NO BREACH OF THE CODE

CASE AUTH/3549/7/21

EMPLOYEE v SANOFI

Lantus rebates

An anonymous complainant raised concerns about Lantus (insulin glargine) rebates offered by Sanofi.

The complainant alleged that he/she had raised issues with his/her superiors regarding potential anti-competitive behaviour and Sanofi's strategy to protect and maintain its market share vs biosimilars and these had been ignored. The complainant alleged that over the past few years, Sanofi had a clear strategy to offer Lantus rebates to prevent biosimilar insulin uptake which the complainant considered to be potentially anti-competitive. The complainant further alleged that as his/her team was a limited resource, whilst it could offer this rebate within any clinical commissioning group (CCG), his/her team had been instructed to only work within high potential areas. Therefore, it was alleged that the entire strategy was based upon working within priority Lantus accounts, ensuring rebates were in place to minimise uptake of biosimilars. The complainant alleged that, internally, discussions often centred upon measuring the effectiveness of these rebates.

The detailed response from Sanofi is given below.

The Panel noted Sanofi's submission that a flat rate Lantus rebate offer was made available to CCGs in England and Health Boards (HBs) in Wales from around 2017; this offer involved rebate payments to CCGs/HBs as a percentage (information provided) of their spend on Lantus. The Panel further noted Sanofi's submission that features of the process included that: a rebate offer must not prevent prescribers being able to prescribe other products; a rebate scheme must not be an inducement to prescribe etc Sanofi's products; rebate discussions must be handled only by trained members of the NHS KAM [key account manager] team; discussions regarding a rebate offer must not take place during a promotional meeting; contracts must be in place before a rebate arrangement commenced; and where a rebate scheme was in place, this must be made available to any CCG/HB that requested it.

The Panel noted that training material stated within a slide headed 'General principles for rebate discussions', *inter alia*: 'a rebate must not prevent prescribers being able to prescribe any other product' and 'Sanofi PCRs [primary care rebates] must be provided to any CCG/LHB/HB/LCG that requests them'. This wording, or similar, was within other training presentations dated May 2019, May 2020 and June 2021.

The Panel noted that the Code excluded from the definition of promotion, measures or trade practices relating to prices, margins or discounts which were in regular use by a

significant proportion of the pharmaceutical industry on 1 January 1993. Further, the relevant supplementary information to Clause 19.1 of the 2021 Code (which covered, *inter alia,* the prohibition on inducements etc to individual health professionals), Terms of Trade, stated that such measures or trade practices were outside the scope of the Code and were excluded from the provisions of that clause. The terms prices, margins and discounts were primarily financial terms. The Panel noted that other trade practices were subject to the Code and had to comply with it. Trade practices relating to prices, margins and discounts might have evolved since 1 January 1993.

The Panel considered that a flat rate rebate scheme was related to prices, margins and discounts. However, it did not know whether such schemes were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993. The Panel noted Sanofi's submission that it firmly believed that the Lantus rebate offer in question reflected arrangements in regular use by a substantial proportion of the pharmaceutical industry on 1 January 1993 and that in Sanofi's view the activity should fall outside the scope of the Code.

In the Panel's view, in principle, a flat rate rebate which met the requirements of a term of trade as set out in the Code was potentially excluded from the provisions of Clause 19.1 and potentially outside the scope of the Code. However, Sanofi had not specifically commented on or provided evidence to demonstrate whether prioritisation of certain key accounts in relation to flat rate rebates and their proactive discussion within such accounts was in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993 as referred to in Clause 1.17 and the relevant supplementary information to Clause 19.1. In the Panel's view, therefore, the allegation regarding prioritisation of, and proactive discussion within, certain key accounts in relation to the rebate potentially brought the activity within the scope of the Code and the Panel decided to proceed on that basis.

The Panel considered that a company might choose to focus its efforts on certain accounts which were expected to have the greatest impact on its business; in the Panel's view this was not necessarily unacceptable as long as the activity complied with the Code.

