*NO BREACH OF THE CODE*

**CASE AUTH/3408/10/20**

# ANONYMOUS NON-CONTACTABLE v AMGEN

## Allegations about prescribing information

**An anonymous, non-contactable complainant alleged that the prescribing information on a detail aid (ref UKIE-P-103-1115-117947(1)) for Blincyto (blinatumomab) produced by Amgen was incorrect and was not the most up to date version. Blincyto was indicated for certain patients with acute lymphoblastic leukaemia.**

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

**The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure for the PMCPA stated that anonymous complaints would be accepted but that, like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities.**

**The Panel noted that the complainant alleged that the prescribing information on the detail aid in question was incorrect and not the most up to date but provided no details of why, in his/her view, this was so. It was not for the Panel to make out a complainant's allegations and the complainant could not be contacted for more information.**

**The Panel noted Amgen's submission that it assumed that the allegation related to the fact that Blincyto was licensed for a new indication (as monotherapy for the treatment of adults with Philadelphia chromosome negative CD19 positive B-precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%.) in January 2019. The Panel noted Amgen's submission that there was no need to amend the prescribing information dated August 2018 on the detail aid at issue as a result of the new indication because the only changes to the prescribing information related to the new indication and the new dosing schedule for that indication and there were no new safety changes. The Panel further noted Amgen's submission that the prescribing information for the indication stated in the detail aid in question was accurate and maintained updated at all times.**

**The Panel noted that the detail aid in question which was certified in November 2018 clearly related to Blincyto's indication as monotherapy for the treatment of adults with Ph-CD19 positive relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL) which was stated on the cover. The Panel noted Amgen's submission that this detail aid was withdrawn on 27 May 2020 and replaced with a new detail aid.**

**The Panel noted that some changes to an SPC might not necessarily have to be reflected in the prescribing information. For example, information relevant only to an indication not being promoted might not need to be included in the prescribing information.**

**The Panel was not an investigatory body and it judged complaints on the evidence provided by both parties. The Panel considered that the complainant had not discharged**

**his/her burden of proof that the prescribing information on the piece of material at issue did not meet the requirements of Clauses 4.1 and 4.2 and in that regard the Panel ruled no breach of the Code.**

An anonymous, non-contactable complainant, who stated that he/she was an employee of Amgen Ltd, complained about the company's Blincyto (blinatumomab) detail aid (ref UKIE-P-103-1115-117947(1)).

Blincyto was indicated for certain patients with acute lymphoblastic leukaemia.

**COMPLAINT**

The complainant alleged that the prescribing information on the detail aid was incorrect and was not the most up to date version.

The complainant stated that he/she complained in good faith because various concerns raised by staff generally were often not heard.

When writing to Amgen, the Authority asked it to consider the requirements of Clause 4.1 of the Code.

**RESPONSE**

Amgen stated that it took compliance with the Code very seriously and conducted its business in a responsible, ethical and professional manner at all times. Amgen had investigated the details of this case and was confident that the detail aid in question was consistent with the requirements of the Code and it thus disagreed with the complainant's allegations regarding incorrect and out of date prescribing information.

Amgen explained that the detail aid was an interactive digital sales aid used by the sales team to promote Blincyto in the treatment of adults with Philadelphia chromosome negative CD19 positive relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL). This primary indication was detailed in the summary of product characteristics (SPC) in November 2018.

The detail aid, which contained prescribing information dated August 2018, was certified for use on 23 November 2018; details and qualifications of the signatories were provided.

The detail aid would have been presented to the customer/potential customer in a digital format during a remote call or face-to-face meeting.

The detail aid was the main interactive detail aid used to promote Blincyto for use as detailed above and remained so until 27 May 2020, when it was withdrawn and replaced with a new detail aid.

Amgen submitted that in compliance with Clause 4.1, the detail aid contained the prescribing information listed in Clause 4.2 of the Code in a clear and legible manner. Specifically, according to Clause 4.2 (iii) the prescribing information needed to contain at least one authorised indication as well as a summary of some of the key information from the SPC relevant to the indication quoted in the material, such as the dosage method for that indication (Clause 4.2 (iv)). The detail aid covered the use of Blincyto in the treatment of adults with

Philadelphia chromosome negative CD19 positive relapsed or refractory B-precursor acute lymphoblastic leukaemia and the embedded prescribing information explicitly covered this indication, as required under Clause 4.2.

