CASE AUTH/3487/3/21

NHS COMMISSIONING MANAGER v SANOFI

Conduct of staff in relation to flu vaccines

An NHS commissioning manager alleged that, with regard to the flu vaccine, a manager of Sanofi Pasteur Vaccines and the Sanofi flu team had encouraged the purchase of quadrivalent vaccine egg grown (QIVe) contrary to official guidelines which recommended the purchase of either adjuvanted quadrivalent vaccine (aQIV) or quadrivalent vaccine cell based (QIVc). Sanofi Pasteur marketed QIVe.

The complainant stated that on 3 February 2021, he/she and a colleague circulated the NHS England/Ireland (NHSE/I) flu reimbursement letter (signed by Professor Powis) to local practices and summarized the key points. This set out the vaccines for each cohort eligible for free NHS flu vaccine: it was recommended those aged 65 years and over should receive aQIV or QIVc where aQIV was not available; at-risk adults, including pregnant women, aged 18 to less than 65 years were recommended QIVc, or QIVe where QIVc was not available.

The complainant stated that in order to ensure that patients within the area had access to the most effective vaccine, additional guidance was issued to local practices in February 2021. Subsequently, a number of enquiries were received about the purchase of QIVe, as an alternative to QIVc, because a number of practices had ordered QIVe ahead of the NHSE/I reimbursement letter and now sought clarification regarding reimbursement or cancellation. As a result, further clarification was sent to practices and others in February 2021 to ensure that practices ordered sufficient stocks of QIVc and aQIV to vaccinate their eligible population to the level indicated by NHSE/I and to, as a minimum, improve on their 2020/21 uptake rates. The clarification was also intended to ensure QIVc would be 'available' and therefore hopefully avoid the purchase of QIVe. If later in the season, as a result of high vaccine uptake rates, further orders of QIVc were required but not available to order, it would be acceptable to order QIVe. 'Not available' was unlikely to be before the flu season had started, ie September at the earliest. This might have resulted in those practices that ordered 'at risk' before the NHSE/I reimbursement letter was published, cancelling their orders of QIVe.

The complainant was asked to respond to a telephone call and an email from a Sanofi manager and a query on behalf of a GP practice.

The complainant was concerned by both the individual's behaviour and the flu team's behaviour. The complainant believed these were linked and both breached the Code in spirit and in letter.

The complainant alleged that the content of the email, sent to a GP practice by the Sanofi flu team contradicted guidance given by the NHSE Regional Commissioners; the email was misleading and led the practice to believe that it would, without question, be reimbursed for its order of QIVe. Clearly the order had been placed recently, when QIVc was available in sufficient volumes to be ordered. The complainant submitted that

thankfully the practice sought additional guidance from its clinical commissioning group (CCG). The complainant was concerned that if practices did not seek additional clarification and acted on the advice of Sanofi, it would lead to conflict between practice and commissioners in the next seven months.

The complainant and his/her practice had clearly stated that they currently did not support the ordering of QIVe when ample supplies of the most effective vaccine were available to order. The complainant and his/her practice did not believe QIVc would become 'unavailable' until later in the season, if at all.

The complainant was particularly concerned about the email from Sanofi's manager including the purpose of his/her engagement activities with an NHS manager who was not a decision maker or a prescriber. The complainant alleged that the tone of the email was threatening, manipulative and sought to undermine confidence in the guidance issued by regional commissioners and cause fear of risk. The Sanofi manager's advice was not accurate and was likely to underpin the comments made by the flu team and ultimately lead to conflict between GP practices and commissioners in the next seven months ie specifically when practices sought reimbursement for the purchase of QIVe vaccine orders placed when QIVc, the most effective vaccine, was available to order.

The complainant provided detail comment on the correspondence submitted that he/she would like to understand whether the Sanofi NHS manager was acting alone or in line with company policies. The complainant questioned whether the Sanofi manager's training included acting to undermine confidence in national commissioning policy, local guidance and making threats regarding the potential consequences of such.

The detailed response from Sanofi is given below.

