CASE AUTH/3168/2/19

COMPLAINANT v JANSSEN

Company website

A contactable individual who described him/herself as a concerned UK health professional, complained about the Janssen Medical Cloud website. The website was described on its homepage as being for healthcare professionals providing information about Janssen, product information, medical education and resources for patient management by disease area. Links were included to prescribing information and the home page included that the website contained promotional content.

The complainant stated that Janssen Medical Cloud appeared to be a website that was promotional and had areas that probably should not be.

The complainant stated that he/she was initially concerned about the way medical was so overtly used on a promotional website but then he/she realised that this was merely the tip of the iceberg. The complainant highlighted a number of concerns.

The detailed response from Janssen is given below.

With regard to various allegations that changes to summaries of product characteristics (SPC) had not been reflected in prescribing information, the Panel ruled no breach of the Code. This applied to material about Edurant, Symtuza, Stelara and Zytiga. The Panel also ruled no breach in relation to Trevicta, Xeplion and Risperdal oral tablets and solution and Risperdal Consta in the Schizophrenia portfolio.

Breaches of the Code were ruled in relation to similar allegations about Trevicta, Xeplion and Risperdal Consta prescribing information within a presentation on Schizophrenia including that high standards had not been maintained.

The Panel ruled a breach of the Code as high standards had not been maintained in relation to an alleged failure to include all the special warnings and precautions for using Edurant. Warnings relating to pregnancy were not included in a table.

The failure to update references to when pages were last updated was not considered to be a matter covered by the requirements for prescribing information and no breach was ruled in relation to two similar allegations in this regard.

The Panel ruled no breach in that the use of a supressed zero in a graph did not exaggerate the differences between the products as alleged. A second graph which also used a suppressed zero was ruled in breach as in this instance the presentation exaggerated the differences between the products.

The Panel ruled a breach as it considered a reference to 'the safe and effective use of Janssen medicines' in a 'meet the team' section might be seen as a claim that such medicines were safe.
The Panel ruled breaches of the Code as a Tremfya video did not have the up-to-date prescribing information. A further breach was ruled due to the lack of clear prominent statement as to where the prescribing information could be found.

No breach was ruled with regard to certification of presentations published in the oncology section on the website.

The Panel ruled that the facility for a health professional to forward materials to colleagues did not amount to disguised promotion. It would be clear to recipients that Janssen had created the email template and that the content was from the company. Prescribing information was available on the website accessed by the link and the email creation was certified as part of the website. No breaches of the Code were ruled.

The Panel did not consider that the website was disguised promotion. It was clearly promotional. The Panel ruled no breach in this regard.

The Panel did not consider that the complainant had shown on the balance of probabilities that the training of Janssen staff failed to meet the requirements of the Code and ruled no breach of the Code.

The Panel considered it was very important that prescribing information was up-to-date. It noted that there were some errors on the website and also noted its rulings above. The Panel considered therefore that high standards had not been maintained and ruled a breach.

The Panel noted the complainant stated that if the majority of the allegations were found to be true, then he/she was alleging a breach of Clause 2. The majority of allegations had not been ruled in breach. The Panel noted the errors with out of date prescribing information and its ruling that high standards had not been maintained. It also noted Janssens's submission that the up to date prescribing information was available on the home page. Clause 2 of the Code was a sign of particular censure and reserved for such use. The Panel considered that based on the allegations, on balance, the circumstances did not warrant a ruling of a breach of Clause 2 of the Code.

A contactable individual who described him/herself as a concerned UK health professional, complained about the Janssen Medical Cloud website. The website was described on its homepage as being for healthcare professionals. It provided information about Janssen and gave access to product information, medical education and resources

for patient management by disease area. Links were included to prescribing information and the home page included that the website contained promotional content.

COMPLAINT

The complainant stated that Janssen Medical Cloud appeared to be a website that was promotional and had areas that probably should not be. The website was clearly promotional – the landing page stated 'This website contains promotional content'. The complainant stated that he/she was initially concerned about the way medical was so overtly used on a promotional website but then he/she realised that this was merely the tip of the iceberg.

