

COMPLAINANT v CHIESI

Allegations about an educational video

CASE SUMMARY

This case was in relation to a short video, hosted on Chiesi’s promotional website, in which a nurse spoke about the use of maintenance and reliever therapy (MART) for the treatment of asthma. The complainant alleged that the video referred to outdated guidelines and that the video, and the webpage on which it appeared, amounted to off-label promotion.

The outcome under the 2024 Code was:

No Breach of Clause 2(x2)	Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry
No Breach of Clause 5.1(x2)	Requirement for companies to maintain high standards at all times
No Breach of Clause 6.1	Requirement that claims must be accurate, up-to-date and not misleading
No Breach of Clause 11.2(x2)	Requirement not to promote a medicine for an unlicensed indication

**This summary is not intended to be read in isolation.
For full details, please see the full case report below.**

FULL CASE REPORT

A complaint about Chiesi Limited was received from a contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below:

“Dear PMCPA complaints, a video that describes MART therapy recommendations is outdated. The video is labelled as Considering suitable patients for MART (UK-FTB-2100071, Aug 2021). The video linkage is [link provided]. In the video HCP [named nurse] discusses that NICE and BTS guidelines recommend that MART can be used for patients on ICS/LABA. This is not a truthful and factual replication of the guidelines. The NICE/BTS/SIGN 2024 guidelines specifically recommend low dose MART therapy for those over 12 years of age when newly diagnosed patients are offered a low dose ICS/formoterol as needed AIR therapy who have uncontrolled asthma despite taking AIR

therapy. These are the only specific newly diagnosed patients that should be initiated on MART, this is not made clear in the video. Only certain ICS/LABA inhalers are licensed for when required AIR therapy and only certain ICS/LABA inhalers are licensed from age 12 and above. The BTS/NICE/SIGN guidance is from 2024 but [named nurse] is presenting guidance from 2019 guidance in this video which is now no longer in place. Critically the 2024 asthma guidelines from BTS/NICE/SIGN guidance for MART in newly diagnosed asthmatics differs significantly from the old guidance which this video references. This video is in breach of clauses 6.1, 5.1 and 2 as the content is no longer clinically relevant. The video is also provided on a page that promotes Trimbaw, Atimos and Clenil in the header of the page although neither of these 3 products have a licence for MART which renders this video promotion off-label. Fostair has a MART licence for 18 years and above but the NICE/BTS/Asthma guidelines recommend MART usage from 12 years which is off-label dosing for Fostair. The age differences between the guideline recommendation and Fostair licenced age is not discussed in the video, These are breaches of clauses 11.2, 5.1 and 2.”

When writing to Chiesi, the PMCPA asked it to consider the requirements of Clauses 11.2, 6.1, 5.1 and 2 of the 2024 Code.

CHIESI'S RESPONSE

The response from Chiesi is reproduced below:

“We write in response to your letter dated 18 July 2025 regarding the above-referenced complaint concerning the video titled '**Considering suitable patients for MART' (UK-FTB-2100071, August 2021)**, hosted on the Chiesi AIR website.

We take alleged breaches of the ABPI Code of Practice (Code) very seriously and welcome the opportunity to respond in an open and transparent manner. We are committed to maintaining the highest standards of clinical accuracy, integrity and compliance across all our activities.

1. Complaint

The complaint concerns a video entitled: '**Considering suitable patients for MART**' (ref. UK-FTB-2100071) (the 'Video') hosted on the Chiesi Air website, and centres around the fact that the Video refers to the 2019 BTS/SIGN Guidelines (the '2019 Guidelines') which were subsequently superseded in by the 2024 BTS/NICE/SIGN Guidelines (the '2024 Guidelines').

2. PMCPA request for information/documentation

As requested, we enclose [list of enclosures]

The following signatories were involved with the approval and reapproval of the two materials described above (Video and webpage): [list of signatories, their job titles and their qualifications]

We have reviewed the allegations in the context of your request for us to consider Clauses 6.1, 11.2, 5.1, and 2 of the 2024 ABPI Code. Our response to each allegation is set out below.

3. Description of the Video and how it can be accessed

When the Video was approved the 2019 Guidelines were the most current and clinically accepted standard of care. The Video discusses which patients are suitable for MART in line with NICE and BTS/SIGN guidelines and specifically describes introducing MART to a patient already on an ICS and a LABA in a combination inhaler. No specific version of the guidelines was referred to within the narrative of the Video.