In the Panel's view, the complainant's concern was solely the allegedly anti-competitive nature of the arrangements. The Panel noted Sanofi's submission that the rebate was available to any CCG/HB that requested it; the Panel further noted that there was no evidence that the rebate scheme had not been made so available. The Panel noted from the evidence before it that there did not appear to have been any formal finding by any judicial authority or appropriate body formally charged with determining matters in relation to competition law that Sanofi had not complied with the relevant laws and regulations in relation to competition law and the rebate scheme in question. In the absence of any judgement by such an authority the complainant had not established that Sanofi had failed to maintain high standards in this regard and on the narrow grounds alleged the Panel ruled no breach of the Code.

In relation to the allegations that the complainant had raised issues with his/her superiors regarding anti-competitive behaviour and Sanofi's strategy to protect and maintain its market share vs biosimilars but to date these had been ignored, the Panel noted that the complainant had provided no evidence to support these allegations.

The Panel was not an investigatory body; it made its rulings on the evidence provided by both parties and the complainant had the burden of proof. The Panel considered that the complainant had not established that his/her concerns had been raised internally and ignored as alleged such that high standards had not been maintained and therefore no breach of the Code was ruled in that regard.

An anonymous complainant who described him/herself as an employee and who was originally contactable but could no longer be contacted using the details provided, complained about Lantus (insulin glargine) rebates offered by Sanofi.

COMPLAINT

The complainant stated that he/she had worked in the pharmaceutical industry in a variety of roles and had never been compelled to raise a complaint. However, he/she stated that recent practices by his/her current employer had left him/her with little option. As an employee of Sanofi, the complainant stated that he/she had raised issues with his/her superiors regarding anti-competitive behaviour and Sanofi's strategy to protect and maintain its market share vs biosimilars. He/she claimed that to date, these had been ignored. The complainant stated that over the past few years Sanofi had a clear strategy to offer Lantus rebates, to prevent biosimilar insulin uptake. The complainant alleged that this was in itself anti-competitive – however, as his/her team was a limited resource, whilst it could offer this rebate within any clinical commissioning group (CCG), his/her team had been instructed to only work within high potential areas. Therefore, the entire strategy was based upon working within priority Lantus accounts, ensuring rebates were in place to minimise uptake of biosimilars. Internally, discussions at business reviews with the complainant's peers and managers, allegedly often centred upon looking at the growth of biosimilars before and after a rebate had been placed, to measure the effectiveness of these rebates. The complainant provided screenshots of certain materials that he/she claimed highlighted this issue.

Within a spreadsheet the complainant stated that by selecting the relevant role filter, that the segmentation defaulted to accounts which were deemed high value, as these were the only accounts the complainant and his/her team worked and therefore offered the rebate. The complainant stated that he/she felt, that with the cost pressures the NHS was under, Sanofi should do more to support the uptake of biosimilars, rather than show what he/she alleged was anti-competitive behaviour.

When writing to Sanofi, the Authority asked it to consider the requirements of Clause 5.1 of the 2021 Code.

RESPONSE

Sanofi submitted that it took its obligation to comply with the Code very seriously. Sanofi was surprised by the complainant's allegations and had carefully investigated the matters raised. Sanofi had, however, identified no evidence indicating a breach of the Code.

1 Application of the Code

Sanofi submitted that measures or trade practices relating to prices, margins and discounts, which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993, were outside the scope of the Code. Other trade practices were subject to the Code. The terms 'prices', 'margins' and 'discounts' were primarily financial terms.

Sanofi submitted that the PMCPA accepted that discounts were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993.

The rebate offers made available by Sanofi were purely financial arrangements comprising a discount arrangement offered in primary care. In circumstances where a discount off-list price offered to a community pharmacist would not benefit the NHS (save to the extent it was taken into account under the pharmacy clawback), discounts in primary care, intended to benefit the NHS, must be organised as a rebate to primary care payors such as CCGs in England and Health Boards (HBs) in Wales. The position was comparable to that in Case AUTH/2321/5/10 which involved cash equivalent rebate payments. In that case, the Panel stated, 'in principle, credit notes and discounts which met the requirements of the relevant supplementary information were excluded from the provisions of Clause 18.1'. The rebate payments in Case AUTH/2321/5/10 were purely financial arrangements comparable to those which were the subject of the current complaint. Sanofi firmly believed that the Lantus rebate offers reflect arrangements in regular use by a substantial proportion of the pharmaceutical industry on 1 January 1993 and that this complaint should fall outside the scope of the Code.