The Panel noted that the Powis letter (dated 3 February) sent, *inter alia*, to all GP practices set out the official NHS guidance about which flu vaccines would be reimbursed as part of the NHS 2021/22 flu vaccine programme for adults; the letter was signed by the national medical director for NHS England. The summary of the key points was clear that aQIV was to be used as the first-choice vaccine in patients 65 and over with QIVc to be used where aQIV was not available. QIVc was to be the vaccine of choice in at risk adults, including pregnant women, aged 18 to less than 65 years; the alternative QIVe was to be used where QIVc was not available. Sanofi Pasteur's vaccine, QIVe, was thus recommended only for second line use in the at-risk population. The letter advised providers to plan their vaccine ordering to at least equal the high levels of uptake achieved in 2020/21. The Panel considered that the official NHS letter implied that QIVe would only be reimbursed in circumstances where QIVc was not available.

The Panel noted that Sanofi's briefing material, issued February 2021, provided its customer facing teams with an understanding of the official NHS flu vaccine reimbursement letter. The material advised the Sanofi team to accept all customer cancellations reactively based on the guidance. On 19 February, the Sanofi flu team sent an email to existing flu customers which stated that 'your flu vaccine order remains fully reimbursable in line with NHS guidelines'. Noting the content of the official NHS letter sent earlier in the month, the Panel queried whether that was correct so early on in the season ie when QIVc could still be ordered. In that regard, the Panel noted from correspondence provided by the complainant, that the email had caused confusion amongst some of its recipients. The Panel noted Sanofi's submission that a link to its

online ordering system 'Vaxishop' was provided so that customers could easily amend or cancel their orders, however it appeared that readers were only pointed in the direction of Vaxishop so that they could 'check' their orders. The Panel did not consider, given they had been told by Sanofi that their flu vaccine order for QIVe would be 'fully reimbursable', that the email would prompt customers to consider cancelling their order.

It appeared to the Panel that practices in the complainant's remit should set out in February to order enough aQIV and QIVc to vaccinate their eligible populations to the level indicated by NHSE/I and to improve uptake in the at-risk group vs the 2020/21 uptake rates. It was made clear that practices were not expected to order QIVe before the flu vaccine season started. If, however, later in the season and not before September, and as a result of higher than planned for vaccine uptake, further orders of QIVc were required but QIVc was no longer available, then it would be acceptable to order QIVe. In those circumstances practices would be reimbursed for the purchase of QIVe.

The Panel noted that both the complainant and Sanofi were concerned to ensure that sufficient vaccines were available for the forthcoming flu vaccination programme; the difference of opinion between the parties was about the status of QIVe and how late in the flu vaccination season practices could wait before they ordered QIVe with any confidence of those orders being fulfilled. The complainant's view was that there should be adequate supplies of aQIV and QIVc if practices ordered sufficient volumes, in excess of uptake figures from the previous flu season, at the outset. QIVe should only be ordered later in the year if more than expected QIVc was needed but was unavailable. The Panel considered that the complainant had in effect advocated that any early orders for QIVe should be switched in QIVc now so that there was unlikely to be a shortfall in the supply of that vaccine in September. However, The Panel considered that ordering in February and ensuring an adequate supply of vaccine doses once the flu vaccination season arrived was not straightforward as the manufacture and distribution of flu vaccines relied upon orders being received months in advance. It was important to Sanofi that practices and the complainant understood that, in the absence of early orders, it was unlikely that the company would have surplus supply of QIVe at the start or during the flu vaccine season and so if orders for QIVe, to be used instead of QIVc in the at risk group, were not placed before September then it was likely that they would not be filled. The email from the Sanofi manager had set out a number of reasons for that view.

Neither the email from customer services at Sanofi dated 19 February and sent to existing flu customers, which stated that 'We would like to reassure you that your flu vaccine order remains fully reimbursable in line with NHS guidelines', nor the email from the manager (19 February), referred to the advice that orders could be amended or cancelled. Neither email referred to the need for practices to have sufficient stock of alternative flu vaccine ordered prior to cancelling any orders for QIVe. The Panel noted that the email from the flu team to existing customers had been misclassified as a purchase-related logistical email and so had been not formally reviewed as per the company's Review and Approval SOP. The email from the manager dated (19 February) had also not been certified; it was sent without discussion or agreement by Sanofi.

The Panel considered that the email from the Sanofi flu team was misleading in that it appeared to guarantee that orders for QIVe already placed in February would be fully reimbursable when the official NHS letter implied that QIVe would only be reimbursable where QIVc was not available. In the Panel's view, it was not for Sanofi to appear to infer

differently. Although the Panel did not consider that the email disparaged health professionals, and so in that regard ruled no breach of the Code, high standards had not been maintained and a breach of the Code was ruled. Although noting its comment and rulings, the Panel did not consider that the email did not recognise the special nature of medicines nor the professional standing of the audience to whom it was directed. No breach of the Code was ruled.

