CLINICAL COMMISIONING GROUP EMPLOYEE v NOVO NORDISK

Conduct of a representative

The head of prescribing and medicines management at a clinical commissioning group (CCG), complained about the promotion of Victoza (liraglutide) by a named Novo Nordisk representative. Victoza was used in adults with insufficiently controlled type 2 diabetes.

The complainant alleged that the representative asked a receptionist to write a note on promotional information for Victoza to inform GPs that the product could be used in estimated glomerular filtration rate (eGFR) <15 and told the receptionist that he/she could not write this him/herself. The complainant provided a scanned copy of the handwritten note and alleged that the statement in question was outside the product's licence.

The detailed response from Novo Nordisk is given below.

The Panel noted the representative denied that he/she had asked the receptionist to write the note. The Panel noted that the parties' accounts differed. The Panel noted the difficulty in dealing with complaints based on one party's word against the other; it was often impossible in such circumstances to determine precisely what had happened. A complainant had the burden of proving his/her complaint on the balance of probabilities. The Panel noted, however, that a high degree of dissatisfaction was usually required before an individual was moved to submit a formal complaint.

The Panel noted that section 4.2 of the Victoza Summary of Product Characteristics (SPC) included:

> **'Renal impairment**
> **No dose adjustment is required for patients with mild, moderate or severe renal impairment. There is no therapeutic experience in patients with end-stage renal disease, and Victoza is therefore not recommended for use in these patients (see sections 5.1 and 5.2).'**

The Panel noted that the Victoza SPC did not specifically define severe renal impairment or end-stage renal disease in terms of eGFR parameters. There was mention of creatine clearance in relation to renal impairment. The Panel noted Novo Nordisk's submission that severe renal impairment was characterised by an eGFR of 15-29 ml/min/1.73m^2 and that it did not advocate the use of Victoza in patients with end-stage renal disease which it stated was an eGFR <15.

The Panel noted that the handwritten note stated, 'can be used in eGFR 15' and not that Victoza could be used in eGFR <15, as alleged. In the Panel's view, an eGFR of 15 was likely to be considered the lower limit of severe renal impairment.

The Panel was concerned to note that when responding to the initial complaint Novo Nordisk had discovered that slides from a training course had referred to Victoza being used in patients with a eGFR down to less than 15 in error. Novo Nordisk explained that the slides were not read out verbatim but were used as a basis for a role play exercise and the presenters were very clear that Victoza could be used in patients with renal impairment down to an eGFR of 15ml/min/1.73m^2. It appeared that the slides were sent to the sales managers. It was not clear whether the slides had been circulated to the representatives. The Panel further noted Novo Nordisk's submission that this error was not reflected in other materials. According to Novo Nordisk the representative in question did not attend this training and his/her manager confirmed that he/she was very clear regarding eGFR and the use of Victoza.

Turning to the materials provided by the complainant, the Panel considered that the statement 'can be used in eGFR 15' was a product claim. It was not acceptable for a representative to handwrite claims on materials for health professionals or to instruct a receptionist to do so on his/her behalf. The Panel considered that the handwritten note did not appear to be inconsistent with the Victoza SPC. It was unlikely something would have been written on the Novo Nordisk materials without any discussion or prompt. However, the Panel did not consider that the complainant had proved on the balance of probabilities that the representative had asked the receptionist to write the note in question. The Panel therefore ruled no breach of the Code including Clause 2 based on the narrow allegation.

The head of prescribing and medicines management at a clinical commissioning group (CCG), complained about the promotion of Victoza (liraglutide) by a named Novo Nordisk representative. Victoza was used in adults with insufficiently controlled type 2 diabetes.

The scanned material provided by the complainant appeared to show four separate pieces of material placed on top of one another. There appeared to be an A4 sized Victoza leavepiece, on top of which was an A5 sized Tresiba (insulin degludec) leavepiece. On top of the Tresiba leavepiece was the business card of the representative in question. Below the business card, and also over the Tresiba leavepiece,

appeared a blank piece of material, the same size as the business card, with a handwritten note that stated, 'can be used in eGFR 15'. A handwritten arrow pointed to the statement with the text 'Added by receptionist on direction of rep'. Below the statement was further handwriting by the practice pharmacist, which stated 'Got receptionist to write this [date and centre name]'.

COMPLAINT

The complainant alleged that a named Novo Nordisk representative was observed on 8 August asking a receptionist to write a note on promotional information for Victoza to inform GPs that the product could be used in estimated glomerular filtration rate (eGFR) <15 and was heard telling the receptionist that he/she could not write this him/herself. The complainant noted that the statement in question was outside the product's licence. The complainant provided a scanned copy of the documents with additional notes added by one of the CCG's team of pharmacists.