If, however, the Panel did not accept this position, Sanofi provided as an alternative, a considered response to the complaint.

2 Background: Lantus rebates offered by Sanofi

Sanofi had identified one primary care rebate offer relating to Lantus in the context of the issues raised by the complainant and the documents they had disclosed.

A flat rate Lantus rebate offer was made available to CCGs in England and HBs in Wales from around 2017. This offer involved rebate payments to CCGs/HBs of a percentage (information provided) of their spend on Lantus.

Approved template letter agreements were made available to the NHS key account managers (NHS KAM) team, updated from time to time, to use for contracting with CCGs and HBs. A copy of the first and most recent versions of the template for England and Wales were provided.

The data used to calculate the rebates payable to CCGs changed over the period from 2017. Details were provided. In all versions, the terms of the flat rate rebate agreement confirmed that the rebate was not intended and did not take effect as an inducement for a person's past present or future willingness to prescribe, administer, recommend etc any product or service sold or provided by Sanofi or to provide any other benefit to Sanofi. CCGs/HBs remained free to use and promote the use within the CCG/HB of any and all diabetes treatments and were under no obligation to use or endorse Lantus products.

A large number of CCGs/HBs took up the flat rate Lantus rebate offer.

Having taken on board feedback from NHS stakeholders that a reduction in list price was preferable as it enabled transparent communications of price during local discussions about medicines choices and removed the administrative burden associated with rebate schemes, in 2021 Sanofi decided to simplify the arrangements by replacing the flat rebate offering with a list price reduction (details provided). The list price for Lantus was reduced from 1 July 2021, before the complaint was made.

In summary, therefore, the Lantus rebate offer was unobjectionable and fully compliant with applicable laws and the ABPI Code. The arrangements were transparent, involved no improper inducements and did not seek to limit the insulin products purchased by CCGs/HBs. The rebate offer was entirely lawful and was not anti-competitive.

3 Accounts offered Lantus rebates and implementation arrangements

Implementation of rebate arrangements

Sanofi was aware of the need to ensure that the offer and implementation of rebate offers were fully compliant with applicable laws, the ABPI Code, and relevant NHS governance policies and requirements. In these circumstances, Sanofi had strict procedures in place which governed the offer and implementation of rebate arrangements, including the following:

- ‘Communications with health professionals regarding the existence and offer of a commercial arrangement were carefully managed. Copies of briefing documents directed to promotional employees in effect since 2018 were provided.

- The NHS KAM team underwent regular training to ensure that rebates offered in primary care were managed compliantly, including in relation to competition aspects. Copies of slide decks used for training in 2018, 2019, 2020 and 2021 were provided. Employees were explicitly asked to contact the Legal team if they have any doubts or questions concerning competition law, including in the context of biosimilar entry.

Sanofi submitted that, as demonstrated by the documents provided, features of the process used by Sanofi for implementation of primary care rebate arrangements included the following elements:

a) A rebate offer must not prevent prescribers being able to prescribe other products.
b) A rebate scheme must not be an inducement to prescribe etc Sanofi’s products.
c) Rebate discussions must be handled only by trained members of the NHS KAM Team.
d) Discussions regarding a rebate offer must not take place during a promotional meeting.
e) Contracts must be in place before a rebate arrangement commences.
f) Where a rebate scheme is in place, this must be made available to any CCG/HB who requests it.