The Panel noted the content of the manager's email and considered that statements such as 'Some CCGs within [named area] are threatening Practices with Non-reimbursement if QIVe is ordered/not cancelled' and 'This demonstrates a complete lack of understanding of the Flu manufacturing and Northern Hemisphere flu dose distribution process' were disparaging. The Panel noted that both Sanofi and the manager recognised that some of the wording had been poorly chosen. The Panel considered that high standards had not been maintained and that the email did not recognise the professional standing of the audience to whom it was directed. Breaches of the Code were ruled including that the manager who had sent the email had not maintained a high standard of ethical conduct.

The Panel was concerned that the emails from the flu team and from the Sanofi manager appeared to call in to question the official NHS guidance with regard to the reimbursement and choice of flu vaccines. The Panel noted the complainant's submission that both communications could have led to conflict between GP practices and commissioners. The Panel considered that such activity brought discredit upon the pharmaceutical industry and a breach of Clause 2 was ruled.

An NHS commissioning manager alleged that, with regard to the flu vaccine, a manager of Sanofi Pasteur Vaccines and the Sanofi flu team had encouraged the purchase of quadrivalent vaccine egg grown (QIVe) contrary to official guidelines which recommended the purchase of either adjuvanted quadrivalent vaccine (aQIV) or quadrivalent vaccine cell based (QIVc). Sanofi Pasteur marketed QIVe.

COMPLAINT

The complainant stated that on 3 February 2021, he/she and a colleague circulated the NHS England/Ireland (NHSE/I) flu reimbursement letter (signed by Professor Powis) to practices in his/her area and summarized the key points in the letter. This set out the recommended vaccines for each cohort eligible for free NHS flu vaccine. The advice regarding the over 65s and the 18-64 age groups at risk included a suitable alternative vaccine to be used when the recommended vaccine was not available.

Those aged 65 years and over	At-risk adults, including pregnant women, aged 18 to less than 65 years
aQIV QIVc (where aQIV not available)	QIVc QIVe (where QIVc is not available)

The complainant stated that in order to ensure that patients had access to the most effective vaccine, additional guidance was issued to practices on 5 February 2021. Subsequently, the complainant and his/her colleague received a number of enquiries regarding the purchase of QIVe as an alternative to QIVc. This was because a number of practices had ordered QIVe (for

those at risk at risk) ahead of the NHSE/I reimbursement letter and now sought clarification regarding reimbursement or cancellation. As a result of those enquiries, further clarification was sent to practices on 18 February 2021.

The purpose of the further clarification was to ensure that practices ordered sufficient stocks of QIVc and aQIV to vaccinate their eligible population to the level indicated by NHSE/I and to, as a minimum, improve on their 2020/21 uptake rates. The clarification was also intended to ensure QIVc would be 'available' and therefore hopefully avoid the purchase of QIVe. However, the complainant and his/her colleague clarified that if later in the season, as a result of high vaccine uptake rates, further orders of QIVc were required but not available to order, it would be acceptable to order QIVe. However, stressing that the complainant and his/her colleague wanted to ensure patients could access the most effective vaccine and that 'not available' was unlikely to be before the flu season had started, ie September at the earliest. This might have resulted in those practices that ordered 'at risk' before the NHSE/I reimbursement letter was published, cancelling their orders of QIVe.

On 18 February one of the complainant's staff received a telephone call and an email from the Sanofi manager (copy provided).

On 19 February a further email raising a query on behalf of a GP practice in Derby was sent by the clinical commissioning group (CCG) (copy provided).

Both correspondence was forwarded to the complainant for response.

The complainant was concerned by both the individual's behaviour and the flu team's behaviour. The complainant believed these were linked and both breached the Code in spirit and in letter.

Company email

The complainant alleged that the following email, sent to the GP practice by the Sanofi flu team, directly contradicted the guidance given by the NHSE Regional Commissioners:

> 'Good Afternoon,
>
> Thanks you for your order of Sanofi Pasteur flu vaccines for the coming 21/22 season.
>
> We would like to reassure you that your flu vaccine order remains fully reimbursable in line with NHS guidelines[1].
>
> To check your order please visit www.vaxishop.co.uk or if you would like to speak to someone please contact your local VAM or customer services on [telephone number] (option 1).
>
> Kind Regards,
>
> Sanofi Flu Team
>
> Customer Services: [telephone number] (option 1)
> Medical Information: [telephone number].'

