NO BREACH OF THE CODE

CASE AUTH/3459/1/21

COMPLAINANT v NAPP

Invokana webcast

A contactable complainant who described him/herself as a concerned UK health professional complained about the promotion of Invokana (canagliflozin) by Napp Pharmaceuticals Limited. The material at issue was an advertisement for a forthcoming promotional Invokana webcast hosted on the Diabetes On The Net website (ref UK-INV-2000106, January 2021).

Invokana, a sodium glucose co-transporter-2 (SGLT2) inhibitor, was indicated for the treatment of certain adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise.

The complainant drew attention to, and provided a link to, a webpage on Diabetes On the Net advertising an upcoming promotional webcast entitled 'SGLT2 inhibitors: Slowing of chronic kidney disease progression in type 2 diabetes'.

The complainant stated that although the slogan was 'protect the kidney to protect the heart', Invokana did not have any licensed indication to have a reno-protective indication. The complainant noted that the licensed indication of Invokana had no mention of reno-protection and in that regard the complainant alleged off-licence promotion.

The complainant stated that there was no mention that Invokana was not to be started in patients with an estimated glomerular filtration rate (eGFR) under 30, so again was off-licence promotion and a potential patient safety matter. The webpage did not provide adequate safety information, such as how the dose should be reduced or indeed that treatment should not be started in certain severities of renal failure - that was extremely salient in a website that purported a reno-protective effect of Invokana.

The complainant noted that it was not stated that Invokana was for adults only, so again, was off-licence promotion.

The complainant referred in particular to session 2 of the webcast which he/she stated appeared to go over reno-protection in more detail. The session was entitled 'Renoprotective effects of SGLT2 inhibitors. Evidence and Mechanisms' and the complainant noted that one of the topics to be covered was 'Invokana license [sic] extension as a result of CREDENCE'. [CREDENCE was Canagliflozin and Renal Endpoints in Diabetes with Established Nephropathy Clinical Evaluation]. The complainant stated that he/she could find no evidence of a licence extension on either the prescribing information provided, the electronic Medicines Compendium (eMC) nor easily available on the European Medicines Agency (EMA) website. The complainant

alleged that either Napp was promoting off-licence or had failed to update its prescribing information with key information.

The detailed response from Napp is given below.

The Panel noted that the complaint was submitted before the webcast was shown and so the webcast itself was not considered by the Panel.

The Panel noted that the Code required that the promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its SPC. The Panel considered that it was not unacceptable for companies to promote the additional benefits that might be afforded from treatment with a particular medicine provided that those benefits were clearly set within the context of the licensed indication. The primary reason to prescribe must be made clear.

The Panel noted from Section 4.1 of the Invokana 100mg SPC that the licensed indication was:

> **'for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise**
>
> **- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications**
>
> **- in addition to other medicinal products for the treatment of diabetes**

For study results with respect to combination of therapies, effects on glycaemic control, cardiovascular and renal events, and the populations studied, see sections 4.4, 4.5 and 5.1.'

Section 5.1 of the SPC stated, below a heading of 'Clinical efficacy and safety', that improvement in glycaemic control and reduction in cardiovascular and renal morbidity and mortality were integral parts of the treatment of type 2 diabetes.

The Panel noted Napp's submission that that the EMA considered that 'treatment of patients with insufficiently controlled type 2 diabetes' was not limited to glycaemic control but included other treatment goals including the prevention of worsening of diabetic complications and the target population (patients with DKD) were not excluded from the current indication. The EMA further considered that both the aim of treatment as well as the target population of the newly proposed indication (treatment of stage 2 or 3 diabetic kidney disease in adults with type 2 diabetes mellitus) was already covered by the approved indication (treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise). Therefore, the separate indication for type 2 diabetes patients with diabetic kidney disease was not warranted.

The Panel noted that as a result of the variation, Sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the Invokana SPC were updated based on the data obtained with the CREDENCE study. The Panel further noted that Section 4.2 stated beneath the heading 'Renal impairment' that for treatment of diabetic kidney disease as add on to standard of care (eg ACE-inhibitors

or ARBs), a dose of 100mg canagliflozin once daily should be used and the reader was referred to a dosage adjustment table below based on the patient's eGFR or CrCl.

In the Panel's view, it was thus not unacceptable to refer to the renal benefits of Invokana in type 2 diabetes patients; it appeared to be an integral part of the treatment of type 2 diabetes.

