**

**The Panel noted Sobi's submission that activity levels or contact rates were not the same as the number of unsolicited calls and any pressure on sales representatives to meet target activity levels did not equate to pressure to conduct unsolicited calls or to fail to comply with Code requirements. Sobi based its UK activity targets on health professional contacts, which encompassed a broad spectrum, including solicited calls and interactions at meetings. The Panel queried whether it was appropriate to set targets for solicited calls noting that some of these could not be planned and in doing so might encourage KAMs to act in a way that might breach the Code to obtain such activity.**

**The Panel noted Sobi's submission that there was an increased focus on activity levels by management because the UK team was not meeting its internal targets and management discussed activity levels at a weekly cross functional meeting.**

**The Panel noted Sobi's submission that such discussion was entirely reasonable and appropriate as activity levels were an important key performance indicator (KPI) for any pharmaceutical sales team and there was nothing in the Code that suggested it would be inappropriate for a company to prioritise this metric. The Panel noted that it appeared that cycle plans also included the number of contacts and these were discussed at team meetings. Whilst the Panel noted that it was not necessarily unacceptable for companies to discuss representative's activity levels, provided the way in which it was done complied with the Code, in the Panel's view, noting the weekly discussions of the activity and the increased focus on activity levels by management as seen in the various correspondence provided by the complainant, the overall approach might be seen to put unreasonable pressure on representatives to increase their activity and potentially breach the Code in doing so. In this regard, the Panel noted that a senior leader sent an email to the sales team in February 2021 which included a screenshot of the activity by week for each named individual Key Account Manager(KAM).**

**Whilst the Panel was concerned that an email from a former manager, on 1 July 2020 to the sales team stated that his understanding that planned activity was unsolicited and should not exceed 3 in one calendar year had been challenged, and overruled, it noted that the email stated that recipients of the email needed to revisit their cycle plans and if a customer visit did not take place in H1 (assumed by the Panel to be the first six months of the year), plan for 3 in H2, unless this was unachievable. On the available information before it, the Panel considered that the email appeared not to be out of line with the supplementary information to the Code.**

**Further, the Panel noted that an email to staff dated 7 July 2020 stated that, through initial work, Sobi had recalibrated its customer interactions based on understanding the total interactions that took place in H1 and compiled its plans for unsolicited interactions in H2 that ensured that no customer would have more than three such interactions over the year.**

**The Panel noted Sobi's submission that its policies provided sufficient clarity on the distinction between (i) unsolicited calls and (ii) all calls, contacts or other interactions comprising engagement with health professionals and that the guidance in force throughout the period covered by the complaint was absolutely clear that sales representatives must not make more than 3 unsolicited calls on a health professional in a given year but stated that it was acceptable to undertake and plan more than 3 contacts/interactions with a health professional per year. The Panel further noted that Sobi acknowledged the importance of distinguishing unsolicited calls from other types of contact and its CRM system allowed such a distinction with markers for unsolicited calls and different types of interaction (emails etc).**

**The Panel nonetheless considered that each representative briefing that related to activity targets needed to stand alone and should refer to the Code requirements and definitions of a call versus a 'contact' as defined by Sobi.**

**In this regard, the Panel noted that the Minimum standards for CRM UK-RoI region (Job-Number: ITM-0889) dated June 2020 defined a call as either a face to face (FtF) meeting, a FtF interaction at a meeting, a virtual or remote meeting, a telephone call or an e-mail exchange; during which a meaningful discussion had taken place and that these should be recorded as product related or non-product related within the CRM. No differentiation was made between solicited and unsolicited calls. The Panel noted that in this document, the minimum standards for commercial teams included that target customers were being seen as required. The Panel noted it stated that if the minimum standards were not achieved on two occasions during a calendar year and there was no reasonable explanation, then the final end of year review rating would be no higher than 'below expectations' which would result in a loss of 50% of the annual bonus.**

**The Panel further noted Sobi's submission that the complainant's territory was changed whilst their activity rate remained the same. It appeared from communication provided by the complainant that his/her activity for virtual/phone meetings per day in November 2020 for haemophilia was almost doubled in February 2021. The communication sent in November 2020 in this regard referred to delivering a certain number of haemophilia calls per week if the daily level was achieved. According to the communication sent in February 2021, in this regard, the activity should be made up of either promotional phone calls or virtual meetings. The Panel noted that no reference was made in either communication as to whether these activities should be solicited or unsolicited. Neither was there a definition of call or contact rates in either communication nor were the relevant requirement of the Code clearly referred to.**

**The Panel noted that the email communications above referred to activity targets, calls and virtual meetings and did not give any details about the requirements of the Code nor distinguish clearly between expected call rates and expected contact rates and the Panel therefore ruled a breach of the Code. There was little information about how a representative was expected to increase their numbers of contacts with health professionals whilst ensuring these were not unsolicited calls. Regardless of any reference to the Code and its requirements, the Panel considered that the pressure placed on the key account managers in setting the activity targets as noted above and failure of each representative briefing to distinguish clearly between expected call rates and expected contact rates meant that on the balance of probabilities, the representative briefing documents advocated a course of action which would be likely to lead to a breach of the Code. Thus, the Panel ruled a breach of the Code.**

**The Panel noted Sobi's submission that it had conducted a full review of the activity recorded in its CRM system for 2020 and the first half of 2021 and could confirm that no individual health professional received more than three unsolicited calls per year but might have had contact with the company considerably more than this as a result of other contacts. Whilst the Panel was concerned about the representative briefing material, it considered that there was no evidence before it that the actual number of calls made on a doctor or other prescriber by a representative had breached the requirements of the Code. The complainant had not provided any evidence that any Sobi representative had made more than three unsolicited calls on any individual health professional per year including the health professional specifically named by the complainant and the Panel therefore ruled no breach of the Code.**

**The Panel considered that the WhatsApp message referred to by the complainant implied that any communication should be recorded as a face to face contact.**

**The complainant made several further allegations regarding how contacts with health professionals were recorded in Sobi's CRM system, including a suggestion that contacts with health professionals in relation to two distinct products be recorded as two separate contacts, and a reference to record emails as contacts in the database. Whilst the Panel noted that how companies decided to record calls was not a Code requirement, the way it instructed its representatives in this regard might fall within the scope of the Code.**

**The Panel noted that according to the transcript provided by the complainant of a meeting held on 16 February, the senior leader stated 'For example, if you have a call next week, pick up the phone and confirm that call. If you tell them what you're going to talk to them about, log it as a promotional call.**

**Further in the transcript provided by the complainant of a meeting held on 19 March 2021, a senior leader stated if I were you and I was having a meaningful conversation dialogue by email with a customer, I'd log it as a phone conversation, if it were me. Because emails, as you know, don't count. Even though they are counted in the click sense, and you will see them come through in there, in terms of the activity, in terms of any conversation that happens with local, across the business, Immunology concluded, emails count for nothing.**

**The Panel considered that encouraging employees to record inaccurate calls, such as recording emails as telephone calls because emails did not 'count', meant that high standards had not been maintained and a breach of the Code was ruled.**

**1.2 Alleged concern that patient identifiers were shared with commercial/medical teams**

**Whilst the Panel questioned the need for the patient ID numbers to be sent to Sobi by the homecare delivery provider and to be circulated to the haematology team, it did not consider that the complainant had established, on the balance of probabilities, that such sharing of patient identifiers with Sobi was in breach of the Code. It thus ruled no breaches of the Code.**

**1.3 Alleged disguised market research/promotion (Take Control Survey)**

**The Panel noted that the Take Control Survey slide deck was rolled out in two waves with some different questions in the second wave. According to Sobi, representatives were requested to present the slides to their customers as part of a promotional call to start the conversation about improving patients' activity levels during the pandemic and were expected to ask their customers four specific questions and record the answers. The Panel noted Sobi's submission that there was no suggested, implied or actual financial incentive associated with the Take Control Survey as alleged.**

**The Panel noted Sobi's submission that the slides were presented as part of a standard promotional call and that it was standard practice to ask health professionals relevant questions during promotional calls. The Panel, on the evidence before it, did not**

**consider that the promotional nature of the material was disguised and so no breach of the Code was ruled.**

**The Panel did not consider that the complainant had established that the use of the campaign and related questions by Sobi meant that high standards had not been maintained and no breach of the Code was ruled.**

**The Panel noted that it appeared from the complaint that the promotional presentation would also be used by MSLs. The Panel did not have any comment from Sobi in relation to use of the promotional slides by the MSLs. The Panel considered that the complainant had not provided evidence in relation to the use of the 'Take control' slides by MSLs and why this in particular was in breach of the Code and the Panel therefore, on the evidence before it, ruled no breach of the Code in this regard.**

**1.4 Sales Manager contacting a patient**

**The Panel noted that the Code did not prohibit pharmaceutical company employees contacting patients; clearly if any such contact was made it needed to comply with the Code. The Panel noted that in this instance contact had been made by an employee. However, the Panel did not consider that the complainant had established that in messaging the individual to try and obtain internal training services, the manager had failed to maintain high standards as alleged and no breach of the Code was ruled.**

**2.1 Health professionals' contracts**

**The Panel noted Sobi's submission that with respect to the first health professional engagement referenced in the complaint, the representative who invited the health professional to speak at a proposed webinar failed to follow Sobi's procedures and did not get prior internal approval of the proposed engagement. Whilst Sobi submitted that the speaking engagement was never performed and the health professional was not paid for any preparatory work until a contract was in place, the Panel noted that preparatory work for the meeting was done by the health professional before a contract was put in place, which was the provision of a service in itself. The Panel therefore ruled a breach of the Code.**

**The Panel noted Sobi's submission that the speaking engagement did not happen and therefore ruled no breach of the Code in relation to the allegation that acquired haemophilia was off label for Elocta.**

**The Panel noted Sobi's submission that with respect to the second health professional engagement referenced in the complaint, several health professionals were engaged to speak at an online meeting. Sobi held a rehearsal one week before the online meeting was due to take place and noted its submission that the contracts for the speaking engagement were signed no later than at that rehearsal which was in advance of the speaking engagement for which the health professionals were paid. Although it was not clear to the Panel whether the health professionals were expected to attend the rehearsal, the Panel considered that the consultants would have done preparatory work prior to the rehearsal. The Panel considered that in failing to have an agreement in place prior to the consultants doing any preparation for the contracted service meant that high standards had not been maintained and a breach of the Code was ruled.**

**2.2 Certification and Review**

**The Panel noted the complainant's allegation that he/she was advised to send a customer a non-approved, medical slide deck that had expired. The Panel noted Sobi's submission that the slide deck was a global slide deck and could be used by local Sobi companies subject to any modifications in line with local requirements. The Panel noted that Sobi made no submission with regard to the deck having expired or not having been approved.**

**The Panel noted Sobi's submission that the complainant was liaising with a health professional who had been engaged as a consultant to speak on behalf of Sobi and was advised that he/she could share a slide deck with the health professional as reference material to use in preparing his/her own presentation. The complainant was not asked to use this slide deck him/herself or to give it to a health professional as a leavepiece.**

**The Panel considered that, if requested, companies could provide material to speakers and that if the meeting were a promotional meeting, then the material provided should comply with the Code. Clearly the final presentation used by a speaker at a company meeting would need to comply with the Code and would need to be certified. Employing a health professional to speak at a meeting was not in itself an opportunity to provide unsolicited material.**

**The Panel considered that in these particular circumstances, the material provided to the speaker did not require certification and thus ruled no breach of the Code. Nor had the company failed to maintain high standards in this regard and no breach of the Code was ruled.**

**The Panel noted Sobi's submission that on the day of a webinar, a typographical error was identified ('Mrs' to 'Ms') and corrected but the entire slide deck was not re-certified before use.**

**The Panel considered that the final form of the slide deck had been amended following certification and therefore ruled a breach of the Code.**

**2.3 Marketing Activities**

**The Panel noted Sobi's submission that an invitation to a webinar was certified for KAMs and other representatives to send to health professionals but it was subsequently discovered that the incorrect document had been added to the email. The attachment was a different document that related to the same meeting series and had also been certified for use with health professionals and was formally withdrawn. The Panel noted that whilst the incorrect document had been sent to the KAMs, it was discovered and withdrawn before it was forwarded to any health professionals; the corrected invitation was sent to health professionals. The Panel did not consider that the complainant had established that the incorrect document had been sent out to health professionals and thus that high standards had not been maintained in this regard. No breach of the Code was ruled.**

**The Panel considered that the material sent out to the commercial field team in preparation for a training session on formularies for Sobi's new product Doptelet was, in effect, briefing material and whilst it would have been helpful to include the black triangle, there was no requirement to do so. In the Panel's view, this clause did not apply and so no breach was ruled.**

**3 Training**

**The Panel noted Sobi's submission that all new representatives/customer facing personnel must have completed an initial training course (ITC) regardless of whether they were employees or contractors. In addition to the product and disease training provided in the ITC, all new Sobi personnel, including representatives, received other relevant training, such as training on pharmacovigilance, data protection and the company's interactive Healthcare Interactions Policy (iHIP) policies that addressed compliance with applicable Code requirements. The Panel noted Sobi's submission that one of the specific employees referred to by the complainant did complete the three day ITC, starting on the same day he/she began his/her role as a key account manager. The second named employee did not require the same training as representatives as his/her role was not primarily a customer-facing one. The Panel noted that Sobi regretted that a limited number of training modules were originally omitted from the training curriculum for a third named employee due to a technical issue but that it did not delay the validation process.**

