

COMPLAINANT v AGB PHARMA

Allegations relating to a promotional video

CASE SUMMARY

This case was in relation to a video hosted on Vimeo about Adaflex (melatonin). The complainant alleged that the video, which could be accessed via a QR code and a direct link included in a booklet for health professionals, failed to include “all the mandatory requirements” for promotional materials, including prescribing information and the adverse event reporting statement.

The outcome under the 2024 Code was:

No Breach of Clause 2	Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry
No Breach of Clause 5.1	Requirement to maintain high standards at all times
No Breach of Clause 8.1	Requirement to certify promotional material
No Breach of Clause 12.1	Requirement to include up-to-date prescribing information
No Breach of Clause 12.3	Requirement to include a clear prominent statement as to where the prescribing information can be found
No Breach of Clause 12.4	Requirement to include the non-proprietary name in promotional material
No Breach of Clause 12.6	Requirement to include a prominent adverse event reporting statement

**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 AGB Pharma was received from an anonymous contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below:

“AGB have produced a promotional booklet on Adaflex for healthcare professionals. The booklet reference code is UK-MEL-AGB 0105, December 2023. The booklet is 4

pages long with the prescribing information provided on page 4. At the top of the first page, the booklet says For healthcare professionals only. On page 3 of the booklet, there is a QR code and direct link provided to a Vimeo video to watch how Adaflex can be crushed and mixed with water. The link provided in the booklet to the video is [URL provided]. When the link is clicked the Vimeo video discusses Adaflex but there is no prescribing information or adverse event reporting provided for Adaflex. The generic name is missing on the video too. As the promotional booklet directly links to the Adaflex video on Vimeo, healthcare professionals need all the mandatory promotional requirements to be met on the video. The video which links out from the booklet is in breach of Clauses 12.1, 12.3, 12.4, 12.6, 8.1, 5.1 & 2.”

When writing to AGB Pharma, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 8.1, 12.1, 12.3, 12.4 and 12.6 of the 2024 Code.

AGB PHARMA’S RESPONSE

The response from AGB Pharma is reproduced below:

“We are writing in response to a complaint received relating to the Adaflex Tear Off Pad (UK-MEL-AGB 0105). We appreciate the opportunity to provide clarification and context.

Commitment to Ethical Standards

At AGB Pharma, we are committed to maintaining the highest standards of ethical conduct and compliance with the ABPI Code of Practice. We are committed to developing accurate and transparent materials that support healthcare professionals and patients alike, with the shared goal of improving patient care. Patient safety and clear communication remain at the core of our approach.

Background and Context

The material in question (UK-MEL-AGB 0105), the Adaflex Tear Off Pad, was certified by a contract final medical signatory previously working on behalf of AGB Pharma. The material was developed as a hard copy tear-off pad resource designed to support HCPs in counselling patients/carers prescribed Adaflex.

- The **outer cover of the tear-off pad** was promotional in nature, containing the necessary prescribing information, adverse event reporting statement, along with meeting all other relevant requirements for promotional material directed at HCPs. However, it did not include any product claims. The cover was prominently labelled with the disclaimer ‘**For Healthcare Professionals Only**’.
- The **inner pages of the pad** (the tear-off sheets) were intended to be handed by HCPs to patients/carers. Each pad contained 50 tear-off sheets and included practical, non-promotional guidance on the administration of Adaflex, including what to do if a dose is missed, food intake considerations, and how the tablet can be crushed and mixed with water. These distinctions are important because prescribing guidance for melatonin can vary between

brands and formulations, with implications for clinical practice and compliance. The resource was solely developed to address the specific needs of families and carers, given the licensed age group of Adaflex (6–17 years), where challenges with swallowing tablets are common. The inner pages were prominently labelled with the disclaimer '**For patients who have been prescribed Adaflex and their parents/carers**'.

To complement this patient guidance, the inner sheets (intended for patients, as mentioned above) included a QR code linking to a short instructional video showing how Adaflex can be crushed and administered in water. **This video was not promotional in nature** but rather designed as an educational tool for patients already prescribed Adaflex, to aid in administration. This video (UK-NON-AGB-0120) was also separately certified as a non-promotional resource for patients/carers.

In parallel, a **digital PDF version of the resource** was also available for HCPs to download and utilise via the promotional Adaflex website (currently under construction). This also included clear disclaimers on the relevant pages, emphasising that the inner pages were intended for patients (including the video accessed via the QR code, which was non-promotional in nature), while the other pages, containing no product claims, were intended for HCPs.

