**CASE/0248/07/24**

# COMPLAINANT v ASTRAZENECA

**Allegations about a promotional email**

## CASE SUMMARY

**This case was in relation to an email sent on behalf of AstraZeneca to Great Britain health professionals, which promoted the use of Forxiga (dapagliflozin) in patients with type 2 diabetes mellitus. The complainant alleged that a claim within the email was misleading and that the email itself was not sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine.**

**The outcome under the 2021 Code was:**

| | |
|---|---|
| **Breach of Clause 5.1** | **Failing to maintain high standards** |
| **Breach of Clause 6.1 (X2)** | **Making a misleading claim** |

| | |
|---|---|
| **No Breach of Clause 2** | **Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry** |

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

## COMPLAINT

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

> "Dear PMCPA,
>
> NICE is mentioned stating that 93% could be eligible for an SGLT2. This is not something that NICE has stated but instead is extrapolated from the guidelines. Not even "up to" 93%, but the figure 93%. The second reference mentioned uses population-based modelling (and is where the 93% figure is from).
>
> This email also does not mention Special warnings and precautions for use - or indeed any safety information at all, namely, inter alia:

Renal impairment

There is limited experience with initiating treatment with dapagliflozin in patients with eGFR < 25 mL/min/1.73m2, and no experience with initiating treatment in patients with eGFR < 15 mL/min/1.73m2. Therefore, it is not recommended to initiate treatment with dapagliflozin in patients with eGFR < 15 mL/min/1.73m2 (see section 4.2).

**Lactose**
The tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

Between one not recommended, and one should not this is putting patient safety at risk - especially as Chronic Kidney Disease is one indication for its use.

These safety cases were neither modelled in the study that this number has been plucked from, and nor is it mentioned in the email to give a rounded evidence before clinicians start using the product.

Please investigate."

When writing to AstraZeneca, the PMCPA asked it to consider the requirements of Clauses 6.1, 5.1 and 2 of the 2021 Code.

## ASTRAZENECA'S RESPONSE

The response from AstraZeneca is reproduced below:

"Thank you for your letter dated 01 August 2024, to AstraZeneca UK ("AstraZeneca") concerning a complaint received on 29 July 2024 regarding a promotional email for Forxiga® (dapagliflozin).

AstraZeneca takes compliance with the ABPI Code of Practice (the "Code") seriously and in the response below consideration has been given to Clauses 6.1, 5.1 and 2 of the 2021 Code.

**Summary of allegations**

1. AstraZeneca email implies that *NICE states 93% of T2DM (type 2 diabetes mellitus) patients could be eligible for an SGLT2 inhibitor*. However, this is not true, and the information is based off population health modelling. The figure 93% is included, not 'up to' 93%.
2. The email does not mention any information about safety and precautions, inter alia, dosing in renal impairment and lactose intolerance. These safety cases were not modelled in the study that the eligible number [93%] of patients has been taken from nor mentioned in the email to which this number is taken from.

AstraZeneca will respond to each of the allegations below.

Background

The email subject to complaint (GB-57194) contains text and a link to a video (hosted on [product website]) intended for primary care healthcare professionals (HCPs) who manage T2DM. The email was sent to General Practitioners (GPs) in Great Britain by Pulse on behalf of AstraZeneca on 29/01/2024.

The intent of the email was to highlight the NICE eligibility criteria and high percentage of patients that may be eligible for treatment with an SGLT2-inhibitor, illustrating potential gaps in clinical care. It does not outline specific eligibility criteria for SGLT2-inhibitors, only those pertaining to the NICE NG28 guidelines as clearly stated.

As the complaint and the allegations are focussed on the email, we have based our response on the content of the email only. Please do inform us if further information is required with regards to the video.

1. AstraZeneca email implies that *NICE states that 93% of T2DM patients could be eligible for an SGLT2 inhibitor*. However, this is not true, and the information is based off population health modelling. The figure 93% is included, not 'up to' 93%.

The NICE NG28 guideline eligibility criteria ("NICE eligibility criteria") recommends that treatment with SGLT2-inhibitors may be considered for the treatment of type 2 diabetes, if:[1]

- The patient's 10-year risk of cardiovascular disease ("CVD") status is >10% by applying QRISK2, an elevated lifetime risk of cardiovascular disease (defined as the presence of 1 or more cardiovascular risk factors in someone under 40)

  Or

- Offered and SGLT2-inhibitor if there is evidence of established atherosclerotic cardiovascular disease ("ASCVD") or heart failure ("HF")

Young *et al*. used a contemporary population-representative UK cohort with T2DM registered with a GP practice to assess the implications of NICE eligibility criteria. Of those not receiving anti-hyperglycaemic treatment (n=153,257), 59.6% of patients were eligible for treatment based on their QRISK2 score and 33.6% were eligible based on established ASCVD or heart failure, which totals to 93.2%.

We acknowledge that the 93% figure is an estimate based on a representative population sample and does not consider additional eligibility considerations for SGLT2-inhibitors. Therefore, the claim was carefully worded to include "could be eligible", so it is clear to the HCP that not all patients that fit the NICE eligibility criteria would necessarily be eligible for an SGLT2-inhibitor.