The Video was embedded in a webpage (the 'Webpage') on the Chiesi AIR website. The Webpage included the Video, references for the guidelines referred to within the video, and the following clear statement: ***'This HCP opinion is not connected, or specific to Chiesi products'***.

It was possible for healthcare professionals to navigate to the Webpage in two different ways:

- Accessing a link on the ***'Fostair for Adult Asthma'*** promotional page which clearly identifies Fostair as only being licensed for adult asthma both in the title and in the content on the page: [links provided]

[Navigation: Home > Our product portfolio for respiratory > The Fostair range > Fostair for adult asthma]

- Accessing a link within the ***'Education and Events'*** library: [link provided]

The ***'Education and Events'*** library hosts a range of videos designed to support healthcare professionals across multiple respiratory disease areas.

The healthcare professional who was speaking in the Video was invited to participate in a filmed interview during which they would be asked their opinion on topics relating to Chiesi products and general respiratory topics. The healthcare professional was verbally briefed before the Video was recorded and a Chiesi [medical employee] was in the room observing the filming and also reviewed the post-production content to ensure it was in line with the SmPC and licences.

4. Reference to Guidelines

The complainant refers to differences between the 2019 Guidelines and the 2024 Guidelines, specifically the introduction of a new treatment approach (AIR, as-needed anti-inflammatory reliever therapy) in the 2024 Guidelines. In so doing, the complainant claims that:

- the Video is ***'not a truthful and factual replication of the guidelines'***;
- the 2019 Guidelines are ***'no longer clinically relevant'***; and

- it is not clear in the video how patients should be initiated onto MART.

Clinical relevance of guideline and clarity on MART prescribing

We accept and acknowledge that the 2019 Guidelines were updated, merged with the 2017 NICE guidelines, and republished in November 2024. The Video itself only refers to 'NICE and BTS/SIGN' (i.e. no specific version of the guidelines), however it is clear from the Webpage which version of the guidelines are being referred to.

Despite the 2024 update, the vast majority of UK local and regional guidelines are still in line with the previous guidelines (i.e. MART posology included, but no reference to AIR therapy).

The 2024 Guidelines recommend that if a patient's asthma is uncontrolled on either low-dose ICS or low-dose ICS/LABA (as described in the Video) then escalation to MART therapy is recommended. It follows that, irrespective of which guidelines are referenced, the guidance for MART initiation described in the Video (i.e. introducing MART to a patient already on an ICS and a LABA in a combination inhaler) remains a valid and clinically relevant option for MART initiation.

Furthermore, the recommendations for MART posology described in the Video and in both versions of the guidelines are in line with the licensed indication for Fostair which permits initiation onto MART therapy from either ICS + SABA or ICS/LABA:

- ***'Fostair is indicated in the regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2-agonist) is appropriate: patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled rapid-acting beta2-agonist or patients already adequately controlled on both inhaled corticosteroids and long-acting beta2-agonists.'***

[Section 4.1, Fostair Summary of Product Characteristics]

Accordingly, we firmly believe that the Video remains clinically relevant and is an accurate representation of initiating MART therapy.

Recommendations related to AIR posology

The complaint makes several references to AIR posology, however the reason for this is unclear, except with respect to the difference between the 2019 Guidelines and the 2024 Guidelines.

None of Chiesi's products are licensed as AIR posology and nor is AIR therapy referred to in the video or anywhere on the Chiesi AIR website. There is no Code requirement to provide details on AIR posology in the Video or on the website.

We also dispute the complainant's allegation that the Video discusses initiation of newly diagnosed patients onto MART therapy. The Video refers to '**... introducing MART to a patient already on an ICS and a LABA in a combination inhaler**', but a patient who has already been prescribed an ICS/LABA combination inhaler prior to MART initiation would not be newly diagnosed.

We firmly believe that despite referencing an earlier version of the 2024 Guidelines, the MART dosing recommendations made in the Video are:

- still in line with current regional and local asthma guidelines;
- a truthful representation of the previous and current versions of the guidelines; and
- consistent with the Fostair Summary of Product Characteristics.

In summary, the advice in the video is capable of substantiation, clinically relevant and has no impact on patient safety. As such, in our respectful submission there has been no breach of Clauses 6.1, 5.1 or 2.