Further, the information required in accordance with Clause 4.2, specifically (iv) (information in the SPC relating to the dosage and method of use), (v) (common adverse reactions likely to be encountered in clinical practice, serious adverse reactions and precautions and contra-indications) and (vi) (any required warning), was placed in such a position that its relationship to the claims and indications for the product could be appreciated by the reader. In addition, in compliance with Clause 4.1 the detail aid had the prescribing information well positioned for ease of reference and that the prescribing information formed part of the detail aid.

Amgen stated that it assumed that the allegation that the prescribing information was 'incorrect' and also 'not the most up to date one' related to the fact that Blincyto was licensed for a new indication (as monotherapy for the treatment of adults with Philadelphia chromosome negative CD19 positive B-precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%.) in January 2019. There was no need to amend the prescribing information in the detail aid in question as the only changes to the prescribing information related to the MRD indication and the new dosing schedule for MRD. Further, there were no new safety changes. Thus, the prescribing information for the indication referred to in the detail aid was accurate and maintained updated at all times.

Finally, Amgen explained that within the company there were many ways employees could raise concerns that they might have about the way in which the company conducted its business. Discussing issues with a line manager or functional head/business unit head were the usual first channels. Furthermore, skip level meetings were held with staff, generally two to three times per year, where they could openly bring up issues or concerns with the general manager. In addition, Amgen had a dedicated compliance manager in the affiliate whom staff could contact to discuss concerns they might have. There was also a global, company-wide Business Conduct Hotline that all employees could use to report concerns and remain anonymous, if they wished. All employees annually completed Amgen's global Code of Conduct training about ethical behaviour that went beyond compliance with the laws and was about doing the right thing in the right way. Amgen confirmed that, based on its internal enquiries, the company had not received any internal complaints through the aforementioned channels in connection with the detail aid from the sales, marketing, regulatory or medical teams.

In summary, Amgen considered that the detail aid complied with the requirements for providing prescribing information as set out in Clauses 4.1 and 4.2 respectively.

**PANEL RULING**

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure for the PMCPA stated that anonymous complaints would be accepted but that, like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities.

The Panel noted that the complainant alleged that the prescribing information on the detail aid in question was incorrect and not the most up to date but provided no details of why, in his/her view, this was so. It was not for the Panel to make out a complainant's allegations and the complainant could not be contacted for more information.

The Panel noted Amgen's submission that it assumed that the allegation related to the fact that Blincyto was licensed for a new indication (as monotherapy for the treatment of adults with Philadelphia chromosome negative CD19 positive B-precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%.) in January 2019. The Panel noted Amgen's submission that there was no need to amend the prescribing information dated August 2018 on the detail aid at issue as a result of the new indication because the only changes to the prescribing information related to the new indication and the new dosing schedule for that indication and there were no new safety changes. The Panel further noted Amgen's submission that the prescribing information for the indication stated in the detail aid in question was accurate and maintained updated at all times.

The Panel noted that the detail aid in question which was certified in November 2018 clearly related to Blincyto's indication as monotherapy for the treatment of adults with Ph-CD19 positive relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL) which was stated on the cover. The Panel noted Amgen's submission that this detail aid was withdrawn on 27 May 2020 and replaced with a new detail aid.

The Panel noted that some changes to an SPC might not necessarily have to be reflected in the prescribing information. For example, information relevant only to an indication not being promoted might not need to be included in the prescribing information.

The Panel was not an investigatory body and it judged complaints on the evidence provided by both parties. The Panel considered that the complainant had not discharged his/her burden of proof that the prescribing information on the piece of material at issue did not meet the requirements of Clauses 4.1 and 4.2 and in that regard the Panel ruled no breach of Clause 4.1.

**Complaint received** **29 October 2020**

**Case completed** **22 April 2021**