The claim *"According to NICE, 93% of T2DM patients could be eligible for an SGLT2-inhibitor"* is correct as the 93% figure is calculated from the eligibility criteria established by NICE in the NG28 guidelines. NICE eligibility criteria are also defined within the email *"According to NICE guidelines, patients aged 40 and over with type 2 diabetes and a*

*QRISK2 score above 10% should be considered for an SGLT2 inhibitor. NICE also recommends offering an SGLT2i to all patients with T2DM and established heart failure or atherosclerotic disease"* and *"Based on this, 93% of T2DM patients could be eligible for an SGLT2 inhibitor because that's how many people in the UK with T2DM have a QRISK2 score greater than 10%, or established HF or ASCVD",* which adequately explains how 93% was derived from NICE eligibility criteria.

The information provided in the email is therefore clear and accurately represents the essence of NICE recommendations. This is not misleading, in line with high standards of the Code and does not bring discredit upon, or reduce confidence in, the pharmaceutical industry.

AstraZeneca therefore refute breach of clause 6.1, clause 5.1 and clause 2 pertaining to this allegation.

2. <u>The email does not mention any information about safety and precautions, inter alia, dosing in renal impairment and lactose intolerance. These safety cases were not modelled in the study that the eligible number [93%] of patients has been taken from nor mentioned in the email to which this number is taken from.</u>

Omission of safety subgroups does not invalidate the 93% estimate itself because the wording "could be eligible" is used throughout the email to reflect that the claim "93%" is not definitive. It is very clear that this is based on the NICE eligibility criteria and does not consider all eligibility requirements for SGLT2-inhibitors. The purpose of the email is to highlight the high percentage of patients that could be eligible for an SGLT2-inhibitor in line with NICE guidelines, to encourage HCP consideration during (appropriate) patient consultations.

The following disclaimer appears at the top of the email: "Prescribing information and adverse event reporting can be found at the end of this email", to signpost the reader to the prescribing information containing readily available safety, warnings and precautions for use in accordance with the Code. The licensed indication is the only information about Forxiga in the email. Taking into consideration the availability of PI (which has the key safety and precautions), email content and intended purpose of highlighting NICE eligibility criteria, there is no implication that there would be no safety considerations and therefore it is not misleading.

Based on the above, AstraZeneca refutes breach of clause 6.1. We ascertain that the claims outlined in the complaint meet the high standards of the Code (clause 5.1) and do not to bring discredit upon, or reduce confidence in, the pharmaceutical industry (clause 2).

**Summary**
It is AstraZeneca's position that:

- The intent of the email was to highlight the high percentage of patients potentially eligible for an SGLT2-inhibitor.
- The email accurately represents SGLT2-inhibitor eligibility derived by NICE and published literature.

- Omission of safety cases not modelled in study does not invalidate the 93% estimate itself because the wording "could be eligible" is used throughout the email to reflect that the claim "93%" is not definitive.
- Safety information is not required in the email as there is no efficacy claims about Forxiga in the email. The only information included is the licensed indication for Forxiga. Prescribing information containing safety considerations is clearly signposted at the top of the email. In addition, the PI states at the top "Consult the Summary of Product Characteristics before prescribing".

AstraZeneca takes its responsibilities under the ABPI Code very seriously. Based on the above detailed response, we maintain that the email is not misleading, high standards have been maintained and this activity has not brought the industry into disrepute and therefore **we refute breaches of Clause 6.1, 5.1 and 2**."

**PANEL RULING**

An anonymous contactable complainant raised allegations regarding a promotional email sent on behalf of AstraZeneca. The email was sent by a third party to Great Britain health professionals and promoted the use of Forxiga (dapagliflozin) in patients with type 2 diabetes mellitus (TD2M).

The email subject line read *"Two very different numbers. One short film: AstraZeneca Promotional email".* The header of the email contained statements, in very small text, highlighting why the individual had been sent the email, the promotional nature of it, who it was intended for, and where to find the prescribing information, adverse events information and information on where an unsubscribe link could be found.

At the start of the substantive content of the email, there was a Forxiga brand logo and a paraphrased indications' statement appeared underneath it. This was followed by a prominent banner, on the left of which was "*93%*" in very large bold red font which was the full height of the banner, and on the right the statement "*According to NICE, 93% of T2DM patients could be eligible for an SGL2 inhibitor*", in a bold but smaller font. The Panel noted the words "93% of T2DM patients" had been emphasised in red while the remainder of the statement was in blue text.

Beneath the banner was a section containing the body of the email which stated in much smaller text:

*"Dear [named health professional]*

*According to NICE guidelines, patients aged 40 and over with type 2 diabetes and a QRISK2 score above 10% should be considered for an SGLT2 inhibitor[2]. NICE also recommends offering an SGLT2i to all patients with T2DM and established heart failure or atherosclerotic disease[2].*

*Based on this **93% of T2DM patients could be eligible for an SGLT2 inhibitor[2,3]**, because that's how many people in the UK with T2DM have a QRISK2 score greater than 10%, or have established HF or ASCVD.[3]*

*But how many of the those eligible patients actually get one?*

***The answer is so different, we have made a video about it.****"*

The remainder of the substantive content comprised links to a two-minute video and the GB prescribing information followed by a list of abbreviations, the references and adverse events reporting information. Footnote 2 referred to the NICE NG28 guidance. Footnote 3 referred to the Young et al publication.