When writing to Novo Nordisk, the Authority asked it to consider the requirements of Clauses 2, 3.2, 9.1 and 15.2 of the Code.

RESPONSE

Novo Nordisk submitted that the representative in question worked within primary care, promoting Victoza and Tresiba. The representative had passed the ABPI medical representatives examination, had completed all relevant training since joining the company and had been trained and validated on product knowledge before making calls on health professionals. Novo Nordisk stated that the representative denied the complainant's allegations and had confirmed that he/she did not ask a receptionist to write a note.

Novo Nordisk provided a summary of the face-to-face interview by a senior member of Novo Nordisk with the representative to ascertain the events of the date in question. The representative was told that a complaint had been made but was not told the details before the meeting. During the investigation the representative was shown the email from the complainant, after he/she had given his/her initial account of the day and the visit in question. The representative recounted that it was a speculative visit to confirm the name of the diabetes specialist nurse with the aim of booking an appointment at a later date. The representative recalled that on entering the practice there were two receptionists at the desk and two patients; he/she waited until the patients had been dealt with before approaching the desk. The representative spoke to one of the receptionists; the other receptionist and the patients had moved away, and he/she was not aware of anyone nearby or within earshot of his/her conversation with the receptionist. The representative asked the receptionist the name of the diabetes specialist nurse and if he/she could make an appointment. The representative was told that the centre did not make appointments to see representatives. The representative left the promotional literature and his/her business card and told the receptionist to ask the nurse to call him/her if he/she had any questions.

When shown the details of the complaint, the representative denied the allegation and stated that it would be inappropriate to ask a receptionist to write notes. The representative stated that he/she would only give such specific, product related information to a health professional in a promotional call.

During the interview, the representative was asked about discussions he/she might have had about the use of Victoza in patients with renal impairment. The representative responded that if having such discussions, he/she would usually use the terminology 'severe' renal impairment; when asked what that meant he/she stated this was 'eGFR 15'.

Novo Nordisk argued that the note on the photocopy provided by the complainant stated 'can be used in eGFR 15'; it did not state eGFR <15 as alleged. The summary of product characteristics (SPC) for Victoza stated:

> '4.2 Posology and method of administration
>
> Special populations
>
> Renal impairment
>
> No dose adjustment is required for patients with mild, moderate or severe renal impairment. There is no therapeutic experience in patients with end-stage renal disease, and Victoza is therefore not recommended for use in these patients (see sections 5.1 and 5.2).'

Novo Nordisk noted that severe renal impairment (chronic kidney disease stage G4) was characterised by an eGFR of 15-29 ml/min/1.73m^2.

Novo Nordisk submitted that based on the representative's testimony and considering his/her experience and training, it could not substantiate that the conversation between the representative and the receptionist took place as alleged. Novo Nordisk was confident that the representative had maintained high compliance standards and denied breaches of Clauses 2, 3.2, 9.1 and 15.2.

In response to a request for further information, Novo Nordisk submitted that a verbal briefing was given via teleconference to the diabetes sales representatives for the leavepiece UK/VT/0418/0186. Novo Nordisk further submitted that the SPC for Victoza was updated in July 2017 and included a change to section 4.2, special populations, to include wording regarding severe renal impairment. A member of the Novo Nordisk medical department briefed the Victoza representatives regarding all the changes to the SPC, including the update to section 4.2 about use in patients with renal impairment, over a web-based teleconference in August 2017. The presentation stated that there was no therapeutic experience in patients with end-stage renal disease and Victoza was therefore not recommended for use in those patients.

Novo Nordisk stated that in their initial training course (ITC) new representatives were trained on the diabetes therapy area, Novo Nordisk products and the focus that they would have as a sales person. During the ITC, representatives were trained on the relevant clinical data for Victoza which included a slide on use in patients with renal impairment. Training was delivered by a medical advisor who trained on the use of Victoza in patients with renal impairment as specified in the SPC and the eGFR and creatine clearance rates. In addition, during the ITC, new representatives were trained on the entire Victoza SPC in a workshop format and key sections of the SPC were analysed, including section 4.2, use of Victoza in special populations. There was a written validation following the training and one of the questions tested the representatives' knowledge about the use of Victoza in patients with renal impairment. Novo Nordisk confirmed that the representative in question had passed the validation.