The complainant highlighted the following:

1 Edurant (rilpivirine) (an antiretroviral for treatment of HIV)

The complainant referred to a table of special warnings which presented material from the summary of product characteristics (SPC) 2016. The complainant stated that the SPC had been updated several times since then, including to both special warnings and pregnancy and lactation. Although the page had apparently been updated in 2017, the references had been last accessed in 2016 so were out-of-date when the website was last updated.

The prescribing information was also alleged to be out-of-date as the version was dated 2017. The complainant alleged a breach of Clause 4.1.

At the bottom of the webpage there was a button which stated 'recommend this content to a colleague'. Pressing this created an email that health professionals could send to their colleagues on behalf of Janssen. This used health professionals to contact their colleagues. This was true of many of the pages of the website. The complainant alleged breaches of Clauses 4.1, 4.2, 4.3, 4.4, 12.1 and 14.1.

2 Prezista (darunavir) (an antiretroviral for the treatment of HIV)

The complainant stated that a graph demonstrated improved renal function after switching from alternative treatments. Whilst there was a difference, the estimated glomerular filtration rate (eGFR) on the y axis only went from 60 to 105, which exaggerated the difference between the two categories. The complainant alleged a breach of Clause 7.2.

There was also the same issue on the graph below; discontinuation rates for treatment-experienced patients ended at 0.2 as opposed to 0 which the complainant alleged exaggerated the difference between the treatments in breach of Clause 7.2.

Again, there was a button that stated 'recommend this content to a colleague'. This created an email that health professionals could send to their colleagues on behalf of Janssen.

3 Symtuza (darunavir, cobicistat, emtricitabine, tenofovir) (a fixed combination of antivirals for treating HIV)

The complainant alleged that the Symtuza prescribing information was out-of-date, in breach of Clause 4.1.

Again, at the bottom of the webpage there was a button that stated 'recommend this content to a colleague'. This created an email that health professionals could send to their colleagues on behalf of Janssen.

4 Schizophrenia section

The complainant alleged that the prescribing information for Trevicta, Xeplion, Invega (all various pharmaceutical forms of palperidone), Risperdal and Consta (different pharmaceutical forms of risperidone) were all out-of-date, in breach of Clause 4.1.

The references of the page had not been reviewed after the significant updates.

5 Pharmacy Academy – Schizophrenia

The complainant stated that with regard to the Pharmacy Academy 2017, most of the links did not work. The link which worked included three lots of prescribing information at the end of the slides. The complainant alleged the prescribing information was out-of-date in breach of Clause 4.1.

6 Rheumatology Section - Stelara

The complainant alleged that in the Rheumatology section of the website, the prescribing information for Stelara (ustekinumab) was out-of-date; in breach of Clause 4.1.

7 'Meet' the medical team

The complainant noted that via a link to medical education readers could 'meet' the medical team. In each instance, there was a biography of what the team members could do for health professionals. Included in every profile was the statement 'Address your questions concerning the safe and effective use of Janssen medicines based on available data'. As this wording was identical in all the profiles throughout the website it appeared to be the company boilerplate. With each use the complainant alleged a breach of Clause 7.9.

8 Tremfya (guselkumab) Video – medical education

The complainant alleged that no prescribing information was available for the Tremfya (guselkumab) video. The complainant alleged a breach of Clauses 4.1 and 4.6.

9 Oncology Section

The complainant alleged that in the oncology section, there were fifteen slide decks all of which described how they would be altered before

they were finally used. The complainant alleged a breach of Clause 14.1 in each instance. None of the slide decks had prescribing information attached, but it was, nonetheless, available by following a link. The prescribing information was, however, out-of-date and a breach of Clause 4.1 was alleged.

10 General

The complainant submitted that there might be other issues on the website, but he/she did not have the time to investigate more deeply.

