INTERIM CASE REPORT

An interim case report has been published in this case as the final report was delayed because the Code of Practice Appeal Board had required audits of Janssen's procedures in relation to the Code (Paragraph 11.2 of the Constitution and Procedure refers).

CASE AUTH/3436/12/20

VOLUNTARY ADMISSION BY JANSSEN

A nurse led Stelara homecare service

Janssen-Cilag voluntarily admitted that it had failed to maintain oversight and high standards in relation to the delivery of a service described by Janssen as a Stelara (ustekinumab) patient support programme delivered by a third-party homecare provider. Stelara was used in the treatment of certain adults with plaque psoriasis, psoriatic arthritis, Crohn's disease or ulcerative colitis.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Janssen.

Janssen stated that the issues related to a failure to appropriately terminate the service with the vendor in 2018, when Janssen believed the service had been cancelled when, in fact, it had continued, and the subsequent lack of ongoing oversight of the programme. In summary Janssen failed to:

- **Provide adequate adverse event reporting training with the vendor**
- **Maintain up-to-date product training with the vendor including provision of updates to the summary of product characteristics (SPC)**
- **Robustly review and store all related materials and documents**
- **Correctly characterise the adverse events reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as being solicited**

Janssen acknowledged that that was not consistent with the high standards to which it held itself and was in breach of the Code. Janssen understood that the Panel might consider that it was also a breach of Clause 2.

The Panel noted that Janssen described the home delivery and nurse administration service as a patient support programme. The Panel noted that the service did not satisfy the requirements of a formal patient support programme as set out in the Code and its supplementary information. The Panel noted that the classification of the service was not the subject of the voluntary admission and thus was not ruled upon. The Panel noted that in general terms such homecare services might be offered as part of a package deal.

The Panel noted Janssen's submission that it commissioned a Stelara homecare service with a service provider in 2010 which was initially for a NHS trust and subsequently expanded to three trusts. The service was to allow patients to have their medication delivered to their homes and to provide either home-based self-administration training or ongoing home nurse-administration support.

The Panel noted Janssen's submission that there was a lack of ongoing oversight of the service between January 2018 and May 2020. As a result of this, Janssen had failed to: provide adequate adverse event reporting training with the vendor; maintain up-to-date product training with the vendor including provision of updates to the summary of product characteristics (SPC); robustly review and store all related materials and documents and correctly characterise the adverse events reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as being solicited.

The Panel noted that during the time-period in question there were two applicable codes: the 2016 and the 2019 Code. The clauses at issue were similar in both versions of the Code so the Panel made its rulings in relation to the 2019 Code.

The Panel noted Janssen's submission that the activity had not been recorded as active since 2018, which resulted in the incorrect reporting of adverse events to the MHRA. The Panel noted Janssen's submission that the service provider continued to report adverse events to Janssen which in turn reported the adverse events to the MHRA as being unsolicited, when in fact they should have been reported as solicited as they were associated with the Stelara homecare service. This was corrected for eleven cases in the safety database in June 2020 as part of Janssen's remediation and corrective actions.

The Panel was extremely concerned with regard to Janssen's submission that documentation relating to the service in question was 'incomplete' and that it was not able to identify agreements prior to Quarter 1, 2018 that described the service. Furthermore, since January 2018, there had not been any documentation in place. The service provider was only able to provide Janssen with the master services agreement (dated July 2015) which did not specifically refer to the Stelara homecare service.

The Panel noted Janssen's submission that the decision to terminate the agreement in 2018 was in the incorrect belief that there were no patients ongoing in the programme and that the service no longer delivered value for patients or the NHS. Further that the decision to terminate the agreement was communicated in a series of emails between Janssen and the vendor between January 2018 and May 2018 and on the company's review of this email exchange it was evident that the instructions were not clear nor fully understood.

The Panel noted Janssen's submission that in May 2020 the service was being provided to 24 patients and given the COVID pandemic, the company deemed it inappropriate to terminate the service immediately. The service would continue to be provided until 11 March 2021.

The Panel noted that Janssen stated that it became aware of the issue on 29 May 2020 and 'immediate' remediation and corrective actions had taken place between 5 June and 28 August 2020. The Panel further noted Janssen's submission that given the complexity of the issue, the extent of the investigation conducted, the escalation to the

highest levels of the global organisation and the prioritisation of corrective and preventive actions, it was not until December 2020 that the company considered that it had the required information to make a voluntary admission to the PMCPA. The Panel queried whether the length of time between identification of the issue which had patient safety implications, in May 2020, and the voluntary admission to the PMCPA, in December 2020, was acceptable.

The Panel had no information before it in relation to the individuals in Janssen or the service provider who were concerned with the preparation or approval of material or activities related to the Stelara homecare service. Whilst the Panel was extremely concerned that individuals in Janssen responsible for the Stelara homecare service did not appropriately terminate the service, and that communication within Janssen and between Janssen and the homecare service provider was extremely poor, the Panel had no evidence before it that relevant staff were not fully conversant with the Code and the relevant laws and regulations and no breach of the Code was ruled in that regard.

