CASE AUTH/2951/4/17

CONSULTANT PHYSICIAN v SANOFI

Promotion of Toujeo

A consultant physician complained about promotion of Toujeo (insulin glargine) by Sanofi. The material at issue presented the outcome of Bailey *et al* 2016 and claimed that Toujeo provided more stable and more evenly distributed steady-state pharmacokinetic/pharmacodynamic (PK/PD) profiles compared with insulin degludec in type 1 diabetes. The interpretation of this data was that Toujeo in clinical practice would significantly reduce the incidence of hypoglycaemia particularly at night in patients with type 1 diabetes. If true this would be a significant clinical benefit.

The complainant stated that he was concerned that Sanofi had over interpreted the data and so he contacted the author of the study who noted that there were two studies comparing Toujeo and Tresiba (insulin degludec marketed by Novo Nordisk). The Sanofi study (Bailey *et al*) investigated 'within-day variability' the fluctuation of the metabolic effect in a treatment interval of 24 hours which (in absolute terms) was lower at a dose of 0.4U/kg, however, no differences were seen at 0.6U/kg. The other study, Heise *et al* investigated day-to-day variability and showed a significantly lower day-to-day variability for Tresiba. Heise *et al* also investigated within-day variability and came to a different conclusion comparing relative within-day variability (fluctuations corrected for the overall metabolic effect) which was higher for Tresiba than for Toujeo.

The author noted that both studies had some limitations however, Heise *et al* had a considerably higher statistical power as it enrolled more patients and did three clamps with either insulin in each individual. The author stated that further analyses was required to better understand the differences between the two studies.'

From this response the complainant considered that the promotional material at issue was at best, significantly incomplete and at worst, intentionally misleading in that it had only selectively quoted from the data.

The detailed response from Sanofi is given below.

The Panel noted that Bailey *et al* was a double-blind cross-over study to compare the steady state pharmacodynamic and pharmacokinetic profiles of Toujeo-300 and degludec-100 with two fixed once-daily dosing regimens (0.4U/kg and 0.6U/kg) in type 1 diabetics over 24 hours. The study authors concluded that Toujeo-300 resulted in less within day variability of the glucodynamic profile vs degludec-100 at a dose clinically relevant for type 1 diabetics (0.4U/kg/day). At the 0.4U/kg dose 6 hour fractions of glucodynamic activity were more evenly distributed over 24 hours with Toujeo-300 versus degludec-100. An overall more stable and more evenly distributed insulin exposure for Toujeo vs degludec-100 over 24 hours was observed in steady state at both dose levels (0.6U/kg/day and 0.4/kg/day). The within day variability of the glucodynamic profile with Toujeo-300 at the 0.6U/kg daily dose was not statistically significant vs degludec. The study authors noted that the potential clinical implications of these findings for people on basal insulin therapy should be evaluated in a larger clinical study.

The Panel noted that whether the presentation of data from a clamp study was acceptable under the Code in relation to any implied clinical benefit depended on the individual circumstances of each case. Care should be taken with such data so as not to mislead as to its significance. The Panel noted the study authors' caveats about the potential clinical implications set out above.

The Panel noted that the data in question was shown to the complainant on an iPad; it was described as the 'Latest Data app' and referenced Bailey *et al* and Bergenstal *et al* (2017) but that two studies were cited only became apparent on close examination. That claims about the PK and PD profile and a reduction in hypoglycaemia were referenced to different studies was not immediately obvious and in the Panel's view the design of the page was such that a reader was invited to link the reduction in hypoglycaemic risk with the flatter and more evenly distributed PK and PD profile. Similar concerns applied to the presentation of data throughout the app.

In the Panel's view, the design and layout of the app was such that readers would associate the findings in Bailey *et al* with the clinical claims about hypoglycaemia. The Panel considered that the material was misleading in this regard as alleged; it implied that the reduction in hypoglycaemic risk was unequivocally attributable to the product's PD and PK profile and that was not so and thus not capable of substantiation. Breaches of the Code were ruled.

The Panel also noted the complainant's allegation that the material was incomplete and misleading as it had selectively quoted from the data. The Panel queried whether the allegation was sufficiently clear: it might be construed as stating that it was not clear that the 0.6U/kg data from Bailey *et al* was not statistically significant, that the daily variation data from Heise *et al* was more clinically relevant and ought to have been included or that its secondary endpoint data of within-day variability ought to have been included or indeed that all of the data from Heise *et al* ought to have been part of the latest data app. The Panel noted that the complainant bore the burden of proof.