Addressing the Complainant's Concerns

The complainant asserts that because the inner patient leaflets contained a QR code linking to the video, the video itself should meet all promotional requirements. We respectfully disagree with this interpretation, and wish to clarify the following:

1. Promotional vs Non-promotional Content

- The **cover page** of the tear-off pad was promotional, directed at HCPs, and included the required prescribing information and adverse event reporting details, along with meeting all other relevant promotional requirements.
- The **tear-off sheets and video** were **non-promotional patient support items** designed exclusively to aid patients/carers in safe and effective administration. Non-promotional patient support items are not required to carry prescribing information or meet the criteria set out for promotional material under the ABPI Code.
- However, at the time of developing this resource, it was considered important that prescribers had access to **contextual information** on Adaflex when counselling patients; therefore, the prescribing information was included, without any accompanying product claims.

2. Intent and Audience

- The QR code and associated video were intended for patients already prescribed Adaflex. The content was **instructional only** (tablet administration) and did not make claims about efficacy, safety

beyond administration advice, or comparative statements. The video also contained the prominent statement at the beginning, **'Information for patients, parents and carers'**.

- As such, the tear-off sheets and associated video did not fall under the remit of promotional activity requiring prescribing information, adverse event reporting information, and the need for meeting requirements relating to the inclusion of the generic name adjacent to the brand name (although the generic name was included next to the most prominent mention of Adaflex on the first frame of the video, for information purposes only), along with other relevant promotional requirements.

3. Updated Materials

- The material in question (UK-MEL-AGB 0105), the Adaflex Tear Off Pad, was withdrawn in March 2025 and replaced with a revised version that is entirely non-promotional in nature, without a promotional HCP-facing cover.

Conclusion

In conclusion:

- The video accessed via the QR code formed part of a **non-promotional patient support item**.
- The inner pages were not designed or intended as promotional material for HCPs, and therefore the requirements under Clauses 8.1, 12.1, 12.3, 12.4, 12.6 **do not apply**. Given this, we also respectfully deny breaches of Clauses 5.1 and 2, while reaffirming our commitment to maintaining the highest standards and upholding both the letter and spirit of the Code.
- We therefore respectfully deny that the video constitutes a breach of the ABPI Code.

AGB Pharma remains committed to the highest standards in its communication with both HCPs and patients, with the overarching aim of supporting safe and effective use of medicines in practice.

We trust this clarifies the intent and structure of the material and addresses the concerns raised.”

PANEL RULING

The complaint related to a video hosted on Vimeo about Adaflex (melatonin). The complainant alleged that the video, which could be accessed via a QR code and a direct link included in a booklet for health professionals, failed to include “all the mandatory requirements” for promotional materials, including prescribing information and the adverse event reporting statement.

The Panel noted AGB Pharma's submission that the booklet in question was a hard copy tear-off pad that was also available as a downloadable pdf from the promotional Adaflex website. The Panel observed that there was no difference in the appearance or the text between the printed and digital versions.

The booklet cover

The Panel noted that the front outer cover of the booklet in question included the prominent statement, "For Healthcare Professionals Only" in an orange box against a dark blue background at the top of the cover. Below this was the brand logo, which included the brand name (Adaflex) and adjacent generic name (melatonin). Beneath this, in a prominent position on the page and large font, was the following text:

"INFORMATION FOR PATIENTS, PARENTS & CARERS

Advice and guidance on how to administer Adaflex, for patients who have been prescribed Adaflex."

The bottom of the front cover included the following in smaller font:

1. The statement, "Produced by AGB-Pharma"
2. The indication for Adaflex
3. An adverse event reporting box
4. The statement, "Prescribing information can be found on the back cover."
5. The job code and date of preparation

The back cover included the prescribing information for Adaflex spread across the full size of the cover and an adverse event reporting box at the bottom.

AGB Pharma submitted that the outer cover was promotional and was prominently labelled with the disclaimer 'For Healthcare Professionals Only'. It submitted that the cover did not include any product claims and met the relevant requirements for promotional material directed at health professionals, including the prescribing information and adverse event reporting statement.

The inner pages

The inner tear-off sheet was two-sided. On the first side, prominent text in a navy-blue banner against a white background at the very top of the page stated, "For patients who have been prescribed Adaflex and their parents/carers". The page included an image of the tablet depicting its actual size, and a description of how to take Adaflex.

The reverse side of the sheet included the same prominent text at the top, stating that this resource was for patients who have been prescribed Adaflex and their parents/carers. This was followed by a prominent heading, "How to Crush & Mix with Water", and three icons illustrating the "spoon method", the "glass method" and the "syringe method". A second, prominent navy-blue banner appeared halfway down the page, stating, "SCAN THE QR CODE TO WATCH HOW ADAFLEX CAN BE CRUSHED & MIXED WITH WATER OR VISIT [LINK]", accompanied by a QR code.

