

COMPLAINANT v ASTRAZENECA

Allegations about a video for Forxiga on the AstraZeneca medical platform website

CASE SUMMARY

This complaint was in relation to a video about chronic kidney disease hosted on AstraZeneca's website. The complainant alleged that mention of SGLT2 inhibitors was indirect promotion of Forxiga (dapagliflozin). AstraZeneca's position was that the video was educational and non-promotional, given that it presented a balanced view of the treatment options, without any prominence being given to an AstraZeneca product.

The outcome under the 2021 Code was:

No Breach of Clause 2	Requirement not to 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 12.1	Requirement to include prescribing information
No Breach of Clause 12.6	Requirement for promotional material on the internet to include a prominent statement as to where prescribing information can be found
No Breach of Clause 12.9	Requirement to include the prominent adverse event reporting statement
No Breach of Clause 15.6	Requirement that promotional material and activities must not be disguised

**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 was received from an anonymous, contactable complainant about AstraZeneca UK Limited.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

"This complaint is about concerns that a promotional video has been classified as non-promotional. Forxiga is a SGLT2 inhibitor and is used in the treatment of chronic kidney disease. Forxiga is an AZ product. A video that was present on the AZ medical platform website had a video which discussed how to treat CKD. The video was hosted in the

Cardiovascular, renal and metabolic section and the presenters included an external HCP and an AZ employee. The title of the video is CKD management made simple [job code and link to webpage provided]. At 7 minutes 23 seconds, the AZ employee has a slide which discusses pharmacological options for treatments of CKD and the slide clearly states SGLT2 inhibitors are a treatment option for CKD. At 7.39, the AZ employee verbally states SGLT2 inhibitors are a more recent treatment addition. At 17 minutes 48 seconds, the external HCP presents a patient case study and specifically verbalises and shows on the slide the need for SGLT2 inhibitor. Considering the mention of SGLT2 inhibitor is an indirect mention of Forxiga and the indication of CKD was the topic of the video, the video did not have prescribing information for the product, nor adverse event reporting. It was also concerning that a medical website would host a promotional video as one would expect medical education to be non-promotional content only, whilst this video was promotional due to implied reference to Forxiga. Code of practice clauses 12.1, 12.6, 12.9, 15.6, 5.1 and 2 are in breach.”

When writing to AstraZeneca, the PMCPA asked it to consider the requirements of Clauses 12.1, 12.6, 12.9, 15.6, 5.1 and 2 of the Code.

ASTRAZENECA’S RESPONSE

The response from AstraZeneca is reproduced below:

“AstraZeneca takes compliance with the ABPI’s Code of Practice for the Pharmaceutical Industry (the ‘Code’) extremely seriously and is committed to maintaining high standards in relation to all information it provides about its products and in all related activities.

The Complaint

The complainant made several allegations, summarised as follows:

- The video, titled ‘Chronic Kidney Disease Management Made Simple,’ contains educational content which indirectly promotes Forxiga® (dapagliflozin) for the treatment of Chronic Kidney Disease (‘CKD’),
- AstraZeneca has not properly reviewed the video to ensure it aligns with the Code in terms of promotional digital content.

AstraZeneca has been asked by the PMCPA to consider these allegations with respect to Clauses 12.1, 12.6, 12.9, 15.6, 5.1, and 2 of the Code.

In summary

It is our opinion that the video is non-promotional and complies with the Code requirements for non-promotional material. Our investigation has been guided by the ABPI and the EFPIA Codes, and AstraZeneca’s internal standard operating procedures.

Context and objective of the video

The video in question, titled ‘Chronic Kidney Disease Management Made Simple,’ is a non-promotional educational video developed by AstraZeneca. The video aims to offer relevant and balanced educational support to Healthcare Professionals (‘HCPs’) in

primary care settings for the effective management of Chronic Kidney Disease ('CKD'). The total duration of the video is 18 minutes and 45 seconds.

The content of the video covers topics pertinent to the management of CKD within the primary care setting. This includes balanced discussions around risk factors, treatment landscape and a case study. The objective is to provide a comprehensive understanding of CKD management focusing on slowing the progression of renal and cardiovascular complications. The video is delivered by two nephrologists with expertise in the disease area, one of whom is an AstraZeneca Medical employee.