**The Panel did not consider that the complainant had established, on the balance of probabilities, that the Sobi employees had not been given relevant training and thus ruled no breach of the Code.**

**The Panel further noted Sobi's submission that contrary to the complainant's allegations, Sobi did retain records of training received by personnel and the complainant's assertion that there was 'normally no follow up' of employees who missed training was without foundation. The Panel further noted Sobi's submission that it could confirm that all product and sales training materials provided to UK representatives were required to be certified in the review system with job codes. The Panel thus, on the evidence before it, ruled no breach of the Code in relation to each of these allegations.**

**The Panel noted Sobi's submission that the out-of-date SPC was used with one of the named employees for internal training as an example to help new starters understand the structure of an SPC and the type of content it may contain; it was not used with customers. Sobi recognised that it would be best practice to only use the most recent SPCs for all purposes and this was what is now being used. The Panel considered that using an out-of-date SPC, even for internal training, meant that Sobi had failed to maintain high standards and a breach of the Code was ruled.**

**Overall**

**The Panel noted its comments and rulings above and did not consider that the circumstances brought discredit to or reduced confidence in the pharmaceutical industry. The Panel therefore ruled no breach of Clause 2. This ruling was appealed by the complainant.**

**The Appeal Board was particularly concerned that a senior leader had encouraged employees to record emails as telephone calls because emails did not 'count' towards overall activity key performance indicators (KPIs). This dishonest approach was completely inappropriate in the Appeal Board's view. The Appeal Board noted that the Panel had ruled a breach of the Code in this regard which had been accepted by Sobi. The Appeal Board noted that other employees had raised concerns about that suggested approach at the meeting in question and it was decided that emails would not be recorded as telephone calls. The senior leader in question had since left Sobi and how to accurately record interactions had been reinforced.**

**The Appeal Board was further concerned that the incorrect version of an SPC was provided during the internal training of an individual before starting his/her role as a representative. The Appeal Board noted that the Panel had ruled a breach of the Code in this regard which had been accepted by Sobi. The Appeal Board noted Sobi's submission that the error was flagged and resolved before the representative interacted with health professionals or other customers. According to Sobi, the representative was validated on the correct version of the SPC prior to any external customer facing contact. Further the representative confirmed that he/she had not shared the incorrect SPC with anyone.**

**The Appeal Board observed that the Panel's remaining breach rulings were in relation to amending 'Mrs' to 'Ms' on the final form of a slide deck without recertification, representative briefing failing to be clear on expected call rates and contact rates, and preparatory work for a meeting being done by a health professional before a contract was put in place.**

**The Appeal Board noted the Panel's rulings of breaches for failing to maintain high standards in relation to a senior leader encouraging the inaccurate recording of calls and use of an out of date SPC for internal training. Despite its concerns above, the Appeal Board considered that, on the evidence before it, on balance, the particular circumstances of this case did not warrant an additional ruling of a breach of Clause 2 which was sign of particular censure and was reserved for such use. The Appeal Board therefore upheld the Panel's ruling of no breach of Clause 2. The appeal on this point was unsuccessful.**

A complainant who described him/herself as an employee of Sobi complained about three matters, field force activities, meetings and marketing material, and representatives training.

**COMPLAINT**

**1 <u>Haematology Field Force Activities</u>**

The complainant stated that the Sobi UK commercial and medical field teams operated in an exceedingly small, rare disease area focusing currently only on haemophilia. Details of the number of customers per KAM and number of target customers were provided'. A target customer was captured within the cycle plan and was the focus of all activity. In addition to the commercial field team there were MSLs including one with management responsibility for the others as well as customer facing time. The combined team had responsibility for two products in haemophilia, Elocta (efmoroctocog alfa) and Alprolix (eftrenonacog alfa). The focus was Elocta as there was a larger patient population that could be switched to treatment. Prior to

2019 the focus was on patient outcomes however with the addition of a new competitor to the market place the focus had become heavily focused on activity.

### 1.1 Alleged pressure to falsify calls and overcall on health professionals

The complainant stated that there had been over the last year significant pressure to increase activity with no regard for the Code. Briefings regarding activity were predominantly done verbally and there were usually no briefing documents. The complainant stated that he/she had seen two documents sent by business intelligence which outlined what constituted a call and included a slide deck on how to record a call.

A 'WhatsApp' message sent on 4 February 2020 from a manager to the sales team before an international conference in February 2020 (European Association for Haemophilia and Allied Disorders (EAHAD)) was provided. The message suggested that '[he/she] was on a call regarding activity the previous day and the consensus from the top was that if you 'smell' a customer at this meeting record it as a F2F' (face to face).

The complainant stated that the pressure for activity appeared to come from global. An activity report was run every Monday for all brands and field teams and there was a meeting with a manager, who reported to the CEO looking at the weekly activity of all the affiliates across Europe including the UK. This was called the Real Time Dashboard Meeting and was attended by senior members of the UK Leadership Team. A slide deck of the information discussed at this meeting was provided, there was one created every week usually by the Business Intelligence Team.

Any discussion regarding activity generally took the form of being verbal with no written briefing document to the sales team, apart from in March 2020 when the first lockdown occurred. The complainant stated that the briefing sent at that time stated that sales representatives could 'maintain' relationships with health professionals during this period if the contact related to an ongoing project. It had been agreed at a Leadership Team level and approved with an email template that could be sent to customers during this time.

The complainant stated that customers who were included in a KAMs Cycle Plan would only be counted as activity on the Real Time Dashboard meeting on a Monday. Questions were raised if a customer was seen outside of this target list. An email sent to the sales team in July 2020 was provided outlining that because of COVID many customers were not seen in H1 and outlining that the senders 'belief around planned activity was that it should not exceed three a year but that he/she had been challenged and overruled' although he/she did not state by whom. An email sent in July 2020 to the sales team requested that a separate list of interactions outside of the Cycle Plan with customers likely to be seen more than three times in the second half of the year due to engagement through projects was created. This approach, the email stated had been discussed with a senior medical employee at the time and was believed to be compliant. The complainant did not recall a separate briefing explaining how this would be compliant. An email response sent in July 2020 included a table which employees had to complete. An email sent the following day thanking employees for completing the task and outlining that the planned range of activities were code compliant was also provided.

An email from a manager to the sales team in November 2020 regarding activity expectations was provided. In July 2020, the sales team was increased as there was going to be an additional product to promote and an additional group of customers to call on. This resulted in a

smaller group of haemophilia customers. The complainant stated that his/her territory had over 90 customers and when this email was sent out, he/she lost a third of those customers to a newly created territory. The complainant provided an email response expressing his/her concerns regarding overcalling and the potential to breach the Code. The complainant never received a response to this email.

The complainant stated that activity continued to be raised at every Friday's cross functional team meeting. An email dated 4 February 2021 from a senior leader to the whole commercial team the day before a cross functional meeting highlighted how far behind they were as a team in terms of activity. It was regularly, verbally, mentioned at these meetings how much pressure was coming from global in terms of activity to the UK leadership team. The complainant alleged that the call rate increased in November 2020; details were provided of the rate increase. The complainant stated that his/her concerns raised at the Friday meeting on 5 February went unheeded. A follow up email sent on 8 February to the sales team and copying in the General Manager, thanked people for their improving activity. There was almost a 50% improvement in activity from the 4 February to the 8 February with only [one] working day of that week left during lockdown.

The transcript and accompanying audio of the last ten minutes of a team meeting held on 16 February, with all the commercial sales team in attendance was provided. A manager stated that there was discussion at the Leadership Team level the previous day about activity and that the UK affiliate performance was looking poor compared to the European teams. The employee explained that this was because the European affiliates had been creative with how they recorded their calls. The employee suggested that the UK needed to 'get savvy' with how it recorded calls and suggested that instead of recording one call for both products as normally done in the CRM system, they should create two calls instead- one for each product. The audio captured the sales force pushing back against this suggestion and that the employee made clear he/she had been asked to 'sound us out'.

The audio and transcript of a meeting, on the afternoon of 16 February 2021 called by a senior leader, in response to the team meeting held that morning was also provided. The employee admitted and apologised for putting the employee running the morning meeting in a difficult position and saying he/she responded to a request from him/her after a conversation he/she had had with the General Manager. The employee also highlighted how the pressure for activity came from global. On page three there was a question from a named employee about logging calls to other members of staff when setting up meetings with health professionals. The senior leader's response was to state 'log them all, log them all. Basically, if you're having a conversation with someone and they know what it's about log it as a promotional phone call'. The outcome of this meeting was to have a workshop on how we could create more projects and meetings to generate more activity. This meeting took place on Wednesday 17 February and was organised by the senior leader.

The complainant stated that on 19 March 2021 at the weekly cross functional meeting the activity figures were provided and the senior leader asked the only MSL, to leave the meeting. The audio and transcript of the remaining meeting was provided. The senior leader, referenced on page two, that he/she and another employee had talked about some things happening in terms of how emails were being recorded. He/she then gave 'permission' to log an email that had 'moved the business forward' (no definition of this was given) as a phone call. This was significant because a phone call counted towards overall activity on the Monday morning Real Time Dashboard meeting. Another employee could also be heard supporting this on page two

and stating that 'I know from conversations with other parts of the business that that maybe being done elsewhere'; he/she had been told by a KAM colleague in another therapeutic area that they were also recording emails as phone calls. The senior leader then continued to reference the pressure for activity. On page 5 he/she stated, 'we've got to do what we can to make this go away for a while'. The complainant stated that he/she could be heard stating that he/she would be uncomfortable doing this and he/she did not action this direction. The complainant stated that he/she could also be heard asking 'how much do we have to do to make it go away' and the senior leader provided the weekly activity commitment figures that the UK had committed they would deliver to the global team. In addition to this, two members of the team were missing from the meeting. These were followed up with separately and stated that 'the majority agree with this direction'. Because of this meeting members of the sales force started to follow this direction. This could be seen in the increased activity figures reported at subsequent cross functional Friday meetings. The complainant attended was the 23 April and it was clear that activity had significantly improved.

All calls were recorded in the CRM system. The data from this pulled through to a series of dashboards. These dashboards contained activity data, patient numbers per account, there was a dashboard which looked at patient numbers and compared the activity that had taken place in that account with the patient numbers. The dashboard also registered who had called on customers eg, the KAM/MSL and how the interaction was logged eg, phone call, email, virtual meeting. It also highlighted per account and per customer. An area of major concern the complainant regularly raised was the contacting of customers by the UK and by the global teams and the significant overcalling on certain customers, eg a named hospital professor at a hospital during 2019. The dashboards would be able to highlight the data on how many times a customer had been seen that year if a member of Sobi had recorded that in the CRM system and would provide clear data on overcalling on health professionals.

### 1.2 Alleged concern that patient identifiers were shared with commercial/medical teams

The complainant stated that the dashboards also contained the data from the homecare provider, which included patient identification numbers. An email sent to employees outlining sales performance for the month including patient gains and losses was provided. The sales team were expected to follow up on any losses. This was less about reporting a potential pharmacovigilance (PV) issue and more around the potential loss of revenue. Patient homecare identifiers could be clearly seen on this email. The complainant stated that he/she raised this issue but the inclusion of identifiers had continued.

### 1.3 Alleged disguised market research/promotion (Take Control Survey)

The complainant stated that throughout the period of the pandemic Haemophilia patients had been less active. The impact of this was that they had used less factor as they were not bleeding as much. This had resulted in a reduction of the IU usage for Elocta which had led to lower revenues. This concerned Sobi greatly. In March 2021 two days before a webinar a senior Sobi employee asked an employee to contact the Chair of a Sobi sponsored promotional webinar taking place on the evening of the 25 March. This was to ask for additional slides to be included in the presentation for that evening (this would be mentioned in the marketing section). These slides were part of a global initiative called the 'Take Control Survey' and a copy was provided. The purpose of this survey was to ascertain what was driving the lower use of factor and whether there was an intention to increase it at any point soon. There was a visual briefing

to the Sales and Medical field team however no copy of the briefing was sent out. The survey required the KAM/MSL to show a series of slides. A copy of the 'Take Control' slide deck which asked four questions which were recorded in the CRM system after recording a promotional call for Elocta against the respective health professional was provided. An email sent by a manager on 1 April to the sales team regarding actioning this survey was provided. The complainant alleged that verbally they were advised that there would be a financial incentive as the aim was to cover as many health professionals as possible. An email on 27 April to the sales team outlining the coverage target for the survey was provided as was an email sent on 28 of April by a senior leader, which contained an email from Business Intelligence. The email had been sent to senior employees and outlined the required coverage and recording of the survey and how it would pull through to the relevant metric dashboards depending on who was recording the interaction. The complainant stated that he/she raised concerns that this could be seen as disguised market research to his/her manager and another named employee on the 14 May. These concerns were ignored. It was apparent that there was now a second wave of this survey. The complainant did not know if there was a new presentation but provided a photograph of the new questions to be asked. A photograph taken from a Teams chat with the commercial sales team and contained the new questions to be asked in wave two was provided. The complainant noted that interestingly the final question referred to the phrase 'intense protection' which had been associated with an Elocta marketing campaign.