In conclusion, the complainant alleged that the Janssen website was dangerously out-of-date and, if relied on by health professionals, could lead to unsafe clinical prescribing decisions. It also appeared designed to blur what the sales department and the medical department did.

The magnitude of the errors, both in number and in severity, made the complainant wonder how this could have not been picked up by any person over the years – training appeared to be inadequate in breach of Clause 16.1.

Given that historically a finding of a breach of Clause 9.1 had been given for one out-of-date prescribing information, this should be viewed in each instance.

If the majority of the allegations were found to be true, the complainant alleged a breach of Clause 2.

RESPONSE

Janssen explained that the Medical Cloud website was a web-based platform that served as a single repository for product and therapy area content directed at medical professionals. The name of the website identified the target audience and separated it from any other Janssen sites eg corporate or patient etc. The website was certified in accordance with Clause 14.1.

Janssen noted that the complainant had correctly highlighted the fact that the website contained promotional content. There was no attempt to disguise the fact that the website included promotional content. This was intended to be a promotional website and all content was presented in that context.

In addition, the website contained broader information that might be of interest to health professionals, including educational resources, tools for health professionals to use with patients, medical information contact details and adverse event reporting information. All content about Janssen medicines, be that branded/promotional or non-branded/educational, was in accordance with the relevant marketing authorization and licensed indications.

Janssen asserted that there was no attempt to disguise promotional content and therefore it denied a breach of Clause 12.1. Nevertheless, Janssen had made the disclaimer more prominent by incorporating it into the title and main image of the homepage.

With regard to the prescribing information, Janssen acknowledged a breach in relation to two items, a downloadable presentation and a video clip (see Points 5 and 8 below).

On the homepage, there was a link to a web-based repository of the most up-to-date prescribing information for each of the marketed products. When an SPC change necessitated a change to the prescribing information, the regulatory team (in consultation with medical affairs) implemented and communicated the changes in line with Janssen's processes. In addition, the regulatory team also approved the web version of the prescribing information to ensure that it had been correctly transposed and formatted, before being posted on the prescribing information portal.

Prescribing information could be accessed from the home page for all promoted products. In addition, each promotional webpage had links to the appropriate prescribing information for therapy area specific medicines.

Thus, Janssen submitted that health professionals had clear access to the most up-to-date prescribing information on the website.

1 Edurant

Janssen stated that the prescribing information for Edurant was last updated in August 2017. Since then, there had been the following two updates to the SPC:

a) October 2018 – Section 4.4: To add warning 'autoimmune hepatitis' within parenthesis to 'Autoimmune disorders'
b) January 2019 – Section 4.9: Overdose - removal of activated charcoal to manage overdose.

Janssen submitted that neither of the above SPC changes mandated changes to the prescribing information, therefore, the prescribing information for Edurant was up-to-date and not in breach of Clause 4.1.

Janssen submitted that the relevant section of the website was last reviewed on 10 October 2017, the last revision of the SPC was 24 August 2018. The updates since July 2016 (the stated access date in the references) to the SPC included:

- Removal of black triangle – not relevant to the table
- Drug-drug interaction (DDI) with simeprevir – No dose adjustment required and therefore not relevant to the table
- 'autoimmune hepatitis' within parenthesis to 'autoimmune disorders' – not relevant to table
- Overdose -removal of activated charcoal to manage overdose – not relevant to table
- Inclusion of additional pregnancy data – additional information added about pharmacokinetic data.

Janssen submitted that as the SPC amendments above were not relevant to the table, it was not considered necessary to update the table. Whilst Janssen accepted that the date of last access (July 2016) was not updated to reflect the review date in 2017, the link directed the user to the most recent SPC on the eMC. Upon reflection, Janssen noted that the original table should have included information on pregnancy as commented on by the complainant. As such, Janssen had since removed the infectious disease sections of the website pending further revision.

The response to the recommend content to a colleague allegation was covered in point 10 below.

