CASE AUTH/3622/3/22 ***NO BREACH OF THE CODE***

COMPLAINANT v ASTRAZENECA

Concerns about a Forxiga advertisement

A complainant who described him/herself as a physician complained about an advertisement for Forxiga (dapagliflozin) on Medscape. Forxiga was marketed by AstraZeneca.

The complainant provided three screenshots of the advertisement. AstraZeneca provided the four frames for the advertisement. The frame not provided by the complainant was the first frame of the advertisement, frame 1.

The complainant was really surprised at the claims made. Although this was a rolling banner, the first one the complainant saw stated to start 10mg Forxiga in chronic kidney disease (CKD), without any qualification apart from a footnote in severe liver failure. However, there were many aetiologies of CKD that were neither covered by this licence, nor the DAPA-CKD trial. None of this was evident, it read as though Forxiga was suitable for all types of CKD, which it was not.

Moreover, these banners did not make it clear that it was only for adults. Patients who were frail and elderly also were at risk. It was not clear that there was limited evidence in patients with an eGFR <25, and many important side-effects like hypoglycemia and DKA were not highlighted other than a footnote reference to adverse events. This was a bad example of glossing over the limitations of treatment and exaggerating the breadth and effect of a medicine. It was also not clear immediately what Forxiga was, and he/she had to look further down the screen to see that it was dapagliflozin.

In another banner, a claim that Forxiga slowed eGFR decline and saved lives had zero context. It was not clear what the studied population was, and what the measured effect was. It was as though it was soliciting a click on the tab to find out more about this broad claim. In fact, the study in diabetes did not really show this, and the DAPA-CKD trial excluded both children and people without albuminuria. This was not clear from the statement 'Forxiga slows eGFR decline and saves lives in CKD patients with T2D vs. placebo on top of standard of care'. It was not clear if the reference to CKD was related to previous banners, or if it meant only T2D patients. This made the complainant have to take the time to understand more of the licence, rather than be given the full information upfront. He/she felt that this banner solicited a click to the promotional website, by giving incomplete information. The complainant alleged this was a poor example of pharmaceutical marketing by withholding information to promote a medicine.

The detailed response from AstraZeneca is given below.

The Panel noted that the banner advertisement consisted of four frames. The first frame included Forxiga's indication and stated 'NEW INDICATION FORXIGA (dapagliflozin) is

now approved for the treatment of CKD in patients with and without T2D'; the second frame included 'FORXIGA slows eGFR decline and saves lives in CKD patients with T2D vs. placebo on top of standard of care'; the third frame included 'Start on 10 mg FORXIGA, stay on 10 mg FORXIGA. Initiate Forxiga in CKD patients with eGFR ≥15 mL/min/1.73mg*' followed by the footnote '*In patients with severe hepatic impairment, a starting dose of 5 mg is recommended. If well tolerated, the dose may be increased to 10 mg'; the fourth and final frame included the statement 'The overall safety profile of FORXIGA in patients with CKD was consistent with the known safety profile of FORXIGA' along with the button labelled 'Discover the data now'.

The Panel noted that the complainant had not referred to the first frame of the advertisement: he/she only commented on the following three frames. In the Panel's view, the first frame added important context to the advertisement as a whole. The four frames ie the linked parts were considered as one advertisement.

A Claims for Forxiga's starting dose

In relation to the allegation that the claim to start on 10mg Forxiga was without qualification except in relation to severe liver failure, the Panel considered that the information on dosing in the third frame of the advertisement, was in line with the Forxiga summary of product characteristics (SPC) which required a lower starting dose of 5mg in patient with severe hepatic impairment. The Panel noted AstraZeneca's submission that there were no requirements to reduce the dose for patients with CKD or based on renal function and/or age. The Panel did not consider that the complainant had established that the claim 'Start on 10 mg FORXIGA, stay on 10 mg FORXIGA', without reference to dosing in CKD, was misleading nor inconsistent with the particulars listed in the Forxiga SPC as alleged. Nor had the company failed to maintain high standards. No breaches of the Code were ruled.