We seek to rely on previous PMCPA cases on similar facts, including but not limited to AUTH/3764/4/23 - Bayer v Roche, in which it was clear from the PMCPA's ruling that referencing older data is acceptable if companies who do this ensure their content is substantiated, consistent with the SmPC and does not constitute off-label promotion.

5. Off-label Promotion

The complaint states:

'The video is provided on a page that promotes Trimbow, Atimos and Clenil in the header of the page although neither of these 3 products have a licence for MART which renders this video promotion off-label'

The Chiesi AIR website, which is clearly intended for healthcare professionals, promotes Chiesi's entire respiratory portfolio, which includes Trimbow, Fostair, Clenil and Atimos. Consequently, links to the prescribing information for all 4 products are included at the top of the page to ensure that users are able to access the relevant Prescribing information at any point during their navigation of the website.

The header and footer are approved separately to each webpage.

Our approach is consistent with the requirements of the Code, which:

- encourages transparency and accessibility of prescribing information in all relevant contexts; and
- through the additional PMCPA Clause 12 guidance (14 October 2024) (https://www.pmcpa.org.uk/media/jckjcbus/clause-12-qas_2024-code-updated-14-october-2024.pdf), confirms that the Code does not necessarily prohibit prescribing information for more than one medicine being on a single webpage and that it is important for health professionals to be able to access the required prescribing information quickly, easily and directly.

Our approach is also consistent with how other pharmaceutical companies have interpreted the updated Clause 12 guidance. By way of example: [link to named pharmaceutical company webpages]

Our approach has previously been the subject of a complaint, AUTH/3765/4/23 - Complainant v Takeda, in which it was reviewed and found not to constitute a breach. In that case, the Panel concluded that it is acceptable to include prescribing information for multiple medicines on a single webpage, provided that the prescribing information for each medicine is clearly distinguishable, the information is easily accessible and not misleading, and the presentation does not obscure or dilute the required information for any individual product.

It is important to note that the licensed indication is always clear on each individual product page, which also provides access to the relevant prescribing information via a single clickable link.

The Video discusses ICS/LABA patients suitable for MART, with no mention of the use of an ICS alone, LABA alone or ICS/LABA/LAMA - therefore there could be no confusion that Glenil, Atimos or Trimbrow is being suggested for this use.

In summary, we firmly resist any assertion that the presence of prescribing information for Chiesi's respiratory portfolio at the top of the Webpage constitutes off-label promotion. As such, we respectfully submit that there has been no breach of Clause 11.2.

6. Age-related Licensing Considerations

The complaint states:

'Only certain ICS/LABA inhalers are licensed for ... AIR therapy and only certain ICS/LABA inhalers are licensed from age 12 and above ... Fostair has a MART licence for 18 years and above, but the NICE/BTS/Asthma guidelines recommend MART usage from 12 years which is off-label for Fostair. The age differences between the guideline recommendation and Fostair licensed age is not discussed in the video'

There is no reference in the video to AIR therapy, either directly or indirectly, and therefore there is no requirement to reference which ICS/LABA inhalers are licensed for AIR therapy or details of their individual licences.

The Video discusses appropriate patients for MART (***'a patient already on an ICS and a LABA in a combination inhaler'***) but makes no reference to either specific ICS/LABA inhalers or to differences between the licensed indications of ICS/LABA inhalers with respect to age.

As we have mentioned earlier, the Video could be accessed using one of two links, to ***'Fostair for Adult Asthma'*** or the ***'Education and Events'*** library:

- The ***'Fostair for Adult Asthma'*** promotional page clearly identifies Fostair as only being licensed for adult asthma (in the title of the page and within its content), so it is not plausible that a user accessing this link would gain a different impression.
- Accessing the Video through the ***'Education and Events'*** library would lead to the Webpage and Video, neither of which directly reference Fostair. Furthermore, even if a user watched the Video via this library and linked the reference to ICS/LABA as

MART therapy with Fostair, they would most likely then access the Prescribing Information which makes it clear that Fostair is only licensed in adult asthma.

In light of the above, we vehemently deny that the Video constitutes off-label promotion of Fostair and therefore that there has been any breach of Clause 11.2, 5.1 or 2.

7. High Standards

The complaint suggests that the Video fails to meet high standards by not reflecting the latest guidance and potentially misleading viewers.

Again, we acknowledge that the Video refers to guidelines which have been superseded, however the Video is clearly dated and contextualised.