2 Prezista

Janssen submitted that the graph, which demonstrated improved renal function, had been faithfully reproduced from the publication. A lower eGFR limit of 60ml/min/1.73m^2 was consistent with the internationally accepted cut off above which kidney function was considered normal. The message was not misleading insofar as the gradual decline in eGFR was reversed/stabilised with a switch from either ATV/r to DRV/r or LPV/r to DRV/r. Janssen denied a breach of Clause 7.2.

Whilst Janssen accepted that the second graph of discontinuation rates for treatment-experienced patients started at 0.2, it did not represent a distorted impression of the data given that 80% of the range was included. Starting the Y-axis at zero would not alter the marked and statistically significant difference between LPV and DRV nor would it reduce the statistically significant difference seen between DRV and the other agents. Janssen denied a breach of Clause 7.2.

Nevertheless, Janssen would review the graphs pending further revision of the infectious disease section of the website.

3 Symtuza

Janssen submitted that the prescribing information for Symtuza was last updated in November 2018, at the same time as the most recent SPC (November 2018). The link on the website was to the Symtuza prescribing information dated November 2018. Janssen denied a breach of Clause 4.1.

4 Schizophrenia portfolio

Janssen provided a table which included the relevant process dates for SPC and prescribing information updates for Trevicta, Xeplion, Invega, Risperdal tablets and oral solution and Risperdal Consta. The date of last revision of the prescribing information reflected the 'date of revision of the text' specified in Section 10 of the SPC and not the date the SPC was 'Last updated on the Electronic Medicines Compendium (eMC)'. Janssen submitted that the prescribing information for all the medicines referred to were current. Janssen denied a breach of Clause 4.1.

Janssen pointed out that whilst the complainant had not identified specific references of concern, it was assumed that the complaint related to the following references due to there being specific mentions of the date of last access:

1 Xeplion. Summary of Product Characteristics. 2018. [Last accessed: May 2018].
2 Trevicta. Summary of Product Characteristics. 2018. [Last accessed: May 2018].

The table below detailed the claims made on the webpage as they related to the latest SPC. Since May 2018 none of the changes to the SPC affected the substantiation of the respective claims. Janssen submitted that the changes in the September SPC did not include any revisions to the section to which the claims were referenced. As such the claim was substantiated by the reference and was not in breach of the Code.

Claim	Source of substantiation from latest SPC
Previous treatment (oral risperidone or paliperidone)1	**4.2 Therapeutic indications:** Xeplion is indicated for maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone.
4 per year dosing with Trevicta2	**4.2 Posology and method of administration** Following the initial TREVICTA dose, TREVICTA should be administered by intramuscular injection once every 3 months (± 2 weeks).

Janssen acknowledged that the text should have been updated to indicate that the references had been checked more recently (in October 2018) but this was not part of the complaint *per se* and did not impact the accuracy of the reference itself.

5 Schizophrenia slides – Pharmacy academy

Janssen noted that this complaint related to a downloadable presentation on schizophrenia. This presentation was available from the URL provided by the complainant from the Big Questions Meeting webpage, which contained prominent links to the correct and current prescribing information for all products at the top.

However, Janssen acknowledged that there had been a breach of Clause 4.1 relating to the prescribing information contained within the presentation. The prescribing information for each of the 3 products mentioned Trevicta, Xeplion and Risperdal Consta attached to the actual downloadable presentation should have been amended in line with SPC updates in September 2018 in relation to Sections 4.4 and 4.5 – Caution is warranted in patients receiving both psychostimulants (eg, methylphenidate) and paliperidone concomitantly, as extrapyramidal symptoms could emerge when adjusting one or

both medications. Gradual withdrawal of stimulant treatment is recommended. Janssen accepted a failure to maintain high standards in breach of Clause 9.1.

All prescribing information containing materials submitted for copy approval were required by the Janssen SOP to be marked as 'containing PI' in the relevant job bag information field. This facilitated identification of materials that required withdrawal/ revision at the time of a prescribing information update. Investigation of the underlying cause for failing to withdrawal this presentation had identified an individual error which resulted in this item not being flagged in the company's approval system as containing prescribing information. Consequently, it was missed in the recall process when the SPC and prescribing information were updated in September 2018. This presentation was withdrawn on 12 March 2019. In line with Janssen's ongoing compliance training framework, Janssen committed to using this case to emphasise the importance of correctly logging all materials containing prescribing information.