B Use of Forxiga in Chronic Kidney Disease (CKD)

Whilst the Panel noted that the CKD data referred to in Section 4.4 of the SPC was clear that there was no experience of the medicine for the treatment of CKD in patients without diabetes who did not have albuminuria, the Panel noted that Forxiga was 'indicated in adults for the treatment of chronic kidney disease', in addition to its indications for type 2 diabetes mellitus and heart failure (Section 4.1 of the SPC). The Panel, noting Forxiga's broad indication in CKD, did not consider that omitting a statement about evidence in CKD patients without diabetes who did not have albuminuria meant that the claims in relation to CKD were inconsistent with the SPC and were misleading in this regard as alleged. Nor had the company failed to maintain high standards. The Panel therefore ruled no breaches of the Code.

C Use of Forxiga in adults

In relation to the allegation that it was not clear that Forxiga was only to be used in adults, the Panel noted that the complainant only provided screenshots of frames 2-4, as described above, and appeared not to have seen the first frame of the advertisement where the indication was given, stating that the medicine was for use in adults. The Panel agreed with AstraZeneca's submission that there was no implication from the images used, which were of a middle aged man, that the medicine was to be used in

children. In the Panel's view, neither the advertisement as a whole or the four individual frames appeared to be inconsistent with the SPC in this regard. Nor had the company failed to maintain high standards. The Panel therefore ruled no breaches of the Code.

D Evidence in patients with eGFR <25 mls/min and alleged failure to highlight important side-effects like hypoglycemia and DKA

The Panel noted that Section 4.2 of the Forxiga SPC stated that no dose adjustment was required based on renal function but it was not recommended to initiate treatment with in patients with an estimated glomerular filtration rate (eGFR) < 15 mL/min/1.73m^2. The Panel noted that frame 3 referred to initiating Forxiga in CKD patients with eGFR ≥15 mL/min/1.73m^2 which it considered was not inconsistent with the Forxiga SPC. Thus, the Panel ruled no breach of the Code.

With regard to the allegation that many important side-effects were not highlighted, such as hypoglycemia and DKA, the Panel noted AstraZeneca's submission that Forxiga's safety profile had been well-established, particularly in patients with type 2 diabetes. AstraZeneca submitted it was not possible to list all known side-effects on a banner advert but there was reference to the SPC and a clear single click link to prescribing information and adverse event reporting provided on each frame.

The Panel did not consider, in the context of the four frames which made up the advertisement and in the particular circumstances of this case, that it was misleading or otherwise an unfair reflection to not have listed Forxiga's side-effects on the advertisement at issue and thus ruled no breach of the Code.

The Panel noted its rulings of no breaches above and did not consider that AstraZeneca had failed to maintain high standards. No breach of the Code was ruled.

E Alleged failure to be clear as to what Forxiga was

The Panel noted that each of the four frames included a prominent logo which included the brand name, Forxiga, directly beneath which was the non-proprietary name, dapagliflozin. The Panel noted that the first frame of the banner advertisement started with the brand name, the non-proprietary name and the indication followed by a claim which also included the non-proprietary name in brackets. The claims on frames 2, 3 and 4 used only the brand name but nonetheless the non-proprietary name was included in the logo on each frame.

The Panel considered that the complainant had not shown, on the balance of probabilities, that the non-proprietary name was not clear in the advertisement and thus ruled no breach of the Code in this regard.

F Claim that Forxiga slows eGFR decline

With regard to the claim in the second frame, 'FORXIGA slows eGFR decline and saves lives in CKD patients with T2D vs. placebo on top of standard of care'. The Panel noted that the final frame appeared to link to a page providing further information on the study, via clicking on through the button 'Discover the data now'. The Panel did not consider that the complainant had shown that the alleged lack of context in relation to the trial

population and the measured effect was, on the balance of probabilities, in breach of the Code and thus ruled no breach.

With regard to the allegation that it was not clear if the reference to CKD was related to previous banners or only T2D diabetes, the Panel noted that the claim 'FORXIGA slows eGFR decline and saves lives in CKD patients with T2D vs. placebo on top of standard of care' made reference to T2D within the claim itself. Further, in relation to the lack of reference that the DAPA-CKD trial excluded children and people without albuminuria, the Panel noted its comments under points B and C above. No breach of the Code was ruled. The Panel did not consider that AstraZeneca had failed to maintain high standards and ruled no breach of the Code.