The video is not intended to promote any specific AstraZeneca medicine and has been designed without branding, brand colours and any reference to a specific medicine, either directly or indirectly. The video presents a balanced view of all treatment options for CKD management and is reflective of the totality of evidence to date. Where Sodium-glucose co-transporter-2 inhibitors ('SGLT2is') are mentioned, they are put in context of all the various treatments for CKD with no specific focus on SGLT2is.

The Website

The [URL provided] website ('the Website') is owned and operated by AstraZeneca UK Limited. The primary objective of the Website is to furnish healthcare professionals ('HCPs') in the UK with educational resources concerning AstraZeneca's therapeutic areas of interest, including but not limited to, cardiovascular, renal, and metabolic diseases. The website and its materials do not include any product related content. Furthermore, no proactive traffic drivers are being used from any AstraZeneca product, corporate and third-party promotional websites, or channels. Additionally, the website is not proactively advertised by AstraZeneca employees.

Sodium-glucose cotransporter inhibitor (SGLT2i) inhibitor treatment landscape in Chronic Kidney Disease

There are multiple SGLT2is with evidence in the treatment of CKD, including Forxiga® (dapagliflozin), Jardiance® (empagliflozin) and Invokana® (canagliflozin) based off primary renal outcome trials and captured in the overall Summary of Product Characteristics ('SmPCs'). Forxiga® is one of the medicinal products within the broader class of SGLT2is that have demonstrated evidence for reducing the progression of renal disease, confirmed by primary renal outcome trials and meta-analysis across the class. It is important to note that the video is not about Forxiga® specifically.

AstraZeneca's Response to the Complaint

Allegation 1 Clause 15.6 disguised promotion

The primary focus of the complaint centres on the contention that the video is promotional. AstraZeneca refutes this assertion that it represents disguised promotion breaching clause 15.6.

1. Clause 1.17 of the ABPI Code states that promotion does not include information relating to human health or diseases provided there is no direct or indirect reference to specific medicines. There is no direct or indirect reference

to a specific medicine in the video. Referring to medicine class, where there are multiple medicines available with primary evidence in CKD does not point (directly or indirectly) to a specific medicine.

2. The AstraZeneca website and video do not mention the name of any specific product by brand or generic name. All discussions of medications are had at class level with the content, tone, branding, look, and feel of the website and video intended as a non-promotional educational resource.
3. Discussion is centred on the NICE NG203 guideline recommendations for the management of CKD and includes holistic patient management which incorporates discussions on blood pressure, glycaemic control, and lipid therapy. The content is balanced and focuses on relevant information regarding CKD to support HCPs in primary care to control the risk factors for CKD and slow the progression of renal and cardiovascular complications in CKD patients. Balanced class-level treatment discussions are included for all these factors, with no emphasis on efficacy between classes or mention of specific products directly or indirectly. SGLT2s were mentioned in the context of all available treatments, and no undue focus was placed on SGLT2s.
4. Multiple SGLT2i medicinal products have established primary evidence for reducing the progression of CKD, as well for the treatment of type 2 diabetes and heart failure (HF) and accordingly reflected within the broad SmPCs.1-8 The video does not indirectly refer to or place additional weight on any specific SGLT2i. Education is reflective of the totality of evidence to date amongst the class, as demonstrated by the various renal outcome trials, meta-analysis and SmPCs.
5. In the case study specifically, where medication classes are mentioned, but in the context of HF management, the discussion remains at class level, in a balanced manner and taking note that there are multiple products across the classes including SGLT2is that have primary evidence for the treatment of heart failure. There is nothing in the video to draw attention to an AstraZeneca specific SGLT2i, and the take home message from the video was not about any AstraZeneca medicine.
6. The AstraZeneca website does not have any links or traffic drivers to or from any websites that mention the name of any product by brand or generic name or to encourage healthcare professionals to access the website. Additionally, the website is not proactively advertised by AstraZeneca employees in any manner.
7. The EFPIA Code encourages and allows pharmaceutical companies to contribute to life-long learning in healthcare ('LLH') through the direct provision of education programmes. The aim of LLH is to increase the scientific knowledge and competence of HCPs to enhance medical practice and improve patient outcomes. Content should be fair, balanced and objective, designed to allow the expression of diverse evidence-based science and fulfil unmet educational needs in healthcare. Member Companies can be engaged in or support different types of educational programs, but such activities must not

constitute Promotion. Whilst we note that the ABPI Code does not draw specific reference to Article 16 of EFPIA, there is nothing to indicate the UK takes a different stance compared to EFPIA with regards to LLH.