The complainant alleged that this was misleading and led the practice to believe that it would, without question, be reimbursed for its order of QIVe. Clearly the order had been placed recently, when QIVc was available in sufficient volumes to be ordered. The complainant submitted that thankfully the practice sought additional guidance from its CCG. The complainant was concerned that some practices might not seek additional clarification, could act on the advice of Sanofi without question, and that this would lead to conflict between practice and commissioners in the next seven months.

The complainant and his/her practice had clearly stated that they did not support the ordering of QIVe at this time, when ample supplies of the most effective vaccine were available to order. The complainant and his/her practice did not believe QIVc would become 'unavailable' until later in the season, if at all.

Email from the Sanofi manager

The complainant was particularly concerned about the content of the email from a Sanofi manager. The complainant's first question would be to understand his/her job role and the purpose of his/her engagement activities with the NHS manager who was not a decision maker or a prescriber.

The complainant alleged that the tone of the Sanofi manager's email was threatening, manipulative and sought to undermine confidence in the guidance issued by regional commissioners and cause fear of risk. The complainant submitted that the Sanofi manager's advice was not accurate and was likely to underpin the comments made by the flu team and would ultimately lead to conflict between GP practices and commissioners in the next seven months ie specifically when practices sought reimbursement from NHSE/I commissioners for the purchase of QIVe vaccine orders placed when QIVc, the most effective vaccine, was available to order.

The complainant submitted that for ease, his/her comments on the Sanofi manager's email appeared in italics as follows:

- Some CCGs within the [area] are threatening Practices with **Non-reimbursement if QIVe is ordered/not cancelled.**

To be clear, the decisions regarding vaccine reimbursement were made at a national level, taking on the advice of the JCVI [Joint Committee on Vaccination and Immunisation]. NHSE/I regional commissioners for the [area] had clarified their definition of what was meant by 'not available'. To describe that as CCGs threatening practices was inaccurate, defamatory and insulting.

- This should be of concern to yourselves from an implementation process and also a contractual process.

The NHS manager who received the email was not responsible for the implementation process or the contractual processes involved in flu and so the complainant questioned why Sanofi's manager had engaged with the NHS manager whose role was to support the implementation of the agreed commissioning policies and to ensure practices complied with the flu specification to the expected quality and standards.

- The JCVI Flu **advice** for this year is absolutely clear, and subsequently the Powis letter (3rd February) that QIVe will be reimbursed. We have yet to see the final Tripartite letter for confirmation of cohorts.

The letter was clear that QIVe should only be used as an alternative to QIVc if QIVc was not available. At this stage of the flu season, when vaccine orders were being placed, QIVc was available. Clearly in order to ensure patients got the most effective vaccine, orders needed to be placed now. Regional commissioners were working hard with practices and CCGs to ensure sufficient volumes of the most effective vaccine were ordered by practices. It was not acceptable behaviour for Sanofi's flu team to encourage practices to act contrary to that advice and to place orders for the alternative vaccine when QIVc was widely available

- This is subject to when QIVc is unavailable. This has not been defined adequately or with any regards to pragmatically implementing the National Flu Programme.

The complainant stated that the commissioners had defined what they interpreted as 'unavailable' and had issued clear clarification to GP practices and CCGs. As commissioners, they had a responsibility to ensure patients got access to the most effective vaccine. If sufficient volumes of aQIV and QIVc were ordered now there was a greater likelihood of patients receiving the most effective vaccine.

- There is an attempt to define this as September 2021. This demonstrates a complete lack of understanding of the Flu manufacturing and Northern Hemisphere flu dose distribution process. Once any orders with SP [Sanofi Pasteur] are cancelled this becomes visible to our Industrial Affairs global manufacturing team and will be re-distributed to other markets with no chance of recovery if required at a later stage. Demand currently outstrips supply by some way again for the next season.