The Panel noted that as part of its admission, Janssen had referred to the training of its field based staff. In the Panel's view, however, Janssen had not made any admission in relation toits representatives not taking an appropriate examination and it ruled no breach of the Code.

The Panel noted Janssen's submission that since 2018, the service provider had not been notified of any SPC updates, there was a lack of documented evidence that the service provider had completed Janssen pharmacovigilance training, and the company had failed to provide product training to the service provider beyond initial set-up training prior to 2018. It was not clear to the Panel what changes to the Stelara SPC had occurred during this time; Janssen made no submission in that regard. The Panel was extremely concerned that for over two years, Janssen had no oversight or management of this Stelara homecare service and that the nurses providing the support had received no training, product or safety updates during that time. The Panel considered that Janssen had failed to maintain high standards and thus ruled a breach of the Code as acknowledged by Janssen.

In the Panel's view, this was an extremely serious matter that had patient safety implications. In the Panel's view, Janssen's lack of oversight and management of the Stelara homecare service, including its failures to provide product and pharmacovigilance training to the nursing team and to notify them of SPC updates for more than two years had brought discredit upon and reduced confidence in the industry; the Panel ruled a breach of Clause 2 of the Code.

The Panel was extremely concerned about its rulings and comments above. The Panel considered that it was crucial that patients, healthcare organisations and others could rely on companies funding homecare services to ensure that the arrangements complied with the Code and were such that patient safety was paramount. The Panel noted that Janssen had taken some steps to address the matters raised and that these had been brought to the attention of the global company. Nonetheless, the nature of the difficulties revealed by the voluntary admission was extremely concerning. The Panel considered it was inexplicable that the Stelara homecare service continued without the company's apparent knowledge from January 2018 until May 2020, given it appeared that monies continued to be paid to the service provider and adverse events processed

(albeit incorrectly characterised). The company's procedures and approach to compliance should have prevented this. The Panel was concerned that neither Janssen nor its service provider were able to locate the relevant contract and thus it was unclear to what standards the service provider operated in relation to the service. This was compounded by the fact that had the relevant SOP which came in to force 25 March 2019 been followed, it might have prevented certain difficulties (governance of contract, training and the requirement for a detailed handover to a new project owner), although its definition of a patient support programme did not appear to be relevant to the Stelara homecare service. Some of the matters raised went to the heart of self-regulation and patient safety. The company's lack of oversight and management of the homecare service at issue had been extremely poor. The Panel decided, in accordance with Paragraph 8.2 of the Constitution and Procedure, to report the company to the Appeal Board for it to consider whether further sanctions were appropriate in this case.

The Appeal Board noted the Panel's comments and rulings of breaches of the Code and that Janssen had provided details about its plan to address the issues and it had apologised.

However, the Appeal Board was deeply concerned about the failings and Janssen's lack of control, checks and oversight that had allowed the patient facing Stelara homecare service to continue without the company's knowledge from January 2018 until May 2020, and that monies had continued to be paid to the service provider. The Appeal Board noted that adverse event reports had been processed by the service provider and reported (albeit incorrectly characterised) by Janssen. The Appeal Board noted Janssen's failure to provide product and pharmacovigilance training to the nursing team and updates on changes to the Stelara SPC. In response to a question, Janssen stated that there had been a number of changes to the SPC during the relevant period including the provision of extra clarity around hypersensitivity reactions and very few changes were material to patient safety; there were no important safety updates which led to an increased risk to patients. Further, the third-party service provider trained its staff to use the electronic medicines compendium (eMC) website for the SPC, which would have been up-to-date; there had been no specific training by Janssen in respect of the meaning of such changes. The adverse events were reported as unsolicited and Janssen submitted that these were given a higher priority than solicited reports. The company had introduced more mechanisms to ensure that pharmacovigilance staff were more aware of ongoing relevant programmes. There were a number of third-party service providers delivering the homecare service which had now been the subject of audit as a result of which one had been terminated.

When questioned by the Appeal Board about the delay in making the voluntary admission, Janssen referred to the decision to understand the root cause of the issue and to make remediations. The COVID-19 pandemic and lockdown and the impact that had on interactions with third party providers and major gaps in staffing had contributed to the delay. The Appeal Board considered that the period from discovery to reporting to the PMCPA was inexplicably long at over 7 months and it noted Janssen's acknowledgment in this regard. The Appeal Board noted Janssen's submission that it had made improvements and changes to ensure that this issue did not recur.

The Appeal Board decided that in accordance with Paragraph 11.3 of the Constitution and Procedure, Janssen should be publicly reprimanded for its failure to have oversight

or control of a patient-facing service for 28 months and for its delay in making its voluntary admission once the errors had come to the company's attention. The Appeal Board also decided to require an audit of Janssen's procedures in relation to the Code. The audit should take place as soon as possible. On receipt of the report of the audit the Appeal Board would consider whether further sanctions were necessary.

On receipt of the November 2021 report of the audit the Appeal Board was very concerned about the findings noting the depth and scale of the difficulties at Janssen. The Appeal Board was particularly concerned about the patient support programmes, noting that such compliance issues were not limited to the patient support programme in question in Case AUTH/3436/12/20. In the Appeal Board's view the failure to have appropriate oversight of the patient support programmes including the failure to train nurses on certain SPC updates was serious. Public and patient confidence in the arrangements for such programmes was paramount.