Accounts offered Lantus rebate arrangements

As indicated above, the Lantus rebate offer was made available to every CCG/HB who requested it. However, the resources available to the NHS KAM Team were limited and in these circumstances Sanofi was not able to direct its promotional efforts and/or separate

proactive discussions about the rebate offer to all accounts. Sanofi therefore prioritised promotional efforts on certain key accounts based on a variety of factors. The documents provided by the complainant correctly reflected this approach, although he/she did not provide the full picture, namely that these rebates were available to any CCG/HB requesting them even if they were not proactively discussed in all accounts. Accordingly, it was Sanofi's view that, while the PMCPA had requested the documents produced by the complainant, these would not assist the PMCPA in considering this complaint, in circumstances where the documents and the prioritisation to which he/she referred were not disputed.

Sanofi submitted that account prioritisation as described above was legitimate and not in any way anti-competitive, even more so as the discount was also generally available to accounts that were not prioritised. In fact, the rebate offered on Lantus to CCGs/HBs was a reflection of (i) Sanofi meeting biosimilar competition and (ii) healthy competition in the market. The structure of the flat rate rebate offer was acceptable and Sanofi was entitled to prioritise discussing the offer with certain key accounts. The offer of a favourable commercial arrangement to compete with biosimilars was consistent with an effective competitive market.

4 Sanofi culture and approach to concerns raised by employees

Sanofi supported a culture of openness and encouraged employees to report any concerns in relation to business conduct or other matters in the Sanofi Code of Ethics, which included compliance with competition law.

The Code of Ethics set out the ethical standards by which the company operated and applied to every Sanofi employee and anyone conducting business on behalf of the company. The Code of Ethics included, amongst others, a principle of 'Integrity in our business practices' which covered (i) dealing with conflicts of interest, (ii) transparency and integrity when participating in public life, (iii) respecting free competition (supporting a competitive marketplace, respecting and adhering to fair competition and trade practice laws), (iv) fighting bribery and corruption, (v) interactive appropriately with patients and patient groups; (vi) acting with the highest standards of integrity and honesty when interacting with the scientific community; and (vii) being transparent about Sanofi products, providing relevant, clear and accessible information to ensure the proper use of its products. The Code of Ethics required employees and those conducting business on behalf of Sanofi to raise concerns, through various channels if they believed its principles were being compromised.

The UK Ethics & Business Integrity Intranet page (a screenshot was provided) advised employees:

> *'If you have a concern or if you believe in good faith that a law, a rule or one of the principles in the Code of Ethics has been or is about to be violated, you can report the matter to the relevant Head of Ethics & Business Integrity (Compliance Officer) or to the secured compliance helplines.*
>
> *A secured communication system is available, composed of a dedicated webpage and a toll-free number available in 28 languages, 24 hours a day, 7 days a week.*
>
> *Employees will not be disciplined or discriminated against even provided that they act in good faith and with no malicious intent, even if the facts reported proved to be inaccurate or no further action is taken.'*

The Compliance Helpline was operated by an external third party. Once a report was received, the Global Ethics and Business Integrity (EBI) Team at Sanofi received a notification of the report and the local Head of EBI was notified to support in initiating an investigation. For illustration purposes, an average of 3 complaints per year had been received via the Compliance Helpline and investigated in the UK in the last 2 years. None had raised competition law concerns.

All employees were required to undergo training on the Code of Ethics, including an induction session provided by the UK Head of Ethics and Business Integrity to all new joiners, mandatory training courses covering the Code of Ethics, Fighting Corruption, Conflicts of Interests and Essentials of Ethics in the Workplace, and regular updates. Details of the Compliance Helpline were provided in many of these trainings.

In addition, as part of ongoing Code training in May 2021, relevant employees (including the NHS KAM team members attending the session) were reminded of the requirement and routes to raise concerns in relation to issues under the Code of Ethics.

Sanofi noted the complainant's assertion that they had:

> '…. *raised issues with [their] superiors regarding anti-competitive behaviour and our strategy to protect and maintain our markets share vs biosimilars. To date these have been ignored.*'

While Sanofi had identified no reports reflecting the issues raised by the complainant through the webpage or Compliance Helpline, it was a matter of concern to Sanofi that the complainant seemed to believe that his/her concerns had been disregarded. As described above, Sanofi took reports from employees regarding business conduct or other matters in the Sanofi Code of Ethics very seriously. In this particular case, it was disappointing that the issues raised by the complainant appeared to have resulted from a misunderstanding of competition law which, had they been raised via the above channels, could have been addressed anonymously and resolved internally. Sanofi would continue to raise awareness of the available channels that allow employees to speak up and report such concerns anonymously and effectively.

