CASE AUTH/2736/9/14

VOLUNTARY ADMISSION BY SANOFI

Relationships with patient organisations

Sanofi voluntarily admitted breaches of the Code in relation to its conduct and disclosure of interactions with patient organisations in 2013 and 2014. The company also voluntarily admitted a potential breach of the Code concerning its support of scientific meetings organised by patient organisations.

In accordance with Paragraph 5.6 of the Constitution and Procedure, the matters were treated as a complaint.

Sanofi referred to media interest in the way that patient organisations interacted with the pharmaceutical industry and it recognised that disclosure was important in ensuring that all such interactions were transparent. Prompted by this, Sanofi examined the disclosures made for patient organisation interactions and discovered that the support which it provided in 2013 had not been disclosed alongside other disclosures that were made for the same year. There were also no written agreements in place for the support provided. Sanofi immediately contacted the relevant organisations and disclosed the support provided.

Sanofi reviewed the disclosure and documentation concerning all support it provided to patient organisations in 2013 and 2014 and discovered that due process was not followed and correct disclosure did not occur, in breach of the Code.

In addition, Sanofi noted that it had sponsored some professional meetings organised by patient organisations but that such sponsorship had not been disclosed as an interaction with those organisations.

The detailed response from Sanofi is given below.

The Panel noted that Sanofi's voluntary admission related to its interactions with patient organisations in 2013 and 2014. Activities carried out in 2013 were subject to the Second 2012 Edition of the Code. That Code required companies which worked with a patient organisation to have a detailed written agreement agreed and certified in advance. Similarly, before a patient organisation provided a service to a pharmaceutical company, a detailed written contract or agreement was needed. Companies were required to make publicly available a list of patient organisations to which they provided support to include a description of the support which was sufficiently complete for readers to understand the significance of the support. Companies were also required to make publicly available a list of patient organisations engaged to provide significant, contracted services to include a description of the nature of the services which was sufficiently complete for readers to understand the arrangement without the need to divulge confidential information; the total amount paid per patient organisation over the reporting period must be declared. Both lists must be updated at least once a year.

The Panel noted that Sanofi had referred to interactions with patient organisations which had occurred before 2013. In that regard, from 1 July 2008 Sanofi would have had to annually publish a list, by no later than 31 March 2009, to cover activities commenced on or after 1 January 2008 or ongoing on that date, of patient organisations to which it had provided support in the previous year. A list of patient organisations engaged to provide significant contracted services had to be declared for the first time by 31 March 2013 to cover activities commenced on or after 1 January 2012 or ongoing on that date. Given the requirement to update its declarations at least once a year, Sanofi would have to amend the lists by no later than 31 March each year for activities carried out in the previous calendar year.

With regard to the activities carried out in 2014 the requirements of the 2014 Code were identical to those of the Second 2012 Edition of the Code except that the clauses had different numbers.

The Panel considered Sanofi's relationship with each patient organisation in turn.

The Panel noted Sanofi's submission that there was no written agreement to cover relationships with a number of patient organisations and breaches of the Code were ruled. The company had also failed to certify sponsorship arrangements with a number of patient organisations and further breaches were ruled. In addition breaches of the Code were ruled with regard to failures to disclose and certify fee for service arrangements.

A breach was ruled with regard to the interaction with one patient organisation as Sanofi had not accurately disclosed the amount paid and the information given was not sufficient for the reader to understand the significance of the support.

The Panel ruled further breaches of the Code as Sanofi's sponsorship of health professional's meetings organised by patient associations had not been publicly declared as interactions with the relevant associations.

The Panel noted the sensitivities surrounding the pharmaceutical industry working with patient organisations; robust agreements setting out the arrangements, and certification of agreements were important steps in ensuring that such interactions complied with the Code and in that regard they underpinned the self-regulatory compliance system. That projects and sponsorship were able

to go ahead without a certified agreement in place was unacceptable. Further, public disclosure of support was an important means of building and maintaining confidence in the industry. The Panel noted that Sanofi had either sponsored or engaged thirteen patient organisations without first having agreements in place to cover more than twenty activities. The company's support for the patient organisations in 2013, although now disclosed (apart from its support for health professionals' meetings) were disclosed six months late in September 2014; some original disclosures had been inaccurate or lacking in detail. The Panel considered that high standards had not been maintained and a breach was ruled.

The systemic failure with respect to the whole process of working with patient organisations was of grave concern. The voluntary admission submitted by Sanofi set out, and to a degree remediated, the situation with respect to patient organisations in 2013 and to date in 2014 however it was clear that Sanofi thought activities in 2012 could also be affected. For the lack of due process to be followed and for it to have gone undetected by the company for such a considerable period of time was totally unacceptable and brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel noted its comments and rulings above. The Panel appreciated that Sanofi had voluntarily admitted its failings in process and procedure, however given the time period and the extent to which such failings had gone undetected, the Panel considered that its concerns about the company's procedures warranted consideration by the Appeal Board. The Panel thus reported Sanofi to the Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure.

The Appeal Board considered that the transparency of a pharmaceutical company's interactions with patient organisations was critical. Whilst interactions with patient organisations was a legitimate activity, the arrangements in place at Sanofi at the relevant time were shambolic and shocking. The Appeal Board noted that Sanofi's voluntary admission was prompted by media criticism in summer 2014 about the relationships between the pharmaceutical industry and patient organisations. The Appeal Board was concerned that the failure had not been discovered earlier, for example as part of the company's preparation for the audit in March 2014 (Case AUTH/2620/7/13). It noted Sanofi's response that the area was part of its work programme. The company was still investigating to see what other interactions had not been disclosed.