G Overall consideration of Clause 2

The Panel, noting its rulings of no breach of the Code above, therefore ruled no breach of the Code.

A complainant who described him/herself as a physician complained about an advertisement for Forxiga (dapagliflozin) on Medscape. Forxiga was marketed by AstraZeneca.

The complainant provided three screenshots of the advertisement. AstraZeneca provided the four frames for the advertisement. The frame not provided by the complainant was the first frame of the advertisement, frame 1, which was headed:

> 'FORXIGA (dapagliflozin) 10mg is indicated in adults for the treatment of insufficiently controlled type 2 diabetes (T2D); symptomatic chronic heart failure with reduced ejection fraction (HFrEF); chronic kidney disease (CKD).'

Frame 1 then referred to a new indication that Forxiga was now approved for the treatment of CKD in patients with and without T2D.
Frame 2 included

> 'FORXIGA slows eGFR decline and saves lives in CKD patients with T2D vs. placebo on top of standard of care.'

Frame 3 included:

> 'Start on 10mg FORXIGA, stay on 10mg Forxiga. Initiate Forxiga in CKD patients with eGFR ≥ 15 mL/min/1.73m^{2}*.'
>
> * in patients with severe hepatic impairment, a starting dose of 5mg is recommended. If well tolerated, the dose may be increased to 10mg.

Frame 4 included:

> 'The overall safety profile of FORXIGA in patients with CKD was consistent with the known safety profile of FORXIGA
>
> Discover the data now.'

COMPLAINT

The complainant stated that he/she saw this advertisement on Medscape two days ago on his/her phone and did not feel that it was appropriate and met the requirements of the pharmaceutical industry. The complainant stated that when the banners suddenly popped up on his/her phone, he/she was really surprised at the claims that were made. Although this was a rolling banner, the first one the complainant saw stated to start 10mg Forxiga in CKD [chronic kidney disease], without any qualification apart from a footnote in severe liver failure. However, there were many aetiologies of CKD that were neither covered by this licence, nor the DAPA-CKD trial. None of this was evident on the banners. It read as though Forxiga was suitable for all types of CKD, which it was not. In fact, both the complainant and one of his/her colleague's, both found that the licence explicitly stated:

> 'There is no experience with dapagliflozin for the treatment of chronic kidney disease in patients without diabetes who do not have albuminuria. Dapagliflozin has not been studied for the treatment of chronic kidney disease in patients with polycystic kidney disease, glomerulonephritis with flares (lupus nephritis or ANCA-associated vasculitis), ongoing or recent requirements of cytotoxic, immunosuppressive or other immunomodulating renal therapy, or in patients who received an organ transplant.'

Moreover, it was also only for adults, and these banners did not make it clear at all, making it dangerous should children be given this mistakenly by clinicians who were not familiar with this medication. Patients who were frail and elderly also were at risk. The complainant stated that he/she did not realise this until much later when he/she looked into it. It was not clear that there was limited evidence in patients with an eGFR <25, and many important side-effects like hypoglycemia and DKA were not highlighted other than a footnote reference to adverse events. This was a bad example of glossing over the limitations of treatment and exaggerating the breadth and effect of a pharmaceutical medicine for the sake of promotion. It was also not clear immediately what Forxiga was, and he/she had to look further down the screen to see that it was dapagliflozin.

In another banner, a claim that Forxiga slowed eGFR decline and saved lives had zero context. It was not clear what the studied population was, and what the measured effect was. It was as though it was soliciting a click on the tab to find out more about this broad claim. In fact, the study in diabetes did not really show this, and the DAPA-CKD trial excluded both children and people without albuminuria. This was not clear from the statement 'Forxiga slows eGFR decline and saves lives in CKD patients with T2D vs. placebo on top of standard of care'. It was not clear if the reference to CKD was related to previous banners, or if it meant only T2D patients. This was confusing and made the complainant have to take the time to understand more of the licence him/herself, rather than be given the full information upfront. He/she felt that this banner solicited a doctor to click to the promotional website, by giving incomplete information. The complainant alleged this was a poor example of pharmaceutical marketing by withholding information to promote a medicine.