The Panel noted the comments made by an author of Bailey *et al* to the complainant: that while Bailey *et al* showed that within-day variability was lower for Toujeo at a dose of 0.4U/kg, no differences were seen at a dose of 0.6U/kg and that Heise *et al* investigated day-to-day variability. According to the complainant the author explained that Heise *et al* showed a significantly lower day-to-day variability for Tresiba but in relation to within-day variability came to a different conclusion (fluctuations corrected for the overall metabolic effect) which was higher for Tresiba than for Toujeo. The Panel noted the author's comment to the complainant about the within-day variability data from Heise *et al* and Bailey *et al* which the Panel considered appeared to be consistent.*

The Panel noted Sanofi's detailed submission about the differences between the two studies and why in its view they were not directly comparable. Sanofi had considered that it would not be able do justice to the discussion of the Heise *et al* study in its promotional material in this instance and could in fact risk confusing readers because in its view Bailey *et al* and Heise *et al* were not directly comparable.

The Panel considered that in principle it was not unacceptable to refer to discrete study results so long as the material overall complied with Code. Context including the nature and purpose of the material was relevant. The Panel noted the author's comment to the complainant about the data in Bailey *et al* and Heise *et al* in relation to within-day variability which the Panel considered were similar.* It also noted its comments above about the nature of the allegation. Noting these points, the Panel did not consider the material incomplete or misleading as alleged and ruled no breach of the Code.

The Panel noted its comments and rulings above with regard to the iPad app at issue and links to clinical benefit. The Panel reviewed the accompanying briefing material and training provided to the representative. The training document when referring to Bailey *et al* stated 'Understand the clinical information on the variability at duration of action data for Toujeo; translate into customer interactions, to strengthen your in call performance'. The following page listed bullet points under the heading 'Commercial relevance' including: 'What are the 3 claims out of this paper - product features?' and 'What are the clinical benefits for your customers and patients? The briefing document presented Bailey *et al* and Bergenstal *et al,* side by side without stating that the results of Bailey *et al* could not be extrapolated to the clinical benefits seen in Bergenstal *et al*. The Panel noted that it was accepted by Sanofi that the representative in question had linked Bailey *et al* to a decreased incidence of hypoglycaemia. The Panel considered that encouraging representatives to identify clinical benefits from Bailey *et al* and failing to instruct them to exercise caution in this regard meant that the material was such that it advocated a course of action likely to breach the Code. A breach of the Code was ruled.

The Panel noted its comments and rulings above and considered that Sanofi had failed to maintain high standards. A breach of the Code was ruled.

[* See post publication note at end of case report]

A consultant physician and community diabetes specialist complained about promotional material for Toujeo (insulin glargine) produced by Sanofi. The material at issue (ref SAGB.TJO.16.12.1140(1)a March 2017) was derived from an abstract (Bailey *et al* 2016) published by the American Diabetes Association entitled 'Insulin glargine 300U/ml [Toujeo] provides more stable and more evenly distributed steady-state PK/PD [pharmacokinetic/pharmacodynamic] profiles compared with insulin degludec in type 1 diabetes'. Toujeo was for the treatment of diabetes mellitus in adults.

COMPLAINT

The complainant noted that Bailey *et al* showed the glucose infusion rate to maintain blood glucose during an insulin clamp following injection of 0.4 units of Toujeo or insulin degludec. The study as presented suggested that there was less variability within the 24 hour period using Toujeo than with insulin degludec and a slightly longer duration of action. The interpretation of this data was that Toujeo in clinical practice would significantly reduce the incidence of hypoglycaemia particularly at night in patients with type 1 diabetes. If true this would be a significant clinical benefit.