The Panel noted Napp's submission that 'protect the kidney to protect the heart' was not mentioned in the advertisement in question, nor did it appear in any of the related materials associated with the promotional webcast. The Panel therefore ruled no breaches of the Code in relation to the slogan.

The Panel considered that the information advertising the upcoming webcast regarding Invokana and the slowing of chronic kidney disease was clearly set within the context of the treatment of type 2 diabetes. The Panel considered that the complainant had not established, on the balance of probabilities, that the webpage promoted Invokana in a manner that was not in accordance with the terms of its marketing authorisation or was inconsistent with its SPC with regards to its renal benefits in type 2 diabetes patients or misleading as alleged. No breaches of the Code were ruled.

With regard to the complainant being unable to find reference to a licence extension in the prescribing information, on the eMC or the EMA website, the Panel noted Napp's submission that the prescribing information was up-to-date, and as detailed above contained information from the SPC related to the dosage and method of use of Invokana 100mg relevant to the extended indication to treat diabetic kidney disease in type 2 diabetic patients with severe albuminuria (urinary albumin:creatinine ratio >30mg/mmol (>300mg/g)) as add on to standard of care (eg ACE inhibitors or angiotensin receptor blockers). The ePAR detailed the recommendations of the CHMP for updates to be made to the SPC to modify the therapeutic indication for Invokana based upon the renal clinical efficacy and safety data from the CREDENCE study. That study provided data on the use of Invokana in addition to standard of care in diabetic kidney disease patients. The Panel, therefore ruled no breaches of the Code in relation the complainant's allegation in this regard.

With regard to the complainant's allegation that the website did not give any details as to the dose of Invokana to be used in renal failure, the Panel noted that the link provided by the complainant was to a webpage which promoted the webcast. Whilst the screenshot provided by the complainant did not provide a link to the prescribing information, what appeared to be the complete webpage provided by Napp and screenshots downloaded by the case preparation manager from the link provided by the complainant did. The prescribing information clearly set out the dosage recommendations for the use of Invokana in varying degrees of renal failure and that patients with an eGFR of less than 30ml/min/1.73m2 should not be initiated on treatment although if already initiated, treatment with 100mg could continue in such patients. The Panel noted the audience the webcast was aimed at and that Invokana (an SGLT2 inhibitor) had been in use since 2013 when the dosage in renal impairment was more restrictive than currently and thus was an area where health professionals would take extra care. The Panel did not consider that the webpage advertising the webcast was misleading as alleged. Information on the safety and the adverse effects of Invokana, including the dosage adjustment

recommendations in renal impairment, was included in the prescribing information. No breaches of the Code were ruled.

With regard to the complainant's allegation that the webpages did not mention that Invokana was only for adults, the Panel, however, noted the prescribing information clearly stated the licensed indication for Invokana ie for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise.

There was no specific mention or impression given on the webpage that Invokana was licensed to treat children with type 2 diabetes. In the Panel's view, although it might have been helpful for the indication to have been included on the webpage advertising the webcast, it was included within the linked prescribing information. The Panel did not consider that the webpage was misleading such that it promoted the use of Invokana in children as alleged. No breaches of the Code were ruled.

The Panel noted its rulings and comments above and considered that there was no evidence that high standards had not been maintained. No breach of the Code was ruled. The Panel consequently ruled no breach of Clause 2.

A contactable complainant who described him/herself as a concerned UK health professional complained about the promotion of Invokana (canagliflozin) by Napp Pharmaceuticals Limited. The material at issue was an advertisement for a forthcoming promotional Invokana webcast hosted on the Diabetes On The Net website (ref UK-INV-2000106, January 2021).

Invokana, a sodium glucose co-transporter-2 (SGLT2) inhibitor, was indicated for the treatment of certain adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise.

Section 4.1 of the Invokana summary of product characteristics (SPC) (Therapeutic indications) also referred readers to Sections 4.4, 4.5 and 5.1 for study results on glycaemic control, renal events and cardiovascular events. Under a heading of 'Clinical efficacy and safety' in Section 5.1, it was stated that improvement in glycaemic control and reduction of cardiovascular and renal morbidity and mortality were integral parts of the treatment of type 2 diabetes.