The complainant considered that this was a very insulting comment. He/she was well aware of the flu manufacturing process and Northern Hemisphere flu dose distribution. Vaccines were ordered now for delivery in Autumn. Deliveries commenced in September and were usually phased. Clearly, if sufficient stocks were ordered there would be availability until well into the flu season before additional supplies were required. Official advice to practices was to reorder QIVc if additional stocks were required. Until the point that QIVc was unavailable, orders of QIVe were not expected to be necessary. The second part of the sentence was a blatant threat. 'If you cancel your orders they will be distributed to other markets and not available to the UK market.' Clearly this demonstrated that Sanofi's manager was more bothered about Sanofi's UK market share than doing what was best for patients or upholding the ABPI Code in spirit or letter! This latter point was clearly an attempt to manipulate the NHS manager and it caused him/her to worry about the risk and to forward his/her email to the complainant to question the local approach.

The complainant stated that this this fell below the standard of professional/ethical behaviour he/she would expect and was not the experience he/she had had working with pharmaceutical representatives from other companies.

- There is a high expectation in the system that the VCRs [vaccination coverage rates] achieved this year will be achieved potentially using a single supplier, and any future cohorts to be defined. This carries considerable assurance risk.

The complainant stated he/she hoped that the VCRs would be higher in 2021/22 than in 2020/21; there would be specific action to encourage uptake. That was also the reason for encouraging practices to order sufficient volumes of the most effective vaccine. The decision to recommend aQIV and QIVc was a national decision based on JCVI advice. The fact that both vaccines were manufactured by the same company would not have escaped its notice. If any future cohorts were defined, this would be accompanied by a national procurement of vaccine supplies as it was this year. It was unclear what Sanofi's manager hoped to achieve by suggesting that the NHS manager should be concerned by the 'perceived risk' he/she had highlighted. The NHS manager was not a prescriber, commissioner or decision maker and did not directly impact on local policy decisions. In any case that would still not constitute a valid reason for practices to order QIVe.

- The narrative from PHE/NHSE for years has been to spread manufacturing and delivery risk across multiple suppliers.

The complainant stated that that was not so this year and asked if it was part of the Sanofi manager's role to attempt to undermine confidence in the national guidance.

- Given the lack of confirmed Influenza in both the Southern and Northern Hemispheres this year the imminent WHO [World Health Organisation] flu strain advice will be challenging. This increases the risk of mis-match. One way to counter this to a certain extent is to have a mixed supply of vaccines that utilise different manufacturing platforms and hence slightly differing seed wild flu strains to maximise yield.

The complainant again asked if it was part of the Sanofi manager's role to create uncertainty and mistrust in national guidance and to persuade practices to order vaccines that were only to be used if the recommended vaccine was unavailable instead of ordering the most effective vaccine when it was widely available. Did Sanofi train its manager to generate concern, fear and mistrust in the guidance and potentially cause conflict between commissioners and GPs in relation to the reimbursement of vaccine orders? The complainant stated that he/she was confident that both the JCVI and the national team had taken all those factors into account when making their decisions. If Sanofi Pasteur had concerns it should voice them nationally and not leave managers to use tactics locally to encourage inappropriate ordering by practices.

In summary, the complainant stated that he/she was very unhappy about the behaviour of Sanofi's manager. The complainant questioned the appropriateness and purpose of the Sanofi manager's engagement with the NHS manager who was not a prescriber, decision maker, commissioner or individual with responsibility for defining local commissioning policy. The Sanofi manager's email was insulting, threatening and misleading in its tone and content and if it reflected the Sanofi manager's discussions with practices, the complainant was deeply concerned about the likely number of practices that had not placed sufficient orders of aQIV and QIVc, the most effective vaccines for the respective cohorts, and were being encouraged to place orders for QIVe which was contrary to the commissioning guidance issued within the area. As a result, that would put commissioners and practices in conflict in the next seven months where they would expect reimbursement for vaccine orders.

The complainant submitted that he/she would like to understand whether the Sanofi manager was acting alone or in line with company policies. The complainant questioned what training had been given to undertake his/her role and did that include acting in a manner which undermined confidence in national commissioning policy, local commissioning guidance and making threats regarding the potential consequences of such.

The complainant was well aware of the expected behaviour in relation to the Code and the need to maintain trust and confidence in the pharmaceutical industry. The complainant submitted that he/she was afraid that this behaviour fell short of what he/she expected in pharmaceutical companies.