The Appeal Board noted that the audit raised broad concerns about compliance and it highlighted many concerns that needed to be addressed.

The Appeal Board noted the comments in the report of the audit about Janssen's presentation to the Appeal Board at its consideration of the report from the Code of Practice Panel (Appeal Board meeting 16 September 2021) and its response to Appeal Board questions about SPC updates at that hearing. The Appeal Board bore in mind Janssen's comments on the report of the audit that at no stage was there an intention to mislead the PMCPA or the Appeal Board. The Appeal Board was concerned about what appeared to be an apparent lack of candour in the presentation and responses to Appeal Board questions, including about the scale of the difficulties at the company. It was important that the Appeal Board was able to rely on the accuracy of a company's submissions.

The Appeal Board acknowledged Janssen's comments on the report of the audit that it was committed to addressing the matters raised in the report of the audit, together with any others discovered as part of this process, as a matter of urgency and had already initiated significant actions.

The Appeal Board decided that Janssen should be re-audited in September 2022. In addition the Appeal Board required Janssen to provide an action plan with relevant time lines by April 2022 and to provide a further updated action plan in preparation for the re-audit. On receipt of the report of the re-audit the Appeal Board would decide whether further sanctions were necessary.

Janssen-Cilag Ltd voluntarily admitted that it had failed to maintain oversight and high standards in relation to the delivery of a service described by Janssen as a Stelara (ustekinumab) patient support programme delivered by a third-party homecare provider. Stelara was used in the treatment of certain adults with plaque psoriasis, psoriatic arthritis, Crohn's disease or ulcerative colitis.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Janssen.

VOLUNTARY ADMISSION

Janssen stated that the issues identified in its investigation were related to a failure to appropriately terminate the service with the vendor in 2018, when Janssen believed the service had been cancelled when, in fact, it had continued, and the subsequent lack of ongoing oversight of the programme. In summary Janssen failed to:

- Provide adequate adverse event reporting training with the vendor
- Maintain up-to-date product training with the vendor including provision of updates to the summary of product characteristics (SPC)
- Robustly review and store all related materials and documents
- Correctly characterise the adverse events reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as being solicited

Janssen acknowledged that that was not consistent with the high standards to which it held itself and was in breach of Clause 9.1. Janssen understood that the Panel might consider that it was also a breach of Clause 2.

Janssen stated that it was committed to upholding the requirements of the Code and to the principle of self-disclosure that underpinned self-regulation. Given the complexity of the issue, the extent of the investigation conducted, the escalation to the highest levels of the global organisation and the prioritisation of corrective and preventive actions, it was not until now that the company considered that it had the required information to disclose this breach.

Details of the service

Janssen explained that in 2010 it commissioned a patient support programme with a homecare service provider, for a single NHS trust which was subsequently expanded to a maximum of three trusts. Stelara was an injectable therapy and had multiple indications for adult use including psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis. The service allowed Stelara patients to have their medicine delivered to their homes and provided them with either home-based self-administration training or ongoing home nurse-administration support. The service benefitted patients who were able to receive injectable medicine in their home. The NHS benefitted from an increase in capacity to manage patients remotely and the added reassurance that patients were compliant with their prescribed treatment.

On 24 March 2020, the homecare service provider contacted Janssen to ask for a new purchase order to be raised in order to make payment for a Stelara patient support programme. Janssen told the service provider that this was not required in the belief that the service had been terminated. On 29 May 2020, the service provider informed Janssen that the service had not stopped and that it was still supporting Stelara patients. Following discussions between a Janssen cross functional team and the service provided, to understand the situation, an investigation was initiated.

Initial investigative findings

1. The patient support programme had been reviewed by Janssen in quarter 1 2018 and a decision was made to terminate the agreement in the incorrect belief that there were no patients ongoing on the programme and that the service no longer delivered value for patients or the NHS.

2. The decision to terminate was communicated in a series of emails between identified individuals in Janssen and the service provider between January 2018 and May 2018. On further review of this email exchange it was evident that the instructions were not clear nor fully understood.

3. The patient support programme had continued to run since quarter 1 2018 without an appropriate contract in place, with the service provider providing nurse-led patient support, not just a delivery service. Janssen continued to pay for the service by an active purchase order managed by an administrator who was not told about the decision to terminate the agreement.

4. There had been no Janssen oversight or management of the activity since 2018 which had resulted in:

    a. The activity not being recorded in the Janssen Pharmacovigilance System Master File (PSMF), as an active patient support programme, since 2018.
    b. The lack of documented evidence that the team from the service provider had completed Janssen pharmacovigilance training.
    c. The failure to provide product training to the service provider's nurse team beyond initial set-up training prior to 2018
    d. The failure to notify the service provider of any SPC updates during that time.
    e. Incorrect reporting of adverse events to the MHRA. The service provider continued to report adverse events to Janssen which in turn reported them to the MHRA as being unsolicited when in fact they should have been reported as solicited, as a result of being associated with the patient support programme.