The complainant stated that because he was concerned about this data, particularly what he considered to be over interpretation, he contacted the author of the study who replied:

> 'The variability issue is a bit confusing as there are two studies comparing Toujeo and Tresiba (insulin degludec marketed by Novo Nordisk). [Bailey *et al*] investigated "within-day variability" which is just another term for the fluctuation of the metabolic effect in a treatment interval of 24 hours which (in absolute terms) was lower at a dose of 0.4U/kg, however, no differences were seen at 0.6U/kg. [Heise *et al*] was recently published and investigated day-to-day variability which I think is what you are interested in most. It showed a significantly lower day-to-day variability for Tresiba as you might have expected. [Heise *et al*] also investigated within-day variability and came to a different conclusion comparing relative within-day variability (fluctuations corrected for the overall metabolic effect) which was higher for Tresiba than for Toujeo.
>
> Both studies have some limitations as the metabolic effect of 0.4U/kg did not always keep blood glucose during the clamp at target levels (which is a pre-requisite to get meaningful glucose infusion rates as parameter for metabolic action). However, [Heise *et al*] had a considerably higher statistical power as it enrolled more patients and did three clamps with either insulin

in each individual. We are waiting for [Bailey *et al*] to be published, but will probably do further analyses to better understand the differences between the two studies.'

From this response the complainant considered that the promotional material at issue was at best, significantly incomplete and at worst, intentionally misleading in that it had only selectively quoted from the data.

The complainant was concerned that other health professionals who might not have the expertise to investigate these claims further would be misled by this material.

When writing to Sanofi, the Authority asked it to bear in mind the requirements of Clauses 7.2, 7.4, 9.1 and 15.9 of the Code.

RESPONSE

Sanofi stated that its investigation of the complaint identified a call made to the complainant on 4 April 2017 by a representative who was accompanied by his/her area sales manager. Both individuals had submitted reports of their recollection of the call.

The material used in the call was presented from the representative's iPad. A copy of the material at issue was provided. The material had only just been released for use – secondary care representatives were recently trained on the new data and a copy of that training and the briefing document to accompany the material was provided. Given the training provided and the briefing document, Sanofi did not believe that its actions had breached Clause 15.9.

Sanofi explained that Bailey *et al* was a double-blind, cross-over euglycemic clamp study which compared the steady-state PD and PK profiles of insulin glargine-300 with that of insulin degludec-100, in two parallel cohorts, with two fixed once-daily dosing regimens in type 1 diabetics. The study results were presented according to the pre-specified study endpoints and study objectives as officially communicated (clinical.trial.gov) when the study started and before the study results.

The study discussed the PK/PD data of both medicines under a 30 hour clamp at the end of each treatment period and concluded that insulin glargine provided more stable and more evenly distributed steady state PD and PK profiles at a daily dose of 0.4 U/kg, compared with insulin degludec in type 1 diabetics. The poster had been presented at various high quality international and national scientific meetings including Diabetes Technology Society (2016), Advanced Technologies and Treatments for Diabetes (2017) and Association of British Clinical Diabetologists (2017).

The approved Sanofi promotional material was based on discussion from Bailey *et al* and accurately reflected the discussion and conclusion of that study. It included the study design which clearly stated it was conducted to assess variability over 24 hours and informed the reader that this was a euglycemic clamp study and conducted consistent with general gold standard methodology. In addition to results at 0.4U/kg daily dose which favoured insulin glargine 300 unit/ml, it also highlighted that the within-day fluctuation of metabolic activity at doses of 0.6U/kg numerically favoured glargine U300 but the difference vs insulin degludec did not reach statistical significance. Also, it did not refer or suggest any connection between less variability and/or flatter profile and incidence of hypoglycaemia. Bailey *et al* was not designed to measure hypoglycaemia.

Sanofi stated that the material did not comment on the recent Heise *et al* study. Sanofi acknowledged that whilst the title of the two studies might appear similar, the two could not be compared as both looked at different endpoints and used different methodology and study design. The primary endpoint in Bailey *et al* was to assess 'within variability' (fluctuation of the smoothed glucose infusion rate (GIR) curve over 24 hours) with insulin glargine 300 and insulin degludec 100. Whereas the primary endpoint with Heise *et al* was to assess 'between days variability' with insulin glargine-300 and insulin degludec-100. Heise *et al*, however, included within day variability assessment as a secondary endpoint. Injections in Bailey *et al* were given during the morning whilst in Heise *et al* injections were administered in the evening. Bailey *et al* looked at both the pharmacokinetics and pharmacodynamics of the two insulins, whilst Heise *et al* assessed only their pharmacodynamics. Furthermore a smoothing factor of 0.25 was applied to individual GIR curves in Heise *et al* whereas in Bailey *et al* a smoothing factor of 0.15 was applied. All the above differences could potentially lead to different results and thus in Sanofi's view the two studies were designed differently and could not be directly compared. In addition, since Sanofi was not close to the intimate details of the design and statistical plan of Heise *et al* and the analysis in both studies was widely considered as complex therefore it was considered, in this instance, that Sanofi would not be able do justice to discussion of Heise *et al* in this promotional material and in fact could risk confusing the recipient. Sanofi noted that full data from Heise *et al* was in the public domain and accessible to all health professionals, therefore they could form their own opinions on the outcomes of both studies. Sanofi had not attempted to restrict health professionals' opinion on PK/PD data of insulin glargine-300 and insulin degludec-100 to Bailey *et al* only and had no intention of directly or indirectly linking its outcomes with hypoglycaemia.