Given the educational nature of the video which contains balanced and up to date information regarding CKD with no direct or indirect reference to a specific medicine, or selectivity in the evidence-base, AstraZeneca strongly refutes the allegation that the video breaches Clause 15.6 of the Code. AstraZeneca maintains the position that the video does not promote any specific product for the treatment of CKD and is therefore non-promotional in nature, and in line with Clause 1.17.

Allegation 2 – 12.1, 12.6 and 12.9 of mandatory Promotional Code Requirements

AstraZeneca does not see it as necessary to address the specific allegations relating to clause 12.1, 12.6 and 12.9 regarding the need for these mandatory promotional requirements for prescribing information ('PI'), a statement as to where the PI can be found and an adverse event reporting statement as set out in the Code given that the video is non-promotional digital asset and has been signed off as such for the reasons outline above.

Additional Allegations

The complainant made additional allegations regarding breaches of Clause 5.1 and Clause 2 of the Code.

AstraZeneca maintains its position that high standards have been upheld by the company at all times.

Our clear intention was one of education in line with the principles of the ABPI Code and LLH as defined in the EFPIA Code. The website and video were formally examined in accordance with our internal Standard Operating Procedures (SOPs) and the Code.

Accordingly, AstraZeneca contends that the high standards required of a pharmaceutical company have been maintained, with no breaches of Clauses 5.1 or 2.

Summary of AstraZeneca's Position

In conclusion, AstraZeneca takes compliance with the Code extremely seriously and is committed to maintaining high standards in relation to all information it provides about its products and its activities.

AstraZeneca has reviewed the allegations and maintain our initial assessment that the video is non-promotional, does not identify any specific product directly or indirectly and complies with the Code requirements for non-promotional material.

Specifically, we refute the complainant's allegations of breaches concerning Clauses 12.1, 12.6, 12.9, 15.6, 5.1, and 2 of the Code."

PANEL RULING

The Panel noted that the Constitution and Procedure stated that the complainant had the burden of proving their complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties.

The complaint related to a 19-minute video titled 'Chronic Kidney Disease Management Made Simple', hosted on a website created and maintained by AstraZeneca. The video had two presenters: a health professional and an AstraZeneca employee. The complaint was that the video was promotional for AstraZeneca's sodium-glucose cotransporter-2 (SGLT2) inhibitor, Forxiga. The complainant alleged breaches of Clauses 12.1, 12.6, 12.9 and 15.6, all of which applied to promotional material.

AstraZeneca submitted that the material in question was not promotional and was intended to offer relevant and balanced educational support to health professionals in primary care settings for the effective management of chronic kidney disease (CKD). AstraZeneca stated that the primary objective of the website, on which the video was hosted, was to provide health professionals in the UK with educational resources concerning AstraZeneca's therapeutic areas of interest, including but not limited to, cardiovascular, renal, and metabolic diseases.

The Panel considered that the essence of this case was firstly about whether the complaint related to promotional material. If the Panel concluded that the material was not promotional, then there could be no breach of any of the clauses raised by the complainant.

The complaint referred to two specific sections of the video that the complainant alleged showed that it was promotional in nature: a slide relating to risk factors and treatment options, and a case study.

The risk factors and treatment options slide

At 7 minutes 23 seconds of the video, the AstraZeneca employee discussed a slide which showed a list of three types of treatments for CKD that have effects on outcomes by targeting risk factors:

- Reduce blood pressure
- Glycaemic control
- Controlling lipids

The speaker stated that this risk factor control "may be achieved through a combination of lifestyle advice and pharmacological intervention". The speaker stated, "Treatments that directly slow progression and act on the kidney include ACE [angiotensin converting enzyme] inhibitors, as well as angiotensin receptor blockers [ARBs], and, more recently, SGLT2 inhibitors" while the following list of treatments appeared on screen:

- Lifestyle advice
- RAAS [renin angiotensin aldosterone system] inhibition (ACE inhibitor / ARB)
- Statins
- SGLT2 inhibitors