5. Documentation related to the service was incomplete. Since quarter 1 2018, when Janssen thought the service had been terminated there had not been any documentation put in place and, prior to that date, due to a number of factors such as lack of central documentation store and change of Janssen staff, Janssen was unable to identify agreements that described the service being delivered by the service provider and supported by Janssen.

    a. There were no materials used by Janssen staff or by Janssen with health professionals that promoted or described the patient support programme.
    b. Janssen was not involved in consenting of patients prescribed Stelara (this was managed by the service provider) and did not have any information sheets or template consent forms that would be used with eligible patients.

Remediation and corrective actions

Immediate actions:

1. 5 June - Janssen UK cross functional team initiated contact with the service provider to commence investigations. The service provider's nurse team list was requested in order to initiate Janssen pharmacovigilance and product training.
2. 22 June - Janssen drug safety corrected the eleven spontaneous case reports in the safety database to show as 'solicited'.

3. 7 July - 18 August – the service provider team working on the Stelara patient support programme completed the pharmacovigilance training via the Janssen Learning Management System.
4. 14 July - Janssen local medical safety specialist recorded the activity in the PSMF Annex B for quarter 2 2020. The office of the QPPV was notified of the quality investigation for awareness.
5. 20 July - Janssen medical team conducted product training with the service provider's nurse team
6. 24 July – The service provider confirmed that its administration policies for all products were regularly reviewed against the current SPC and deployed across its operational team.
7. 28 August - formal review by Janssen leadership staff with creation of a patient support programme steering committee (UK managing director, medical director, commercial portfolio director, legal director and EMEA healthcare compliance officer) to provide continued oversight of investigation and next steps.

Further investigation and ongoing actions:

Janssen stated that the issue was escalated to its global audit and assurance office and to the regional group company chairman, following which the UK senior leadership steering committee instructed an in-depth investigation be carried out across all Janssen UK ongoing patient support programmes. This was conducted by representatives from medical compliance, the homecare commercial team and the local safety team with further input from other experts as required, including finance, legal and an experienced external medical signatory who was contracted to have external expertise on this investigation. Janssen noted that the external Code compliance specialist was contracted to independently review the patient support programme project and to recommend specific actions to prevent similar recurrences as well as more general compliance improvements.

Areas identified for improvement by the team included:

1. Updates to existing standard operating procedures (SOPs) and procedures to include:

    i. Revision of training processes to enable validated vendor pharmacovigilance training
    ii. Requirement for product training schedule with clear accountability and oversight
    iii. Robust process for timely distribution, tracking and recording SPC updates to the vendor with annual effectiveness checks. Handover of patient support programmes to new activity owners
    iv. A clearly defined process to terminate a patient support programme
    v. Standards for regular service review meetings with vendors
    vi. Requirements to oversee invoice payments

2. Enhancements to patient support programme master services agreements and works orders to:

    i. Clarify expectations of vendors
    ii. Define key performance indicators
    iii. Agree mechanism for Janssen audit

3. Training of:

    i. Janssen activity owners on the relevant SOPs with annual refresher training to follow
    ii. Field based staff on active patient support programmes within role scope

As well as a detailed investigation of the patient support programme at issue, a review of all Janssen patient support programmes was initiated to ensure ongoing programmes were being delivered in line with relevant policies and processes. The areas identified for improvement would also be applied to all ongoing patient support programmes. Janssen stated that it took this failing seriously as reflected by the escalation of the findings to the highest levels of its global organisation including the EU leadership team, Janssen's global healthcare compliance function and regional and global pharmaceutical group chairs.

Janssen stated that it had already implemented some of the recommendations and was committed to improving the culture of compliance led by the leadership team.

Janssen stated that it had also demonstrated, through swift remediation actions, its commitment to maintaining high standards and ensuring the safety of patients. Janssen was also committed to ongoing improvements to its policies and processes for the design and implementation of patient support programmes to ensure that similar failings of oversight, and the consequences thereof, did not reoccur.

Janssen stated that for all current and future patient support programmes it aimed to have correct and robust documentation that described the service. It also aimed to have appropriate and comprehensive company oversight in the interest of patients and healthcare services.

When writing to Janssen, the Authority asked it to consider the requirements of Clauses 16.1 and 16.3 of the Code in addition to Clauses 9.1 and 2 as cited by Janssen.

RESPONSE

Janssen noted that it had accepted that it had failed to maintain high standards as required by the Code and as it would expect of itself. Janssen stated that it had also accepted that the Panel might wish to consider that the company had reduced confidence in the industry by the failure in oversight it had recognised. Janssen hoped that the Panel could accept that the company had acted swiftly and meaningfully in response to the issues it had noted, both in terms of a thorough review and also in terms of immediate actions and remediation.

With regard to Clauses 16.1 and 16.3, Janssen stated that it had clear processes to ensure all personnel were appropriately trained in relation to the requirements of the Code and Janssen's policies. Specifically, in relation to patient support programmes, Janssen issued a policy effective 25 March 2019 . This was rolled out via Janssen's compliance training platform to the list of personnel cited in the policy.

In addition to having to undertake this training upon starting in the listed roles, all personnel also received additional training when processes were updated.