The Appeal Board was extremely concerned that such a long term systemic failure across the entire Sanofi business regarding multiple payments to multiple patient organisations had occurred. Staff had failed to follow the relevant standard operating procedure (SOP) and Sanofi's governance of its SOP was very poor. This was a very serious matter.

The Appeal Board was extremely concerned about the breadth and scale of the failings and decided that, in accordance with Paragraph 11.3 of the Constitution and Procedure, the company should be publicly reprimanded.

The Appeal Board also decided to require an audit of Sanofi's procedures in relation to the Code. Given the company's ongoing and planned compliance activities, the Appeal Board decided that the audit should be conducted in March 2015 at the same time as the re-audit required in Case AUTH/2620/7/13. On receipt of the audit report and Sanofi's comments upon it, the Appeal Board would consider whether further sanctions were necessary.

On receipt of the March audit report the Appeal Board noted that Sanofi had made progress since the audit in October 2014; a new, senior manager was fully involved and leading many of the company's compliance initiatives.

The Appeal Board however, noted its concern about some of the company's activities and considered that Sanofi should address the matters raised as a priority. On the basis that this work was completed, the progress otherwise shown in the March 2015 audit was continued and a company-wide focus and responsibility for compliance was maintained, the Appeal Board decided that no further action was required.

Sanofi voluntarily admitted breaches of the Code in relation to its conduct and disclosure of interactions with patient organisations in 2013 and 2014. The company also voluntarily admitted a potential breach of the Code concerning its support of scientific meetings organised by patient organisations.

In accordance with Paragraph 5.6 of the Constitution and Procedure, the matters were treated as a complaint.

VOLUNTARY ADMISSION

Sanofi stated that it was currently undertaking a comprehensive project to review and improve procedures relating to compliance with the Code. The company stated it was committed to ensuring that a robust infrastructure existed, supported by a culture in which compliance with the Code was seen to enable business activity. In line with this strong leadership position, Sanofi submitted that it took immediate steps to prevent breaches of the Code as soon as the issues outlined below were realised, performed a thorough investigation, implemented robust corrective actions and submitted this voluntary admission.

Sanofi was aware of the recent media interest in the way that patient organisations interacted with the pharmaceutical industry and it recognised that disclosure was important in ensuring that all such interactions were transparent. Prompted by this, Sanofi examined the disclosures made for patient organisation interactions in 2013 and on 9 July 2014 discovered that the support which it provided in 2013 to Beating Bowel Cancer and the Rarer Cancers

Foundation had not been disclosed alongside other disclosures that were made for the same year. It was also apparent that there were no written agreements in place for the support provided.

Sanofi stated that it immediately contacted those patient organisations and requested permission to disclose the support provided. In both cases the disclosure was made as soon as possible after permission was granted, on 18 July 2014.

Having identified that no written agreement was in place before providing support and the failure to disclose that support, Sanofi realised that it was important to review the disclosure and documentation concerning the provision of all support it provided to patient organisations in 2013 and 2014. The review revealed that on a number of occasions due process was not followed, correct disclosure did not occur, and this had led to breaches of the Code.

As a result of this finding, Sanofi instigated an investigation reporting to the general manager and medical director, to identify the root cause and corrective actions that needed to be implemented. This revealed that although there was a properly defined process which clearly identified the steps to be taken when supporting or engaging patient organisations, this was not widely understood nor adequately trained to existing or new staff. There was also a process failure in that the financial systems allowed payment to be made without confirmation that all the requirements of the Code had been met.

This combination of factors had resulted in the following failures with regard to interactions with patient organisations in 2013: 2 disclosures referred to an incorrect financial figure; 3 disclosures contained no financial information; 15 activities were not disclosed and 16 activities were undertaken without a signed agreement outlining the nature of the support/service. Twelve disclosures met all the requirements of the Code.

In addition, although disclosure for activities undertaken in 2014 were not yet due, it was clear that five activities had been supported without a signed agreement in place.

Relationships with patient organisations subject to the Second 2012 Edition of the Code

Sanofi submitted that the following declarations all concerned payments made to patient organisations for activities undertaken in 2013. Although disclosure of payments was due in 2014, Sanofi had considered the requirements of the Second 2012 Edition of the Code on the basis that it was this version of the Code which was effective when the sponsorship/fees for service were provided.

The Second 2012 Edition of the Code required disclosure by the end of the first quarter of the following year. Where disclosure occurred after 31 March 2014 a breach of the Second 2012 Edition of the Code was declared.

A moot point was whether the disclosure should be judged by the 2014 Code which had removed a specific date by which disclosure should occur and instead required this to be 'at least once a year'. Sanofi's previous disclosure was 28 March 2013 – if the declarations were considered against the 2014 Code the disclosures would be similarly late. The clauses cited below were therefore from the Second 2012 Edition of the Code.

1 In 2013 Sanofi paid Team Blood Glucose £2,500 to support participation in the Richmond Park 5K/10K run to raise awareness of diabetes and the importance of regular exercise. In addition, Sanofi paid Team Blood Glucose to provide a motivational speaker for an internal meeting. As no formal written agreements were in place between the two organisations for either activity, Sanofi had thus failed to certify such agreements in advance in breach of Clauses 14.3 and 23.3. Furthermore, although disclosed in September 2014, the sponsorship and service fee were not disclosed within the required timeline in breach of Clauses 23.7 and 23.8 respectively.

2 In 2013 Sanofi paid Heart UK £12,000 to sponsor four continuing professional development accredited articles on hypercholesterolaemia published in the Primary Care Cardiovascular Journal. Heart UK was also paid a further £31,143 in sponsorship of a Royal College of General Practitioners' online training programme in lipid management.