The Video does not misrepresent the current standard of care or promote unsafe practices. The content remains aligned with local and regional guidelines still in use, clinical practice and consistent with the Fostair Summary of Product Characteristics. Furthermore, it does not promote specific products or recommend off-label use.

We seek to rely on previous PMCPA cases on similar facts, including but not limited to Case AUTH/0244/07/24 - Complainant v GSK. In that particular case, a breach of Clause 5.1 was found on the grounds that GSK had produced prescribing information which was not only misleading but also missed an important safety component. The current case can be distinguished on the basis that the Video was neither misleading nor posed any safety risks. As such, in our respectful submission, we should not be found in breach of Clause 5.1.

8. Upholding Confidence in the Industry

The complainant alleges that the Video's outdated content undermines trust in the pharmaceutical industry and brings discredit to it.

We vehemently deny this allegation for all the reasons set out in this letter. The Video content is educational, not promotional. It does not contain safety-critical omissions or misleading claims. There is no evidence of harm or unethical conduct. The Video is intended to support clinical decision-making and is clearly dated. It does not imply off-label use or misrepresent product licensing.

As per the Supplementary Information to Clause 2: '***A ruling of a breach of Clause 2 is a sign of particular censure and is reserved for such circumstances***'. In our submission, the facts being considered do not amount to the circumstances required for such censure.

The Supplementary Information to Clause 2 goes on to provide numerous examples of activities likely to constitute a breach of Clause 2, but none of these are in any way representative of the activities which relate to the current complaint. As such, it would be inappropriate, in our respectful submission, for a breach of Clause 2 to be ruled.

Conclusion

In conclusion, we deny that we are in breach of Clauses 6.1, 11.2, 5.1 or 2 of the Code for the reasons set out in this letter.

I trust that this response is sufficient for your purposes but please let me know if you require any further information at this time or in the future in order to fully consider our response.”

PANEL RULING

This case was in relation to a short video (1m29s) titled “*Considering suitable patients for maintenance and reliever therapy (MART)*” (August 2021). The sole content of the video was a nurse talking to the camera about the use of maintenance and reliever therapy (MART). The video was hosted on Chiesi’s promotional website and was accessible either via the “*Fostair for Adult Asthma*” webpage or the “*Education and Events*” library. Fostair 100/6 (beclometasone / formoterol) pMDI and NEXThaler was licensed for MART in asthma at the time of the complaint.

The complainant raised several concerns about the video which the Panel interpreted as the following allegations:

1. The content of the video, from 2021, was outdated and not an accurate representation of the updated guidelines published in 2024 in relation to MART initiation. The complainant specifically cited information regarding the use of MART in newly diagnosed patients.

The complainant alleged breaches of Clauses 6.1, 5.1 and 2.

2. The video constituted off-label promotion because:
 - a. the promotional webpage on which the video was hosted included a header with links to the prescribing information for Trimbaw (beclometasone / formoterol / glycopyrronium), Clenil (beclometasone) and Atimos (formoterol) which were not licensed for MART; and
 - b. the video did not discuss the differences in age between Fostair’s license for MART being over 18 years old, whereas the guidelines recommend MART from 12 years old.

The complainant alleged breaches of Clauses 11.2, 5.1 and 2.

BTS, NICE and SIGN guidelines

The first matter for the Panel to consider was whether the content of the video was misleading because it was based on outdated guidelines and whether it reflected the recommendations of the updated guidelines. The Panel considered the relevant extract of the video to be the nurse’s opening two sentences:

“I would consider using MART therapy for patients in line with NICE recommended guidelines and also the BTS/SIGN guidelines. So if they’re already on an inhaled corticosteroid and a long-acting bronchodilator in a combination inhaler, then I would introduce MART with support, education and advice on how best to use it”.

The Panel noted that the opening sentence referred to two separate guidelines:

- the NICE (National Institute for Health and Care Excellence) guideline
- the BTS (British Thoracic Society) / SIGN (Scottish Intercollegiate Guidelines Network) guideline

At the time the video was produced in 2021, these were separate documents. However, in November 2024, BTS, NICE and SIGN published one consolidated guideline. The webpage on which Chiesi's video was hosted (if the viewer scrolled down through approximately three frames of content) cited 2017 NICE guidance (which the reference stated was last updated in 2021) and the BTS/SIGN guideline from 2019. The Panel noted that the video had been recertified by Chiesi in June 2023 and May 2025.

The Panel reviewed the context in which MART appeared in each of the guidelines.