The patient support programme in question was commissioned in response to a request by an NHS trust specifically for its needs. As Janssen did not promote it as a service, it was not necessary to train Janssen representatives as might be expected for a Janssen promoted service.

Janssen provided anonymised copies of the email trails between identified personnel in Janssen and in the service provider with regard to termination of the patient support programme. The emails showed that the person within Janssen believed that the agreement had been terminated and that the service provider only continued to provide an NHS dispense and delivery service. Due to changes in personnel and a failure to inform the Janssen administrator that the service was terminated, Janssen continued to pay for the service when invoiced by the service provider.

Janssen noted that the process for terminating a service would be included in the planned update to the Janssen patient programme SOP to avoid a recurrence in the future.

With regard to agreements and arrangements prior to assumed termination in 2018, Janssen stated that it had requested copies of the contracts from the service provider. Unfortunately, the service provider was also not able to furnish Janssen with any documentation beyond the master services agreement. The Stelara programme was not specifically referred to in that agreement, however the master services agreement and Schedule 1 covered important elements of responsibility and accountability between the NHS referrer and the service provider for patient support programmes. That included expectations in relation to recruitment, training and appraisal of nursing staff, requirements for training staff on and reporting of adverse events, structure for managing clinical governance, etc.

As the service was entered into upon request of a single NHS trust (and expanded by NHS to include up to three), Janssen had no role to play in the creation or provision of materials to promote the service or to provide to patients. As such, there were no materials to provide.

In 2018, when Janssen believed the service was being terminated, there were 18 patients registered to only receive an NHS dispense and deliver service. Since 2018, after Janssen had considered the service terminated, 14 new patients were enrolled on the programme and received nurse visits over and above the NHS dispense and deliver service. During that period 8 patients had also withdrawn from the service such that by May 2020 a service was still being provided to 24 patients.

Janssen submitted that payments to the service provider were not disclosed on Disclosure UK. At the time, Janssen did not consider homecare providers were healthcare organisations and therefore subject to the requirements of disclosure; the company considered that any such agreements constituted a commercial arrangement.

Following publication of the case report for Case AUTH/2883/10/16 in May 2020, which clarified that patient support programme service providers were considered healthcare organisations, Janssen had revised its approach to disclosure of patient support programmes. From 2021 onwards Janssen would disclose in aggregate the portion of payments to healthcare organisations that were directly associated with clinical staffing costs associated with the delivery of the service.

Janssen submitted that the service provider was currently continuing to provide the Stelara patient support programme in question.

Janssen submitted that when this issue surfaced, and especially given the Covid-19 restrictions, it was not deemed appropriate to terminate services with immediate effect as this would have placed an additional burden on the NHS and increased uncertainty and anxiety for patients. As outlined above, Janssen undertook immediate remediation actions with the service provider to ensure key patient support programme requirements were met. More recently, and following consultation with the National Homecare Medicines Committee (NHMC), Janssen issued a 6 month notice of termination on 11 September 2020 for the Stelara patient support programme . The service provider would continue to provide the remediated Stelara nurse service until 11 March 2021.

Janssen reiterated that it took these failings seriously. It was committed to implementing the recommendations of the Janssen investigation and review team, which included an independent external code compliance specialist, to strengthen the company's processes for the design and implementation of patient support programmes.

PANEL RULING

The Panel noted that Janssen described the home delivery and nurse administration service as a patient support programme. The Panel noted that the service did not satisfy the requirements of a formal patient support programme as set out in Clause 18.2 and its supplementary information. The Panel noted that the classification of the service was not the subject of the voluntary admission and thus was not ruled upon by the Panel. The Panel noted that in general terms such homecare services might be offered as part of a package deal.

The Panel noted Janssen's submission that it commissioned a Stelara homecare service with a service provider in 2010 which was initially for a single NHS trust and subsequently expanded to three trusts. The service was for patients prescribed Stelara, an injectable therapy, to allow them to have their medication delivered to their homes and to provide them with either home-based self-administration training or ongoing home nurse-administration support.

The Panel noted Janssen's submission that it did not appropriately terminate the Stelara homecare service in January 2018 and as a result there was a subsequent lack of ongoing oversight of the service between January 2018 and May 2020. As a result of this, Janssen had failed to: provide adequate adverse event reporting training with the vendor; maintain up-to-date product training with the vendor including provision of updates to the summary of product characteristics (SPC); robustly review and store all related materials and documents and correctly characterise the adverse events reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as being solicited.

The Panel noted that during the time-period in question there were two applicable codes: the 2016 and the 2019 Code. Clauses 9.1, 2, 16.1 and 16.3 were similar in both versions of the Code so the Panel made its rulings in relation to the 2019 Code.

The Panel noted Janssen's submission that the activity had not been recorded in the Pharmacovigilance System Master File (PSMF), as an active patient support programme, since 2018, which resulted in the incorrect reporting of adverse events to the MHRA. The Panel noted Janssen's submission that the service provider continued to report adverse events to

Janssen which in turn reported the adverse events to the MHRA as being unsolicited, when in fact they should have been reported as solicited as they were associated with the Stelara homecare service; this was corrected for eleven cases in the safety database on 22 June 2020 as part of Janssen's remediation and corrective actions.