COMPLAINT

The complainant drew attention to, and provided a link to, a webpage on Diabetes On the Net advertising an upcoming promotional webcast entitled 'SGLT2 inhibitors: Slowing of chronic kidney disease progression in type 2 diabetes'.

The complainant stated that although the slogan was 'protect the kidney to protect the heart', Invokana did not have any licensed indication to have a reno-protective indication. The complainant noted that the licensed indication of Invokana had no mention of reno-protection and in that regard the complainant alleged off-licence promotion.

The complainant stated that there was no mention that Invokana was not to be started in patients with an estimated glomerular filtration rate (eGFR) under 30, so again was off-licence promotion and a potential patient safety matter. The webpage did not provide adequate safety information, such as how the dose should be reduced or indeed that treatment should not be

started in certain severities of renal failure - that was extremely salient in a website that purported a reno-protective effect of Invokana.

The complainant noted that it was not stated that Invokana was for adults only, so again, was off-licence promotion.

The complainant provided screenshots from the webpage which detailed the agenda and referred in particular to session 2 of the webcast which he/she stated appeared to go over reno-protection in more detail. The session was entitled 'Renoprotective effects of SGLT2 inhibitors. Evidence and Mechanisms' and the complainant noted that one of the topics to be covered was 'Invokana license [sic] extension as a result of CREDENCE'. [CREDENCE was Canagliflozin and Renal Endpoints in Diabetes with Established Nephropathy Clinical Evaluation]. The complainant stated that he/she could find no evidence of a licence extension on either the prescribing information provided on the web page, the electronic Medicines Compendium (eMC) nor easily available on the European Medicines Agency (EMA) website. The complainant alleged that either Napp was promoting off-licence or had failed to update its prescribing information with key information.

When writing to Napp, the Authority asked it to consider the requirements of Clauses 3.2 and 7.2 in relation to the allegations regarding promoting unlicensed indications and off-licence and the licence extension and Clauses 7.2 and 7.9 in relation to the allegations about reducing the dose or not using the product in certain severities of renal failure. The company was also asked to bear in mind the requirements of Clauses 9.1 and 2.

RESPONSE

Napp noted the complainant's reference to off-licence promotion with regard to the slogan 'protect the kidney to protect the heart' and his/her submission that the licensed indication for Invokana made no mention of renoprotection and was thus off-licence promotion. Napp submitted, however, that 'protect the kidney to protect the heart*'* was not mentioned in the advertisement in question, nor did it appear in any of the related materials associated with the promotional webcast.

With respect to the licensed indication for Invokana, Napp explained that on 2 July 2020 the European Commission (EC) approved the extension of the indication of Invokana 100mg to include the renal outcome data from the CREDENCE trial; a dedicated renal outcomes trial in patients with diabetic kidney disease and type 2 diabetes mellitus. The results of the trial were considered robust and clinically relevant. The European Medicines Agency (EMA) granted an indication extension to include the management of diabetic kidney disease. A separate indication for the treatment of diabetic kidney disease in Section 4.1 of the SPC was not considered warranted since the already approved indication 'treatment of patients with insufficiently controlled type 2 diabetes' was considered to cover both the aim of the treatment, which was not limited to glycaemic control but covered as well other treatment goals including the prevention of worsening of diabetic complications and the target population (patients with diabetic kidney disease) were not excluded from the current indication. The indication extension for insufficiently controlled type 2 diabetes now included the management of diabetic kidney disease for Invokana. Napp provided a copy of the May 2020 Invokana European Public Assessment (ePAR) detailing that and referred in particular to page 63, section 2.4.3, page 93, sections 3.7.3 and 3.8 and page 94, section 4.

Subsequently, Invokana 100mg was now approved with an extended indication to treat diabetic kidney disease in patients with type 2 diabetes mellitus with severe albuminuria (urinary albumin:creatinine ratio >30mg/mmol (>300mg/g)) as add on to standard of care (eg ACE inhibitors or angiotensin receptor blockers). The Invokana 100mg SPC (copy provided) detailed that indication extension in Section 4.1 which now included 'renal events'. Section 4.2 (posology) of the SPC now also reflected that type 2 diabetics with an eGFR of ≥45 to <60ml/min/1.73m^2 could now be initiated on Invokana 100mg. In addition, type 2 diabetics with severe albuminuria (urinary albumin:creatinine ratio >30mg/mmol (>300mg/g)) and an eGFR ≥30ml/min/1.73m^2 could now be initiated on Invokana 100mg and maintained on treatment until dialysis or renal transplantation. Finally, the renal outcomes data from the CREDENCE trial were now incorporated within section 5.1 of the licence for Invokana. Napp therefore refuted breaches of Clauses 3.2 and 7.2 as Invokana 100mg had been advertised within its licensed indication; for the treatment of diabetic kidney disease in type 2 diabetics with severe albuminuria (urinary albumin:creatinine ratio >30mg/mmol (>300mg/g)) as add on to standard of care.