Previous NICE 2017 and BTS/SIGN 2019 guidelines

Section 1.6 of the 2017 NICE guideline ("*Pharmacological treatment pathway for adults (aged 17 and over)*") recommended offering a short-acting beta agonist (SABA) as required. Where uncontrolled on SABA or symptoms indicated the need for maintenance therapy, low dose inhaled corticosteroid (ICS) was recommended as first-line maintenance therapy. If asthma remained uncontrolled, it was recommended to add a leukotriene receptor antagonist (LTRA) followed by the addition of a long-acting beta₂-agonist (LABA), with or without continuation of the LTRA, if still uncontrolled. The Panel observed the following step was to offer to change the ICS and LABA to MART with a low maintenance ICS dose, with a further option to increase to a moderate maintenance ICS dose if control was not achieved (either continuing on a MART regimen or changing to a fixed-dose of an ICS and a LABA, with a SABA as a reliever therapy).

Figure 2 of the 2019 BTS/SIGN guideline ("*Summary of management in adults*") similarly included the use of SABA as required, with the initiation of low-dose ICS as a regular preventer. Initial add-on therapy was to add inhaled LABA to low-dose ICS (fixed dose or MART), following which escalation options included increasing ICS to medium dose or adding LTRA (stopping the LABA if no response). Section 7.3.5 of the guideline included that the use of a single combination inhaler for MART was an alternative approach to the introduction of a fixed-dose twice daily combination ICS/LABA inhaler and a recommendation was to "*consider the option of combined maintenance and reliever therapy in adult patients who have a history of asthma attacks on medium dose ICS or ICS/LABA*".

Consolidated 2024 BTS/NICE/SIGN guideline

The Panel noted that the 2017 NICE and 2019 BTS/SIGN guidelines had been superseded by a single consolidated guideline in 2024 titled "*Asthma: diagnosis, monitoring and chronic asthma management (BTS, NICE, SIGN)*". The consolidated guideline expressly stated it "*represented a significant change in practice*", particularly in relation to the use of SABA in newly diagnosed patients with asthma.

The Panel considered the context in which MART appeared in Section 1.7 ("*Pharmacological management in people aged 12 and over*") and Algorithm C of the 2024 guideline.

For people with newly diagnosed asthma, instead of a SABA, the 2024 guideline recommended as needed anti-inflammatory reliever (AIR) therapy using a low-dose ICS/formoterol combination inhaler, licensed for such use, to be taken as needed for symptom relief. If asthma remained uncontrolled, it was recommended to start low-dose MART, with escalation to moderate-dose MART if control was not achieved on low-dose. In addition, the guideline recommended that if the newly diagnosed person needing asthma treatment presented as highly symptomatic or with a severe exacerbation, treatment with low-dose MART could be started in addition to treating the acute symptoms as indicated.

For people already diagnosed and receiving treatment in line with the previous NICE and BTS/SIGN guidelines, the 2024 guideline recommended changing people with confirmed asthma on SABA only treatment to a low-dose ICS/formoterol combination inhaler (as-needed AIR therapy). Low-dose MART was recommended where people with asthma were not controlled on low-dose ICS; low-dose ICS/LABA; low-dose ICS plus LTRA; or low-dose ICS/LABA plus LTRA, plus SABA as needed. Moderate-dose MART treatment was recommended for people with asthma not controlled on moderate-dose ICS; moderate-dose ICS/LABA; moderate-dose ICS plus LTRA and/or LAMA; moderate-dose ICS/LABA plus LTRA and/or LAMA, plus SABA as needed.

Allegation 1 - misleading presentation of MART in light of updated 2024 guidelines

Clause 6.1 of the Code stated that:

“Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis.

Material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine.”

The complainant alleged that the content of the video was outdated, not an accurate reflection of the 2024 guidelines and thus no longer clinically relevant. In this regard, the Panel considered whether the statement (that the introduction of MART in people on an ICS/LABA in a combination inhaler) was still up-to-date and accurate in relation to the current 2024 guidelines.

The Panel noted that the video was produced in 2021 and referred generally to “NICE” and “BTS/SIGN” guidelines as separate guidelines without specifying a particular version. At the time the video was produced, the NICE guideline (2017) and BTS/SIGN guideline (2019) were the applicable guidelines and both included MART as an option for patients whose asthma remained uncontrolled on ICS therapy with LABA.