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 5.1, 6.1, 11.2 and 2 of the Code.

RESPONSE

AstraZeneca noted the concerns expressed by the complainant but fundamentally disagreed that the claims made and the type of promotion used contravened the Code in any way.

AstraZeneca submitted that it would establish that:

- All information included in this banner advertisement was accurate, balanced, fair, objective and unambiguous. It was based on up-to-date information and did not mislead or exaggerate.
- The generic name was clearly included on every mention of brand name on the first frame, and most prominent mention of brand name on all subsequent frames thereafter.
- All information about Forxiga was consistent with its summary of product characteristics (SPC).
- Forxiga full indication was included on the first frame of the banner advert, and a clear, single click link to prescribing information was available on each frame.
- All serious and common side-effects were included in the prescribing information, available one click away from the advertisement.
- One of the four frames was dedicated to summarised safety information for Forxiga.
- All claims could be substantiated by the SPC or clinical papers (DAPA-CKD trial Heerspink *et al* 2020;, DECLARE-TIMI 58 study Wiviott *et al* 2019.).
- It was acceptable for banner adverts to click through to further information.

AstraZeneca addressed each of the allegations according to the relevant clauses of the Code.

AstraZeneca stated that the use of banner advertisements was a legitimate means of promotion and, given the limited space and time to view the content, their purpose was to create awareness, and provide an opportunity for health professionals to click through to another page where further information and context was provided. This particular banner provided the reader with the opportunity to click through to the Forxiga website where information and context on the data underpinning the claims was provided, as well as dosing and safety information. The full prescribing information was made available to all readers by a single, direct click link from every frame of the banner advertisement.

Each banner frame was shown for the following durations:

Frame 1 – 8.5 seconds
Frame 2 – 6.5 seconds
Frame 3 – 8.5 seconds
Frame 4 – 6.5 seconds.

1 Not immediately clear what Forxiga was (ie unclear generic name)

AstraZeneca submitted that the generic name was included after every mention (including the first mention) of the brand name on the first frame, and on the most prominent mention of the brand name on all subsequent frames thereafter. On every frame the generic name was legible. Therefore, AstraZeneca denied the alleged breaches of 5.1.

2 Concern with the claim 'Start on 10mg Forxiga' without any qualification apart from the footnote in severe liver failure

AstraZeneca drew attention to Section 4.2 of the Forxiga SPC which stated that Forxiga could be administered as one single 10mg tablet and could be taken at any time of day with or without food. Furthermore, the recommended starting dose for those with chronic kidney disease (CKD) was 10mg dapagliflozin once daily and no dose adjustment or titration was required. Patients also did not require a dose adjustment based upon their renal function and/or age, which were often common reasons requiring different or lower starting or maintenance doses of medicines. A recommended starting dose of 5mg for patients with severe hepatic impairment was provided as part of the banner advertisement, despite this being the case for only a small percentage of patients diagnosed with co-morbid severe hepatic impairment.

AstraZeneca therefore submitted that the claim to start on 10mg and stay on 10mg was consistent with SPC and not misleading and denied breaches of Clauses 5.1, 6.1 and 11.2.

3 Banner advertisement read as though Forxiga was suitable for all types of CKD, which was not the case

AstraZeneca submitted that Forxiga was indicated in adults with CKD as evidenced by section 4.1 of the SPC. This was made very clear on the first frame of the banner advertisement. Furthermore, there were no specific contraindications related to CKD listed in section 4.3 of the SPC. AstraZeneca, therefore, believed Forxiga had been advertised in line with the SPC.

Prescribing information, including a list of warnings and precautions, was available through a single, direct click link from each frame of the banner advertisement.

Therefore, AstraZeneca denied the alleged breaches of Clauses 5.1, 6.1 and 11.2.

4 Banner advertisement did not make it clear that Forxiga was only for adults

The complainant only submitted screenshots of 3 frames of the complete 4 frame advertisement. From the full banner advertisement AstraZeneca submitted that the first frame included the statement:

> 'Forxiga (dapagliflozin) 10mg is indicated in adults for the treatment of insufficiently controlled type diabetes (T2D); symptomatic chronic heart failure with reduced ejection fraction (HHrEF); chronic kidney disease (CKD).'