Noting that there were two allegations, the Panel considered each in turn.

Allegation 1 – the 93% claim

The complainant alleged that the claim in the banner was misleading as the 93% figure was not found in the referenced NICE NG28 guidance, but was instead taken from a population-based modelling study (the Young et al publication).

AstraZeneca submitted that the intent of the email was to highlight the NICE eligibility criteria, the high percentage of patients that might be eligible for treatment with an SGLT2-inhibitor, and illustrate potential gaps in clinical care. AstraZeneca acknowledged that the email did not outline specific eligibility criteria for SGLT2-inhibitors; only those pertaining to the NICE NG28 guidance.

The Panel noted that the NICE guidance did not make any reference to the percentage of patients that could be eligible for treatment with a SGLT2-inhibitor. The 93% figure had been taken from Young et al. which had used a contemporary population-representative UK cohort of T2DM patients registered with a GP practice to assess the implications of NICE eligibility criteria.

The Panel considered the immediate and overall impression that the email would have created for a busy health professional. Clause 6.1 of the Code required claims to be "*accurate, balanced, fair, objective and unambiguous*" and that "*they must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis*" and that they "*must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine*".

The Panel considered the overwhelming emphasis put on the headline claim, and particularly the *"93%"* which, taken together with the other elements highlighted in the email (T2DM patients and NICE), would likely create the key take out message that the NICE Guidance endorsed the use of an SGLT2 in 93% of patients with Type 2 diabetes which was not so. In the Panel's view, the use of the words "*could be eligible*" did not negate the misleading impression created and further context should have been provided to qualify the 93% claim. Having considered the evidence before it, the Panel ruled a **breach of Clause 6.1.**

The Panel noted the complaint was limited to the content of the email itself and, as no allegations had been raised regarding the video embedded in the email, made no further comment in this respect.

Allegation 2 - omission of safety information such as renal impairment and lactose

The second part of the complaint related to an alleged absence of safety information in the email. The complainant referred specifically to the use of dapagliflozin in patients with renal impairment or rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. The Panel interpreted the complainant's allegation to be that health professionals receiving the email had not been provided with adequate context for the 93% figure cited by way of special warnings and precautions for use, and this was therefore an alleged breach of Clause 6.1 which required that:

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

AstraZeneca submitted that the omission of safety subgroups did not invalidate the 93% figure. It acknowledged that this figure was an "*estimate*" but believed that the use of the wording "*could be eligible*" in the email reflected that the 93% claim was not definitive. AstraZeneca further submitted that it was very clear that the claim was based on the NICE eligibility criteria and did not consider all eligibility requirements for SGLT2-inhibitors. AstraZeneca maintained the purpose of the email was to highlight the high percentage of patients that could be eligible for an SGLT2-inhibitor in line with NICE guidance, to encourage health professionals to consider this therapeutic option during (appropriate) patient consultations.

In the Panel's view, when considering the acceptability of materials, it was necessary to assess the overall and immediate impression created, including the layout and balance of the various elements. While the use of qualifiers like "*could*" might, in some circumstances, add adequate caveats or nuance to messaging, that was not always the case and did not avoid the need for clear substantiation and provision of balanced information.

The Panel noted AstraZeneca's response that the email contained a link to the prescribing information which contained safety information, warnings and precautions for use. However, in the particular circumstances of this case, where the email placed a considerable amount of emphasis on the high percentage of patients that could be eligible for treatment, the Panel concluded that the omission of any safety information within the body of the email itself such as a statement advising prescribers to consult the Summary of Product Characteristics before prescribing, to ensure Forxiga was an appropriate treatment choice, meant that the email lacked balance.

The Panel did not consider that there was a requirement to include specific safety information regarding renal impairment or lactose. However, due to the strength and prominence of the claim, coupled with the omission of any safety information, the Panel considered the email to be insufficiently balanced and ruled a **breach of Clause 6.1.**

Clause 5.1 and Clause 2

The email related solely to the type 2 diabetes indication for Forxiga. The Panel noted other indications had been included in the indications statement at the top of the email which could have added further confusion to the overall intent of the email.

The Panel's overall impression of the email was that it was being used to encourage the consideration of Forxiga, based on a 93% claim which misleadingly suggested that that figure was "*according to NICE*" i.e. it had come directly from NICE. The Panel noted in AstraZeneca's

response that it conceded that the figure in question was "*derived from*" Young et al., yet this sentiment was not shown in the email itself. Due to the undue emphasis placed on the statement in question, the omission of safety information and the unbalanced nature of the email, the Panel concluded that high standards had not been maintained, and ruled a **breach of 5.1**.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and reserved for such. The Panel considered that the breach rulings above adequately covered the allegations in this case. The Panel therefore ruled **no breach of Clause 2**.

**Complaint received** **29 July 2024**

**Case completed** **22 August 2025**