The Panel observed that the 2024 guideline represented both a consolidation and a substantive change in the overall structure of asthma management, including changes to the role of SABA therapy and the introduction of AIR therapy. The Panel took account of the fact that the video did not reflect these changes because it was based on earlier guidelines which had since been superseded and that links to these guidelines were cited in footnotes further down the webpage that hosted the video.

However, the Panel considered that the complaint related to the content of the video itself and specifically whether the opening statements at issue remained accurate and relevant. The Panel further took account of the context – that the video was of short duration and did not imply it was intended to provide a comprehensive overview of the asthma guidelines.

In the Panel's view, the statement in the video that, in line with guidelines, MART could be introduced in patients already receiving an ICS/LABA in a combination inhaler was not, in itself, inconsistent with the updated 2024 guideline. The Panel interpreted the 2024 guidelines to continue to recommend MART as an escalation option for people whose asthma was not controlled on ICS/LABA, amongst other combinations and regimens. The video was of short duration and did not cover newly diagnosed patients, use of AIR therapy or SABA inhalers.

On balance, the Panel considered the complainant had not established that the speaker's statement regarding the introduction of MART, in the circumstances the speaker described, was inaccurate or no longer clinically relevant at the time of the complaint. On the narrow allegation, the Panel ruled **no breach of Clause 6.1**.

The Panel considered that companies had a responsibility to ensure that promotional materials remained accurate and based on an up-to-date evaluation of all the evidence. The Panel noted its concerns regarding the webpage of the video citing 2017 and 2019 guidelines, which had subsequently been superseded by the 2024 guideline, that included significant changes. However, the Panel took account of its ruling of no breach above in relation to the narrow allegation and considered, in the circumstances of this case, the complainant had not established that high standards had not been maintained nor that Chiesi had brought discredit upon, or reduced confidence in, the pharmaceutical industry. The Panel ruled **no breaches of Clause 5.1 and Clause 2**.

Allegation 2a – off-label promotion of Trimbow, Atimos and Clenil

This aspect of the complaint related to the header of the promotional webpage on which the MART video at issue was hosted. The complainant alleged that the presence of links to Trimbow, Atimos and Clenil rendered the video off-label promotion of those medicines because they were not licensed for MART.

The Panel observed that the links appeared in a banner in significantly smaller font and were presented on a grey background compared to the white background of the rest of the webpage. The banner included links to the prescribing information for Trimbow, Atimos, Clenil and Fostair which Chiesi submitted were to ensure users were able to access the relevant prescribing information at any point during their navigation of the website (given that the Chiesi AIR website promoted its entire respiratory portfolio). Chiesi submitted that the header and footer were approved separately to each webpage.

The Panel considered the banner in the header was sufficiently distinct from the content of the page that hosted the video. In the circumstances of this case, and taking into account the overall impression of the webpage, the Panel did not consider that the presence of prescribing information links in the header, which appeared to be static across a website that promoted Chiesi's entire respiratory portfolio, promoted these products for MART. The Panel therefore ruled **no breach of Clause 11.2**.

Allegation 2b – off-label promotion of Fostair

The complainant also alleged that the video promoted Fostair off-label because the 2024 guideline recommended MART from 12 years old, whereas Fostair was only licensed for adults 18 years and above.

The Panel noted Chiesi's submission that the video was accessible via a webpage titled "*Fostair for Adult Asthma*" but also that it could be accessed through the "*Education and Events*" library.

As with allegation 1, the Panel acknowledged that the video was of short duration and did not imply it was intended to provide a comprehensive overview of the asthma guidelines. There was no mention of Fostair in the video, nor discussion of ages, either in the context of Fostair or in the context of the guidelines. The Panel therefore did not consider that the video suggested that Fostair was suitable from the age of 12. The Panel was not satisfied that the complainant had made out their case that Fostair had been promoted off-label for an unlicensed age group and ruled **no breach of Clause 11.2**.

Allegation 2 – high standards and discredit

The complainant cited a breach of Clauses 5.1 and 2 with regard to their allegations of off-label promotion. The Panel noted its rulings of no breach above and, in the absence of any other allegations, evidence or factors in relation to allegation 2, the Panel concluded it had not been established that there had been a failure to maintain high standards nor that discredit had been brought upon the industry in this regard. The Panel therefore ruled **no breaches of Clause 5.1 and Clause 2**.

Complaint received **16 July 2025**

Case completed **12 February 2026**