Furthermore, the imagery used did not in any way imply that Forxiga should or could be used in children.

AstraZeneca denied the accusation that the banner advertisement did not make it clear that the medication was only intended for adults and refuted the alleged breaches of Clauses 5.1 and 11.2.

5 Not clear that there is limited evidence in patients with eGFR <25mls/min

AstraZeneca stated that Section 4.2 posology and method of administration of the SPC contained the following statement:

'It is not recommended to initiate treatment with dapagliflozin in patients with an estimated glomerular filtration rate (eGFR) < 15 mL/min/1.73m^2'.

Therefore the claim 'initiate Forxiga in CKD patients with eGFR >15mL/min/1.73m^2' was consistent with the SPC. AstraZeneca denied the alleged breaches of Clauses 5.1, 6.1 and 11.2 of the Code.

6 Many important side-effects were not highlighted other than a footnote reference to adverse events

AstraZeneca acknowledged that there were side-effects associated with all medicines, including dapagliflozin. Forxiga had been available and prescribed for several years and the safety profile had been well-established, especially in those patients with type 2 diabetes. The results from the DAPA-CKD trial showed a safety profile that was consistent with the previously observed safety profile of Forxiga and this information was provided in the statement 'The overall safety profile of Forxiga in patients with CKD was consistent with the known safety profile of Forxiga'. Whilst it was not possible to list all the known side-effects of the medicine on a banner advertisement, this statement referenced the SPC and there was also a clear single click link to prescribing information and adverse event reporting provided on every frame of the advertisement.

AstraZeneca submitted it had provided sufficient information and opportunity for the healthcare professional to find and understand the warnings and precautions and side-effect profile associated with Forxiga in order to make an informed prescribing decision on the appropriate use of Forxiga. Therefore, AstraZeneca denied the alleged breaches of Clauses 5.1, 6.1 and 11.2.

7 Concern with claim 'Forxiga slows eGFR decline and saves lives in CKD patients with T2D vs placebo on top of standard care'

AstraZeneca stated that the results from the DAPA-CKD trial showed that in patients with CKD, Forxiga vs placebo on top of standard of care significantly reduced the primary composite endpoint of ≥50% sustained decline in eGFR, reaching end-stage kidney disease and renal or CV death (HR 0.61 p<0.001). Furthermore these results were consistent in those with and without T2D. In a key secondary outcome, Forxiga also reduced the risk of all-cause mortality (HR 0.69, p<0.004), a result again that was consistent in both those with and without type 2 diabetes. The DECLARE-TIMI 58 study which studied type 2 diabetic patients taking Forxiga vs placebo on top of standard of care, showed a reduction in the secondary composite of a sustained confirmed ≥40% decrease in eGFR to eGFR <60 mL/min/1.73 m^2 and/or end-stage kidney disease (dialysis ≥ 90 days or kidney transplantation, sustained confirmed eGFR < 15 mL/min/1.73 m^2) and/or renal or cardiovascular death (HR 0.76, p<0.001). This was a nominal finding due to hierarchical testing, however the result was consistent with the results observed in the DAPA-CKD trial. AstraZeneca submitted that there was sufficient context provided in the claim which was consistent with SPC and not misleading. Therefore, AstraZeneca denied the alleged breaches of Clauses 5.1 and 6.1.

Based on the information provided above, AstraZeneca was confident that all relevant information was included, and that the claims made concerning Forxiga were neither exaggerated nor misleading.

Therefore, AstraZeneca strongly denied all the alleged breaches of the Code, including Clause 2.

Summary

It was AstraZeneca's position that, given the information provided above, the claims in the banner advertisements were consistent with the SPC. There were multiple links to prescribing information and to the AstraZeneca website: these provide sufficient information and context for a healthcare professional to make an informed prescribing decision for their patients. Therefore, the information was not misleading and did not put patient safety at risk. AstraZeneca categorically denied all allegations made by the complainant and any suggestions that any clauses of the Code had been breached.