### 1.4 Sales Manager contacting patients

The complainant stated that on 16 April 2021 a sales manager sent an email and a publication to the commercial sales team. The email stated that he/she had been speaking with a named Haemophilia patient, who ran his/her own consultancy, to organise some training. In copy were other senior managers. The complainant noted that Sobi's own internal policy known as iHIP stated that Patient Organisations should be dealt with by the Patient Access Team.

## 2 Meetings and Marketing Material

### 2.1 Health professional contracts

The complainant stated that he/she had a virtual meeting with a health professional in January 2021 who raised a complaint regarding a virtual meeting he/she had been asked to present at. The meeting had been cancelled and the health professional had completed the slide presentation at the request of the complainant's commercial colleague, who was organising the meeting. A Haemophilia team asked the named employee if he/she could organise a speaker on 'Acquired Haemophilia'. The commercial colleague had contacted the customer, as the complainant was away when the request came in.

The complainant stated that the problem with the meeting was twofold - acquired haemophilia was off label for Elocta. The second problem was at the point the speaker complained, he/she had completed and sent in the presentation and did not have a speaker contract in place and was concerned he/she would not be paid. The complainant stated that he/she escalated the complaint to a senior medical employee who advised that if a new date could be given for the meeting that would alleviate the problem regarding the speaker contract not being organised, despite the complainant raising the fact that acquired haemophilia was off label. The complainant stated that he/she also raised the issue on the same day with the general manager who offered to apologise to the customer. An email of 28 January from the complainant outlining in writing the options he/she had been given by a senior medical employee regarding

the meeting was provided. An email from a senior medical employee,28 February 2021, highlighting that evidence had come to light in the use of Sobi's main competitor in acquired haemophilia and that the meeting could no longer go ahead was also provided. The commercial colleague responded to the senior medical employee's email, still trying to gain agreement for the meeting and the complainant highlighted two issues, one that the commercial colleague still did not understand the topic was 'off label' and two that he/she still did not understand the internal process for meeting approval. The complainant stated that he/she believed this was a consequence of the issues that were raised in section three regarding training. An email that the meeting could not go ahead was provided.

The complainant stated that a second webinar took place on 20 April 2021, this time utilising health professionals from a named area. There was a slide rehearsal for the health professionals the week commencing 2 April. The complainant was advised by a colleague that the health professional contracts were only signed on the evening of the rehearsal and the work by all three health professionals had been completed by that point, again because of problems with the electronic system.

### 2.2 Certification and Review

An email from a medical employee to the complainant regarding a slide deck that he/she had raised questions about was provided. The medical employee advised the complainant that he/she could send a customer a non-approved, medical slide deck that had expired. The complainant stated that he/she did not send the deck and raised his/her concerns with his/her manager at the time. The complainant stated that he/she did not believe that the manager took any action. The slide deck should never have been made available for a commercial colleague and should have been approved for medical to leave behind.

The complainant provided an email dated 16 March 2021 regarding providing medical review for the slides for a commercial webinar taking place on 25 March. The complainant stated that on 23 March the sender of the email was asked by a senior employee to approach the chair of the webinar to ask to include additional slides which were part of a new global initiative called the 'Take Control' survey. The sender of the email contacted the complainant as he/she was, according to the complainant, uncomfortable with it. The sender of the email spoke with the chair on Wednesday 24 March and subsequently added the slides to the deck. The complainant believed that the sender of the email then provided the medical review on that slide deck after he/she added the slides.

The complainant provided an email from the sender of the email in relation to the above, to an external agency, which was responsible for the logistics of the webinar series organised by Sobi. The slides (PP-10851) that he/she was sending to the agency were meant to be the final, approved version for the webinar taking place that evening (25 March 2021). The email highlighted that he/she had raised that the name of one of the health professionals was inaccurate, he/she had amended it on the slide deck he/she was sending to the agency. He/she then asked a member of the marketing team to amend the name in Vault. The complainant alleged that the final deck was not reapproved in Vault with these changes.

### 2.3 Marketing activities

The complainant provided an email forwarded on 1 March 2021 to [another named employee] and the complainant explaining why the sender pulled an invitation to a commercial webinar the

company was involved in. The sender was responsible for sending out an invite for a commercial webinar taking place on 25 March 2021 and had sent the wrong link and the 'briefing document had the wrong job bag code'. A further email from the sender to the team withdrawing that link was provided. The [named employee] raised the issue on a weekly webinar meeting which took place on Tuesday 2 March 2021 at 3pm. The complainant stated that he/she told the sender that he/she needed to withdraw the link sent out on the 26 February in error. This was not actioned until Wednesday 3 March at 09.21am.

A photograph of training material sent out to the commercial field team in September 2020 with job bag code ITM-0995 in preparation for a training session on formularies for a new product, Doptelet was provided. The material was missing a black triangle. The complainant stated that he/she had the original document.

## 3 Training

The complainant stated that the responsibility for onboarding new starters was with the training and HR functions. The complainant named a training employee and HR and alleged that there was no formal product training for Haematology within Sobi. New Haematology permanent staff received a series of online modules which were assigned through Sobi's online platform, via Global training. The online platform also included training which related to policies, procedures, and compliance. The complainant alleged that the material contained within the online platform was not reapproved by the UK approval system, and it was not always checked as to whether the correct modules had been included for everyone. Haematology team members would then attend three days induction as led by Global although this appeared to be only for permanent staff as two named contractors did not attend this initial training course (ITC).

Once a Haematology representative started, a training employee contacted a member of the medical team, to organise product 'classroom' training for new UK commercial starters. The training employee then sent the new starter an outline of a schedule of training. However, there was no formal curriculum that had been developed as to what was the minimum standard for new commercial sales representatives to cover. In addition it appeared that new commercial haematology staff did not go through classroom training with medical. The complainant did not know of any product training completed by one of the named contractors. Training was normally allocated by Global and despite being one of the very few affiliates to have a training employee there seemed to be no storage of validations or training that had taken place. Training was usually delivered by a named medical employee and there was normally no follow up if people had missed this. The complainant provided an email from one of the contractors to the sales team regarding the 'Take Control' survey. In this email he/she stated that when '[name] is back from leave, we will receive training on the slides'. The complainant stated that he/she did not receive any training on these slides.

### 3.1 Onboarding of new haematology sales representatives

The complainant stated that in July 2020 Haematology was restructured and three new positions were created. According to the complainant it became apparent one month after starting that one of the new starters online system was missing crucial training courses. The representative had raised it with the training employee and his/her manager but no action was taken.

The complainant provided an email from the representative to a medical employee and the complainant highlighting that there had been a training session where the representative raised that he/she had been sent the wrong summary of product characteristics (SPC) by the training employee. The representative confirmed that he/she had not shared the SPC. A copy of the SPC from 2016 which was attached to the email was provided. The complainant stated that despite raising this with his/her manager and the training employee and medical employee being aware of this, the SPC was not formally withdrawn. It was an additional concern that not all new field commercial staff had had final written product validations and for those who did they were not stored anywhere. The complainant alleged that a further new starter had experienced the same problems regarding training modules. In fact, all four new starters experienced the same problem and lack of defined curriculum and training. The complainant stated that he/she believed it was this that had contributed to the meeting that another named employee attempted to organise on acquired haemophilia. He/she had not been adequately trained on either the therapy area or the process required for organising meetings.

### 3.2 Training Records

The complainant stated that employees were to attend training and complete a quiz. The complainant had received no confirmation at all as to whether he/she had passed or failed the quiz. There was also no record of the training validation kept in a central point. This was an additional problem as there was no accurate record of any training, he/she had received since being with Sobi.

The complainant provided an email from the training employee to the UK organisation outlining that action would now be taken to follow up on any SOP training not completed. The complainant believed this was in response to concerns he/she raised on 14 May, in an investigation meeting with a named employee. The complainant did not know if this had been actioned however prior to this no action was ever taken.

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When writing to Sobi, the Authority asked it to consider the requirements of Clauses 2, 4.10, 9.1, 12.1, 14.1, 15.1, 15.4, 15.9 and 23.1 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 took all complaints seriously. Sobi stated that it had found it particularly challenging to respond to this complaint due to its length, complexity and lack of specificity regarding the Code. Although the complainant identified a number of issues or concerns and had provided a significant amount of documentation, the complainant did not identify any specific clauses of the Code to which those issues or concerns related and did not explain how the alleged issue or concern might be in breach of the Code. Nonetheless Sobi had sought to investigate the allegations thoroughly and respond fully and transparently, taking into account the clauses identified by the PMCPA and where appropriate using Sobi's best efforts to determine what breach the complaint was alleging.

Sobi did not believe that the complainant had established any specific breaches of the Code and certainly none that would bring discredit on or reduce confidence in the pharmaceutical

industry or that would otherwise be worthy of particular censure under Clause 2. Nor that the cumulative effect of the alleged breaches when taken together, would indicate any systemic problems or amount to a breach of Clause 2. Sobi submitted that demonstrated below, it had robust policies and procedures in place that were designed to ensure compliance with the Code, and it provided appropriate training to its representatives, to ensure compliance with those policies and procedures.

## 1 Haematology Field Force Activities

### 1.1 Alleged pressure to falsify calls and overcall on health professionals

Sobi acknowledged that the past 18 months, with repeated lockdowns and restrictions on in-person meetings with health professionals, had been difficult and stressful for its key account managers who might have found it challenging to maintain activity levels and achieve their performance targets. Nonetheless, Sobi refuted any suggestion that Sobi had encouraged or pressured its representatives to falsify records or conduct unsolicited calls on health professionals in excess of the maximum permitted under the Code.

Sobi in particular recognised the need for representatives to limit their calling on customers so that they did not cause inconvenience. Sobi confirmed no health professional had received more than 3 unsolicited calls per year, but might have had contact with the company considerably more than this as a result of other contacts.

Under this heading, the complainant described a wide range of issues or incidents, without linking them to a specific section of the Code or stating how the issue or incident amounted to a breach of the Code. Sobi responded to the allegations in relation to the requirements of the specific clause of the Code identified by the PMCPA and sought to address each specific allegation in relation to what seemed to be the most relevant clause.

**Clause 15.4 (frequency and timing of health professional calls)**

Sobi referred to Clause 15.4 of the Code and its supplementary information and submitted that the Code provided that representatives should not normally make more than three unsolicited calls per year on an individual health professional. There were no specific limits on the number of solicited calls or other interactions that a representative might have with a health professional.

Sobi stated that the complainant had not provided any evidence that any Sobi representative had made more than three unsolicited calls on any individual health professional per year, nor that Sobi had taken any action to encourage, pressurize or incentivize a representative to make more than three unsolicited calls on any individual health professional per year. Sobi had never asked its representatives to exceed the limit of three unsolicited calls per health professional per year and its customer relationship management (‘CRM’) records confirmed that no health professional had received more than 3 unsolicited calls from the company per year. Consequently, the complainant had failed to substantiate any alleged breach of Clause 15.4 and Sobi strongly refuted any breach of Clause 15.4.

Sobi had extensive written procedures and guides around health professional interactions, which it provided to its representatives. The interactive Healthcare Interactions Policy (iHIP) was the first port of call for all employees that wished to consult Sobi’s compliance policies. iHIP was continuously reviewed and updated and contained comprehensive information on

global and local requirements for all activities. It was accessible to representatives online 24/7. As part of their on-boarding process, all new employees were given a live demonstration on the use of iHIP, with a focus on those sections that were of particular relevance to the individual's role.

The section of iHIP addressing field interactions applicable from 2019 onwards stated:

> 'In addition to ensuring that calls on HCPs do not cause an inconvenience, sales representatives should not normally call on a doctor or other prescriber more than 3 times per year (this did not include group presentations, requests made by the HCP or following up on an adverse event which might be made in addition to the 3 visits per year). Representatives should treat prescribers' time with respect and not give them cause to believe their time was wasted.'

In March 2021, changes were introduced to the latest version of iHIP to enhance the wording and provide clarity on the distinction between unsolicited calls and other contacts. In particular, while the updated guidance continued to be explicit that the number of unsolicited calls on a particular health professional should not exceed 3 per year, it confirmed that it was permissible to plan and undertake additional interactions that were not unsolicited calls:

> 'In addition to ensuring that calls on HCPs did not cause an inconvenience, sales representatives should not call on a doctor or other prescriber more than 3 times per year (this did not include group presentations, requests made by the HCP or following up on an adverse event which might be made in addition to the 3 unsolicited calls per year). It was therefore acceptable to undertake and plan more than 3 contacts / interactions with an HCP per year, however no more than 3 unsolicited calls should be undertaken. Representatives should treat prescribers' time with respect, not cause inconvenience and observe the wishes of individual HCPs and the relevant arrangements in force at any particular Trust, Centre or Hospital.'

The guidance in force throughout the period covered by the complaint was therefore absolutely clear that representatives must not make more than 3 unsolicited calls on a health professional in a given year, although additional interactions, such as group meetings or interactions requested by the health professional, were permissible.

Sobi believed that its policies provided sufficient clarity on the distinction between (i) unsolicited calls and (ii) all calls, contacts or other interactions comprising engagement with health professionals, in case there was any doubt among its representatives. For example, in addition to the relevant section of iHIP (discussed above), the UK/ROI Leadership Team provided written guidance on its expectations for recording activity levels in a May 2020 briefing which clarified that Sobi recorded activity based on 'contact rates'.

Sobi stated that it had not provided any briefings, whether oral or written, to representatives asking employees to increase the number of unsolicited calls on health professionals. Additionally, Sobi strove to ensure that all briefings and trainings were clear on this point to avoid any misinterpretation.