Napp noted that the complainant had stated that there was no mention that Invokana was not to be started in eGFR under 30ml/min/1.73m^2 and in doing so had referred to off-licence promotion and a potential patient safety matter. The complainant had also submitted that the web page did not provide adequate safety information, such as how the dose should be reduced or indeed that treatment should not be started in certain severities of renal failure - which was extremely salient in a website that was purporting a reno-protective effect of the product.

With regard to the above, Napp noted that the prescribing information could be found at the top of the web page, in which the promotional webcast was advertised, as bold blue text within a yellow rectangular box. This was prominently displayed, and a single click link on the webpage on which the promotional Napp webcast was advertised was in line with the requirements of Clause 4 of the Code for promotional materials. The prescribing information (copy provided) contained abbreviated information from the SPC relating to the dosage and method of use of Invokana relevant to dosage adjustment recommendations in renal impairment. As tabulated in the 'Dosage & Administration' section of the prescribing information, for patients with an eGFR <30ml/min/1.73m^2, Invokana could not be initiated but might be continued with a dosage of 100mg if the patient was already taking it. Napp therefore refuted a breach of Clause 7.2 as the claims purporting to the reno-protective effects of Invokana were substantiated and were not misleading and were consistent with the SPC. Napp also refuted a breach of Clause 7.9 as the information on the safety and the adverse effects of Invokana, including the dosage adjustment recommendations in renal impairment, was clearly included in the prescribing information. With regard to the complainant being unable to find reference to a licence extension in the prescribing information, on the eMC or the EMA website, Napp submitted that the prescribing information provided on the web page was up-to-date, and as detailed above it contained information from the SPC related to the dosage and method of use of Invokana 100mg relevant to the extended indication to treat diabetic kidney disease in type 2 diabetic patients with severe albuminuria (urinary albumin:creatinine ratio >30mg/mmol (>300mg/g)) as add on to standard of care (eg ACE inhibitors or angiotensin receptor blockers). Although Napp would not expect health professionals to need to refer to the Invokana ePAR to find information about the licence, dosage and safety of Invokana 100mg as the prescribing information was prominently displayed on the webpage and contained all this relevant information, it nonetheless provided a link to the ePAR which it stated was readily accessible on the EMA website. The ePAR detailed the recommendations of the Committee for Medicinal Products for Human Use (CHMP) for updates to be made to Sections 4.1, 4.2, 4.4, 4.8, 5.1 and 6.6 of the SPC to modify the therapeutic

indication for Invokana based upon the renal clinical efficacy and safety data from the CREDENCE study. That study provided data on the use of Invokana in addition to standard of care in diabetic kidney disease patients and as such that was reflected in the Invokana licence, which had been appropriately and accurately represented on the promotional registration webpage for the promotional webcast. Napp refuted breaches of Clauses 3.2 and 7.2.

In summary, Napp submitted that it had explained how it had maintained high standards (Clause 9.1) and made clear why it refuted breaches of Clauses 3.2, 7.2 and 7.9. Napp firmly believed that it had upheld the highest standards and had not brought discredit upon, or reduced confidence in, the pharmaceutical industry, as per Clause 2 and therefore refuted a breach of Clause 2.