In conclusion, Sanofi considered that the discussion in its promotional material was neither incomplete nor misleading. The comparisons were accurate, balanced, fair, and based on up-to-date data. Sanofi denied breaches of Clauses 7.2 or 7.4.

As stated above, the investigation into the complaint had included obtaining reports from both the representative and his/her manager regarding the call made to the complainant. The following exert was from the representative's report:

'Firstly, I outlined where the Bailey data was presented, who the main author was, and co-author. I also stated that it had been presented as a poster at the [American Diabetic Association] in Boston in October 2016.

I then went through the study objective and design stating that it was a euglycaemic clamp study and finally the endpoint of the study which I stated was within-day variability.

I was asked about the number of patients in the study which I stated was 48, run in two parallel cohorts at the 0.4 and 0.6U/kg.

I presented him the data showing the PK/PD data for both products. I spoke about mimicking endogenous insulin and asked which line best represented that profile. [The complainant] took the iPad and scrutinised the data, after which he commented that he had expected the lines to be the other way round. He also commented that both products had similar tail off points which was something else he wasn't expecting to see. I stated that this data had bought the two insulins a lot closer than was first thought.

[The complainant] stated that he knew the author very well and that he would telephone him to question the results.

I stated that as a result of the lower PK/PD profile of Toujeo you would expect to see a lower incidence of hypos in type 1 patients.'

The representative then went on to present the other study in the material.

Whilst the initial report from the manager did not mention the representative linking the PK/PD data and a lower risk of hypoglycaemia in type 1 patients, upon asking for clarification the manager stated *'he did talk about "reduced fluctuations may result in a more predictable glucose profile and less hypoglycaemia"'.*

Sanofi concluded upon considering the statements made by the representative carefully in conjunction with reviewing the materials, training and briefing documents, that the representative had acted outside of the training and briefing provided when he/she linked the PK/PD data presented and a potential clinical outcome. As such Sanofi admitted a breach of Clause 15.2 as the representative had failed to maintain high standards.

As a result of the investigation into this complaint, senior managers met to discuss what action should be taken. In the case of the individual concerned disciplinary action had been commenced, which would be progressed using the company's usual disciplinary process. In addition, everyone who had already been briefed on the new material had received a second briefing (copy provided) to reinforce the correct use of the material. Sanofi considered this was a preventative action as it had no evidence to suggest that other representatives had made such incorrect claims.

In conclusion, Sanofi did not consider that it had breached the Code in relation to the clauses specified. However, it did consider that the representative in question had not maintained high standards; the individual and hence the company had breached Clause 15.2.

Further comments from the complainant

In response to a question raised by the Panel the complainant stated that he was shown the data on a laptop as stated by Sanofi and was also offered follow-up printed material which he declined. The complainant stated that Sanofi's submission that he took the iPad and scrutinised the data, after which he commented that he had expected the lines to be the other way round was correct.

Further comments from Sanofi

In response to a request for further information from the Panel about, *inter alia*, the complainant's reference to an abstract Sanofi stated that the Bailey *et al* data was not included in any of its printed material and no printed material was made available to the complainant during the call.

Sanofi also stated that the FAQ handler mentioned in the Winning with Toujeo training slide deck (ref SAGB.TJO.17.02.0144ad) did not exist. According to Sanofi there was a plan to produce a FAQ document but it had not been produced at the time that the original complaint was received. It was decided that a written FAQ document was not sufficient and that field teams required a more in depth briefing of the data. This occurred by way of the updated representative briefing material which was submitted with the original response.