Sobi submitted that the complainant did not differentiate between unsolicited calls on health professionals and contacts or other interactions with health professionals. While Sobi UK always briefed its representatives in compliance with the Code, the limit on the number of

unsolicited calls was a requirement that was specific to the UK. The equivalent codes in other European countries did not distinguish between unsolicited calls and other interactions. As a result, Sobi as a global / European organization tracked the total contact rates for health professionals and established activity targets for its European businesses, including Sobi UK, based on all contacts. Sobi UK therefore based its activity targets on health professional contacts, which encompassed a broad spectrum of communication, including solicited calls and interactions at meetings. Sobi had conducted a full review of the activity recorded in Sobi's CRM system for 2020 and the first half of 2021 and details were provided. During that entire 18 month period, the average number of unsolicited calls per health professional in the calendar year 2020 was far below the 3 per health professional permitted under the Code. Further, Sobi's CRM records showed that no individual health professional received more than three unsolicited calls per year. In fact only two health professionals received even three unsolicited calls per year. Unsolicited calls therefore made up a small proportion of the overall contacts that Sobi made with health professionals, which was an entirely expected characteristic of promotion in the rare disease space. There were a relatively small number of health professionals practising in the haemophilia space and Sobi, like many other pharmaceutical companies that specialized in rare diseases, had close and ongoing relationships with almost all of its customers. Health professional engagements in the rare disease space were often requested by health professionals who were seeking to educate themselves about the products and/or were based on an existing relationship. These activities typically took the form of responding to requests for on-label information, speaking engagements and meetings.

*Alleged Pressure to Increase Activity*

Sobi stated that the complainant made multiple allegations regarding pressure to increase activity levels and asserted that this pressure came from the Global organization. Sobi acknowledged that the unique circumstances of the past 18 months had been challenging for representatives who might have found it stressful and challenging to maintain the activity levels expected of them. However, activity levels or contact rates were not the same as the number of unsolicited calls and any pressure on sales representatives to meet target activity levels did not equate to pressure to conduct unsolicited calls or to fail to comply with Code requirements. Indeed, Sobi thought it was significant that the complainant had repeatedly referred to pressure to increase activity levels but had not once suggested that they interpreted this as pressure to increase the number of unsolicited calls on health professionals.

The complainant stated that 'Activity continued to be raised at every Friday's cross functional team meeting'. Firstly, Sobi did not believe that the complainant was alleging that Sobi increased activity targets in such meetings, but if this was the intent of the allegation, Sobi refuted this. Rather, Sobi believed that the complainant meant that management discussed activity levels in each of these meetings. Sobi acknowledged this to be true but did not consider this raised any concerns under the Code. Regularly discussing activity levels during meetings with representatives was entirely reasonable and appropriate. Activity levels were an important key performance indicator (KPI) for any pharmaceutical sales team and there was nothing in the Code that suggested it would be inappropriate for a company to prioritize this metric.

For context, during the period relating to this allegation, there was an increased focus on activity levels by management because the UK team was not meeting its internal targets. In running any business, it was essential to have KPIs and to react when these were not being achieved. In such circumstances, any well-run business must focus on its KPIs in a similar way to Sobi. Doing so did not constitute encouragement (implicit or otherwise) to breach any ethical

standards. The complainant had not produced or identified any evidence to suggest that Sobi's efforts to increase activity levels encouraged or suggested that representatives engaged in behaviour that might breach the Code.

As requested, Sobi provided a copy of relevant email communications between the UK and the Global organization regarding the establishment of target activity levels for the UK business for the first half of 2021 and the need for the UK business to increase its activity levels. A senior leader for Haematology prepared the initial proposal for 2021 activity rates for UK/Ireland, which was sent to global colleagues. A global employee responded with comments, challenging certain assumptions and comparing the proposed rates for the UK/Ireland with those for the other big 5 European countries and asking if further increases closer to the average for the other countries would be possible. The UK then sent an updated proposal with some increases to the rates, although still lower than other countries. Sobi stated that as could be seen from the emails provided, there was nothing untoward in these communications and there was no undue pressure on the UK business to increase activities at the expense of compliance with the Code. It was clear that the UK was free to negotiate changes to the levels proposed by the Global organization to tailor them to the specifics of the UK market, including in particular challenges in the UK due to the ongoing pandemic situation.

As requested, Sobi also enclosed print outs of dashboards relating to activity data for the period from November 2020 to April 2021. The dashboards pulled data from Sobi's CRM database to allow activity to be reviewed in relation to individual health professionals, hospitals, Sobi personnel, products or type of interactions and to be measured against targets where applicable. The CRM system and the dashboards recorded all types of contact with health professionals, including emails, phone calls, virtual meetings and face to face visits. They also recorded interactions by all relevant Sobi personnel, not just representatives, and so included, for example, medical-related interactions. The metrics shown did not distinguish between unsolicited calls and other visits with health professionals, although the raw data in the CRM system included that information and as noted above, in reviewing the raw data in that CRM database Sobi found no evidence that any health professional had received more than three unsolicited calls per year.

*Cycle Plans*

Sobi provided screen shots of cycle plans for 2021. Each representative prepared a cycle plan for their territory on a twice-yearly basis. Cycle plans identified the target customers in the representative's territory and the number of planned interactions for each such customer. Prior to 2020, the representatives' cycle plans only included plans for unsolicited calls on the target customers. Management recognized that this did not give a full picture of all the interactions with the target customers that would be anticipated during the relevant period, such as meetings at international congresses responding to requests for on-label information, speaking engagements and meetings. As a result, since then cycle plans had included details of all planned interactions with target customers, including both unsolicited calls and interactions at planned meetings or other events or related to existing projects.

The cycle plans were not standalone documents but were live documents recorded and updated in real-time on the dashboard database for each representative. The appendix contained the screen shots of the cycle plans for a particular representative and showed the rows for target customers visible on the screen.

Sobi noted that the complainant provided an email and suggested that this email was a request to create a separate list of interactions outside of the cycle plan with customers likely to be seen more than three times in the second half of the year due to engagement through projects. However, this did not accurately describe the email. Rather, the email indicated that the cycle plans that had been prepared for the first half of 2020 did not include some planned interactions with health professionals, such as interactions with health professionals at webinars or other projects. The purpose of the email was to request key account managers (KAMs) to identify these additional planned interactions, so that they could be included in the relevant cycle plans. The email made no reference to exceeding 3 contacts per health professional in the second half of the year, but Sobi noted that these additional planned interactions were not unsolicited calls and so did not count towards the limit on 3 unsolicited calls per health professional per year.

Sobi referred to the email provided by the complainant which stated that the additional planned interactions had been incorporated into the relevant cycle but which also expressly confirmed that the plans for unsolicited interactions with health professionals had been compiled to ensure that no customer would have more than 3 such unsolicited interactions over the year. Therefore, rather than demonstrating a breach of the Code, the allegations and supporting documentation provided by the complainant actually substantiated the efforts taken by the company to ensure compliance with the Code by not exceeding 3 unsolicited calls on a health professional in a year.

The PMCPA requested a copy of the list of additional planned interactions with health professionals that were originally outside the scope of the Cycle Plans. This included meetings at international congresses, responding to requests for on-label information, speaking engagements and meetings. Sobi had not been able to identify any such list since the manager who requested it was no longer employed by Sobi. As far as Sobi was aware, the information provided to that manager by the representatives was not retained or consolidated into a separate document.

*Change in territory*

Sobi acknowledged that the complainant's territory was changed and that the target activity rate remained the same, but Sobi did not consider that this was a breach of the Code or could create a risk of non-compliance with the Code. Sobi restructured the territories for its representatives in haemophilia. It was noted that one territory had a disproportionately larger customer base (details were provided) but the target activity rate for each KAM was the same. As a result of the restructuring, the number of customers assigned to the complainant was reduced to bring this in line with other territories and it remained within the same range as the other KAMs, while the complainant's overall target activity rate also remained the same as the other KAMs.

As pointed out previously, the target activity rates were for all relevant contacts with health professionals; the targets were not limited to unsolicited calls. Sobi believed that the target activity rates were realistic and could readily be achieved without the need to conduct unsolicited calls in excess of the permitted maximum. As mentioned above, Sobi's CRM data showed that the majority of the KAMs' interactions with health professionals were not unsolicited calls and that in no case had a health professional received more than 3 unsolicited calls in a year. Indeed, as previously discussed, the iHIP policy was explicit that there might not be more than 3 unsolicited calls per health professional per year, but that additional interactions were permitted. Further, Sobi noted that KAMs' bonuses were based entirely on sales, so there was

no financial incentive for KAMs to undertake unsolicited calls in excess of the Sobi policy and Code requirements.

*WhatsApp message*

Sobi noted that the complainant provided a copy of a 4 February 2020 WhatsApp message but did not explain his/her concerns. The creator of the WhatsApp group had since left the company and, from the image provided, Sobi was unable to identify the members of the group to investigate to whom the sender addressed the message. However, from the context it seemed likely that the recipients of the message were Sobi's UK key account managers (ie representatives) for haemophilia, who were attending EAHAD, a major international congress.

The message concerned recording health professional contacts in Sobi's CRM system and encouraged the recipients to record any interactions with health professionals at the congress as a contact. Sobi believed that the recording of contacts in the company's CRM system was an internal matter which was not within the scope of the Code, although Sobi acknowledged the importance of distinguishing unsolicited calls from other types of contact as per Clause 15.4 of the Code and Sobi's CRM system allowed the company to make such a distinction with markers for unsolicited calls and different types of interaction (emails etc.). Further, it was clear that the message did not address or encourage unsolicited calls on health professionals or any other inappropriate behaviour. Indeed, recording interactions with health professionals at a congress as a contact in the company's CRM system should have the exact opposite effect. If such an interaction, which was expressly excluded from the scope of an unsolicited call under Clause 15.4 of the Code, was recorded as a contact within the CRM system, this would count towards the KAM's activity targets and therefore reduce the incentive for the KAM to seek additional contacts with the health professional to meet their target.

*Other allegations relating to recording contacts in CRM system*

The complainant had made several further allegations regarding how contacts with health professionals were recorded in Sobi's CRM system, including (i) a suggestion that contacts with health professionals in relation to two distinct products be recorded as two separate contacts, (ii) a suggestion to record all calls with health professionals and other members of staff in the CRM database, and (iii) a reference to recording emails to health professionals as contacts in the database.

It was unclear to Sobi how the complainant considered that these concerns about the company's practices for recording of health professional interactions in its CRM system would amount to a breach of the Code. The Code did not dictate how organizations recorded their interactions with health professionals. Whether Sobi encouraged its representatives to record email communications with health professionals as contacts in its CRM system, or to submit separate entries for different parts of a call addressing two separate products, was an internal matter which Sobi did not believe would be within the scope of the Code. That said, Sobi acknowledged the importance of distinguishing unsolicited calls from other types of contact as per Clause 15.4 of the Code and Sobi's CRM system allowed it to make such a distinction and representatives were aware of the Code limit of 3 unsolicited calls per customer per year and were reminded of this in briefing sessions and by reference to the information in iHIP.

Further, none of these allegations could be interpreted as encouraging Sobi's representatives to make unsolicited calls in excess of the maximum permitted under the Code and, if anything,

they should have the exact opposite effect. If the activities described by the complainant were recorded as a contact within the CRM system, these would count towards the KAM's activity targets and therefore reduce the incentive for the KAM to seek additional contacts with the health professional to meet their target.

*Alleged overcalling on individual health professionals*

The complainant made an unsubstantiated allegation of overcalling on a named health professional. Sobi stated that this health professional was an internationally renowned expert in haematology. He/she was an investigator in a Sobi-sponsored clinical trial and was also engaged by Sobi periodically to speak at company-sponsored meetings or to provide other consultancy services. Sobi had reviewed the records from its CRM database for 2019 relating to interactions with the health professional. During that period, the complainant had two face to face meetings with that health professional in one month, neither of which were unsolicited calls. A number of other interactions with him/her were recorded for the relevant period, Sobi stated that these concerned, for example, his/her participation as an investigator in a Sobi-sponsored clinical trial, his/her participation in an advisory board, briefing for two speaker engagements. These interactions were carried out by Sobi Medical Affairs roles and/or appropriate Global commercial roles and none were unsolicited calls. Therefore, there had not been any over-calling on this particular health professional and no breach of Clause 15.4 in relation to the company's interactions with that individual.

**Clause 15.9 (representative briefing materials)**

Sobi rejected the complainant's allegation that briefings regarding activity were predominantly done verbally and that there were usually no briefing documents. Sobi submitted that it provided written materials to its representatives on both its medicines and how they should be promoted, as required by Clause 15.9, and there was no Sobi policy of not providing written briefings to its representatives.

The complainant had already provided one such document providing guidance on how the commercial teams should record remote customer engagements. Sobi took its responsibilities under the Code extremely seriously, and as could be seen from the complainant's enclosure, the slides contained information on compliance basics and reference to further detailed information in the iHIP documentation. As requested, Sobi provided a copy of the instructions to representatives regarding how to use Sobi's CRM system to record contacts with health professionals, while the iHIP policy included guidance on interactions with health professionals.