The Panel was extremely concerned with regard to Janssen's submission that documentation relating to the service in question was 'incomplete'; the Panel noted Janssen's submission that the company was not able to identify agreements prior to Quarter 1 2018 that described the service being delivered by the vendor and supported by Janssen. Furthermore, since January 2018, there had not been any documentation in place. The Panel noted, in response to a query raised by the Case Preparation Manager, Janssen's submission that it had requested a copy of the contract from the service provider but it was only able to provide Janssen with the master services agreement (dated July 2015) which did not specifically refer to the Stelara homecare service.

The Panel noted Janssen's submission that the decision to terminate the agreement in 2018 was in the incorrect belief that there were no patients ongoing in the programme and that the service no longer delivered value for patients or the NHS. The Panel further noted Janssen's submission that the decision to terminate the agreement was communicated in a series of emails between it and the vendor between January 2018 and May 2018 and on the company's review of this email exchange it was evident that the instructions were not clear nor fully understood.

The Panel noted Janssen's submission that it continued to pay for the service by an active purchase order managed by an administrator who was not told about the decision to terminate the agreement. Janssen was contacted on 24 March 2020 by the vendor with a request for a new purchase order to be raised. The Panel noted Janssen's submission that it informed the vendor that this was not required in the belief that the service had been terminated; on the 29 May 2020 the vendor informed Janssen that the service had not ceased and that the vendor was still supporting Stelara patients. The Panel was unclear what communication, if any, occurred between the two parties in the period between 24 March and 29 May 2020.

The Panel noted Janssen's submission that in May 2020 the service was being provided to 24 patients and at that time, given the COVID pandemic, the company deemed it inappropriate to terminate the service immediately and following consultation with the National Homecare Medicines Committee, it issued a six month notice of termination in September 2020 and therefore the service would continue to be provided until 11 March 2021.

The Panel noted that Janssen stated that it became aware of the issue on 29 May 2020 and 'immediate' remediation and corrective actions had taken place between 5 June and 28 August 2020. The Panel further noted Janssen's submission that given the complexity of the issue, the extent of the investigation conducted, the escalation to the highest levels of the global organisation and the prioritisation of corrective and preventive actions, it was not until December 2020 that the company considered that it had the required information to make a voluntary admission to the PMCPA. The Panel queried whether the length of time between identification of the issue which had patient safety implications, in May 2020, and the voluntary admission to the PMCPA, in December 2020, was acceptable.

The Panel noted that Clause 16.1 stated that all relevant personnel including representatives and members of staff, and others retained by way of contract, concerned in any way with the

preparation or approval of material or activities covered by the Code must be fully conversant with the Code and the relevant laws and regulations. The Panel further noted Janssen's submission that the Stelara homecare service was commissioned in response to a request by an NHS trust specifically for their needs and that Janssen did not promote it as a service, and therefore it was not necessary to train representatives about this service. The Panel noted Janssen's submission that it issued a policy effective 25 March 2019 titled Policy for Managing Patient Safety in Patient Support Programmes (version 1). The Panel noted that the objective of this Policy stated:

> 'The purpose of this policy is to establish a standard of practice for the initiation and ongoing management of Patient Support Programmes (PSP) by Project Owners (PO) in Janssen UK and Janssen Sciences Ireland, to ensure patient safety is maintained throughout the lifecycle of the project. Its aim is to ensure compliance with the ABPI Code of Practice and the IPHA Code of Practice.'

It was unclear to the Panel what was in place prior to this policy and at the time that the Stelara homecare service was started in 2010; Janssen made no submission in that regard.

The Panel had no information before it in relation to the individuals in Janssen or the service provider who were concerned with the preparation or approval of material or activities related to the Stelara homecare service to whom Clause 16.1 applied. Whilst the Panel was extremely concerned that individuals in Janssen responsible for the Stelara homecare service did not appropriately terminate the service, and that communication within Janssen and between Janssen and the homecare service provider was extremely poor, the Panel had no evidence before it that a breach of Clause 16.1 had occurred. The Panel ruled no breach of Clause 16.1 in that regard.

Clause 16.3 stated that representatives must take an appropriate examination within their first year of employment as a representative and must pass it within two years of starting such employment. The Panel noted that as part of its admission, Janssen had referred to the training of its field based staff. In the Panel's view, however, Janssen had not made any admission in relation to Clause 16.3 and there was no evidence before the Panel that the requirements of Clause 16.3 had not been met. Therefore, the Panel ruled no breach of Clause 16.3.

The Panel noted Janssen's submission that since 2018, the service provider had not been notified of any SPC updates, there was a lack of documented evidence that the service provider had completed Janssen pharmacovigilance training, and the company had failed to provide product training to the service provider beyond initial set-up training which had occurred prior to 2018. It was not clear to the Panel what changes to the Stelara SPC had occurred during this time; Janssen made no submission in that regard. The Panel was extremely concerned that for over two years, Janssen had no oversight or management of this Stelara homecare service and that the nurses providing the support had received no training, product or safety updates during that time. The Panel considered that Janssen had failed to maintain high standards and thus ruled a breach of Clause 9.1 as acknowledged by Janssen.