PANEL RULING

The Panel noted that the complainant provided a link to a webpage (ref UK-INV-2000106) on the Diabetes On the Net website which advertised an upcoming promotional Invokana webcast and invited health professionals to register for it. The Panel noted that the webpage included a link to the canagliflozin prescribing information and what looked like an opening slide of the webcast which included the title of the presentation 'SGLT2 inhibitors: Slowing of chronic kidney disease progression in type 2 diabetes'. The Panel noted that the webpage stated that the Napp sponsored webcast was now open for registration. It introduced the webcast by stating that diabetic kidney disease (DKD) was of increasing importance to clinicians involved on the care and management of people with type 2 diabetes, and early detection was essential to improve outcomes. The 45 minute webcast followed by a 15 minute live Q&A session was to be broadcast at two different times on 28 January 2021 and was described as being developed to examine the latest guidance discussed in a recently published consensus statement and that attending would provide insights into: How regular renal reviews and monitoring of urine albumin to creatinine ratio (ACR) and estimated glomerular filtration rate (eGFR) were essential in slowing progression to end stage kidney disease; the reno-protective effects of SGLT2 inhibitors drawing on the evidence from recent studies such as CREDENCE and the international guidelines on the use of SGLT2 inhibitors and implications for clinical practice. The agenda listed 3 sessions by 3 different speakers including two GPs and one Professor of medicine with interests in diabetes followed by a fourth live Q&A session. According to the agenda session 1 (Introduction to DKD and SGLT2 inhibitors and the importance of regular reviews in managing DKD) would cover, *inter alia*, SGLT2 inhibitors in the management of type 2 diabetes, defining DKD and improving patients DKD outcomes. Session 2 (Renoprotective effects of SGLT2 inhibitors: Evidence and mechanisms) would cover, *inter alia*, renal results for the cardiovascular trials with SGLT2 inhibitors, what the CREDENCE trial meant for patients with renal disease; Invokana's licence extension, and the SGLT2 inhibitor mechanism of action and the mechanism of renal protection. Session 3 (Guidelines in using SGLT2 inhibitors and implications for clinical practice) would cover various guidelines and best practice examples of how SGLT2 inhibitors had been incorporated into local guidelines and could improve patient care.

The Panel noted that the complaint was submitted before the webcast was shown and so the webcast itself was not considered by the Panel.

The Panel noted that Clause 3.2 required that the promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its SPC. The Panel considered that it was not unacceptable for companies

to promote the additional benefits that might be afforded from treatment with a particular medicine provided that those benefits were clearly set within the context of the licensed indication. The primary reason to prescribe must be made clear.

The Panel noted from Section 4.1 of the Invokana 100mg SPC that the licensed indication was:

> 'for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise
>
> - as monotherapy when metformin is considered inappropriate due to intolerance or contraindications
>
> - in addition to other medicinal products for the treatment of diabetes

For study results with respect to combination of therapies, effects on glycaemic control, cardiovascular and renal events, and the populations studied, see sections 4.4, 4.5 and 5.1.'

In section 5.1 of the SPC it was stated, below a heading of 'Clinical efficacy and safety', that improvement in glycaemic control and reduction in cardiovascular and renal morbidity and mortality were integral parts of the treatment of type 2 diabetes.

The Panel noted Napp's submission that that the EMA considered that 'treatment of patients with insufficiently controlled type 2 diabetes' was not limited to glycaemic control but included other treatment goals including the prevention of worsening of diabetic complications and the target population (patients with DKD) were not excluded from the current indication. The EMA further considered that both the aim of treatment as well as the target population of the newly proposed indication (treatment of stage 2 or 3 diabetic kidney disease in adults with type 2 diabetes mellitus) was already covered by the approved indication (treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise). Therefore, the separate indication for type 2 diabetes patients with diabetic kidney disease was not warranted.

The Panel noted that as a result of the variation, Sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the Invokana SPC were updated based on the data obtained with the CREDENCE study. The Panel further noted that Section 4.2 stated beneath the heading 'Renal impairment' that for treatment of diabetic kidney disease as add on to standard of care (eg ACE-inhibitors or ARBs), a dose of 100mg canagliflozin once daily should be used and the reader was referred to a dosage adjustment table below based on the patient's eGFR or CrCl.

In the Panel's view, it was thus not unacceptable to refer to the renal benefits of Invokana in type 2 diabetes patients; it appeared to be an integral part of the treatment of type 2 diabetes.

The Panel noted that the complainant referred to the slogan 'protect the kidney to protect the heart' when alleging the off-licence promotion of Invokana as the licensed indication of canagliflozin had no mention of reno-protection. The complainant further referred to a general promotion of the reno-protective effect of the product and session 2 of the webcast covering the topic in greater detail.

The Panel noted Napp's submission that 'protect the kidney to protect the heart' was not mentioned in the advertisement in question, nor did it appear in any of the related materials

associated with the promotional webcast. The Panel therefore ruled no breach of Clauses 3.2 and 7.2 in relation to the slogan.