**Clause 9.1 (high standards)**

Sobi submitted that it was fully compliant with its requirements under the Code in relation to limiting the number of unsolicited calls on health professionals to a maximum of 3 per year and having certified briefing materials for representatives. Sobi stated that it had robust policies in place and, as discussed further below, provide appropriate training to all relevant personnel. Sobi therefore believed that Sobi had maintained high standards at all times in relation to this issue and there was no basis for a finding of a breach of Clause 9.1.

**1.2 Alleged sharing of patient identifiers with commercial/medical teams**

The complainant alleged that the Sobi's database contained 'patient identification numbers' and that these identifiers were shared with the Commercial and Medical teams. Sobi strongly refuted any suggestion that Sobi had breached the Code in relation to its possession or use of any patient identification numbers.

Sobi submitted that the homecare delivery provider that supplied Sobi's products to NHS patients provided regular reports to Sobi concerning the number of patients supplied at each treatment centre. Each individual patient had been assigned a unique ID number by the homecare delivery provider to enable the number of patients at each centre at any given time to be accurately recorded and these patient identification numbers were included in the reports sent to Sobi. Sobi used these numbers to keep track of the number of patients using its products at each treatment centre.

Other than the ID number, Sobi did not receive any personal information about the patients, so the information provided to Sobi had been de-identified. Sobi had no means of identifying any individual patients from those ID numbers and had no access to other personal information relating to such patients that could possibly allow Sobi to re-identify the patients. Sobi submitted that this information, which was used by Sobi solely for its own internal purposes and was not shared with anyone outside the organization, was effectively anonymized. Sobi believed its use of this information was compliant with all applicable UK data protection laws and guidance and there was no risk to patient confidentiality. Sobi submitted that it had maintained high standards at all times and did not consider there to be any basis for a finding of a breach of Clause 9.1 or Clause 2 in this regard.

### 1.3 Alleged disguised market research/promotion (Take Control Survey)

Sobi stated that the focus of the global promotional campaign, 'Take Control', was to highlight the importance of increased physical fitness and optimal treatment for patients with haemophilia to promote long term joint health. This was particularly important in the context of the pandemic, since Covid-19 restrictions had impacted the ability of people with haemophilia to keep active. Research had also shown that Covid-19 reduced adherence to prophylactic therapy therefore raising awareness of the importance of adequate treatment was critical. It was unclear exactly what the complainant was alleging was wrong with this campaign or how it might be in breach of the Code, but the complainant had referred to it as possible 'disguised market research/promotion'. The complainant also claimed that no briefing document was sent out and that some sort of financial incentive was associated with the survey. The PMCPA had asked Sobi to respond in relation to Clauses 9.1, 12.1, 15.4 and 15.9.

Sobi stated that representatives were requested to present the campaign slides to customers as part of a promotional call to start the conversation about improving patients' activity levels during the pandemic. As part of their presentation representatives were expected to ask their customers four specific questions, and to record the answers. The survey was a key part of Sobi's preparations for the anticipated increase in activity levels among patients as lockdown restrictions eased.

Following a global briefing on 25 March 2021, on 30 March 2021 a presentation was given to representatives and other personnel in the UK which provided an introduction to the upcoming campaign and explained how the campaign had worked in other countries. This was the presentation referred to by the complaint as missing. Sobi provided a copy of that internal presentation and stated that it was not provided directly to representatives, nor were they

expected to use any of the content or messages until such time as they received bespoke UK approved briefing materials. Following this introduction, representatives were provided with the Take Control slide deck and formal certified briefing materials on the use of that slide deck. The campaign was rolled out in two waves, with some different questions in the second wave. Sobi provided copies of the briefing material used in both waves and submitted that there was no suggested, implied or actual financial incentive associated with the Take Control survey.

Clause 12.1 stated that promotional materials and activities must not be disguised. Sobi stated that the slide deck was clearly promotional. Every slide had the company and brand names in logo format and had the look and feel of promotional material. The opening slide had clear direction where to find the prescribing information, which was included in the final slide. Health professionals would have been in no doubt this was promotional material. It was not disguised as market research or as a non-promotional activity. It was standard practice to ask health professionals relevant questions during promotional presentations. There were a number of reasons for doing this, eg to ensure tailoring of the presentation to areas that were particularly relevant for the health professional, to increase engagement, or for gaining field insights as in this case. Questions and questionnaires were often used at the end of meetings to gain feedback from participants and used by companies to measure the success of the event, how to improve and ideas for new topics. There were no rules in the Code or otherwise that prohibited representatives from asking questions and recording the answers during promotional meetings or when using promotional materials. Sobi submitted that it was not in breach of Clause 12.1.

It was unclear to Sobi how Clause 15.4 was relevant to this particular allegation. The slides were presented to health professionals as part of a standard promotional call. There was no suggestion that such calls caused any inconvenience to the health professionals or were in excess of the number of unsolicited calls permitted per health professional per year. Sobi was therefore not in breach of Clause 15.4.

Sobi prepared and provided briefing materials its KAMs. The complainant was mistaken in the assertion that no copy of the briefing material was sent out. Sobi was therefore not in breach of Clause 15.9.

The complainant had not identified anything inappropriate about the Take Control survey or that would be in breach of any specific requirements of the Code. Sobi submitted it had maintained high standards at all times in relation to the Take Control survey and was not in breach of Clause 9.1

### 1.4 Sales Manager contacting patients

The complainant alleged that the sales manager contacted a patient and that Sobi's internal policy provided that patient organizations should only be contacted by the patient access team. However, it was unclear what specific requirements of the Code the complainant considered would be breached by the alleged behaviour.

The complainant referred to an email from the interim manager dated 16 April 2021. That email attached a publication from the BMJ authored by an individual with haemophilia. Contrary to the complainant's belief, the email did not say that the manager had been speaking with the individual. Rather, it just stated that the manager was trying to organize a talk from the individual. Sobi understood that the manager sent a message to the individual via that

individual's professional Linked-In page but did not speak with the individual and no subsequent meeting or talk took place.

As acknowledged by the complainant, the individual was a consultant with his own consultancy company and the individual was contacted in his professional capacity. The fact that the consultant was also a patient was irrelevant since the proposed interaction was commercial in nature – namely to obtain expert training services. There was nothing in the Code that specified that commercial personnel might not contact potential consultants, even if those consultants also happened to be patients.

The company was demonstrably not a patient organization, but a commercial venture founded by this individual that he/she described as 'an independent consultancy' that provided 'expert strategy consulting in the development of national and global activation campaigns with commercial healthcare companies, multi-agencies and charity partners'. Therefore, Sobi's policies on interactions with patient organizations were not relevant to this allegation. Nonetheless, Sobi provided a copy of the relevant internal policy on interactions with patients, caregivers and patient organizations as would have been applicable at the time of the email and the current version of that policy. Contrary to the complainant's suggestion, this policy did not require that only patient access team members dealt with patient organizations.

The complainant had not provided any evidence to suggest that the manager's limited interactions with a potential consultant were in any way inappropriate or in breach of the Code, nor were they in breach of Sobi's policies. In this matter, Sobi had maintained high standards at all times and was therefore not in breach of Clause 9.1.

**2.1 Health professional contracts**

Sobi noted that the complainant had made several allegations regarding contracts with health professionals for speaking engagements. Sobi referred to Clause 23.1 of the Code relating to the use of consultants provided that 'a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services.'

Sobi submitted that its policy on Consultancy Engagements reflected the requirements of the Code. Any activity lead who wished to engage a health professional consultant must complete an internal approval form and obtain line manager approval of the proposed engagement. A draft consultancy agreement must be prepared and provided to the health professional. When the health professional was being engaged as a speaker or meeting chair, a speaker briefing should be prepared and reviewed through the company's procedure for the review and approval of promotional and non-promotional materials. Finally, the policy stated that the contractual agreement must be signed by both parties before the consultancy engagement took place.

With respect to the first health professional engagement referenced in the complaint, the speaking engagement was never performed and the health professional was not paid for any preparatory work until a contract was in place. Unfortunately, the representative who invited the health professional to speak at a proposed webinar failed to follow Sobi's procedures and did not get prior internal approval of the proposed engagement. Sobi's senior management became aware of this deviation on 27 January 2021, before the speaking engagement was due to take place.

Sobi's management cancelled the meeting on 28 January and put in place a CAPA on 3 February 2021 to address the representative's deviation from the company's established procedures. Sobi and the health professional agreed a contract and after execution of the contract, Sobi paid the health professional for the preparatory work that the health professional had already done before the meeting was cancelled. Sobi believed that this response was proportionate, considering there was no evidence that the failure to follow procedures was a systemic issue.

With respect to the second health professional engagement referenced in the complaint, several health professionals were engaged to speak at an online meeting. Sobi held a rehearsal a week before the online meeting was due to take place, and the contracts for the speaking engagement were signed no later than at that rehearsal. Again, the contracts were signed in advance of the speaking engagement for which the health professionals were paid. All necessary internal approval forms had been completed in advance of the rehearsal and the scope of the requested services had been made clear through the briefing notes provided to the health professionals.

Sobi denied a breach of Clause 23.1, given that signed contracts were in place with the health professionals before the events at which the health professionals were requested to speak. Given that Sobi had appropriate policies in place regarding the engagement of health professionals as consultants and given that Sobi acted swiftly to implement a CAPA on the occasion when there was a deviation from Sobi's policy, Sobi did not believe that it had failed to maintain high standards and that there had been any breach of Clause 9.1.

### 2.2 Certification and Review

The complainant alleged that he/she was advised to send a non-approved medical slide deck to a health professional. This slide deck was prepared by Sobi's global organization concerning the medical rationale for a personalized treatment regimen. The slide deck could be used by local Sobi companies subject to any modifications required to comply with local requirements and subject to approval in accordance with local procedures. A copy of this global slide deck was provided by Sobi. The complainant was liaising with a health professional who had been engaged as a consultant to speak on behalf of Sobi. All appropriate contracts were in place. The complainant was advised that they could share this slide deck with the health professional, as reference material for the health professional to use in preparing his/her own presentation. The complainant was not asked to use this slide deck herself or to give it to a health professional as a leave piece. The provision of such preparatory materials to a consultant engaged as a speaker was not promotion and such preparatory materials were not promotional materials that require certification under Clause 14.1. Rather, the consultant's own final presentation on behalf of the company must be reviewed and certified or examined by the company as applicable in accordance with the requirements of Clause 14.

Sobi understood that the complainant was uncomfortable with providing the materials to the health professional and did not share the slides with the speaker. Sobi's Medical team then took over liaising with the speaker. However, it was permissible under the Code for Sobi to provide slides to an external consultant for use to develop their own presentation, so long as the consultant's final presentation was reviewed and approved in accordance with the applicable procedures prior to use, as happened in this case. There was no prohibition on such preparatory materials being provided to the consultant by a representative. There was no

evidence that Sobi has failed to maintain high standards in this regard and therefore Sobi was not in breach of Clause 9.1.

The second allegation concerned a slide deck for a webinar. The slide deck for the webinar was reviewed and certified in accordance with Sobi's procedures in advance of the webinar. On the day of the webinar, the complainant himself/herself identified a typographical error with the title of one of the speakers in the agenda slide. This error was corrected (a simple change from 'Mrs' to 'Ms'), but the entire slide deck was not re-certified before use. Although Sobi regretted that it did not follow its procedure in this instance, the nature of the edit was unrelated to any promotional content. The PMCPA recognised that email templates might be certified for use, allowing simple changes to be made to allow changes in salutations, dates, venues without the need for individual certification as long as the company could be confident that any changes did not affect compliance with the Code (Case AUTH/3168/2/19 - Complainant v Janssen). This administrative change in the title of one of the speakers did not impact any of the other content or compliance with the Code and Sobi believed should be viewed in the same light as certified email template changes.

**2.3 Marketing Activities**

The complainant had made an allegation regarding an invitation to a webinar that was to be sent to health professionals. It was unclear from the complaint what provisions of the Code he/she considered might have been breached in this instance or how the alleged conduct might have constituted a breach.

An invitation to a webinar was prepared for KAMs and other representatives to send to health professionals. The invitation was reviewed and certified in accordance with Sobi's procedures and provided to the KAMs via email for distribution. It was subsequently discovered that the incorrect document had been added to the email. The attachment was a different document that related to the same meeting series and had also been certified for use with health professionals. That document was therefore formally withdrawn, as demonstrated by the complainant in their documentation, and a new invitation was prepared, reviewed and certified. Although the original document had been provided to KAMs for use, Sobi's understanding was that it was not distributed to any health professionals before it was withdrawn.

Sobi's procedures operated exactly as they should: an error was identified with some material that had been certified; the material in question was withdrawn and the Sobi personnel who had received the material were instructed not to send it to health professionals; subsequently, a corrected invitation was prepared, reviewed and certified, and this correct invitation was sent to health professionals. Sobi had therefore maintained high standards at all times and was not in breach of Clause 9.1.

The complainant had also alleged that some training materials for a new product were provided to the commercial team for training purposes, but they did not include the black triangle symbol. The document in question was an internal training slide deck for company representatives explaining a new formulary document for a Sobi product. The document made clear that it was intended for internal use only, so it was not intended to be shown to health professionals.