The bottom half of the page included information on what to do if you take more Adaflex than you should or if you forget to take Adaflex, and the most common side effects and a statement about reporting of side effects. The job code and date of preparation were present at the bottom of the page.

AGB Pharma submitted that the inner pages of the tear-off pad were intended to be handed by the health professional to patients/carers and were prominently labelled with the disclaimer 'For patients who have been prescribed Adaflex and their parents/carers'. AGB Pharma submitted that the inner sheets included practical, non-promotional guidance on the administration of Adaflex, including what to do if a dose is missed, food intake considerations, and how the tablet can be crushed and mixed with water. The Panel noted AGB Pharma's submission that these distinctions are important because prescribing guidance for melatonin can vary between brands and formulations, with implications for clinical practice and compliance.

The video

The opening screen of the video at issue included the statement, "Information for patients, parents and carers" at the top, followed by a prominent heading, "How to take your Adaflex using a glass". An icon of a glass appeared adjacent to large text stating, "Adaflex tablets can be swallowed whole or crushed and mixed with water. This video will show you how to crush and mix Adaflex with water using a glass". A reporting of side effects statement for patients appeared on the bottom, left, of the frame in small font. The video demonstrated how to take an Adaflex tablet using a glass. The final screen of the video listed the most common side effects, and included a reporting of side effects statement in a prominent, blue box, followed by the date of preparation, job code, and the AGB Pharma logo.

AGB Pharma submitted that the video, which was instructional, was not promotional and was designed as an educational tool for patients already prescribed Adaflex, and certified separately as a non-promotional resource.

The complainant's allegations

The Panel noted that the allegations were specifically in relation to the video, which the complainant had accessed using the link included in the tear-off pad. The complainant raised a number of clauses, with the primary allegation being that the video needed to meet the requirements for promotional material because the promotional booklet directly linked to the video.

The Panel noted AGB Pharma's submission that:

- the outer cover of the booklet was promotional
- the inner pages were non-promotional
- the video was non-promotional and certified separately.

The Panel noted that the internal briefing document for the tear-off pad stated that the promotional tear off pad was designed to support healthcare professionals to provide further information to patients, parents and carers, when Adaflex has been prescribed. It was approved for proactive use, to provide to health professionals during a promotional call.

The Panel noted AGB Pharma's submission that at the time of developing this resource, it was considered important that prescribers had access to contextual information on Adaflex when

counselling patients; therefore, the prescribing information was included on the outer cover of the tear-off pad, without any accompanying product claims.

The Panel considered that while the outer cover was promotional, and the resource as a whole was approved as a promotional item, the inner pages of the tear-off pad included only non-promotional information intended for patients and carers. In the Panel's view, the outer cover was clear that the tear-off sheets were intended for patients, parents and carers, and included advice and guidance for patients who had been prescribed Adaflex. The Panel noted the general principle that materials should be capable of standing alone. In the Panel's view, while the outer cover and inner pages were approved as a single item, it considered that the outer cover and each tear-off sheet were capable of standing alone.

The Panel noted that the link to the video in question was present only on the inner, non-promotional, pages and not on the outer cover. The Panel considered that the video, which was separately certified as a non-promotional item, was instructional in nature, did not include any product claims, and was clearly labelled as being information for patients, parents and carers. In the Panel's view, the video was also capable of standing alone.

Noting the above and that the allegation related specifically to the video, the Panel concluded that the video was non-promotional and therefore did not require prescribing information; accordingly, the Panel ruled **no breach of Clause 12.1** and **no breach of Clause 12.3**.

The Panel observed that the generic name appeared adjacent to the most prominent display of the brand name, Adaflex, on the video's first frame; nonetheless, because the video was non-promotional, **Clause 12.4** was not applicable and **no breach** was ruled.

The complainant cited Clause 12.6 concerning the adverse event reporting statement. The Panel considered that this clause did not apply to the non-promotional video, and it ruled **no breach of Clause 12.6**.

The complainant also cited Clause 8.1 in relation to certification of the video. The Panel noted that the video had been certified as a non-promotional item, and that Clause 8.1 was applicable only to promotional material. Having determined that the video was non-promotional, the Panel ruled **no breach of Clause 8.1**.

Noting its rulings of no breach of the Code above, the Panel concluded that AGB Pharma had not failed to maintain high standards at all times, nor brought discredit upon, or reduced confidence in the pharmaceutical industry. The Panel ruled **no breach of Clause 5.1** and **no breach of Clause 2** accordingly.

Complaint received **19 August 2025**

Case completed **27 February 2026**