PANEL RULING

The Panel noted the complainant's allegation that the material used by the representative based on Bailey *et al* (2016) suggested that there was less variability within a 24 hour period and a slightly longer duration of action with Toujeo compared with degludec insulin which was interpreted to mean that the use of Toujeo in clinical practice would significantly reduce the incidence of hypoglycaemic episodes, especially at night, and that this over interpreted the data. The complainant, noting the study author's comments, also alleged that the material was incomplete or intentionally misleading.

The Panel noted that Bailey *et al* was a double-blind cross-over euglycemic 30 hour clamp study comparing the steady state pharmacodynamic and pharmacokinetic profiles of Toujeo-300 and degludec-100 with two fixed once-daily dosing regimens(0.4U/kg and 0.6U/kg) in type 1 diabetics over 24 hours. The study authors concluded that Toujeo-300 resulted in less within day variability of the glucodynamic profile versus degludec-100 at a dose clinically relevant for type 1 diabetics (0.4U/kg/day). At the 0.4U/kg dose 6 hour fractions of glucodynamic activity were more evenly distributed over 24 hours with Toujeo-300 versus degludec-100. An overall more stable and more evenly distributed insulin exposure for Toujeo versus degludec-100

over 24 hours was observed in steady state at both dose levels (0.6U/kg/day and 0.4/kg/day). The within day variability of the glucodynamic profile with Toujeo-300 at the 0.6U/kg daily dose was not statistically significant versus degludec. The study authors noted that the potential clinical implications of these findings for people on basal insulin therapy should be evaluated in a larger clinical study.

The Panel noted that whether the presentation of data from a clamp study was acceptable under the Code in relation to any implied clinical benefit depended on the individual circumstances of each case. Care should be taken with such data so as not to mislead as to its significance. The Panel noted the study authors' caveats about the potential clinical implications set out above.

The Panel noted that both parties agreed that the data in question was in a digital format shown to the complainant on the representative's iPad. It was also agreed that the complainant had held the iPad to scrutinise the data. The material in question was described as the 'Latest Data app'. It appeared from the material provided by Sanofi that this app was one of seven autonomous apps available for representatives to use with health professionals on their iPads. The Panel noted that the app in question referenced two studies, Bailey *et al* and Bergenstal *et al* (2017). The Panel queried whether the data from these studies was sufficiently differentiated in the app. It was only on close examination that it was apparent that the data was referenced to two separate studies. For example, the first page headed 'Latest data' featured two prominent adjacent highlighted boxes. The first box was prominently headed 'PK/PD profile' which was described as a flatter and more evenly distributed insulin profile versus Lantus and insulin degludec. The Lantus data within this box was referenced to Bergenstal *et al* and the degludec data to Bailey *et al*. The adjacent box read 'Reducing hypoglycaemic risk vs. Lantus in adults with type 1 diabetes' and was referenced to Bergenstal *et al*. That the claims were referenced to different studies was not immediately obvious and in the Panel's view the design of the page was such that a reader was invited to link the reduction in hypoglycaemic risk with the flatter and more evenly distributed PK and PD profile. Similar concerns applied to the presentation of data throughout the app. The uniform design meant that it was not always immediately clear which study the data derived from. The Panel did not have sight of the original app but on the printed copy it appeared that after the first page described above pages 2-7 cited Bergenstal *et al*, pages 8-10 cited Bailey *et al*, and after a reproduction of the first page (page 11) pages 12 and 13 cited Bergenstal *et al*. Page 12 bore prominent headline claims: 'Reducing hypoglycaemic risk in adults with type 1 diabetes' and showed the annualised risk of nocturnal and severe hypoglycaemia including a relative risk reduction of 55% of Toujeo versus Lantus and the bold strapline 'In people with T1 DM Toujeo was associated with significantly lower annualised rates of nocturnal or severe hypoglycaemic events than Lantus'. The Panel noted that a health professional would normally be taken through the app by a representative but noted that it must nonetheless be capable of standing alone with regard to the requirements of the Code. The Panel also noted that the complainant had held the iPad to independently scrutinise the data.