   Sanofi submitted that the public disclosure of support to Heart UK was inaccurate in that the level of funding was incorrect (£24,000 as opposed to £12,000, and £42,958 as opposed to £31,143 respectively). Furthermore, in one instance the disclosure contained insufficient detail to enable the reader to understand the significance of the support (disclosed only as 'Direct project funding').

   Written agreements were produced and certified before the activity took place in accordance with the requirements of the Code.

   Sanofi admitted breaches of Clause 23.7 in respect to the inaccurate and insufficient disclosure of the support it had provided.

3 In 2013 Sanofi paid the Rarer Cancers Foundation £5,000 to support the Foundation's public affairs campaign. The lack of a formal written agreement between the two organisations governing this sponsorship meant that Sanofi had failed to certify such an agreement in advance in breach of Clauses 14.3 and 23.3. Furthermore, although disclosed in September 2014 the sponsorship and service fee [sic] were not disclosed within the required timeline in breach of Clause 23.7.

4 In 2013 Sanofi paid Leukaemia Care £10,000 to support patient support events. The lack of a formal written agreement between the two organisations governing this sponsorship meant that Sanofi had failed to certify such an agreement in advance in breach of Clauses 14.3 and 23.3.

Furthermore, although disclosed in September 2014 the sponsorship and service fee [sic] were not disclosed within the required timeline in breach of Clause 23.7.

5 In 2013 Sanofi paid the National Kidney Federation £14,000 in unrestricted sponsorship of the Foundation's general charitable objective of supporting patients with kidney disease. The lack of a formal written agreement between the two organisations governing this sponsorship meant that Sanofi had failed to certify such an agreement in advance in breach of Clauses 14.3 and 23.3. Furthermore, although disclosed in September 2014 the sponsorship and service fee [sic] were not disclosed within the required timeline in breach of Clause 23.7. [Post consideration of the case Sanofi advised that £4,100 was paid to the National Kidney Federation not £14,000 as previously stated].

6 In 2013 Sanofi paid Beating Bowel Cancer the following: £5,000 to support a public affairs campaign in the devolved nations (unspecified); £5,000 to support an 'Access for All' campaign in Scotland; £10,000 to further support its public affairs campaign in the devolved nations (specifically Scotland and Wales) and £110 to purchase tickets for Sanofi personnel to attend a Beating Bowel Cancer fund-raising event.

In the same period Sanofi paid Beating Bowel Cancer to provide the following: a speaker for an internal Sanofi meeting; support for the development of a patient pathway document for use by Sanofi internally and with health professionals and a presentation from the chief executive at a Sanofi internal meeting.

The lack of any formal written agreements between the two organisations governing these interactions meant that Sanofi had failed to certify such agreements in advance in breach of Clauses 14.3 and 23.3. Furthermore, although disclosed in September 2014 the sponsorship and service fees were not disclosed within the required timeline in breach of Clauses 23.7 and 23.8 respectively.

7 In 2013, Sanofi organised a national competition for patient organisations and invited applications in open competition for three bursaries to be awarded by an independent panel of judges. Three bursaries were awarded as follows: Anaphylaxis Campaign received £25,000 to develop support groups for parents of children with severe food allergies; the Brittle Bone Society received £15,000 to establish support groups for children with osteogenesis imperfecta and Tommy's received £10,000 to support education on mental wellbeing during pregnancy.

The lack of formal written agreements between the company and any of the three organisations meant that Sanofi had failed to certify such agreements in advance in breach of Clauses 14.3 and 23.3. Furthermore, although these bursaries were disclosed in an area of Sanofi's public UK website, this was separate to the section in which disclosure to patient organisations was made and, regardless, failed to include the financial sums paid to each organisation in breach of Clause 23.7.

8 In 2013 Sanofi paid £1,500 to Diabetes Flight Project Ltd in support of a 'Flying with Diabetes Day' to provide education on diabetes and flight experience for people with diabetes, their friends and families. Diabetes Flight Project was a private company that raised awareness of diabetes and worked with other patient organisations to support their objectives.

The lack of a formal written agreement between the two organisations governing this sponsorship meant that Sanofi had failed to certify such an agreement in advance in breach of Clauses 14.3 and 23.3. Furthermore, although disclosed in September 2014, the sponsorship and service fee [sic] were not disclosed within the required timeline in breach of Clause 23.7.

Relationships with patient organisations subject to the 2014 Code

1 In 2014 Sanofi paid Diabetes UK £20,000 in sponsorship of patient care events, to provide support to individual patients with diabetes. The lack of a formal written agreement between the two organisations for this activity meant that Sanofi had failed to certify such an agreement in advance in breach of Clauses 14.3 and 23.3.

2 In 2014 Sanofi paid Heart UK £23,000 in sponsorship of a familial hypercholesterolaemia (FH) audit project, aimed at systematically improving the diagnosis of FH within primary care. The pilot offered a model that could be implemented by other Clinical Commissioning Groups in England. The lack of a formal written agreement between the two organisations for this activity meant that Sanofi had failed to certify such an agreement in advance in breach of Clauses 14.3 and 23.3.

3 In 2014 Sanofi paid Database of Individual Patient Experience (DIPEx) £2,000 in sponsorship of the Launch of Healthtalk at the House of Lords. Healthtalk was an online resource for patients and medical professionals. The lack of a formal written agreement between the two organisations for this activity meant that Sanofi had failed to certify such an agreement in advance in breach of Clauses 14.3 and 23.3.

4 In 2014 Sanofi paid Arthritis and Musculoskeletal Alliance (AMRA) £5,000 in sponsorship of its core capacity building and advocacy activities and to help to initiate new activities. The lack of a formal written agreement between the two organisations for either activity meant that Sanofi had failed to certify such an agreement in advance in breach of Clauses 14.3 and 23.3.

