CASE AUTH/3496/3/21

COMPLAINANT V ABBVIE

Promotion of Skyrizi

A contactable complainant who described him/herself as a health professional complained about a digital banner advertisement for Skyrizi (risankizumab) placed by AbbVie Ltd on the British Dermatological Nursing Group website. Skyrizi was indicated for the treatment of moderate to severe plaque psoriasis in adults who were candidates for systemic therapy.

The banner featured the claim 'BAD [British Association of Dermatologists] Guidelines recommend Skyrizi as a first line biologic' and an asterisk led readers to the footnote, 'For adults with psoriasis who fulfil the criteria for biologic therapy, using the decision aid to inform treatment choice. This is not a comprehensive data source. Please refer to full published guidelines and drug [summaries of product characteristics (SPCs)].'

The complainant alleged that the banner advertisement suggested that the BAD Guidelines directly recommended Skyrizi. The BAD Guidelines did not mention Skyrizi as first choice, they referred to any of the licensed biologic therapies.

The complainant alleged that the suggestion that Skyrizi was recommended (ie it was inferred that it was the only one to be recommended) as first line biologic was misleading; it was clearly a good option but the recommendation was not only for Skyrizi but for all the biologics. The impression, by reading the banner, however, was that BAD explicitly picked risankizumab out of all the other biologic options, which was clearly incorrect. The complainant alleged that AbbVie was stretching the boundaries.

The detailed response from AbbVie is given below.

The Panel noted that the banner advertisement at issue featured the Skyrizi product logo in the top left hand corner and in the centre of the banner, in bold capital letters was the claim 'BAD Guidelines recommend Skyrizi as a first line biologic[2*]'.

The Panel noted that the claim was referenced to Smith et al 2020 which was the 'British Association of Dermatologists guidelines for biologic therapy for psoriasis 2020: a rapid update'; it stated that the update was part of an annual review to factor in the latest evidence for biological medicines evaluated in the 2017 publication of the guideline, and newer biological medicines licensed for psoriasis in the UK or were expected to be licensed in the near future.

The Panel noted that Smith *et al* commented on biological therapy as a whole and did not detail any specific medicine – risankizumab was only mentioned twice in the guidelines, once in the list of biologics included in the review and once within the footnote to a figure. Under a heading of 'Criteria for biologic therapy', the authors stated that such therapy should be offered to certain patients with psoriasis who required systemic

therapy and under a heading of 'Choice of biologic therapy in adults', it was stated that any of the currently licensed biologic therapies could be offered as first-line therapy. The Panel considered that it was clear that Smith *et al* did not single out risankizumab from the other biologics available.

The Panel noted that risankizumab (Skyrizi) was one of the biologics that could be used as a first line therapy in adults with psoriasis who fulfilled the criteria for biologic therapy in the BAD guidelines. The advertisement was not clear that Skyrizi had not been specifically recommended by BAD but had instead been listed as one of the many licensed biologic options. The Panel considered the immediate impression of the claim 'BAD Guidelines recommend Skyrizi as a first line biologic' to a busy health professional and considered that it misleadingly implied that the BAD guidelines had singled out Skyrizi from the other biologics available and specifically recommended it, which was not so. Such an impression could not be substantiated. Breaches of the Code were ruled.

A contactable complainant who described him/herself as a health professional who wished to remain anonymous complained about a digital banner advertisement (ref UK-RISN-200416) for Skyrizi (risankizumab) placed by AbbVie Ltd on the British Dermatological Nursing Group website. Skyrizi was indicated for the treatment of moderate to severe plaque psoriasis in adults who were candidates for systemic therapy.

The banner featured the claim 'BAD [British Association of Dermatologists] Guidelines recommend Skyrizi as a first line biologic'. The claim was referenced to the 'BAD Guidelines for biologic therapy for psoriasis 2020: a rapid update' (Smith *et al* 2020) and an asterisk led readers to the footnote, 'For adults with psoriasis who fulfil the criteria for biologic therapy, using the decision aid to inform treatment choice. This is not a comprehensive data source. Please refer to full published guidelines and drug [summaries of product characteristics (SPCs)].'

COMPLAINT

The complainant alleged that the banner advertisement suggested that the BAD Guidelines directly recommended Skyrizi. The complainant submitted that the BAD Guidelines did not mention Skyrizi as first choice, they mentioned *any* (emphasis added by complainant) of the licensed biologic therapies. The complainant provided an extract from the guidelines:

> 'Choice of biologic therapy in adults
>
> R15 (++) Offer any of the currently licensed biologic therapies as first-line therapy (and with reference to R18 and R19) to adults with psoriasis who fulfil the criteria for biologic therapy (see R4 and R5), using the decision aid (see File S1: Table S2) to inform treatment choice.
>
> R16 (++) Offer any of the currently licensed biologic therapies (and with reference to R18 and R19) when psoriasis has not responded to a first biologic therapy. Use the decision aid (see File S1: Table S2) and take into account all factors detailed in R14 to select the most appropriate agent.'