In the Panel's view, the design and layout of the app, particularly the first page headed 'Latest Data', was such that readers would associate the findings in Bailey *et al*, a clamp study, with the clinical claims about hypoglycaemia. The Panel noted the study authors' caveats in this regard. The Panel also noted Sanofi's submission that Bailey *et al* did not refer to or suggest any connection between less variability or a flatter profile and the incidence of hypoglycaemia and it was not designed to measure this. The Panel considered that the material was misleading in this regard as alleged; it implied that the reduction in hypoglycaemic risk was unequivocally attributable to the product's pharmacodynamic and pharmacokinetic profile as seen in Bailey *et al* and that was not so. Further, such an implication was not capable of substantiation. A breach of Clauses 7.2 and 7.4 were ruled.

The Panel also noted the complainant's allegation that the material was incomplete and misleading as it had selectively quoted from the data. The Panel queried whether the allegation was sufficiently clear: it might be construed as stating that it was not clear that the 0.6U/kg data from Bailey *et al* was not statistically significant, that the daily variation data from Heise *et al* was more clinically relevant and ought to have been included or that its secondary endpoint data of within day variability ought to have been included or indeed that all of the data from Heise *et al* ought to have been part of the latest data app. The Panel noted that the complainant bore the burden of proof.

The Panel noted the comments made by an author of Bailey *et al* to the complainant: that while Bailey *et al* showed that within-day variability was lower for Toujeo at a dose of 0.4U/kg, no differences were seen at a dose of 0.6U/kg and that a recently published study (Heise *et al*) investigated day-to-day variability. According to the complainant the author explained that Heise *et al* showed a significantly lower day-to-day variability for Tresiba but in relation to within-day variability came to a different conclusion (fluctuations corrected for the overall metabolic effect) which was higher for Tresiba than for Toujeo. The Panel noted the author's comment to the complainant about the within-day variability data from Heise *et al* and Bailey *et al* which the Panel considered appeared to be consistent.*

The Panel noted Sanofi's detailed submission about the differences between the two studies and why in its view they were not directly comparable. Sanofi had considered that it would not be able do justice to the discussion of Heise *et al* in its promotional material in this instance and could in fact risk confusing readers because in its view Bailey *et al* and Heise *et al* were not directly comparable.

The Panel considered that in principle it was not unacceptable to refer to discrete study results so

long as the material overall complied with Code. Context including the nature and purpose of the material was relevant. The Panel noted the author's comment to the complainant about the data in Bailey *et al* and Heise *et al* in relation to within-day variability which the Panel considered were similar.* It also noted its comments above about the nature of the allegation. Noting these points, the Panel did not consider the material incomplete or misleading as alleged and ruled no breach of Clause 7.2.

The Panel noted its comments and rulings above with regard to the iPad app at issue and links to clinical benefit. The Panel reviewed the accompanying briefing material and training provided to the representative. The training document (ref SAGB.TJO.17.02.0144ad) when referring to Bailey *et al* stated 'Understand the clinical information on the variability at duration of action data for Toujeo; translate into customer interactions to strengthen your in call performance'. The following page listed bullet points under the heading 'Commercial relevance including: 'What are 3 claims out of this paper-product features?' and 'What are the clinical benefits for your customers and patients?'. The briefing document (ref SAGB.TJO.16.12.1140(1)b) presented the two studies, Bailey *et al* and Bergenstal *et al*, side by side without stating that the results of Bailey *et al* could not be extrapolated to the clinical benefits seen in Bergenstal *et al*. The Panel noted that it was accepted by Sanofi that the representative in question had linked Bailey *et al* to a decreased incidence of hypoglycaemia. The Panel considered that encouraging representatives to identify clinical benefits from Bailey *et al* and failing to instruct representatives to exercise caution in this regard meant that the material was such that it advocated a course of action likely to breach the Code. A breach of Clause 15.9 was ruled.

The Panel noted its comments and rulings above and considered that Sanofi had failed to maintain high standards. A breach of Clause 9.1 was ruled.

*** Post publication note**

Following publication of the original case report, the PMCPA received information from a third party that Heise *et al* 2016 showed that Tresiba had both a lower-day-to-day and within-day variability than Toujeo contrary to the information provided by the complainant. The Panel had not had sight of Heise *et al* 2016. The case report was updated and the third party advised that it was not possible to change the Panel's ruling which was due to a number of factors not only the complainant's reference to the within-day variability data from Heise *et al*. The third party was also advised that it could make its own complaint if it wished.

Complaint received **6 April 2017**

Case completed **12 September 2017**

Post publication note added January 2018