6 Rheumatology section - Stelara

Janssen submitted that the prescribing information for Stelara was last updated in April 2018. Since then, there had been the following two revisions to the SPC text:

1 July 2018
- Section 4.4: addition on information on sodium content
- Section 4.8: deletion of immunogenicity paragraph
- Section 5.1: addition on immunogenicity paragraph.

2 November 2018
- Section 4.4: addition of paragraph on respiratory hypersensitivity reactions.
- Section 4.8: addition of allergic alveolitis and eosinophilic pneumonia under frequency of rare.

Janssen submitted that neither of the above revisions to the SPCs mandated updates to the prescribing information, therefore, the prescribing information for Stelara on the website in question was up-to-date and not in breach of Clause 4.1.

7 Meet the team link to medical colleagues

Janssen stated that as described previously, content under each therapy area was signposted as being of promotional, medical educational or other utility. The links to the medical team were only available from the medical education content pages, in the case of rheumatology, from the Janssen eXchange Hub.

Each of the team members had a short description of their individual experience, what their MSL role could offer the health professional, their qualifications and any publications.

Regarding the allegation of a breach of Clause 7.9, Janssen did not agree that the description of the service the MSL could offer implied either directly or indirectly that any Janssen medicines were 'safe'. Janssen denied a breach of Clause 7.9.

8 Tremfya video

The prescribing information for Tremfya could be found at the end of the video and therefore the video complied with the requirements of Clause 4.5 and did not breach Clause 4.6. Janssen accepted that the prescribing information was out-of-date and was therefore in breach of Clause 4.1. This video had been withdrawn as of 22 March 2019.

9 Oncology slides

Janssen stated that there were 15 presentations in the Medical Education, Prostate Cancer Hub section under the 'slides and case studies' tab. On clicking this tab, the health professional was presented with a selection of presentations for viewing and download. All the presentations related to disease area topics of interest, with a small number discussing medicines in a balanced manner. In line with the Code, prescribing information was clearly available and accessible from the top of the same website page.

The prescribing information for Zytiga (February 2019) was current with the most recent revision of the SPC text which took place on 26 February 2019. Janssen denied all breaches of Clause 4.1 in relation to these presentations.

Janssen accepted that all 15 presentations had an in-house comment on the standard disclaimer slide, which should have been removed before final certification. Nevertheless, each of the presentations had been certified with the comment in place and published on the website as approved in final form, with the comment in situ and in line with the requirements of Clause 14.1.

The comment referred to by the complainant was:

> 'Reviewers please note – disclaimer slide included for review purposes in all speaker presentations but will be included only once when the showreel is compiled for the Summit meeting – ok?'

There was no instruction for content slides to be altered, and signatories certified the slides with this information to hand. Janssen denied a breach of Clause 14.1

10 Recommend content to a colleague

Janssen stated that it was not clear from the complainant as to why he/she considered the clauses cited had been breached.

The 'recommend to a colleague' functionality was available at the bottom of some website pages. Upon clicking it, an outlook email from the referring health professional was opened bearing the following:

'Subject: *Recommended content from Janssen.*

Content: *I thought this content from Janssen would interest you. Link to JMC page.'*

The reference to Janssen in the header and in the opening sentence was a clear indication that the content was not independent. Since there was also nothing in the text to indicate the material was non-promotional, it was difficult to see how any recipient of the email could be tricked into opening it. Consequently, Janssen denied any allegation of Clause 12.1.

The email generated did not contain any product information (other than in some cases the product name within the link). Janssen did not believe that in this context there was a requirement for prescribing information to be included in the email and therefore it refuted any breaches of Clauses 4.1, 4.2, and 4.4. Furthermore, the only reference to a brand might be found in the details of the web link. As such, Janssen did not agree that the non-proprietary name was required and therefore denied a breach of Clause 4.3.