AstraZeneca subscribed fully to the high ethical and moral spirit of the Code and took its responsibilities under the Code very seriously.

PANEL RULING

The Panel noted that AstraZeneca's response was in a different order to the complaint. The Panel decided to consider the allegations in the order raised by the complainant.

The Panel noted that the banner advertisement consisted of four frames which were displayed for between 6.5 and 8.5 seconds each. The first frame included Forxiga's indication and stated 'NEW INDICATION FORXIGA (dapagliflozin) is now approved for the treatment of CKD in patients with and without T2D'; the second frame included 'FORXIGA slows eGFR decline and saves lives in CKD patients with T2D vs. placebo on top of standard of care'; the third frame included 'Start on 10 mg FORXIGA, stay on 10 mg FORXIGA. Initiate Forxiga in CKD patients with eGFR ≥15 mL/min/1.73mg*' followed by the footnote '*In patients with severe hepatic impairment, a starting dose of 5 mg is recommended. If well tolerated, the dose may be increased to 10 mg'; the fourth and final frame included the statement 'The overall safety profile of FORXIGA in patients with CKD was consistent with the known safety profile of FORXIGA' along with the button labelled 'Discover the data now'.

The Panel noted that the complainant had not referred to the first frame of the advertisement: he/she only commented on the following three frames. In the Panel's view, the first frame added important context to the advertisement as a whole. The four frames ie the linked parts were considered as one advertisement as set out in the supplementary information to Clause 12.1 Advertisements in Electronic Journals.

A Claims for Forxiga's starting dose (point 2 in AstraZeneca's response)

In relation to the allegation that the claim to start on 10mg Forxiga was without qualification except in relation to severe liver failure, the Panel considered that the information on dosing in the third frame of the advertisement, was in line with the Forxiga SPC which required a lower starting dose of 5mg in patient with severe hepatic impairment. The Panel noted AstraZeneca's submission that there were no requirements to reduce the dose for patients with CKD or based on renal function and/or age. The Panel did not consider that the complainant had established that the claim 'Start on 10 mg FORXIGA, stay on 10 mg FORXIGA', without reference to dosing in CKD, was misleading nor inconsistent with the particulars listed in the Forxiga SPC as

alleged and no breach of Clauses 6.1 and 11.2 were ruled. The Panel thus ruled no breach of Clause 5.1 accordingly.

B Use of Forxiga in Chronic Kidney Disease (CKD) (point 3 in AstraZeneca's response)

Whilst the Panel noted that the CKD data referred to in the SPC, under Section 4.4 Special warnings and precautions for use, was clear that there was no experience of the medicine for the treatment of CKD in patients without diabetes who did not have albuminuria, the Panel noted that Forxiga was 'indicated in adults for the treatment of chronic kidney disease', in addition to its indications for type 2 diabetes mellitus and heart failure (Section 4.1 of the SPC). The Panel, noting Forxiga's broad indication in CKD, did not consider that omitting a statement about evidence in CKD patients without diabetes who did not have albuminuria meant that the claims in relation to CKD were inconsistent with the SPC and were misleading in this regard as alleged. The Panel therefore ruled no breach of Clauses 11.2 and 6.1. Nor had the company failed to maintain high standards in this regard and no breach of Clause 5.1 was ruled.

C Use of Forxiga in adults (point 4 in AstraZeneca's response)

In relation to the allegation that it was not clear that Forxiga was only to be used in adults, the Panel noted that the complainant only provided screenshots of frames 2-4, as described above, and appeared not to have seen the first frame of the advertisement where the indication was given, stating that the medicine was for use in adults. The Panel agreed with AstraZeneca's submission that there was no implication from the images used, which were of a middle aged man, that the medicine was to be used in children. In the Panel's view, neither the advertisement as a whole or the four individual frames appeared to be inconsistent with the SPC in this regard. The Panel therefore ruled no breach of Clause 11.2 and consequently no breach of Clause 5.1.