Sanofi submitted that senior managers were in no doubt that this failing required immediate and decisive action. When the failure of process was identified, all payments to patient organisations were immediately suspended and where disclosure had not been made or was incorrect the relevant

organisations were contacted to confirm agreement for disclosure to occur. All disclosures from 2013 interactions were now, belatedly, correctly disclosed.

Patient organisation payments were unable to be processed unless scrutinised and approved by the head of promotional affairs, pending the implementation of a new management process, which was being developed taking into account the findings of the compliance officer's investigation.

Sanofi submitted that it had created a new position of transparency manager, within the medical division, to oversee all processes which supported transparency, including the disclosure of patient organisation interactions. Interactions would be managed and captured within a bespoke electronic system that would support comprehensive, accurate and timely disclosure for 2015. Payments to patient organisations would be flagged in financial systems making it mandatory for compliance with the Code to be checked and completed before payment was released. Finally, comprehensive training would be provided for all company personnel.

In conclusion, Sanofi stated that it had identified a failing in its processes governing disclosure of interactions with patient organisations which had led to numerous breaches of the Code. Sanofi considered that this clearly indicated that it had not maintained high standards in breach of Clause 9.1.

Sanofi contended that this had not, however, brought discredit on the industry, and through the actions it had taken in both making a voluntary admission and immediately strengthening its procedures to ensure compliance, it had supported the transparency standards that the public deserved. On this basis, Sanofi denied a breach of Clause 2.

Finally, Sanofi confirmed that this declaration was specific to 2013/14. The same processes that caused failings in this period existed before 2013. The voluntary admissions above were the result of several weeks' investigation, and were made now so as to avoid any delay that would occur if earlier periods were to be examined. Given that the deficiencies had been identified, acted upon and were being addressed as a result of the investigation conducted, Sanofi asked what the PMCPA expected with regard to investigating further historical cases of failure of process before 2013.

Support to meetings organised by patient organisations

In addition to the voluntary admissions above, Sanofi queried how a professional meeting organised by a patient organisation should be treated as regards compliance with the Code. These were principally meetings of health professionals and to date had been approved and supported in accordance with the requirements of the Code with respect to sponsorship of meetings.

Sanofi had supported several professional conferences during 2013/14 and had managed these as 'Meetings', in keeping with the requirements of Clause 19. Reviewing other member companies' disclosure sites, it was clear that there was no consistent pattern of disclosure when a health professional meeting was organised by a patient organisation. For example, two named companies declared their sponsorship of the Heart Rhythm Conference organised by the Arrhythmia Alliance, whereas another did not disclose its sponsorship of the Diabetes UK Professional Conference.

Sanofi therefore asked the PMCPA to consider the following professional meetings which took place in 2013 and which it sponsored in accordance with Clause 19 of the Code, but had not disclosed as an interaction with a patient organisation. Sanofi therefore asked the PMCPA to consider whether these were in breach of Clause 23.7 of the Second 2012 Edition of the Code:

With regard to the Diabetes UK Annual Professional Conference 2013, Sanofi had paid: £55,440 to be platinum sponsors; £11,340 for a second small exhibition space; £10,450 for two satellite symposia; £2,000 for freestanding screen advertising and £825 for sponsorship of delegate bags. Sanofi stated that it had also paid Diabetes UK the following: £13,704 to sponsor the Diabetes Innovator Meeting 2013; £20,000 to sponsor the Young Diabetologists Forum Meeting; £4,000 to sponsor the Young Diabetologists Forum Caledonian Meeting; £15,000 to sponsor the Young Diabetologists Forum Retinopathy Meeting and £600 to sponsor exhibition space at the South West Professional Meeting.

In conclusion, Sanofi saw that the industry was undecided as to whether support of a professional meeting, organised by a patient organisation, fell within the disclosure requirements relating to the latter. Sanofi would appreciate the PMCPA's determination on this matter.

Sanofi remained committed to its programme of review and improvement in both cultural and process aspects of Code compliance, and was determined to work with the Authority to conclude a review and determination in both of these matters.

Sanofi was advised that, in accordance with Paragraph 5.6 of the Constitution and Procedure, the matter would be treated as a complaint and it was asked to comment in relation to the requirements of Clauses 2, 9.1, 14.3, 23.3, 23.7 and 23.8 of the Second 2012 Edition of the Code (amended) and Clauses 2, 9.1, 14.3 and 24.3 of the 2014 Code.

RESPONSE

Sanofi stated that it had no further comment.

In response to specific questions from the case preparation manager, Sanofi provided further information as follows:

1 Material sent to patient organisations to inform them of the payment and disclosure

Sanofi provided a template letter used by its communications team (responsible for the process) with the individuals accountable for interactions with each of the patient organisations which were to have

support disclosed in March 2013. It was intended that the template would be adapted to include specific detail for each organisation and then sent by the accountable individuals. Sanofi had no record of the actual materials that were sent.

Sanofi also provided a print out from its patient group database which listed interactions in 2013; this was used by the communications team to track support provided to patient organisations in order to enable disclosure at the appropriate time.