5 Overall conclusion and response to the complaint

For the purposes of this response, Sanofi referred, consistent with the PMCPA's letter, to Clause 5.1 of the 2021 Code.

As explained above, the Lantus rebate arrangement was appropriately reflected in agreements with CCGs/HBs, were transparent, benefited the NHS rather than any individual and did not limit the CCGs'/HBs' use or procurement of insulin products. The rebate arrangement did not act as an inducement to prescribe, supply etc Lantus or any other Sanofi medicine or to offer Sanofi any other benefit. The rebate arrangements were proactively discussed with key accounts in circumstances where Sanofi did not have the resource necessary to discuss them with all CCGs/HBs in the UK, although the arrangements were made available to any CCG/HB who requested them. Nothing about the arrangements, which were generally available to any CCG/HB, was anti-competitive in any way. As set out above, the rebate offered to CCGs/HBs was a reflection of healthy competition in the market.

While Sanofi believed that this complaint should fall outside the scope of the Code, it had, at all material times, been careful to ensure that its rebate offers were compliant with applicable laws, the ABPI Code and NHS policies.

In the above circumstances, if the PMCPA concluded that the Lantus rebate arrangements fell within the scope of the Code, Sanofi firmly believed that high standards were consistently and comprehensively maintained and there had been no breach of Clause 5.1 of the 2021 Code.

PANEL RULING

The Panel noted that Sanofi had been asked to respond to the requirements of the 2021 Code. The Panel noted that the complainant referred to recent practices but also provided materials relating to arrangements in 2019. In relation to the subject matter of the complaint the Panel did not consider that there were material differences between the 2019 and 2021 Code and the Panel accordingly made its rulings under the 2021 Code.

The Panel noted the complainant's allegation that Sanofi had a strategy to offer Lantus rebates to prevent biosimilar insulin uptake, which the complainant deemed to be anti-competitive, and that whilst Sanofi could offer this rebate within any clinical commissioning group (CCG), the complainant's team had been instructed to only work within high potential areas and priority Lantus accounts ensuring rebates were in place to minimise the uptake of biosimilars.

The Panel noted Sanofi's submission that a flat rate Lantus rebate offer was made available to CCGs in England and Health Boards (HBs) in Wales from around 2017; this offer involved rebate payments to CCGs/HBs of a percentage (information provided) of their spend on Lantus. The Panel further noted Sanofi's submission that features of the process used by Sanofi for implementation of primary care rebate arrangements included that: a rebate offer must not prevent prescribers being able to prescribe other products; a rebate scheme must not be an inducement to prescribe etc Sanofi's products; rebate discussions must be handled only by trained members of the NHS KAM Team; discussions regarding a rebate offer must not take place during a promotional meeting; contracts must be in place before a rebate arrangement commenced; and where a rebate scheme was in place, this must be made available to any CCG/HB that requested it.

The Panel noted that training material entitled 'Managing Sanofi Primary Care Rebates (PCRs) Compliantly' (ref SAGB.SA.18.05.0707 May 2018) stated within a slide headed 'General principles for rebate discussions', *inter alia*: 'a rebate must not prevent prescribers being able to prescribe any other product' and 'Sanofi PCRs [primary care rebates] must be provided to any CCG/LHB/HB/LCG that requests them'. This wording, or similar, was within other training presentations dated May 2019 (ref SAGB.SA.19.05.0823), May 2020 (ref MAT-GB-2000001) and June 2021 (ref MAT-GB-2102385).

The Panel noted that Clause 1.17 excluded from the definition of promotion, measures or trade practices relating to prices, margins or discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993. Further, the supplementary information to Clause 19.1 (which covered, *inter alia,* the prohibition on inducements etc to individual health professionals), Terms of Trade, stated that such measures or trade practices were outside the scope of the Code and were excluded from the provisions of that clause. The terms prices, margins and discounts were primarily financial terms. The Panel noted that other

trade practices were subject to the Code and had to comply with it. The Panel noted that trade practices relating to prices, margins and discounts might have evolved since 1 January 1993.