Clause 2 was a sign of particular censure and reserved for such use. In the Panel's view, this was an extremely serious matter that had patient safety implications. The Panel noted that the examples of activities that were likely to be in breach of Clause 2 included prejudicing patient safety. In the Panel's view, Janssen's lack of oversight and management of the Stelara homecare service, including its failures to provide product and pharmacovigilance training to the

nursing team and to notify them of SPC updates for more than two years had brought discredit upon and reduced confidence in the industry; the Panel ruled a breach of Clause 2.

The Panel was extremely concerned about its rulings and comments above. The Panel considered that it was crucial that patients, healthcare organisations and others could rely on companies funding homecare services to ensure that the arrangements complied with the Code and were such that patient safety was paramount. The Panel noted that Janssen had taken some steps to address the matters raised and that these had been brought to the attention of the global company. Nonetheless, the nature of the difficulties revealed by the voluntary admission was extremely concerning. The Panel considered it was inexplicable that the Stelara homecare service continued without the company's apparent knowledge from January 2018 until May 2020, given it appeared that monies continued to be paid to the service provider and adverse events processed (albeit incorrectly characterised). The company's procedures and approach to compliance should have prevented this. The Panel was concerned that neither Janssen nor its service provider were able to locate the relevant contract and thus it was unclear to what standards the service provider operated in relation to the Stelara homecare service. This was compounded by the fact that had the relevant SOP which came in to force 25 March 2019 been followed, it might have prevented certain difficulties (governance of contract, training and the requirement for a detailed handover to a new project owner), although its definition of a patient support programme did not appear to be relevant to the Stelara homecare service. Some of the matters raised went to the heart of self-regulation and patient safety. The company's lack of oversight and management of the homecare service at issue had been extremely poor. The Panel decided, in accordance with Paragraph 8.2 of the Constitution and Procedure, to report the company to the Appeal Board for it to consider whether further sanctions were appropriate in this case.

* * * * *

During the consideration of this case, the Panel noted Janssen's submission that payments to the homecare provider were not disclosed on Disclosure UK as at the time, Janssen did not consider homecare providers to be a healthcare organisation and therefore subject to the requirements of disclosure; Janssen believed that any such agreements constituted a commercial arrangement. The Panel further noted Janssen's submission that following publication of Case AUTH/2883/10/16 in May 2020, which clarified to Janssen that patient support service providers were considered healthcare organisations, the company had revised its approach to disclosure of patient support programmes and from 2021 onwards, Janssen would disclose in aggregate the portion of payments to healthcare organisations that were directly associated with clinical staffing costs associated with the delivery of the service. The Panel disagreed with Janssen's submission that Case AUTH/2883/10/16 was published in May 2020. Case AUTH/2883/10/16 was first published in May 2017 as an interim case report which gave the Panel's ruling and position on the matter. Furthermore, the 2019 Code, which came into operation on 1 January 2019, stated in the supplementary information of section 18.1 (Package deals), *inter alia*, 'The supplementary information to Clause 1.10 exempts package deals relating to ordinary course purchases and sales of medicines from the requirement to disclose. Transfers of value made in the course of other package deals would need to be disclosed in accordance with Clause 24'. The Panel requested that Janssen be advised of its concerns in that regard.

COMMENTS FROM JANSSEN ON THE REPORT

Janssen accepted the Panel's rulings of breaches of the Code.

* * * *

At the consideration of the report, Janssen stated that the company was committed to self-regulation, patient safety and a strong culture of quality and compliance.

Janssen apologised for its lack of oversight and attention that resulted in this situation. Despite the fact that this was a highly unusual situation, Janssen was embarrassed by the case and took full responsibility for having allowed it to occur. Janssen submitted that the root cause of the situation was a failure in termination of the programme which meant that the activity continued for some time after Janssen believed it had been stopped. Janssen submitted that this situation was an isolated incident which did not reflect a broad deficiency but investigations and Janssen's action plan had allowed solutions and improvements that would have broader benefits to oversight and control in the interests of patients and customers.

Janssen recognised that in this very unusual situation it had failed. Janssen submitted that its failure to terminate the programme correctly was the root cause of the subsequent failings. This resulted in failures in ongoing oversight and management of the programme including with respect to training of the provider. Escalation of issue was initially slow – exacerbated due to issues caused by Covid. Once aware of the issue, senior management prioritised investigation of the situation. There was no evidence of issues with regard to any other programmes. The third-party provider had continued to conduct training of its employees and continued to report suspected adverse events. An action plan was put in place to rectify the situation and to prevent recurrence. Once the full facts were ascertained and actions were in place to prevent any risk to patient safety, the issue was reported to the PMCPA.

Janssen submitted that it had strengthened oversight and control in this area including:

- Start up and close down procedures to ensure all services were initiated and terminated appropriately.
- Control mechanisms to ensure all patient facing activities were managed by appropriately trained staff.
- Dedicated specialist responsibility for managing programmes within commercial brand teams.
- Additional oversight of all vendors providing patient programmes from Programme Vendor Manager.
- Improvements to management of agreements

Further, there were quarterly meetings with senior managers and subject matter experts to review programmes and provide oversight of all patient services and wide-ranging initiatives to further strengthen how Janssen operated in the UK through the Culture of Quality and Compliance programme.