Sobi referred to Clause 4.10 and its supplementary information. The company acknowledged there was a requirement that training materials for representatives were certified in the same way as promotional material to ensure they were held to the same high standards as externally

facing materials in terms of information provided, claims made and substantiation required, there was an allowance that these particular materials were not going to prescribers and as such companies routinely certified them without including the prescribing information or other obligatory information required to be included in promotional materials under Clause 4 of the Code. Sobi would also draw attention to slide 10 of the presentation, which discussed the formulary document that was approved for distribution to health professionals and included an image of the first page of that formulary document. That image showed that the formulary document itself, which would be shared with health professionals, included the black triangle symbol prominently in accordance with Clause 4.10. As such Sobi denied a breach of Clause 4.10.

## 3 Training

The complainant had made a number of allegations regarding Sobi's training for representatives. These could broadly be summarized as an allegation that there was no formal training curriculum for new representatives and an allegation that training records were incomplete.

As a general comment, Sobi drew attention to the fact that the complainant held a sales role, rather than a managerial role or a role within Sobi's HR or compliance functions. Therefore, the complainant did not have access to the training records of other personnel and could not know exactly what training such personnel received. The complainant's allegations were therefore speculative in nature, or at best based on incomplete information.

The complainant alleged that there was 'no formal product training for Haematology' and 'no formal curriculum' that covered minimum standards for new representatives. Sobi submitted that these claims were incorrect. All new representatives must complete an initial training course (ITC). A summary of the core modules within the ITC was provided. This training course was provided to all new customer-facing personnel, regardless of whether they were employees or contractors. Personnel in other roles received training tailored to their particular function.

In addition to the product and disease training provided in the ITC, all new Sobi personnel, including representatives, received other relevant training, such as training on pharmacovigilance, data protection and the company's iHIP policies that addressed compliance with applicable Code requirements.

Contrary to the complainant's allegations, Sobi stated that records of training were captured both inside and outside of the Sobi Career system, depending on the topic, the role of the person being trained and who was providing the training. How Sobi chose to store its records was an internal matter and there was no requirement under the Code for all training records for all personnel to be compiled in a single location. There was also no requirement under the Code that individual employees had access at all times to a comprehensive listing of all the training that they had undertaken.

The assertion that there was 'normally no follow up' of employees who missed training was without foundation. Any follow up on missing training for employees other than the complainant, which might be conducted by email or phone, would not be apparent to the complainant. Such follow up would not concern the complainant and so they would not necessarily be informed.

The complainant also alleged that global training materials were not reapproved by the UK approval system, which was incorrect. Sobi confirmed that all product and sales training materials provided to UK representatives were required to be certified in its review system with job codes.

Regarding the complainant's allegations that specific employees were not trained when starting, Sobi regretted that a limited number of training modules were originally omitted from the training curriculum for the employee named by the complainant in the company's online platform . For background, these modules were part of the disease training program (specifically, coagulation cascade). This was due to a technical issue that did not delay the validation process. Sobi responded to this limited shortcoming by commending the named employee for escalating the issue, with the intention of promoting the 'speak up' culture Sobi strove to maintain. Regarding the similar allegations concerning 'all four new starters' experiencing 'problems regarding training modules,' the complainant had not provided sufficient details or evidence for Sobi to respond precisely. However, Sobi would like to reiterate that there was a distinct difference between disease training for haematology and process training (eg iHIP). All staff, including KAMs, were re-trained on processes and the Code following the aforementioned iHIP relaunch in March 2021.

Regarding the SPC that was sent to the employee named by the complainant, Sobi would like to clarify that the SPC was used as an example, only for internal training purposes to help new starters understand the structure of an SPC and the type of content it might contain. The SPC in question was not used with customers. At the time this came to light, Sobi recognized that it would be best practice to only use the most recent SPCs for all purposes and this was what was now being used.

Sobi stated that it took a proactive approach to training and tackled concerns as they arose. Sobi also strove to continually improve its processes, as evidenced by the enhanced focus on follow up of training referenced in the documentation provided by the complainant. Beyond the curriculum for new representatives, Sobi had so far organized six mandatory trainings relating to the topics covered by iHIP, and vendor sourced mandatory training for all Vault users in 2021. Sobi therefore provided and guided all of its representatives through a comprehensive and rigorous training regime that satisfied the Code. The complainant had not provided any evidence to the contrary and therefore Sobi refuted any alleged breach of Clause 15.1.

Sobi stated that it took its responsibilities to train representatives adequately extremely seriously. As outlined above, Sobi did provide appropriate training to representatives in accordance with the requirements of the Code and maintained records of such training. No evidence had been provided that Sobi did not maintain high standards at all times in this regard, and therefore Sobi was not in breach of Clause 9.1.

**Clause 2**

In relation to the allegation of a breach of Clause 2, Sobi refuted that any of its materials or activities were such to bring discredit upon or reduce confidence in the industry. Clause 2 was a sign of particular censure and reserved for such circumstances. None of the allegations in this complaint related to prejudicing patient safety, promoting prior to licence, inducements to prescribe or any of the other examples cited in the supplementary information as likely to be in breach of Clause 2.

Sobi 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. Sobi had refuted all the allegations made by the complainant and had robust policies and procedures in place to ensure compliance with the Code.

**PANEL RULING**

The Panel noted that the Constitution and Procedure stated that the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties.

**1 Haematology Field Force Activities**

**1.1 Alleged pressure to falsify calls and overcall on health professionals**

The Panel noted the complainant's concern that there had been significant pressure to increase activity over the last year with no regard for the Code; the complainant stated that the call rate had almost doubled on two thirds of the number customers and alleged overcalling on certain customers.

The Panel noted that the supplementary information to Clause 15.4 stated, *inter alia*, that the number of calls made on a doctor or other prescriber by a representative each year should not normally exceed three on average. This did not include attendance at group meetings and such like, a visit requested by the doctor or other prescriber or a visit to respond to a specific enquiry or follow up a report of an adverse reaction, all of which could be additional to the three visits allowed. The supplementary information also included that when briefing representatives, companies should distinguish clearly between expected call rates and expected contact rates. Contacts include those at group meetings, visits requested by doctors or other prescribers, visits in response to specific enquiries and visits to follow up adverse reaction reports. Targets must be realistic and not such that representatives breach the Code in order to meet them.

Clause 15.9 stated that briefing material for representatives must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code. As set out in the supplementary information, the detailed briefing material referred to in this clause consisted of both the training material used to instruct representatives about a medicine and the instructions given to them as to how the product should be promoted.

The Panel noted that Sobi rejected the allegation that briefings regarding activity were predominantly done verbally and that there were usually no written briefing documents. The Panel noted that the complainant bore the burden of proof and did not consider that he/she had established his/her case on the balance of probabilities in relation to this allegation and no breach of Clause 15.9 was ruled in this regard.

The Panel noted Sobi's acknowledgement that the unique circumstances of the 18 months prior to the complaint had been difficult and stressful for its key account managers who might have found it challenging to maintain the expected activity levels. Nonetheless, Sobi refuted any suggestion that it had encouraged or pressured its representatives to falsify records or conduct unsolicited calls on health professionals in excess of the maximum permitted under the Code.

The Panel noted Sobi's submission that as a global/European organisation, it tracked the total contact rates for health professionals and established activity targets for its European businesses, including Sobi UK, based on all contacts. The Panel noted Sobi's submission that activity levels or contact rates were not the same as the number of unsolicited calls and any pressure on sales representatives to meet target activity levels did not equate to pressure to conduct unsolicited calls or to fail to comply with Code requirements. Sobi UK therefore based its activity targets on health professional contacts, which encompassed a broad spectrum of communication, including solicited calls and interactions at meetings. The Panel queried whether it was appropriate to set targets for solicited calls noting that some of these could not be planned and in doing so might encourage KAMs to act in a way that might breach the Code to obtain such activity.

The Panel noted that communications between the UK and the global organisation regarding the need for the UK business to increase its activity levels and Sobi's submission that the UK was free to negotiate changes to the levels proposed by the global organisation to tailor them to the specifics of the UK market, including in particular challenges in the UK due to the pandemic situation.

The Panel noted Sobi's submission that during the period relating to this complaint, there was an increased focus on activity levels by management because the UK team was not meeting its internal targets and management discussed activity levels at a weekly cross functional meeting.

The Panel noted Sobi's submission that such discussion was entirely reasonable and appropriate as activity levels were an important key performance indicator (KPI) for any pharmaceutical sales team and there was nothing in the Code that suggested it would be inappropriate for a company to prioritise this metric. The Panel noted that it appeared that cycle plans also included the number of contacts and these were discussed at team meetings. Whilst the Panel noted that it was not necessarily unacceptable for companies to discuss representative's activity levels, provided the way in which it was done complied with the Code, in the Panel's view, noting the weekly discussions of the activity and the increased focus on activity levels by management as seen in the various correspondence provided by the complainant, the overall approach might be seen to put unreasonable pressure on representatives to increase their activity and potentially breach the Code in doing so. In this regard, the Panel noted that a senior leader sent an email to the sales team on 4 February 2021 which included a screenshot of the activity by week for each named individual KAM.

Whilst the Panel was concerned that an email from a former manager, on 1 July 2020 to the sales team stated that his/her understanding that planned activity was unsolicited and should not exceed 3 in one calendar year had been challenged, and overruled, it noted that the email stated that recipients of the email needed to revisit their cycle plans and if a customer visit did not take place in H1 (assumed by the Panel to be the first six months of the year), plan for 3 in H2, unless this was unachievable. On the available information before it, the Panel considered that the email appeared not to be out of line with the supplementary information to Clause 15.4.

Further, the Panel noted that an email from a senior employee dated 7 July 2020 stated that, through initial work, Sobi had recalibrated its customer interactions based on understanding the total interactions that took place in H1 and compiled its plans for unsolicited interactions in H2 that ensured that no customer would have more than three such interactions over the year.

The Panel noted Sobi's submission that its policies provided sufficient clarity on the distinction between (i) unsolicited calls and (ii) all calls, contacts or other interactions comprising engagement with health professionals and that the guidance in force throughout the period covered by the complaint was absolutely clear that sales representatives must not make more than 3 unsolicited calls on a health professional in a given year but stated that it was acceptable to undertake and plan more than 3 contacts/interactions with a health professional per year. In this regard Sobi referred to the relevant section of its interactive Healthcare Interactions Policy and written guidance from the UK/ROI Leadership Team on its expectations for recording activity levels in a May 2020 briefing. The Panel further noted that Sobi acknowledged the importance of distinguishing unsolicited calls from other types of contact and its CRM system allowed such a distinction with markers for unsolicited calls and different types of interaction (emails etc).

The Panel nonetheless considered that each representative briefing that related to activity targets needed to stand alone and should refer to the Code requirements and definitions of a call versus a 'contact' as defined by Sobi.

In this regard, the Panel noted that the Minimum standards for CRM UK-RoI region (Job-Number: ITM-0889) dated June 2020 defined a call as either a face to face (FtF) meeting, a FtF interaction at a meeting, a virtual or remote meeting, a telephone call or an e-mail exchange; during which a meaningful discussion had taken place and that these should be recorded as product related or non-product related within the CRM. No differentiation was made between solicited and unsolicited calls. The Panel noted that in this document, the minimum standards for commercial teams included that target customers were being seen as required. The Panel noted it stated that if the minimum standards were not achieved on two occasions during a calendar year and there was no reasonable explanation, then the final end of year review rating would be no higher than 'below expectations' which would result in a loss of 50% of the annual bonus.

The Panel further noted Sobi's submission that the complainant's territory was changed whilst their activity rate remained the same. It appeared from communication provided by the complainant that his/her activity increased in terms of the number of virtual/phone meetings per day from November 2020 to February 2021. The Panel referred to the information regarding the actual numbers. According to the communication sent in February 2021, in this regard, the activity should be made up of either promotional phone calls or virtual meetings. The Panel noted that no reference was made in either communication as to whether these activities should be solicited or unsolicited. Neither was there a definition of call or contact rates in either communication nor were the relevant requirement of Clause 15.4 and its supplementary information clearly referred to.

The Panel noted that the complainant raised concerns that the 'aspirational' target would mean that after 37 days on territory, he/she would then be starting the cycle of seeing the same customers again, if there was no request by a doctor or other prescriber or other call in order to respond to a specific enquiry or to follow up an adverse events with the potential to risk over calling on this customer group. According to the complainant, no response from the company was received in this regard. The Panel noted that Sobi did not provide any comment in this regard.

The Panel noted that the email communications above referred to activity targets, calls and virtual meetings and did not give any details about the requirements of the Code nor distinguish

clearly between expected call rates and expected contact rates and the Panel therefore ruled a breach of Clause 15.4. There was little information about how a representative was expected to increase their numbers of contacts with health professionals whilst ensuring these were not unsolicited calls. Regardless of any reference to the Code and its requirements, the Panel considered that the pressure placed on the key account managers in setting the activity targets as noted above and failure of each representative briefing to distinguish clearly between expected call rates and expected contact rates meant that on the balance of probabilities, the representative briefing documents advocated a course of action which would be likely to lead to a breach of the Code. Thus, the Panel ruled a breach of Clause 15.9.

The Panel noted Sobi's submission that it had conducted a full review of the activity recorded in its CRM system for 2020 and the first half of 2021 and could confirm that no individual health professional received more than three unsolicited calls per year but might have had contact with the company considerably more than this as a result of other contacts. Whilst the Panel was concerned about the representative briefing material, it considered that there was no evidence before it that the actual number of calls made on a doctor or other prescriber by a representative had breached the requirements of the Code. The complainant had not provided any evidence that any Sobi representative had made more than three unsolicited calls on any individual health professional per year including the health professional specifically named by the complainant and the Panel therefore ruled no breach of Clause 15.4.