The email's creation was certified as part of the website itself. No further certification was necessary; consequently, the requirements of Clause 14.1 had already been met.

11 General

Janssen stated that all personnel involved in the creation and approval of content were appropriately trained on the requirements of the Code. This included online modules, SOP training, mentoring, supervision and Code updates delivered every 3 months by a third-party compliance agency. Janssen denied a breach of Clause 16.1.

Given the scale of the website, approval of content was done in sections or pages depending on the interconnectivity. Individual pieces for upload onto the website were approved as standalone items which sat in a separately approved frame. This facilitated the dynamic nature of web-based content whilst reducing the need to approve the entire site each time a change was made. This meant that there was no specific date on which the entire website was approved. All web-based content was on the current materials list and it was Janssen's policy to review and reapprove all web-based content at least every 12 months. All content that was flagged in the approval system as containing prescribing information was updated when the supporting prescribing information changed. Investigation had confirmed that the 2 items that were not updated following a prescribing information change were as a result of individual error. As indicated previously, Janssen would emphasise to originators and signatories the importance of checking that materials were correctly flagged as containing prescribing information or not.

Finally, as most of the items were properly clarified, Janssen denied a breach of Clause 2.

PANEL RULING

The Panel addressed the specific points raised by the complainant as follows.

1 Edurant

The Panel noted the material provided by Janssen was a webpage headed 'Edurant' and included sections on tolerability, efficacy and DDIs (drug-drug interactions) which included a table headed 'Special warnings and precautions when prescribing Edurant' referenced to the Edurant SPC 2016. The Panel noted Janssen's submission that the information was reviewed on 10 October 2017 and the last revision of the SPC was 24 August 2018. The company did not amend the table as in its view the amendments to the SPC since July 2016 were not relevant to the table. However, the date of last access (July 2016) was not updated.

It was not entirely clear whether the table headed 'Special warnings and precautions when prescribing Edurant' was part of the section 'drug-drug interactions'. The Panel noted that the table included more than simply information about drug-drug interactions but did not include any of the special warnings and precautions for use in Section 4.4 of the Edurant SPC including information on pregnancy.

Section 4.6 of the July 2017 SPC Fertility, pregnancy and lactation stated that there was no or limited data from the use in pregnant women and that animal studies did not indicate direct or indirect harmful effects with respect to reproductive toxicity. It also stated that as a precautionary measure it was preferable to avoid the use of Edurant during pregnancy. The August 2017 SPC had an update to Section 4.6 to include the additional information that lower exposures of Edurant were observed during pregnancy, therefore viral load should be monitored closely. In addition, information was added to Section 4.4 Special warnings and precautions for use which stated, *inter alia*, that Edurant should be used during pregnancy only if the potential benefit justified the potential risk.

The Panel considered that although the table appeared under a section headed drug-drug interactions (DDIs), given the subheading to the table 'Special warnings and precautions ...' and its content, the table would be seen as including all the relevant information. The special warnings and precautions for use from Section 4.4 of the Edurant SPC, including pregnancy, should have therefore been included in the table and the failure to do so was misleading and high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel considered that the references were not up-to-date but this was not a matter covered by Clause 4.1 as alleged by the complainant; Clause 4.1 related to the provision of prescribing information. No breach of Clause 4.1 was ruled in that regard.

With regard to the allegation that the prescribing information was out-of-date, the Panel noted Janssen's submission that it was last updated in August 2017 and that the two SPC updates since this date did not mandate changes to the prescribing information. The complainant bore the burden of proof and, in the Panel's view, he/she had

not established that the prescribing information was not up-to-date. The Panel thus ruled no breach of Clause 4.1.

The allegation regarding recommend content to a colleague was covered in point 10 below.