In summary, Janssen recognised its failings related to the situation and it had self-reported to ensure visibility of the case and enable industry learning. Janssen had taken these short-comings very seriously and understood the concerns raised by the Panel. An investigation into the root causes of the issue was prioritised and led by senior management. Janssen submitted that it was an isolated situation which did not reflect any broader deficiency. Risk to patient safety was low as services were provided by a third party that continued training of staff and reporting of suspected adverse events. Janssen submitted that it had addressed the situation

with corrective and preventative actions and would continue to invest in and grow its culture as there were real benefits to this.

APPEAL BOARD CONSIDERATION OF THE REPORT FROM THE PANEL

The Appeal Board noted the Panel's comments and rulings of breaches of Clauses 2 and 9.1 of the Code including its decision to report Janssen to the Appeal Board. The Appeal Board noted that Janssen had provided details about its plan to address the issues and it had apologised.

However, the Appeal Board was deeply concerned about the failings and Janssen's lack of control, checks and oversight that had allowed the patient facing Stelara homecare service to continue without the company's knowledge from January 2018 until May 2020, and that monies had continued to be paid to the service provider. The Appeal Board noted that adverse event reports had been processed by the service provider and reported (albeit incorrectly characterised) by Janssen. The Appeal Board noted Janssen's failure to provide product and pharmacovigilance training to the nursing team and updates on changes to the Stelara SPC. The Appeal Board noted that in response to a question, Janssen stated that there had been a number of changes to the SPC during the relevant period including the provision of extra clarity around hypersensitivity reactions and very few changes were material to patient safety. The company also stated that there were no important safety updates which led to an increased risk to patients. Further, the third-party service provider trained its staff to use the electronic medicines compendium (eMC) website for the SPC, which would have been up-to-date; there had been no specific training by Janssen in respect of the meaning of such changes. The adverse events were reported as unsolicited and Janssen stated that these were given a higher priority than solicited reports. The company had introduced more mechanisms to ensure that pharmacovigilance staff were more aware of ongoing relevant programmes. There were a number of third-party service providers delivering the homecare service which had now been the subject of audit as a result of which one had been terminated.

When questioned by the Appeal Board about the reasons for the delay in making the voluntary admission, the Janssen representatives referred to the decision to understand the root cause of the issue and to make remediations. Janssen representatives at the appeal submitted that the COVID-19 pandemic and lockdown and the impact that had on interactions with third party providers and major gaps in staffing had contributed to the delay. The Appeal Board considered that the period from discovery to reporting to the PMCPA was inexplicably long at over 7 months and it noted Janssen's acknowledgment in this regard. The Appeal Board noted Janssen's submission that it had made improvements and changes to ensure that this issue did not recur.

The Appeal Board decided that in accordance with Paragraph 11.3 of the Constitution and Procedure, Janssen should be publicly reprimanded for its failure to have oversight or control of a patient-facing service for 28 months and for its delay in making its voluntary admission once the errors had come to the company's attention. The Appeal Board also decided to require an audit of Janssen's procedures in relation to the Code. The audit should take place as soon as possible. On receipt of the report of the audit the Appeal Board would consider whether further sanctions were necessary.

FURTHER CONSIDERATION BY THE APPEAL BOARD

On receipt of the November 2021 report of the audit the Appeal Board was very concerned about the findings noting the depth and scale of the difficulties at Janssen. The Appeal Board

was particularly concerned about the patient support programmes, noting that such compliance issues were not limited to the patient support programme in question in Case AUTH/3436/12/20. In the Appeal Board's view the failure to have appropriate oversight of the patient support programmes including the failure to train nurses on certain SPC updates was serious. Public and patient confidence in the arrangements for such programmes was paramount.

The Appeal Board noted that the audit raised broad concerns about compliance and it highlighted many concerns that needed to be addressed.

The Appeal Board noted the comments in the report of the audit about Janssen's presentation to the Appeal Board at its consideration of the report from the Code of Practice Panel (Appeal Board meeting 16 September 2021) and its response to Appeal Board questions about SPC updates at that hearing. The Appeal Board bore in mind Janssen's comments on the report of the audit that at no stage was there an intention to mislead the PMCPA or the Appeal Board. The Appeal Board was concerned about what appeared to be an apparent lack of candour in the presentation and responses to Appeal Board questions, including about the scale of the difficulties at the company. It was important that the Appeal Board was able to rely on the accuracy of a company's submissions.

The Appeal Board acknowledged Janssen's comments on the report of the audit that it was committed to addressing the matters raised in the report of the audit, together with any others discovered as part of this process, as a matter of urgency and had already initiated significant actions.

The Appeal Board decided that Janssen should be re-audited in September 2022. In addition the Appeal Board required Janssen to provide an action plan with relevant time lines by April 2022 and to provide a further updated action plan in preparation for the re-audit. On receipt of the report of the re-audit the Appeal Board would decide whether further sanctions were necessary.

Voluntary admission 1 December 2020

Undertaking received 5 July 2021

Appeal Board consideration 16 September 2021 and 18 January 2022

Interim case report first published 24 March 2022