D Evidence in patients with eGFR <25 mls/min and alleged failure to highlight important side-effects like hypoglycemia and DKA (points 5 and 6 in AstraZeneca's response)

The Panel noted the Forxiga SPC, Section 4.2, special populations, Renal impairment, stated that no dose adjustment was required based on renal function but it was not recommended to initiate treatment with in patients with an estimated glomerular filtration rate (eGFR) < 15 mL/min/1.73m^2. The Panel noted that frame 3 referred to initiating Forxiga in CKD patients with eGFR ≥15 mL/min/1.73m^2 which it considered was not inconsistent with the Forxiga SPC. Thus the Panel ruled no breach of Clause 11.2.

With regard to the allegation that many important side-effects were not highlighted, such as hypoglycemia and DKA, the Panel noted AstraZeneca's submission that Forxiga's safety profile had been well-established, particularly in patients with type 2 diabetes, and the results from the DAPA-CKD trial showed that 'The overall safety profile of Forxiga in patients with CKD was consistent with the known safety profile of Forxiga'. AstraZeneca submitted it was not possible to list all known side-effects on a banner advert but there was reference to the SPC and a clear single click link to prescribing information and adverse event reporting provided on each frame.

The Panel did not consider, in the context of the four frames which made up the advertisement and in the particular circumstances of this case, that it was misleading or otherwise an unfair

reflection to not have listed Forxiga's side-effects on the advertisement at issue and thus ruled no breach of Clause 6.1.

The Panel noted its rulings of no breaches of Clauses 11.2 and 6.1 above and did not consider that AstraZeneca had failed to maintain high standards. No breach of Clause 5.1 was ruled.

E Alleged failure to be clear as to what Forxiga was (point 1 in AstraZeneca's response)

The Panel considered that the allegation in this regard was not entirely clear. The complainant referred to having to scroll down the material to see the non-proprietary name. Although Clause 12.3 had not been raised by the case preparation manager, AstraZeneca responded in relation to Clause 12.3 which, *inter alia,* required that the non-proprietary name of a medicine, or a list of the active ingredients using approved names where such exist, to appear immediately adjacent to the most prominent display of the brand name although such detail was not provided by the complainant. AstraZeneca's response was that there was no breach of Clause 5.1. The Panel decided to consider this matter under Clause 5.1.

The Panel noted that each of the four frames included a prominent logo which included the brand name, Forxiga, directly beneath which was the non-proprietary name, dapagliflozin. The Panel noted that the first frame of the banner advertisement started with the brand name, the non-proprietary name and the indication followed by a claim which also included the non-proprietary name in brackets. The claims on frames 2, 3 and 4 used only the brand name but nonetheless the non-proprietary name was included in the logo on each frame.

The Panel considered that the complainant had not shown, on the balance of probabilities, that the non-proprietary name was not clear in the advertisement and thus ruled no breach of Clause 5.1 in this regard.

F Claim that Forxiga slows eGFR decline (point 7 in AstraZeneca's response)

With regard to the claim in the second frame, 'FORXIGA slows eGFR decline and saves lives in CKD patients with T2D vs. placebo on top of standard of care', the Panel noted the complainant's allegation that there was no context around the study. The Panel noted that that another frame, the final frame, appeared to link to a page providing further information on the study, via clicking on through the button 'Discover the data now'. The Panel did not consider that the complainant had shown that the alleged lack of context in relation to the trial population and the measured effect was, on the balance of probabilities, in breach of the Clause 6.1 of the Code and thus ruled no breach of that clause.

With regard to the allegation that it was not clear if the reference to CKD was related to previous banners or only T2D diabetes, the Panel noted that the claim 'FORXIGA slows eGFR decline and saves lives in CKD patients with T2D vs. placebo on top of standard of care' made reference to T2D within the claim itself. Further, in relation to the lack of reference that the DAPA-CKD trial excluded children and people without albuminuria, the Panel noted its comments in under points B and C above. No breach of Clause 6.1 was ruled.

The Panel, noting its rulings of no breach of Clause 6.1 above did not consider that AstraZeneca had failed to maintain high standards and ruled no breach of Clause 5.1.

G Overall consideration of Clause 2

The Panel, noting its rulings of no breach of the Code above, therefore ruled no breach of Clause 2.

Complaint received **15 March 2022**

Case completed **16 December 2022**