2 Prezista

The Panel noted that the graph compared the effects of atazanavir or lopinavir on eGFR decline prior to a switch to darunavir (all in addition to ritonavir) and the effect of that switch on eGFR. Although the y axis started at 60, the Panel did not consider that this necessarily meant that the graph was misleading. The graph on the Janssen website was similar to that in the published paper. The data presented did not go below 90 so the space between 60 and 90 was blank. The values for mean (95% confidence interval) eGFR slope estimates pre and post-switch were given. All the data was presented, there were no values which were off the scale. In the circumstances the Panel did not consider that the presentation exaggerated the differences between the products as alleged and therefore ruled no breach of Clause 7.2.

The second graph referred to by the complainant was headed 'Discontinuation rates for treatment-experienced patients'. Real world data for rilpivirine, darunavir, raltegravir, efavirenz, atazanavir, entecavir and lopinavir were presented with the y axis scale (proportion of patients on treatment) starting at 0.2 and finishing at 1. The graph was positioned under a subheading 'the majority of treatment-experienced patients continue with their treatment when on darunavir'. The Panel considered that this graph was misleading as it gave the impression due to the absence of some of the y axis (0.2-0) that most, if not all, patients on lopinavir discontinued therapy and this was not so.

The Panel considered that the presentation exaggerated the differences between the products as alleged and ruled a breach of Clause 7.2 of the Code.

The allegation regarding recommend content to a colleague is covered in point 10 below.

3 Symtuza

The Panel noted the submission from Janssen that the prescribing information for Symtuza was last updated in November 2018 which was the same date as the most recent SPC and the prescribing information links on the homepage and each promotional webpage were to the up-to-date information. The Panel thus ruled no breach of Clause 4.1.

The allegation regarding recommend content to a colleague is covered in point 10 below.

4 Schizophrenia

The Panel noted the submission from Janssen that the prescribing information links on the homepage and each promotional webpage were to the up-to-date information. The Panel thus ruled no breach of Clause 4.1 for each of the products.
The Panel noted Janssen's submission that the complainant had not provided specific concerns regarding the references. Janssen provided further information. The company acknowledged that the references should have been updated to indicate that they had been checked more recently. The company submitted that this was not part of the complaint and did not impact the accuracy of the reference itself.

The Panel considered that the references were not up-to-date but this was not a matter covered by Clause 4.1 as alleged by the complainant; Clause 4.1 related to the provision of prescribing information. No breach of Clause 4.1 was ruled in that regard.

5 Pharmacy Academy

The Panel noted from Janssen's submission that the prescribing information for Trevicta, Xeplion and Risperdal Consta within the presentation had not been updated to reflect SPC updates in relation to Sections 4.4 and 4.5 and the need for caution in certain patients. A breach of Clause 4.1 was ruled for each out-of-date prescribing information. The Panel ruled that Janssen had failed to maintain high standards in breach of Clause 9.1 as acknowledged by the company.

6 Rheumatology Section – Stelara

The Panel noted the submission from Janssen that the prescribing information links on the homepage and each promotional webpage were to the up-to-date information. The Panel noted Janssen's submission that the Stelara prescribing information was last updated in April 2018 and since that date there had been two revisions to the SPC which Janssen stated did not mandate updates to the prescribing information. The complainant bore the burden of proof and, in the Panel's view, he/she had not established that the prescribing information was not up-to-date. The Panel thus ruled no breach of Clause 4.1 in relation to Stelara.

7 Meet the medical team

The Panel noted Janssen's submission that the links to the medical team were only available from the medical education content pages. The Panel queried whether readers would see the site as containing promotional and non-promotional elements. The Panel noted that the Janssen exchange hub referred to events, including videos, one of which referred to an overview of a Janssen product (guselkumab) others referred to treating conditions in which Janssen had an interest.

The website included an option to meet the team, providing contacts for MSLs and the medical education manager. The further details about one of the MSLs included a list of what an MSL could do for you and the first point was 'address your questions concerning the safe and effective use of Janssen medicines based on available data'. This appeared to be a standard description as it was included in the profiles of all the MSLs named.