2 Payments to patient associations

Sanofi stated that payments were initiated by the individual who was responsible for leading the respective interaction with the patient organisation. The Sanofi finance system operated a 'delegation of authority level' which meant that a payment initiated by an individual needed to be approved by someone in their management line, but whether this was done by the first or second line manager depended on the level of authority granted to the manager. The higher the sum, the more senior the approver must be. These delegations of authority were applied to all payments, but there was no functionality in the system to flag patient organisations as a distinct group to the approver, so that even if fully aware of the required process (Sanofi referred to Point 4 below concerning why the standard operating procedure (SOP) was not followed), the approver was not always clear that additional requirements were in place for that particular payee. When the current issues concerning payment were uncovered, an immediate preventative action was implemented such that only one individual in the UK company could initiate a payment to a patient organisation. That individual sat in the medical department and now used one consistent financial code which indicated the payment was to a patient association. This provided an additional check to track payments for disclosure. In addition, the relevant members of the procurement and finance teams had been fully orientated to the requirements and questioned any payment being raised to an organisation that might be a patient group, raising it to the medical team for confirmation of due process.

Sanofi stated that prior to a raised final payment being triggered, the head of promotional affairs reviewed all paperwork to ensure the correct documentation was in place.

Sanofi submitted that it was currently in the final stages of procuring and implementing a single automated information technology system (iDisclose) to process and manage all transfers of value to health professionals, healthcare organisations and patient groups in order to comply with the requirements of the 2014 Code for disclosures of transfers of value made from 1 January 2015. The iDisclose system and associated workflows would mandate that all payments to individuals or organisations which required disclosure under the Code would be managed by a new transparency team (incremental resource) which was currently being recruited (three full-time equivalent staff members). Sanofi referred to Point 4d below.

3 The SOP in use when the Code was breached

Sanofi stated that there were two relevant published SOPs in use at the time of the breaches. The first SOP, PA SOP-003-v02, 'Review and Approval of proposed projects or support involving patient or professional groups', was under the authorship and accountability of the promotional affairs team and effective from 10 May 2011. This policy stated that a defined project specific project owner was accountable for documentation relating to that project. This was replaced by COMMS-SOP-001-v01.1, 'Patients Associations', under the accountability and authorship of the communications team; it was available in the Sanofi Document Control Portal (DCP) and effective from 2 April 2013. It stated 'The Communications and Government Affairs teams have overall accountability for the strategic management and co ordination of our relationships with UK patient organisations, consistent with Global Sanofi guidance. They also have accountability in terms of our interface with Global on patient group activity and in relation to compliance and corporate audit. As such, the Communications and Government Affairs teams should be engaged in any review/approval processes'. Sanofi stated that the author of the SOP was the communications director, UK and Ireland, who left the organisation in June 2014.

As a result of the findings of the Sanofi investigation the SOP was under significant revision and was being moved to the medical department for oversight. The SOP was being updated to take on board all that had been found and ensure that what happened could not happen again.

4 Reasons the SOP was not followed

Sanofi stated that due to the seriousness of the breach, it had reviewed events so as to fully understand why the SOP was not followed, to inform the action plan required by Sanofi UK and ultimately to ensure these breaches could not occur again.

The points of relevance and the remedial action taken were as follows:

a) Training

The quality team within the medical function managed the organisation's SOP repository relating to regulated systems. The defined protocol for the inclusion of an SOP was that key stakeholders needed to have been trained on it by the author and subsequently evidenced by way of a formal training record.

The training records of the SOP showed that only three people had been trained on it in April and May 2013. It was clear that not enough people were trained in the SOP. To correct this, relevant staff had been trained on the interim solution which was co-ordinated by medical (see Point 4b below) and once the updated SOP was finalised, a group of senior individuals had been identified as requiring training along with all final medical and non-medical signatories. This training would take place in October.

b) Clarity in roles and responsibilities

Details of the responsibilities of the SOP were provided and the conclusions was that responsibilities for patient association oversight were only partly adhered to.

As a result of this, the medical director called a mandated meeting of all senior leaders of departments (commercial divisions, government affairs, communications, promotional affairs, financial controlling, medical and procurement) who could have been involved in patient organisations, to inform them of the findings and the actions that were being taken to rectify the situation moving forward. This group was made accountable for communication within their teams to ensure no payments were made except via the one person charged with this, and re-iterated exactly what was needed to work with patient organisations in a compliant way as per Clauses 14.3 and 24. All ongoing work was requested to be reviewed and to ensure that the appropriate review and written contracts were in place.

The revised SOP was currently being written and would ensure greater role clarity and accountability at each step. In addition, only individuals deemed competent after formal training and assessment would be able to lead interactions with patient organisations in future (and this point was captured in the revised SOP).

c) Oversight

As already indicated, it was agreed that the owner of the process and respective SOP was moved to a function that had greater oversight and was more closely aligned to the Code. The medical function (promotional affairs) had taken this responsibility immediately as an interim measure and it would be confirmed in the updated SOP which would move to the oversight of the transparency team.

d) Automation of capture and consistency in capture of information on patient organisation financial transactions

Sanofi recognised that it needed to strengthen internal controls in order to ensure that payments to patient organisations could only be made once all the necessary documentation required for the Code and internally defined policies and procedures had been met.

Measures had already begun to restrict such payments to patient organisations and filter these through one department within medical as an interim ahead of the revised SOP being trained and in place. Similarly, in the interim and in collaboration with procurement, additional controls were being developed around the financial processes including:

i) Identification of patient organisations through a specific type of vendor account
ii) Modification of the vendor account form to include identification of patient organisations
iii) Quarterly checks of the financial account types to ensure all patient organisations had been correctly identified and tagged
iv) Attachment of the contracts and supporting documentation with all purchase requisitions
v) A recommendation to complete a six monthly report based upon the patient association 'grouping' from the company's computer system to identify all payments made to those vendor accounts had also been made and agreed. This report could then be reconciled to the manual 'tracker' in the short-term in order to ensure that no payments to patient organisations were made outside of the newly defined processes.