The Panel considered, however, that the information on the webpage advertising the upcoming webcast regarding Invokana and the slowing of chronic kidney disease including session 2 was clearly set within the context of the treatment of type 2 diabetes. The Panel considered that the complainant bore the burden of proof and had not established, on the balance of probabilities, that the webpage promoted Invokana in a manner that was not in accordance with the terms of its marketing authorisation or was inconsistent with its SPC with regards to its renal benefits in type 2 diabetes patients as alleged. No breach of Clause 3.2 was ruled. Nor did it consider that the webpage was misleading in that regard and the Panel ruled no breach of Clause 7.2.

With regard to the complainant being unable to find reference to a licence extension in the prescribing information, on the eMC or the EMA website, the Panel noted Napp's submission that the prescribing information provided as a link from the webpages was up-to-date, and as detailed above contained information from the SPC related to the dosage and method of use of Invokana 100mg relevant to the extended indication to treat diabetic kidney disease in type 2 diabetic patients with severe albuminuria (urinary albumin:creatinine ratio >30mg/mmol (>300mg/g)) as add on to standard of care (eg ACE inhibitors or angiotensin receptor blockers). The ePAR detailed the recommendations of the CHMP for updates to be made to Sections 4.1, 4.2, 4.4, 4.8, 5.1 and 6.6 of the SPC to modify the therapeutic indication for Invokana based upon the renal clinical efficacy and safety data from the CREDENCE study. That study provided data on the use of Invokana in addition to standard of care in diabetic kidney disease patients and as such that was reflected in the Invokana licence. The Panel, therefore ruled no breach of Clauses 3.2 and 7.2 in relation the complainant's allegation in this regard.

With regard to the complainant's allegation that the website did not give any details as to the dose of Invokana to be used in renal failure, the Panel noted that the link provided by the complainant was to a webpage which promoted the webcast. Whilst the screenshot provided by the complainant did not provide a link to the prescribing information, what appeared to be the complete webpage provided by Napp and screenshots downloaded by the case preparation manager from the link provided by the complainant did – there was a 'button' in the top right-hand corner marked 'Prescribing information for canagliflozin can be found here'. The Panel noted that the prescribing information clearly set out the dosage recommendations for the use of Invokana in varying degrees of renal failure and that patients with an eGFR of less than 30ml/min/1.73m^2 should not be initiated on treatment although if already initiated, treatment with 100mg could continue in such patients. The Panel noted the audience the webcast was aimed at and that Invokana (an SGLT2 inhibitor) had been in use since 2013 when the dosage in renal impairment was more restrictive than currently and thus was an area where health professionals would take extra care. The Panel noting its comments above did not consider that, particularly given its purpose and content, the webpage advertising the webcast was misleading as alleged. No breach of Clause 7.2 was ruled.

The Panel noted that Clause 7.9 stated that information and claims about adverse reactions must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product had no adverse reactions, toxic hazards or risks of addiction or dependency. The word 'safe' must not be used without qualification. The Panel did not consider that the complainant had raised an allegation in that regard. Nonetheless, the Panel noted Napp's submission that the information on the safety and the adverse effects of Invokana,

including the dosage adjustment recommendations in renal impairment, was included in the prescribing information. The Panel therefore ruled no breach of Clause 7.9.

The Panel noted the complainant's allegation that the webpages did not mention that Invokana was only for adults. The Panel noted that Napp had made no submission in that regard. The Panel, however, noted the link to the prescribing information in the top right-hand corner of the webpage advertising the webcast. The prescribing information clearly stated the licensed indication for Invokana ie for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise.

The Panel noted that there was no specific mention or impression given on the webpage that Invokana was licensed to treat children with type 2 diabetes. In the Panel's view, although it might have been helpful for the indication to have been included on the webpage advertising the webcast, it was included within the linked prescribing information. The Panel noted the content and layout of the webpage at issue and did not consider that the webpage was misleading such that it promoted the use of Invokana in children as alleged. No breach of Clauses 3.2 and 7.2 were ruled.

The Panel noted its rulings and comments above and considered that there was no evidence that high standards had not been maintained. No breach of Clause 9.1 was ruled. The Panel consequently ruled no breach of Clause 2.

Complaint received **19 January 2021**

Case completed **19 July 2021**