The complainant alleged that the suggestion that Skyrizi was recommended (ie it was inferred that it was the only one to be recommended) as first line biologic was misleading; it was clearly

a good option but the recommendation was not only for Skyrizi but for all the biologics. The impression, by reading the banner, however, was that BAD explicitly picked risankizumab out of all the other biologic options, which was clearly incorrect. The complainant considered that AbbVie was stretching the boundaries.

When writing to AbbVie, the Authority asked it to consider the requirements of Clauses 7.2 and 7.4 of the Code.

RESPONSE

AbbVie noted that the banner advertisement stated 'BAD Guidelines recommend Skyrizi as a first line biologic'. Skyrizi (risankizumab) was a licensed biologic therapy for adults with moderate to severe plaque psoriasis who were candidates for systemic therapy. The BAD Guidelines (Smith *et al*) enabled the choice of any of the currently licensed biological therapies as first-line therapy. Skyrizi fulfilled those criteria and was therefore an appropriate option to use as first-line therapy.

AbbVie submitted that the advertisement stated that the BAD Guidelines recommended Skyrizi as 'a' first line biologic rather than as 'the' or 'the only' first line biologic in order to not mislead, rather to position it as an option. The material did not claim that the BAD Guideline recommended Skyrizi exclusively and there was nothing in the advertisement to support an interpretation of exclusive recommendation. Skyrizi, as risankizumab, was also explicitly included within the scope of recommendations (Smith *et al*) as shown below:

> 'The overall aim of the guideline is to provide up-to-date, evidence-based recommendations on the use of biologic therapies targeting tumour necrosis factor (TNF) (adalimumab, etanercept, certolizumab pegol, infliximab), interleukin (IL)-12/23p40 (ustekinumab), IL-17A (ixekizumab, secukinumab), IL-17RA (brodalumab) and IL-23p19 (guselkumab, risankizumab, tildrakizumab) in adults, children and young people for the treatment of psoriasis'

AbbVie stated that the banner advertisement included the statement to use the decision aid to inform treatment choice, as per Recommendation 15 of the BAD Guidelines and to refer to the full published guidelines and drug SPCs.

Based on the above, AbbVie submitted that the claim was capable of substantiation as referenced by the BAD Guidelines (Smith *et al*) and that the advertisement was not misleading or inaccurate and was in accordance with the requirements of Clauses 7.2 and 7.4 of the Code.

PANEL RULING

The Panel noted that the banner advertisement at issue featured the Skyrizi product logo in the top left hand corner and in the centre of the banner, in bold capital letters was the claim 'BAD Guidelines recommend Skyrizi as a first line biologic[2*]'.

The Panel noted that the claim was referenced to Smith *et al* 2020 which was the 'British Association of Dermatologists guidelines for biologic therapy for psoriasis 2020: a rapid update'; it stated that the update was part of an annual review to factor in the latest evidence for biological medicines evaluated in the 2017 publication of the guideline, and newer biological

medicines that had been licensed for psoriasis in the UK or were expected to be licensed in the near future.

The Panel noted from Smith *et al* that the authors aimed to provide up-to-date, evidence-based recommendations on the use of a number of biologic therapies for the treatment of psoriasis, of which risankizumab (Skyrizi) was one, and was mentioned as one of eleven medicines in the opening paragraph of the guidelines.

The Panel noted that within the review, Smith *et al* commented on biological therapy as a whole and did not detail any specific medicine – risankizumab was only mentioned twice in the guidelines, once in the list of biologics included in the review and once within the footnote to a figure. Under a heading of 'Criteria for biologic therapy', the authors stated that such therapy should be offered to certain patients with psoriasis who required systemic therapy and under a heading of 'Choice of biologic therapy in adults', it was stated that any of the currently licensed biologic therapies could be offered as first-line therapy. The Panel considered that it was clear that Smith *et al* did not single out risankizumab from the other biologics available.

The Panel noted that risankizumab (Skyrizi) was one of the biologics that could be used as a first line therapy in adults with psoriasis who fulfilled the criteria for biologic therapy in the BAD guidelines. The Panel considered that the advertisement was not clear that Skyrizi had not been specifically recommended by BAD but had instead been listed as one of the many licensed biologic options. The Panel considered the immediate impression of the claim 'BAD Guidelines recommend Skyrizi as a first line biologic' to a busy health professional and considered that it misleadingly implied that the BAD guidelines had singled out Skyrizi from the other biologics available and specifically recommended it, which was not so. A breach of Clause 7.2 was ruled.

The Panel considered that the misleading impression given by the claim could not be substantiated and a breach of Clause 7.4 was ruled.

Complaint received **26 March 2021**

Case completed **13 October 2021**