The Panel considered that the reference to the safe and effective use of Janssen medicines might be seen as a claim that such medicines were safe. Although there might be a difference between the medicine being safe and the safe use of that medicine Clause 7.9 stated that the word 'safe' must not be used without qualification. Clause 7 was not limited to promotional material. The Panel considered that on balance the reference to safe and effective use of Janssen's medicines did not meet the requirements of Clause 7.9 and a breach was ruled.

8 Tremfya video

The Panel noted Janssen's submission that prescribing information was provided at the end of the video but it was not up to date. In that regard the Panel ruled a breach of Clause 4.1 of the Code as acknowledged by Janssen. The Panel noted that it appeared from the information provided by Janssen that the video was no longer available and the webpage on which the video had appeared did not contain a clear prominent statement as to where the prescribing information could be found. Similarly the beginning of the video did not include such a statement. The Panel therefore ruled a breach of Clause 4.6.

9 Oncology section

The Panel noted the submission from Janssen that the prescribing information was clearly available and accessible from the webpage and that the prescribing information for Zytiga was up-to-date. The Panel thus ruled no breach of Clause 4.1.

With regard to the internal comment for reviewers which had been published, the Panel noted Janssen's submission that the presentations had been certified with the comment in place. The Panel considered that what was published on the website had been certified as required by the Code and thus ruled no breach of Clause 14.1 of the Code.

10 Recommend content to a colleague

With regard to the facility for health professionals to forward materials to colleagues (allegations in points 1, 2, and 3 of the complaint), the Panel noted Janssen's submission that the email generated when using this facility referred to Janssen in the subject and in the content.

The Panel considered that it would be sufficiently clear to recipients of these emails that Janssen had created the email template for one health professional to send to another and that the content was from the Janssen website.

The Panel noted that promotional material did not need to be labelled as such, however, it must not be disguised, and the identity of the responsible pharmaceutical company or a pharmaceutical company's involvement must be obvious at the outset. In the Panel's view, those receiving the emails from health professionals would be aware that the material was from Janssen, the example provided included a product name in the URL, and would be likely to assume it was promotional. Further the complainant had not proved on the balance of probabilities that the material accessed from the emails in question constituted disguised promotion. The Panel ruled no breach of Clause 12.1.

The content of the email was a link to the Janssen material. The example provided by Janssen included a URL link that mentioned a product name but with no further information about the product in the email. The Panel noted Janssen's submission that prescribing information was on the webpage accessed from the URL. In these circumstances, the Panel ruled no breach of Clauses 4.1, 4.2, 4.3 and 4.4.

Janssen submitted that the email creation was certified as part of the website. Each individual email was not certified. The Panel noted that the differences between the emails would be the address of the sender and of the recipient health professional and any other content added by that health professional. The Panel considered that in the circumstances the certification requirements had been met. No breach of Clause 14.1 was ruled.

11 General

The Panel noted Janssen's submission that the website had been certified in accordance with Clause 14.1 ie as promotional material. The Panel did not consider that the website was disguised promotion. It was clearly promotional. The Panel ruled no breach of Clause 12.1.

The Panel did not consider that the complainant had shown on the balance of probabilities that the training of Janssen staff failed to meet the requirements of Clause 16.1. The Panel noted the company's submission about the training it provided staff. The Panel ruled no breach of Clause 16.1.

The Panel considered it was very important that prescribing information was up-to-date. It noted that there were some errors on the website and also noted its rulings above. The Panel considered therefore that high standards had not been maintained and ruled a breach of Clause 9.1.

The Panel noted the complainant's allegation was that if the majority of the allegations were found to be true then he/she was alleging a breach of Clause 2. The majority of allegations had not been ruled in breach. The Panel noted the errors with out of date prescribing information and its ruling of a breach of Clause 9.1 and Janssens's submission that the up to date prescribing information was available on the home page. Clause 2 of the Code was a sign of particular censure and reserved for such use. The Panel considered that based on the allegations, on balance, the circumstances did not warrant a ruling of a breach of Clause 2 of the Code.

Complaint received **27 February 2019**

Case completed **27 June 2019**