Novo Nordisk explained that at a training course in July 2018 for, *inter alia*, the primary care sales force, a presentation regarding the strategy and campaign for Victoza (UK/VT/0618/0311), was delivered. The presentation included two profiles of patients who might benefit from Victoza. The focus was patients whose HbA1c levels were not on target with their current treatments. During the presentation, the presenters demonstrated how a sales call might be conducted using the patient profiles as examples. One of the profiles focused on a patient who might have renal impairment. Novo Nordisk submitted that whilst responding as above it discovered that the presentation in question had a typographical error. The slide stated 'Victoza offers not only reductions in HbA1c and weight and can be used in patients with a eGFR down to less than 15…'. Novo Nordisk submitted that the sentence did not make sense and was an unfortunate error that was not reflected in the other materials. Novo Nordisk explained that the slides for the role play were not read out verbatim by the two presenters but instead were used as a basis for the role play and the presenters were very clear during the role play that Victoza could be used in patients with renal impairment down to an eGFR of 15ml/min/1.73m^2. Novo Nordisk further explained that the representative in question did not attend this training. His/her manager had confirmed that the representative was very clear regarding the parameters of eGFR and the use of Victoza. Novo Nordisk stated that this aligned with the interview it carried out with the representative.

Novo Nordisk submitted that following the discovery of the typographical error, for the avoidance of doubt, a briefing document was prepared in August 2018 and sent to the sales teams to ensure that there was absolute clarity regarding the use of Victoza in patients with renal impairment.

Novo Nordisk concluded by stating that it did not advocate the use of Victoza in patients with end stage renal disease (eGFR <15) and all relevant staff had been trained and were clear on the use of Victoza in patients with renal impairment.

PANEL RULING

The Panel noted the complainant's allegation that a named Novo Nordisk representative asked a receptionist to write a note on promotional information for Victoza to inform GPs that the product could be used in eGFR<15 which was outside the product's licence. Novo Nordisk stated that the representative denied the allegations and confirmed that he/she had not asked the receptionist to write the note. The Panel noted that the parties' accounts differed. The Panel noted the difficulty in dealing with complaints based on one party's word against the other; it was often impossible in such circumstances to determine precisely what had happened. The introduction to the Constitution and Procedure stated that a complainant had the burden of proving their complaint on the balance of probabilities. The Panel noted, however, that a high degree of dissatisfaction was usually required before an individual was moved to submit a formal complaint.

The Panel considered from the scanned material provided by the complainant whether the handwritten note 'can be used in EGFR 15' was in relation to Victoza or Tresiba. The complainant referred to Victoza and therefore the Panel considered the statement in relation to Victoza.

The Panel noted that the Victoza SPC stated in section 4.2, under the sub-heading special populations:

> '*Renal impairment*
> No dose adjustment is required for patients with mild, moderate or severe renal impairment. There is no therapeutic experience in patients with end-stage renal disease, and Victoza is therefore not recommended for use in these patients (see sections 5.1 and 5.2).'

The Panel noted that the Victoza SPC did not specifically define severe renal impairment or end-stage renal disease in terms of eGFR parameters. There was mention of creatine clearance in relation to renal impairment. The Panel noted Novo Nordisk's submission that severe renal impairment was characterised by an eGFR of 15-29 ml/min/1.73m^2 and that it did not advocate the use of Victoza in patients with end-stage renal disease which it stated was an eGFR less than 15.

The Panel noted that the handwritten note stated, 'can be used in eGFR 15'. It did not state that the product could be used in eGFR less than 15, as alleged. In the Panel's view, an eGFR of 15 was likely to be considered the lower limit of severe renal impairment.

The Panel was concerned to note that Novo Nordisk discovered that slides from a training course held in July 2018 contained an error. One slide stated 'Victoza offers not only reductions in HbA1c and weight and can be used in patients with a eGFR down to less than 15 …'. Novo Nordisk explained that the slides were not read out verbatim but instead were used as a basis for a role play exercise and the presenters were very clear during the role

play that Victoza could be used in patients with renal impairment down to an eGFR of 15ml/min/1.73m^2. It appeared that the slides were sent to the sales managers. It was not clear whether the slides had been circulated to the representatives. The Panel further noted Novo Nordisk's submission that this error was not reflected in other materials. According to Novo Nordisk the representative in question did not attend the July 2018 training and his/her manager confirmed that he/she was very clear regarding the parameters of eGFR and the use of Victoza.

Turning to the materials provided by the complainant, the Panel considered that the statement 'can be used in eGFR 15' was a product claim. It was not acceptable for a representative to handwrite claims on materials for health professionals or to instruct a receptionist to do so on his/her behalf. The Panel considered that the handwritten note did not appear to be inconsistent with the Victoza SPC. The Panel noted that it was unlikely something would have been written on the Novo Nordisk materials without any discussion or prompt. However, the Panel did not consider that the complainant had proved on the balance of probabilities that the representative had asked the receptionist to write the note in question. The Panel therefore ruled no breach of Clauses 15.2, 3.2, 9.1 and 2 based on the narrow allegation.

Complaint received **15 August 2018**

Case completed **16 October 2018**