The case study

Towards the end of the video, the health professional speaker presented a case study. It involved a patient with a history of type 2 diabetes and ischaemic heart disease (and evidence of CKD) who presented with dyspnoea and was diagnosed as having heart failure with reduced ejection fraction. At 17 minutes 9 seconds, the health professional stated:

“His treatment now will need to be adjusted on the basis of him having heart failure in addition to his CKD and diabetes. And while we would all agree that maximisation of inhibition of the renin-angiotensin system by ACE inhibitors, angiotensin 2 blockers is a commonality in terms of the treatment, he may also benefit now from mineralocorticoid receptor antagonists, beta-blockers, he may need symptomatic treatment diuretics. And also, you may need to consider whether some of the drugs that we use for glycaemic control, particularly the SGLT2 inhibitors, would be beneficial for him in the context of his heart failure”.

References to SGLT2 inhibitors

The complainant alleged that the references to SGLT2 inhibitors in these two sections of the video were an indirect or implied mention of Forxiga. Given Forxiga was an AstraZeneca product, the complainant alleged that this meant that the video was therefore promotional.

Panel's conclusion

The Panel noted the definition of “promotion” in Clause 1.17 of the Code and that it specifically excluded “information relating to human health or diseases provided there is no direct or indirect reference to specific medicines”.

The complainant accepted in their complaint that although the video mentioned the drug class, it did not contain an express mention of any specific product. However, the Panel noted that it was an accepted principle under the Code that a product could be promoted without its name ever being mentioned. Whether a reference to a class of medicines amounts to a reference to a specific medicine should be decided on a case-by-case basis: context is important.

The Panel acknowledged that, at the time of the complaint, AstraZeneca was not the only company that had an SGLT2 inhibitor available for the treatment of CKD. In its response to the complaint, AstraZeneca cited Jardiance and Invokana as other SGLT2 inhibitors with evidence in the treatment of CKD. Both of these were products of pharmaceutical companies other than AstraZeneca.

In relation to the first mention of SGLT2 inhibitors within the video (in the risk factors and treatment options section), the Panel acknowledged that SGLT2 inhibitors were given as one example of an available pharmacological treatment, among a list of other treatment options. The Panel accepted that the speaker did not mention any specific SGLT2 inhibitor and it was given equal prominence as a treatment option alongside the others mentioned.

The Panel considered whether the mention of SGLT2 inhibitors being a “more recent option” could be interpreted as giving undue emphasis to this class of medicines. The Panel concluded that it was a statement of fact about a relatively recent indication for this class of medicines. The

Panel therefore did not conclude that this was a factor that pointed towards the video being promotional.

In relation to the case study, the Panel noted that the speaker particularly highlighted SGLT2 inhibitors by saying:

“you may need to consider whether some of the drugs that we use for glycaemic control, particularly the SGLT2 inhibitors, would be beneficial for him in the context of his heart failure” (Panel’s emphasis).

However, the Panel considered that the reference to SGLT2 inhibitors was not a reference to any particular medicine because there were multiple SGLT2 inhibitors available for the indication discussed. It therefore followed that even if a reference to SGLT2 inhibitors could be considered an indirect reference to Forxiga, it was also an indirect reference to products of other companies, and there was no emphasis on any specific AstraZeneca medicine.

Overall, the Panel considered the video to include a balanced presentation of the treatment options available. The Panel’s impression of the video, in particular the slide and case study referred to above, was that it was neutral and did not appear to be promotional in nature. Although there was an AstraZeneca speaker and the slides were headed with an AstraZeneca logo, that was consistent with AstraZeneca’s submission that this was a company-produced educational support tool for health professionals in primary care settings. The video did not use Forxiga branding or brand colours.

The Panel concluded that, on balance, this video was “information relating to human health or diseases” and therefore the exclusion from the definition of “promotion” in Clause 1.17 applied.

Given that the Panel did not consider the video to be promotional, the clauses to which the Panel was referred did not apply. The Panel therefore **ruled no breaches of Clauses 12.1, 12.6, 12.9 and 15.6.**

Due to fact that the Panel did not consider the video to be a breach any of the above clauses, the Panel similarly concluded that there had been no failure to maintain high standards, nor had the materials brought discredit upon, or reduced confidence in, the pharmaceutical industry. On that basis, the Panel **ruled no breaches of Clauses 5.1 and 2.**

Complaint received 6 October 2023

Case completed 3 December 2024