The Panel considered that a flat rate rebate scheme was related to prices, margins and discounts. However, it did not know whether such schemes were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993. The Panel noted Sanofi's submission that it firmly believed that the Lantus rebate offer in question reflected arrangements in regular use by a substantial proportion of the pharmaceutical industry on 1 January 1993 and that in Sanofi's view the activity should fall outside the scope of the Code.

In the Panel's view, in principle, a flat rate rebate which met the requirements of a term of trade as set out in the Code was potentially excluded from the provisions of Clause 19.1 and potentially outside the scope of the Code. However, Sanofi had not specifically commented on or provided evidence to demonstrate whether prioritisation of certain key accounts in relation to flat rate rebates and their proactive discussion within such accounts was in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993 as referred to at Clause 1.17 and the relevant supplementary information to Clause 19.1. In the Panel's view, therefore, the allegation regarding prioritisation of, and proactive discussion within, certain key accounts in relation to the rebate potentially brought the activity within the scope of the Code and the Panel decided to proceed on that basis.

The Panel noted Sanofi's submission that it had identified certain key accounts and focussed its promotional efforts (including proactive discussion of Lantus rebate offers) on those key accounts; however, the rebates were available to any CCG/HB requesting them even if they were not proactively discussed in those accounts.

The Panel considered that a company might choose to focus its efforts on certain accounts which were expected to have the greatest impact on its business; in the Panel's view this was not necessarily unacceptable as long as the activity complied with the Code.

The Panel noted the complainant's allegation that Sanofi's strategy to offer Lantus rebates to prevent biosimilar insulin uptake was anti-competitive and in this regard he/she noted that the entire strategy was based upon working within priority Lantus accounts. In the Panel's view, the complainant's concern was solely that the arrangements were allegedly anti-competitive. The Panel noted Sanofi's submission that the rebate was available to any CCG/HB that requested it; the Panel further noted that there was no evidence that the rebate scheme had not been made so available. The Panel noted that Sanofi had not been asked to respond to Clause 3.4 of the Code which stated that companies must comply with all applicable codes, laws and regulations to which they are subject. The Panel considered the matter under the broad requirements of Clause 5.1 to which Sanofi had been asked to respond. The Panel noted from the evidence before it that there did not appear to have been any formal finding by any judicial authority or appropriate body formally charged with determining matters in relation to competition law that Sanofi had not complied with the relevant laws and regulations in relation to competition law and the rebate scheme in question. In the absence of any judgement by such an authority the complainant had not established that Sanofi had failed to maintain high standards in this regard and on the narrow ground alleged the Panel ruled no breach of Clause 5.1.

In relation to the allegations that the complainant had raised issues with his/her superiors regarding anti-competitive behaviour and Sanofi's strategy to protect and maintain its market

share vs biosimilars but to date these had been ignored, the Panel noted that the complainant had provided no evidence to support these allegations.

The Panel noted that the opening slide of the 'Managing Sanofi Primary Care Rebates (PCRs) Compliantly' training slides (MAT-GB-2000001, date of preparation May 2020), was headed 'Reminder of competition law and biosimilar entry' and stated, *inter alia*, 'Please contact the UK&IE Legal Team if you have any doubts or questions relating to competition law, including how it applies to Sanofi in the context of biosimilar entry'.

The Panel further noted Sanofi's submission that its Compliance Helpline was operated by an external third party and an average of 3 complaints per year had been received via this helpline and investigated in the UK in the last 2 years; none had raised competition law concerns.

The Panel was not an investigatory body; it made its rulings on the evidence provided by both parties and the complainant had the burden of proof. The Panel considered that the complainant had not established that his/her concerns had been raised internally and ignored as alleged such that high standards had not been maintained and therefore no breach of Clause 5.1 was ruled in that regard.

Complaint received **25 July 2021**

Case completed **13 May 2022**