In the longer term an internal control framework around patient association payments would be incorporated within the iDisclose system. The processing of payments made to support patient organisations would be met through iDisclose. This system would be configured so that only individuals with a pre-specified authority could initiate a patient association transaction, allowing strict control of who accessed that part of the system, which in turn enabled a tight control of the training of those who were given such access. In addition, the automated workflow would only permit progress to payment if all requirements built into the system were met, and oversight of this would be managed by the dedicated transparency team.

Summary

Sanofi stated that it took this matter extremely seriously as evidenced by the investigation and the immediate, interim and long-term corrective and preventive actions described. The company was fully aware of the importance of transparency to the reputation of the pharmaceutical industry and this was why it had given the management of this issue the utmost priority. Sanofi believed that it had demonstrated a clear and unwavering commitment to transparency in its approach to addressing the breaches in this case, making a voluntary admission, and importantly, in identifying, contracting for, and disclosing all payments made to patient organisations in 2013 and 2014. In this regard, transparency had been achieved, albeit outside of the required timeframe. Whilst Sanofi understood that lack of transparency in financial interactions with patient organisations might bring discredit upon the industry, and in such cases a breach of Clause 2 might be warranted, it believed that in this case the fact that it achieved transparency together with the robustness of its approach meant that it had not breached Clause 2 of the Code.

PANEL RULING

The Panel noted that Sanofi's voluntary admission related to its interactions with patient organisations in 2013 and 2014. Activities carried out in 2013 were subject to the Second 2012 Edition of the Code. Clause 23.3 of that Code required companies which worked with a patient organisation to have a written agreement in place which set out exactly what had

been agreed, including funding, in relation to every significant activity or on-going relationship. Clause 14.3 required such agreements to be certified in advance. When a patient organisation provided a service to a pharmaceutical company then Clause 23.8 required a written contract or agreement to be agreed in advance of the commencement of the services which specified the nature of the services to be provided and the basis for payment of those services. Clause 23.7 of the Second 2012 Edition of the Code required companies to make publicly available a list of patient organisations to which they provided support to include a description of the support which was sufficiently complete to enable the average reader to understand the significance of the support. The list of organisations being given support must be updated at least once a year. Clause 23.8 required each company to make publicly available a list of patient organisations it had engaged to provide significant, contracted services. The list must include a description of the nature of the services which was sufficiently complete to enable the average reader to form an understanding of the arrangement without the need to divulge confidential information; the total amount paid per patient organisation over the reporting period must be declared. The list of patient organisations engaged must be updated at least once a year. The Panel noted that Sanofi had referred to interactions with patient organisations which had occurred before 2013. In that regard, from 1 July 2008 Sanofi would have had to annually publish a list, by no later than 31 March 2009, to cover activities commenced on or after 1 January 2008 or ongoing on that date, of patient organisations to which it had provided support in the previous year. A list of patient organisations engaged to provide significant contracted services had to be declared for the first time by 31 March 2013 to cover activities commenced on or after 1 January 2012 or ongoing on that date. Given the requirement to update its declarations at least once a year, Sanofi would have to amend the lists by no later than 31 March each year for activities carried out in the previous calendar year.

With regard to the activities carried out in 2014 the requirements of the 2014 Code were identical to those of the Second 2012 Edition of the Code except that Clause 24, not Clause 23, of the 2014 Code governed relations with patient organisations.

The Panel considered Sanofi's relationship with each patient organisation in 2013 in turn. The following rulings were made under the Second 2012 Edition of the Code:

1 The Panel noted that Sanofi had paid Team Blood Glucose £2,500 to support one of its activities. The organisation had also been paid to provide a motivational speaker for a Sanofi internal meeting. The Panel noted Sanofi's submission that there was no written agreement to cover either relationship. A breach of Clause 23.3 and thus also of Clause 14.3 was ruled with regard to the sponsorship arrangement. A breach of Clause 23.8 and thus also of Clause 14.3 was ruled with regard to the fee for service. Further, Sanofi had not disclosed its sponsorship by 31 March 2014 and so the Panel ruled a breach of Clause 23.7 and similarly ruled a breach of Clause 23.8 for the late disclosure of the service provided by Team Blood Glucose.

2 In 2013 Sanofi paid Heart UK £12,000 to sponsor four continuing professional development accredited articles on hypercholesterolaemia published in the Primary Care Cardiovascular Journal. Sanofi also paid Heart UK a further £31,143 in sponsorship of a Royal College of General Practitioners online training programme in lipid management. The Panel noted Sanofi's submission that it had not accurately disclosed the amount paid in sponsorship for either activity and in one instance the information given was not sufficient for the reader to understand the significance of the support. The Panel thus ruled a breach of Clause 23.7 with regard to each disclosure.

3 In 2013 Sanofi paid the Rarer Cancers Foundation £5,000 to support a public affairs campaign. The Panel noted Sanofi's submission that there was no written agreement to cover this support. A breach of Clause 23.3 and thus also of Clause 14.3 was ruled. Further, as Sanofi had not disclosed its support by 31 March 2014, a breach of Clause 23.7 was ruled.

4 In 2013 Sanofi paid Leukaemia Care £10,000 to support patient support events. The Panel noted Sanofi's submission that there was no written agreement to cover this support. A breach of Clause 23.3 and thus also of 14.3 was ruled. Further, as Sanofi did not publicly disclose its support by 31 March 2014, a breach of Clause 23.7 was ruled.

5 In 2013 Sanofi paid the National Kidney Federation an unrestricted grant of £14,000. The Panel noted Sanofi's submission that there was no written agreement to cover such support. A breach of Clause 23.3 and thus also of Clause 14.3 was ruled. Further, as Sanofi did not publicly disclose its support by 31 March 2014 a breach of Clause 23.7 was ruled. [Post consideration of the case Sanofi advised that £4,100 was paid to the National Kidney Federation not £14,000 as previously stated].