The Panel noted that the complainant referred to an internal WhatsApp message, sent prior to a major international congress, from a former manager, which, stated, *inter alia*, 'The consensus from the top is that if you 'smell' a customer, record it as a face to face… Sign of the times I'm afraid' and went on to state 'I am very keen that our team is seen in the best possible light'. The Panel considered that the WhatsApp message implied that any communication should be recorded as a face to face contact.

The complainant made several further allegations regarding how contacts with health professionals were recorded in Sobi's CRM system, including a suggestion that contacts with health professionals in relation to two distinct products be recorded as two separate contacts, and a reference to record emails as contacts in the database. Whilst the Panel noted that how companies decided to record calls was not a Code requirement, the way it instructed its representatives in this regard might fall within the scope of the Code.

The Panel noted that according to the transcript provided by the complainant of a meeting held on 16 February, a senior leader stated 'For example, if you have a call next week, pick up the phone and confirm that call. If you tell them what you're going to talk to them about, log it as a promotional call. So that's not lying, you know, that's not being deceitful, that's maximising the opportunity that you've got next week so that out of one call you basically get two, because you followed it, then you can follow it up with another to make three. So I'm just trying to think of ways that we can increase that number because it's so important that we increase the activity in whatever way we can'.

Further the transcript provided by the complainant of a meeting held on 19 March 2021, a senior director leader if I were you and I was having a meaningful conversation dialogue by email with a customer, I'd log it as a phone conversation, if it were me. Because emails, as you know, don't count. Even though they are counted in the click sense, and you will see them come through in there, in terms of the Dashboard, in terms of any conversation that happens with local, across the business, Immunology concluded, emails count for nothing.

The Panel considered that encouraging employees to record inaccurate calls, such as recording emails as telephone calls because emails did not 'count', meant that high standards had not been maintained and a breach of Clause 9.1 was ruled.

### 1.2 Alleged concern that patient identifiers were shared with commercial/medical teams

The Panel noted Sobi's submission that the homecare delivery provider that supplied Sobi's products to NHS patients provided Sobi with regular reports concerning the number of patients it was supplying with Sobi's products at each treatment centre. Each individual patient had been assigned a unique ID number by the homecare delivery provider to enable the number of patients at each centre at any given time to be accurately recorded and the ID numbers were included in the reports sent to Sobi. These reports were circulated to the haematology team. The Panel noted Sobi's submission that it did not receive any personal information about the patients and it had no means of identifying any individual patients from those ID numbers. Further, the information, which was used by Sobi solely for its own internal purposes and not shared with anyone outside the organisation, was effectively anonymised and therefore was, according to Sobi, compliant with all applicable UK data protection laws and guidance and there was no risk to patient confidentiality.

Whilst the Panel questioned the need for the patient ID numbers to be sent to Sobi and to be circulated to the haematology team, it did not consider that the complainant had established, on the balance of probabilities, that such sharing of patient identifiers with Sobi was in breach of the Code. It thus ruled no breach of Clauses 9.1 and 2.

### 1.3 Alleged disguised market research/promotion (Take Control Survey)

The Panel noted Sobi's explanation that 'Take Control' was a global promotional campaign, the focus of which was to highlight the importance of increased physical fitness and optimal treatment for patients with haemophilia which was particularly important in the context of Covid-19 as restrictions had impacted the ability of people with haemophilia to keep active. Research showed that Covid-19 reduced adherence to prophylactic therapy. The Panel noted that the slide deck was rolled out in two waves with some different questions in the second wave. According to Sobi, representatives were requested to present the slides to their customers as part of a promotional call to start the conversation about improving patients' activity levels during the pandemic and were expected to ask their customers four specific questions and record the answers. The Panel noted Sobi's submission that there was no suggested, implied or actual financial incentive associated with the Take Control Survey as alleged.

The Panel noted Sobi's submission that the slides were presented to health professionals as part of a standard promotional call and that it was standard practice to ask health professionals relevant questions during promotional calls. The Panel, on the evidence before it, did not consider that the promotional nature of the material was disguised and so no breach of Clause 12.1 was ruled.

The Panel noted that Sobi provided copies of the relevant briefing material related to waves 1 and 2 to its representatives and thus the Panel ruled no breach of Clause 15.9.

The Panel did not consider that the complainant had raised an allegation in relation to Clause 15.4 and thus it ruled no breach of that clause.

The Panel did not consider that the complainant had established that the use of the campaign and related questions by Sobi meant that high standards had not been maintained and no breach of Clause 9.1 was ruled.

The Panel noted that it appeared from the complaint that the promotional presentation would also be used by MSLs. The Panel did not have any comment from Sobi in relation to use of the promotional slides by the MSLs. The Panel considered that the complainant had not provided evidence in relation to the use of the 'Take control' slides by MSLs and why this in particular was in breach of the Code and the Panel therefore, on the evidence before it, ruled no breach of Clause 9.1 in this regard.

**1.4 Sales Manager contacting a patient**

The Panel noted Sobi's submission that a sales manager tried to contact an individual who, although a patient, was a consultant with his/her own consultancy company to arrange a talk; Sobi stated that the company was not a patient organisation. The Panel noted Sobi's submission that the manager sent a message to the individual via that individual's professional LinkedIn page but did not speak with the individual and no subsequent meeting or talk took place.

The Panel noted that the Code did not prohibit pharmaceutical company employees contacting patients; clearly if any such contact was made it needed to comply with the Code. The Panel noted that in this instance contact had been made by an employee. However, the Panel did not consider that the complainant had established that in messaging the individual to try and obtain internal training services, the manager had failed to maintain high standards as alleged and no breach of Clause 9.1 was ruled.

**2.1 Health professionals' contracts**

Clause 23.1 of the Code relating to the use of consultants required that 'a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services'.

The Panel noted Sobi's submission that with respect to the first health professional engagement referenced in the complaint, the representative who invited the health professional to speak at a proposed webinar failed to follow Sobi's procedures and did not get prior internal approval of the proposed engagement. Whilst Sobi submitted that the speaking engagement was never performed and the health professional was not paid for any preparatory work until a contract was in place, the Panel noted that preparatory work for the meeting was done by the health professional before a contract was put in place, which was the provision of a service in itself. The Panel therefore ruled a breach of Clause 23.1.

The Panel noted Sobi's submission that the speaking engagement did not happen and therefore ruled no breach of Clause 9.1 in relation to the allegation that acquired haemophilia was off label for Elocta.

The Panel noted Sobi's submission that with respect to the second health professional engagement referenced in the complaint, several health professionals were engaged to speak at an online meeting. Sobi held a rehearsal one week before the online meeting was due to take place and noted its submission that the contracts for the speaking engagement were signed no later than at that rehearsal which was in advance of the speaking engagement for which the health professionals were paid. Although it was not clear to the Panel whether the health professionals were expected to attend the rehearsal, the Panel considered that the consultants would have done preparatory work prior to the rehearsal. The Panel considered that in failing to have an agreement in place prior to the consultants doing any preparation for the contracted service meant that high standards had not been maintained and a breach of Clause 9.1 was ruled.

**2.2 Certification and Review**

The Panel noted the complainant's allegation that he/she was advised to send a customer a non-approved, medical slide deck that had expired. The Panel noted Sobi's submission that the slide deck was a global slide deck and could be used by local Sobi companies subject to any modifications in line with local requirements. The Panel noted the slide deck had the job code and date of preparation 'NP-7931 August 2019'. The Panel noted that Sobi made no submission with regard to the deck having expired or not having been approved.

The Panel noted Sobi's submission that the complainant was liaising with a health professional who had been engaged as a consultant to speak on behalf of Sobi and was advised that he/she could share a slide deck with the health professional as reference material to use in preparing his/her own presentation. The complainant was not asked to use this slide deck him/herself or to give it to a health professional as a leavepiece.

The Panel noted Sobi's submission that the provision of such preparatory materials to a consultant engaged as a speaker was not promotion and such preparatory materials did not require certification under Clause 14.1.

The Panel considered that, if requested, companies could provide material to speakers and that if the meeting were a promotional meeting, then the material provided should comply with the Code. Clearly the final presentation used by a speaker at a company meeting would need to comply with the Code and would need to be certified. Employing a health professional to speak at a meeting was not in itself an opportunity to provide unsolicited material.

The Panel considered that in these particular circumstances, the material provided to the speaker did not require certification and thus ruled no breach of Clause 14.1. Nor had the company failed to maintain high standards in this regard and no breach of Clause 9.1 was ruled.

The Panel noted Sobi's submission that on the day of a webinar, a typographical error was identified ('Mrs' to 'Ms') and corrected but the entire slide deck was not re-certified before use.

The Panel noted that Clause 14.1 required that, *inter alia*, 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 in the manner provided for by this clause.

The Panel considered that the final form of the slide deck had been amended following certification and therefore ruled a breach of Clause 14.1.

### 2.3 Marketing Activities

The Panel noted Sobi's submission that an invitation to a webinar was certified for KAMs and other representatives to send to health professionals but it was subsequently discovered that the incorrect document had been added to the email. The attachment was a different document that related to the same meeting series and had also been certified for use with health professionals and was formally withdrawn. The Panel noted that whilst the incorrect document had been sent to the KAMs, it was discovered and withdrawn before it was forwarded to any health professionals; the corrected invitation was sent to health professionals. The Panel did not consider that the complainant had established that the incorrect document had been sent out to health professionals and thus that high standards had not been maintained in this regard. No breach of Clause 9.1 was ruled.

Clause 4.10 stated that when required by the licensing authority, all promotional material must show an inverted black equilateral triangle to denote that additional monitoring is required in relation to adverse reactions.

The Panel noted that Clause 4.10 referred to promotional materials. The Panel considered that the material sent out to the commercial field team in preparation for a training session on formularies for Sobi's new product Doptelet was, in effect, briefing material and whilst it would have been helpful to include the black triangle, there was no requirement to do so. In the Panel's view, Clause 4.10 did not apply and so no breach was ruled.

## 3 Training

The Panel noted Sobi's submission that all new representatives/customer facing personnel must have completed an initial training course (ITC) regardless of whether they were employees or contractors. In addition to the product and disease training provided in the ITC, all new Sobi personnel, including representatives, received other relevant training, such as training on pharmacovigilance, data protection and the company's interactive Healthcare Interactions Policy (iHIP) policies that addressed compliance with applicable Code requirements. The Panel noted Sobi's submission that one of the specific employees referred to by the complainant did complete the three day ITC, starting on the same day he/she began his/her role as a key account manager. The second named employee did not require the same training as representatives as his/her role was not primarily a customer-facing one. The Panel noted that Sobi regretted that a limited number of training modules were originally omitted from the training curriculum for a third named employee due to a technical issue but that it did not delay the validation process.

The Panel did not consider that the complainant had established, on the balance of probabilities, that the Sobi employees had not been given relevant training and thus ruled no breach of Clause 15.1.

The Panel further noted Sobi's submission that contrary to the complainant's allegations, Sobi did retain records of training received by personnel and the complainant's assertion that there was 'normally no follow up' of employees who missed training was without foundation. The Panel further noted Sobi's submission that it could confirm that all product and sales training materials provided to UK representatives were required to be certified in in its review system

with job codes. The Panel thus, on the evidence before it, ruled no breach of Clause 9.1 in relation to each of these allegations.

The Panel noted Sobi's submission that the out-of-date SPC was used with one of the named employees for internal training as an example to help new starters understand the structure of an SPC and the type of content it may contain; it was not used with customers. Sobi recognised that it would be best practice to only use the most recent SPCs for all purposes and this was what was now being used. The Panel considered that using an out-of-date SPC, even for internal training, meant that Sobi had failed to maintain high standards and a breach of Clause 9.1 was ruled.

**Overall**

The Panel noted its comments and rulings above and did not consider that the circumstances brought discredit to or reduced confidence in the pharmaceutical industry. The Panel therefore ruled no breach of Clause 2.

**APPEAL BY THE COMPLAINANT**

The complainant stated that his/her complaint and documentation submitted to the Panel in July 2021 outlined three key matters pertaining to field force activities, meetings, and marketing materials and representatives training. Having read the respondent's reply and the subsequent ruling by the Panel, the complainant decided to appeal the finding of no breach of Clause 2.

Section 1.1 Alleged Pressure to falsify calls and overcall on health professionals.

The complainant noted that the Panel ruled Sobi in breach of Clauses 15.4, 15.9 and 9.1. The complainant stated that despite Sobi's claims that representative briefings regarding activity were done through written briefings, the transcripts of senior Sobi managers encouraging sales representatives to inaccurately record calls which resulted in a breach of Clause 9.1 provided evidence that senior managers had little or no regard for the Code, indeed by directing activity that advocated breaching the Code in itself reduced confidence in the industry as a whole, particularly at a time of great pressure to the NHS. Coupled with the cumulative Code breaches within this complaint highlighted Sobi's lack of commitment to the Code.