6 In 2013 Sanofi paid the charity £20,110 in sponsorship for four activities; the company had also paid the charity to provide three services. The Panel noted Sanofi's submission that there were no written agreements to cover its support for and provision of services by the organisation. Breaches of Clause 23.3 were ruled with regard to each of the four sponsorship activities and breaches of Clause 23.8 were ruled in relation to the fees for service. Breaches of Clause 14.3 were ruled with respect to each of the seven activities. Further, as Sanofi had not publicly declared its sponsorship by 31 March 2014 the Panel ruled four breaches of Clause 23.7; it similarly ruled three breaches of Clause 23.8 for the late disclosure of the three services provided by Beating Bowel Cancer.

During its consideration of this matter, the Panel noted that Sanofi had paid Beating Bowel Cancer £110 for tickets for Sanofi personnel to attend a fund raising event. The Panel had no details as to the arrangements for the event or who attended but it requested that Sanofi's attention be drawn to Clause 23.2 of the Second 2012 Edition of the Code which stated that the requirements of Clause 19 of the Code applied to companies supporting patient organisation meetings. The supplementary information to Clause 19.1 of that Code stated that meetings which were wholly or mainly of a social or sporting nature were unacceptable. The Panel queried the acceptability under the Code of Sanofi's attendance at the fund raiser and asked that Sanofi be advised of its concerns in this regard.

7 In 2013 Sanofi organised a national competition for patient organisations the outcome of which was that the Anaphylaxis Campaign was awarded £25,000, the Brittle Bone Society was awarded £15,000 and Tommy's was awarded £10,000. The Panel noted Sanofi's submission that there were no written agreements to cover these bursaries. A breach of Clause 23.3 and thus also of Clause 14.3 was ruled with regard to each bursary. Further, as Sanofi had not disclosed the amount paid per organisation three breaches of Clause 23.7 were ruled.

8 The Panel noted that in 2013 Sanofi paid £1,500 via Diabetes Flight Projects Ltd to support a 'Flying with Diabetes Day' which provided education on diabetes and flight experience for people with diabetes, their friends and families. Although Diabetes Flight Projects Ltd was not a patient organisation the money given to it by Sanofi was used to support a patient activity day. In that regard the Panel considered that Diabetes Flight Projects Ltd had acted in support of patients and families and so Sanofi's sponsorship of the company for that activity was covered by the Code. The Panel noted Sanofi's submission that there was no written agreement to cover its support. A breach of Clause 23.3 and thus also of Clause 14.3 was ruled. Further, as Sanofi had not publicly disclosed its support before 31 March 2014, a breach of Clause 23.7 was ruled.

The Panel considered Sanofi's relationship with each patient organisation in 2014 in turn. The following rulings are made under the 2014 Code:

1 In 2014 Sanofi paid Diabetes UK £20,000 to sponsor patient care events. The Panel noted Sanofi's submission that there was no written agreement for this sponsorship. A breach of Clause 24.3 and thus also of Clause 14.3 was ruled.

2 In 2014 Sanofi paid Heart UK £23,000 to sponsor a familial hypercholesterolaemia audit project. The Panel noted Sanofi's submission that there was no written agreement for this sponsorship. A breach of Clause 24.3 and thus of Clause 14.3 was ruled.

3 In 2014 Sanofi paid DIPEx £2,000 to sponsor an online resource for patients and medical professionals. The Panel noted Sanofi's submission that there was no written agreement for this sponsorship. A breach of Clause 24.3 and thus of Clause 14.3 was ruled.

4 In 2014 Sanofi paid AMRA £5,000 to sponsor its core capacity building and advocacy activities and to help to initiate new activities. The Panel noted Sanofi's submission that there was no written agreement for this sponsorship. A breach of Clause 24.3 and thus also of Clause 14.3 was ruled.

The Panel noted Sanofi's submission that the process failings that had resulted in the voluntary admissions regarding the above, existed before 2013. Sanofi had queried what it should do about any historical cases of failure of process. In the Panel's view the company should review all of its historical interactions with patient organisations and take whatever remedial action seemed appropriate to ensure compliance with the relevant Codes, company procedures and any undertaking given in this case. Whether the matter subsequently became the subject of another voluntary admission would be for Sanofi to decide.

The Panel noted Sanofi's voluntary admission with regard to its sponsorship of health professionals' meetings organised by patient organisations; the company had supported several such meetings during 2013/14. In the Panel's view, such sponsorship was covered by Clause 23 of the Second 2012 Edition of the Code and Clause 24 of the 2014 Code. Both clauses referred to relationships with patient organisations and did not exempt sponsorship of meetings held for health professionals. In order for a company to be transparent about its interactions with patient organisations it was important that all such interactions were publicly declared – the required description of the nature of the support would show why the support was given.

The Panel noted that in 2013, Sanofi had paid Diabetes UK a total of £80,055 with regard to its Annual Professional Conference. The monies had been paid to enable Sanofi to be a platinum sponsor, have a second exhibition space, hold two satellite symposia, have some free standing screen advertising and sponsor delegate bags. Further, Sanofi had sponsored five other meetings in 2013 for a total of £53,304. The Panel noted Sanofi's submission that none of the above had been disclosed as an interaction with a patient organisation. Breaches of Clause 23.7 of the Second 2012 Edition of the Code were ruled with regard to each sponsorship arrangement.

During its consideration of this matter, the Panel noted that Sanofi had paid Diabetes UK £825 to sponsor delegate bags at its 2013 Annual Professional Conference. The Panel noted from Clause 18.3 that the items which might be provided to health professionals and appropriate administrative staff attending scientific meetings and conferences were limited to inexpensive notebooks, pens and pencils; conference bags were thus outside that limit. The Panel was concerned that

the sponsorship of the delegate bags was not in line with the requirements of the Code and it asked that Sanofi be so advised.

The Panel noted the sensitivities surrounding the pharmaceutical industry working with patient organisations; robust agreements setting out the arrangements, and certification of those agreements were important steps in ensuring that such interactions complied with the Code and in that regard they underpinned the self-regulatory compliance system. That projects and sponsorship were able to go ahead without a certified agreement in place was unacceptable. Further, public disclosure of support was an important means of building and maintaining confidence in the industry. The Panel noted that Sanofi had either sponsored or engaged thirteen patient organisations without first having agreements in place to cover more than twenty activities. The company's support for the patient organisations in 2013, although now disclosed (apart from it support for health professionals' meetings) was disclosed six months late in September 2014; some original disclosures had been inaccurate or lacking in detail. The Panel considered that high standards had not been maintained. A breach of Clause 9.1 of the 2014 Code was ruled (the requirements of Clause 9.1 in the 2014 Code and in the Second 2012 Edition of the Code were identical and so the Panel did not make separate rulings in that regard).

The Panel noted compliant and robust processes and procedures, which were appropriately trained into an organisation were the basics of any compliance program. The systemic failure with respect to the whole process of working with patient organisations was of grave concern. The voluntary admission submitted by Sanofi set out and to a degree remediated the situation with respect to patient organisations in 2013 and to date in 2014 however it was clear that Sanofi thought activities in 2012 could also be affected. For the lack of due process to be followed and for it to have gone undetected by the company for such a considerable period of time was totally unacceptable and brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 of the 2014 Code was ruled (the requirements of Clause 2 in the 2014 Code and in the Second 2012 Edition of the Code were identical and so the Panel did not make separate rulings in that regard).

The Panel noted its comments and rulings above. The Panel appreciated that Sanofi had voluntarily admitted its failings in process and procedure, however given the time period and the extent to which such failings had gone undetected, the Panel considered that its concerns about the company's procedures warranted consideration by the Appeal Board. The Panel thus reported Sanofi to the Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure.

During its consideration of this case the Panel noted the template letter that had been sent to patient organisations to inform them that Sanofi intended to publicly disclose the specific amount of financial support provided in 2013. The letter informed the recipient that a brief description of the nature of the support would be published; that brief description was not included in the letter itself. The Panel was very concerned that Sanofi had stated that it had no record of the actual materials which were sent. In the Panel's view, each letter, given that it was material related to working with patient organisations, should have been certified according to Clause 14.3 of the Code. The Panel requested that Sanofi be advised of its concerns in this regard.

COMMENTS FROM SANOFI ON THE REPORT

At the consideration of the report Sanofi stated that the company fully recognised the severity of this case which was why, when it discovered the issues all interactions with patient organisations were immediately stopped and it self reported the matter to the Authority. The failings highlighted by this case reflected how the company had historically dealt with compliance. It was now introducing wide ranging changes in company infrastructure and culture to address these issues. Details were given. Sanofi was confident that major compliance failures would no longer go unnoticed.

APPEAL BOARD CONSIDERATION OF THE REPORT FROM THE PANEL

The Appeal Board considered that the transparency of a pharmaceutical company's interactions with patient organisations was critical. Whilst interactions with patient organisations was a legitimate activity, the arrangements in place at Sanofi at the relevant time were shambolic and shocking. The Appeal Board noted that Sanofi's voluntary admission was prompted by media criticism in summer 2014 about the relationships between the pharmaceutical industry and patient organisations. The Appeal Board was concerned that the failure had not been discovered earlier, for example as part of the company's preparation for the audit in March 2014 (Case AUTH/2620/7/13). It noted Sanofi's response that the area was part of its work programme. The company was still investigating to see what other interactions had not been disclosed.

The Appeal Board was extremely concerned that such a long term systemic failure across the entire Sanofi business regarding multiple payments to multiple patient organisations had occurred. Staff had failed to follow the relevant SOP and Sanofi's governance of its SOP was very poor. This was a very serious matter.

The Appeal Board was extremely concerned about the breadth and scale of the failings and decided that, in accordance with Paragraph 11.3 of the Constitution and Procedure, the company should be publicly reprimanded.

The Appeal Board also decided to require an audit of Sanofi's procedures in relation to the Code. Given the company's ongoing and planned compliance activities, the Appeal Board decided that the audit in this case should be conducted in March 2015 at the same time as the re-audit required in Case

AUTH/2620/7/13. On receipt of the audit report and Sanofi's comments upon it, the Appeal Board would consider whether further sanctions were necessary.

APPEAL BOARD FURTHER CONSIDERATION

Sanofi was audited in March 2015, and on receipt of the audit report the Appeal Board noted that Sanofi had made progress since the audit in October 2014; a new, senior manager was fully involved and leading many of the company's compliance initiatives.

The Appeal Board however, noted its concern about some of the company's activities and considered that Sanofi should address the matters raised as a priority. On the basis that this work was completed, the progress otherwise shown in the March 2015 audit was continued and a company-wide focus and responsibility for compliance was maintained, the Appeal Board decided that no further action was required.

Complaint received	**26 September 2014**
Undertaking received	**10 November 2014**
Appeal Board consideration	**10 December 2014, 16 April 2015**
Interim Case Report first published	**12 February 2015**
Case completed	**16 April 2015**