Section 3 Training:

The complainant stated that in Case AUTH/3345/5/20 (Health professional v Sobi) the Panel ruled Sobi in breach of Clauses 9.1 of the Code for failing to maintain high standards and Clause 2 for bringing the industry into disrepute. As part of the sanctions of this case Sobi was required to give an undertaking to avoid this behaviour again. Furthermore, the Panel considered that 'the failure to include accurate information about a product's side effects was such as to bring discredit upon and reduce confidence in the pharmaceutical industry'. An out-of-date SPC, used as an 'example' as submitted by Sobi, placed not only a new employee, who had little idea of what the current version would be, at risk of a potential breach of the Code if receiving a request from a health professional to provide a copy of the SPC but also failed to include accurate information about a product's side effects. In addition to this the SPC submitted as evidence in this complaint did not contain 'example' stamped across the document and this was the original document sent to the employee at Sobi. It seems odd that this element was missing.

The complainant alleged that Sobi's failure in using an out-of-date SPC and the Panel's finding of a breach of Clause 9.1 raised questions regarding significant concerns about patient safety. The fact that Sobi submitted that the SPC was used as an 'example' also raised questions regarding Sobi's internal [SOP] management. In addition, the fact that it was not withdrawn immediately, despite this being raised with Sobi senior managers and the medical employee as noted in the complaint, further highlighted poor internal processes in place to manage what was, a critical piece of information, as required by every sales representative role in the industry. The complainant queried what message this sent regarding prejudicing patient safety and accurate prescribing information being provided to health professionals by a breach of Clause 2 not being found.

The complainant noted that in Case AUTH/3151/1/19 (Anonymous Employees v Otsuka Europe) the Appeal Board found Otsuka in breach of Clause 2 for the cumulative effects of Otsuka's failings including the failing of managing SPC updates and the process of managing those updates. It appeared clear to the complainant that Sobi had cumulative failings within this complaint including the management of its internal processes, the directing of sales representatives by senior managers verbally to breach the Code as well as having poor processes in place to manage its certification, review and health professional contracts. There was a culture of fear within Sobi UK that did not encourage its employees to raise concerns regarding breaches of the Code for fear of retribution.

The complainant stated that it was with these points in mind that he/she wished to appeal the Panel's ruling and respectfully requested that the Appeal Board consider finding Sobi in breach of Clause 2.

**RESPONSE FROM SOBI**

Sobi accepted all of the rulings from the Panel in this case and provided an undertaking to take all possible steps to avoid similar breaches of the Code in the future. Sobi sincerely regretted that these events occurred. Sobi was fully committed to addressing the matters highlighted by the case and would apply learnings from the rulings to continue to improve its processes and procedures. Sobi was disappointed that the complainant viewed the Panel's rulings as insufficient and had appealed the ruling of no breach of Clause 2.

Sobi noted that the Panel's ruling made clear that it specifically considered Clause 2 overall when assessing the complaint. A breach of Clause 2 was for bringing discredit upon or reducing confidence in the pharmaceutical industry. It was a sign of particular censure reserved for examples such as activities prejudicing patient safety, excessive hospitality, inducements to prescribe, unacceptable payments, breach of undertaking, promotion prior to marketing authorisation and multiple breaches of a serious nature. The Panel concluded that the circumstances did not bring discredit upon or reduce confidence in the pharmaceutical industry and therefore ruled no breach of Clause 2.

Sobi submitted that the rulings by the Panel adequately addressed the nature of the breaches. Sobi strongly supported the Panel's ruling that there had not been a breach of Clause 2 overall for the following reasons:

- Patient safety was not compromised at any time;
- Health professionals did not receive misleading information;

- There was no evidence of overcalling on health professionals; and
- Most issues mentioned in the complaint had been raised internally demonstrating the company's culture of openness and willingness to resolve concerns and improve processes.

Section 1.1 Alleged pressure to falsify calls and overcall healthcare professionals

Sobi noted that the complainant alleged that that the Panel's finding that Sobi was in breach of Clauses 15.4, 15.9 and 9.1 provided evidence of senior managers having little or no regard for the Code and that directing activity that advocated breaching the Code in itself reduced confidence in the industry and coupled with the cumulative breaches of the Code within this complaint highlighted Sobi's lack of commitment to the Code.

Sobi submitted that whilst it was disappointing that a senior leader briefed teams to record activity differently in the customer relationship management (CRM) system, the Panel found that there was no evidence before it that the actual number of calls made on a doctor or other prescriber by a representative had breached the requirements of the Code. The complainant had not provided any evidence that any Sobi representative had made more than three unsolicited calls on any individual health professional per year including the health professional specifically named by the complainant and the Panel therefore ruled no breach of Clause 15.4. Sobi did however accept the Panel's finding of a breach of Clause 9.1 in relation to high standards. Other briefings and examples of clarification provided in Sobi's response showed that the company did refer to the Code requirements for unsolicited call rates when briefing representatives. In addition, Sobi strengthened wording in its internal UK ROI Healthcare Interaction Policy (iHIP) (March 2021) to address the requirement not to overcall or inconvenience health professionals. Sobi would continue to take learnings from the case to ensure that it was very clear each and every time cycle planning and activity discussions and briefings on activity took place, that these must be reviewed and approved as such to ensure that they met the Code requirements, and that where they constituted a briefing, they were appropriately certified as per the Code.

Sobi submitted that the cumulative effect of the breaches ruled would not be such that, taken together, they would indicate any systemic problems or amount to a breach of Clause 2. There had been no evidence presented by the complainant that Sobi had systemic compliance issues or a culture of disregard for the Code.

Section 3 Training

Sobi recognised the importance of patient safety and regretted that an incorrect version of an SPC was used with one individual as part of their initial training before starting their role as a representative. It was important to clarify that the error was flagged and resolved swiftly before the representative interacted with health professionals or other customers.

Sobi noted that a reference provided by the complainant included a confirmation from the sales representative that they had not shared the incorrect SPC with anyone. The sales representative was validated (passed the Sobi internal field role examination) with the correct version of the SPC. The sales representative had no external customer facing contact prior to that validation and thus the out-of-date SPC was not used with a customer nor was there any risk that it could have been so used. Whilst Sobi fully accepted that the incorrect version should not have been provided during the internal training and Sobi would continue to put in place

further enhancements and process controls to ensure that this did not happen again, Sobi strongly refuted that patient safety was compromised and that it did not warrant a breach of Clause 2.

The complainant referred to a previous case (Case AUTH/3345/5/20) and associated undertaking, alleging that there were significant concerns regarding patient safety. Sobi submitted that the circumstances of the cases were very different. The previous case involved the inclusion of inaccurate information about a product's side effects in promotional material externally used with health professionals. It had nothing to do with using an out-of-date SPC as part of representative training. Sobi had fully accepted the rulings and seriousness of that case and put in place corrective procedures to prevent the errors from taking place (including town hall briefings and training to all staff on 12 October 2020 followed by a validation assessment).

Processes

Sobi noted that the complainant had also referred to Case AUTH3151/1/19 as a precedent where the Appeal Board ruled a breach of Clause 2 for cumulative failings and also accused Sobi of those cumulative failings. Sobi acknowledged and accepted the rulings of the Panel in the present case but submitted that they did not amount to a breach of Clause 2, which was reserved as a sign of particular censure. The Otsuka Europe case (Case AUTH 3151/1/19) was one of repeated failure to appropriately update SPCs and prescribing information and showed a lack of clear process for both the creation and revision of prescribing information and SPC updates; that Otsuka Europe had certified and internally distributed to multiple affiliates incorrect prescribing information which omitted important safety information and a change to the licensed indication; and that the lack of clear communication about completion dates for an SPC update caused confusion with regard to a critical process. As such, Otsuka Europe did not appeal and accepted the breach of Clause 2. Sobi submitted that the breaches in its case did not amount to a similar systemic failure or bring the industry into disrepute.

In relation to the complainant's reference to a culture of fear within Sobi UK, Sobi refuted this and highlighted that it had an open speak up culture within Sobi UK, where queries, concerns and deviations were openly addressed without fear of retaliation. Sobi created the new role of UK ROI Compliance Director in August 2021 to reinforce the commitment to compliance and this role was part of the Leadership team. The Leadership team and line managers actively encouraged all staff to raise concerns or queries directly with their managers, compliance director or HR. Sobi hoped that staff felt comfortable speaking to their manager or other advisory roles, however if individuals still did not feel comfortable, Sobi also had a hotline which allowed them to make a report to a third party. Ethics Point, an independent company, managed the hotline and individuals could raise concerns over the phone or online and choose to be contactable or remain anonymous. In addition, as set out in Sobi's Global Code of Conduct, the company had a global policy on non-retaliation. The Code of Conduct was a mandatory training assigned by Global to all Sobi employees as part of the on-boarding process (via online learning platform Sobi Career) and typically the Code of Conduct was also assigned as a refresher every two years or when it was updated.

Finally, Sobi submitted that in relation to one of the matters described in the original complaint, the complainant directly raised this/her concerns about the deviation of process for the health professional contract and discussed this with the General Manager (27 January 2021). During that discussion the General Manager thanked the complainant for raising the issue and also expressed Sobi's commitment to work to rectify the situation, including the willingness of the

General Manager to call the health professional directly to apologise. This highlighted how seriously management took such matters and that there was a culture of openness to take accountability for mistakes and to thank staff for raising concerns so that Sobi had opportunities to correct or improve processes. There were no negative consequence for raising concerns.

The Compliance Director had also introduced Friday Compliance Corner drop-in conference call sessions for staff to join and raise queries or concerns and obtain points of clarification in an open informal setting.

**Summary**

Sobi acknowledged and thanked the Panel for its robust and thorough review of a complex case and had accepted the findings in full. Sobi submitted that the Panel had made the correct rulings and the company strongly refuted the arguments put forward by the complainant that this case warranted a ruling of a breach of Clause 2. No new information or evidence had been submitted to change the Panel's original decision. Sobi remained fully committed to patient safety and the Code and there was no evidence in any of these findings that patient safety had been compromised at any point and that any of the actions brought discredit on the industry.

**FINAL COMMENTS FROM THE COMPLAINANT**

The complainant having read through Sobi's comments stated that the cumulative findings of the original Panel, the number of breaches of the Code including Clause 9.1 for high standards and in particular the failure to provide an up to date SPC for training of a representative were grounds enough to warrant not only an appeal on the grounds of patient safety but also the consideration of a breach of Clause 2.

In relation to Sobi's comments regarding the SPC issue that 'it is important to clarify that the error was flagged and resolved swiftly before the representative interacted with healthcare professionals', the complainant stated that in the original complaint to the Panel the email from a training employee to the KAM, with the out-of-date SPC, was sent on the 14 July 2020 and not flagged until the 21 August 2020 as being the incorrect version. This highlighted that not only was the error not flagged and not resolved swiftly but that there was ample opportunity for the representative to have unwittingly interacted with healthcare professionals not knowing that they were in receipt of the incorrect SPC. In addition to this, a training employee who was a member of the Sobi leadership team was also clearly unaware of this, which further highlighted that despite having policies and procedures in place they were not being followed.

The complainant noted that Sobi had highlighted its commitment to compliance by creating a Compliance Director role in August 2021 as well as its internal 'Code of Conduct-Speaking Up' policy. The complainant queried why Sobi waited so long to appoint a Compliance Director and if Sobi had to take compliance more seriously given the fact that it had received this complaint in July 2021.

The complainant further submitted that the evidence submitted as part of the complaint highlighted that in several instances it was managers and senior managers within Sobi who encouraged non-adherence to the Code. It therefore seemed difficult to understand how comfortable anyone within Sobi would feel raising any concerns about Code breaches under the 'Code of Conduct- Speaking Up' policy to arguably the same group of managers who encouraged activities that could be seen as breaching the Code of Practice.

**APPEAL BOARD RULING**

The Appeal Board was particularly concerned that a senior leader had encouraged employees to record emails as telephone calls because emails did not 'count' towards overall activity key performance indicators (KPIs). This dishonest approach was completely inappropriate in the Appeal Board's view. The Appeal Board noted that the Panel had ruled a breach of Clause 9.1 in this regard which had been accepted by Sobi. The Appeal Board noted from the Sobi representatives at the appeal that other employees had raised concerns about that suggested approach at the meeting in question and it was decided that emails would not be recorded as telephone calls. The senior leader in question had since left Sobi and how to accurately record interactions had been reinforced.

The Appeal Board was further concerned that the incorrect version of an SPC was provided during the internal training of an individual before starting his/her role as a representative. The Appeal Board noted that the Panel had ruled a breach of Clause 9.1 in this regard which had been accepted by Sobi. The Appeal Board noted Sobi's submission that the error was flagged and resolved before the representative interacted with health professionals or other customers. According to Sobi, the representative was validated on the correct version of the SPC and had had no external customer facing contact prior to that validation. Further the representative confirmed that he/she had not shared the incorrect SPC with anyone.

The Appeal Board observed that the Panel's remaining breach rulings were in relation to amending 'Mrs' to 'Ms' on the final form of a slide deck without recertification, representative briefing failing to be clear on expected call rates and contact rates, and preparatory work for a meeting being done by a health professional before a contract was put in place.

The Appeal Board noted the Panel's rulings of breaches of Clause 9.1 in relation to a senior leader encouraging the inaccurate recording of calls and use of an out of date SPC for internal training. Despite its concerns above, the Appeal Board considered that, on the evidence before it, on balance, the particular circumstances of this case did not warrant an additional ruling of a breach of Clause 2 which was sign of particular censure and was reserved for such use. The Appeal Board therefore upheld the Panel's ruling of no breach of Clause 2. The appeal on this point was unsuccessful.

**Complaint received** **8 July 2021**

**Case completed** **7 July 2022**