The complainant submitted that he/she would like the behaviour of the Sanofi manager and the Sanofi flu team to be investigated. Furthermore, in an attempt to ensure patients in the area received access to the most effective vaccines aQIV and QIVc, and to help restore the reputation of Sanofi, the complainant would like the company to proactively cancel existing orders for QIVe, and encourage practices to re-order aQIV and QIVc as soon as possible.

The complainant was alleged breaches of Clauses 2, 9 and 15.

When writing to Sanofi, the Authority asked it to consider the requirements of Clauses 2, 8.2, 9.1, 9.2 and 15.2 of the Code.

RESPONSE

Sanofi noted that the complainant had raised concerns about an email sent to existing Sanofi flu customers by the Sanofi flu team and an email sent by a Sanofi manager to an NHS manager with whom he/she had a working relationship. The complainant considered that the behaviours were linked and breached the letter and spirit of the Code.

Sanofi submitted that it took these matters very seriously and had conducted a thorough investigation including interviews with relevant staff. Sanofi acknowledged the complainant's concerns but would like to provide reassurance that the intent behind the materials in question was to help maintain public health and patient safety.

Context and background to the events related to this complaint

Sanofi submitted that following publication on 3 February 2021 of the NHS flu reimbursement letter for the 2021/22 season (the Powis letter), which advised that for the at-risk adult population (those aged 18-65, including pregnant women), QIVc and QIVe vaccines would be reimbursed (QIVe where QIVc was not available), it received several questions from customers about reimbursement indicating they were concerned or confused and requests to cancel orders of QIVe vaccine followed. As Sanofi believed that its field staff would continue to receive questions about the Powis letter, an approved field force briefing document was certified and circulated to relevant Sanofi field teams. This briefing stated, 'The Sanofi Pasteur customer facing team are advised to accept all customer cancellations reactively based on this guidance'.

Sanofi explained that the vaccine manufacturing process was complex and began ahead of the flu season with planned production being based on pre-booked orders globally. Pre-bookings for any one season were generally taken during the previous September to November, with anticipated numbers passed to Sanofi global manufacturing at the beginning of December.

Vaccines, by their nature, took several months to produce, turnaround for flu vaccines was particularly tight as production had to start as soon as possible after the WHO had announced the flu strains (January to February) with all testing, filling, packaging and licensing procedures completed in time for delivery at the start of the flu season (beginning of September). In any given season there would be no guarantee that suppliers would have surplus stock at the start of the flu season, rather it was likely that they would not. Given that, there was considerable concern within Sanofi Pasteur that if practices waited to order QIVe until later in the year, that could lead to a shortage of flu vaccines which could result in at-risk people not receiving vaccine.

Company email

Sanofi submitted that the complainant stated that the content of an email sent to existing flu customers from the Sanofi flu team on 19 February 2021, contradicted the guidance given by the NHS regional commissioners regarding reimbursement.

In response, Sanofi stated that in light of questions raised by its customers, the Sanofi flu team developed and sent the email to re-iterate vaccine reimbursement in line with the Powis letter in order to help ensure there were sufficient supplies of vaccines for this vulnerable group at the start of the 2021/22 flu season. A link to Sanofi's on-line ordering system 'Vaxishop' was provided, so customers could easily amend or cancel their orders. The instruction to the field force, as per the company briefing referred to above, was to accept cancellations. During a subsequent operational call, field teams were verbally told to remind their customers, in the interests of patient safety, to check they had sufficient stock ordered from the alternative manufacturer before cancelling their Sanofi order. This year Sanofi flu orders could be cancelled up to 12 weeks before the first planned delivery (usually at the start of September) giving surgeries ample opportunity to ensure they had sufficient stocks of vaccine booked for their at-risk populations.

Sanofi submitted that the email in question, which referred to the Powis letter, was a one-off communication sent from a central mailbox on 19 February 2021 only to customers who had already ordered QIVe for the 2021/22 season. The email was created by the marketing team and subsequently reviewed and approved by two senior managers. Because the email was only sent to customers with existing orders and was specifically about those orders, it was misclassified as a purchase-related logistical email which fell outside of the scope of promotion and so it was not formally reviewed in the company material review system as per Sanofi's Review and Approval Standard Operating Procedure (SOP). Sanofi stated that it would implement corrective actions to mitigate re-occurrence in the future.

Sanofi did not consider that the email contradicted advice given in the local NHS briefing as alleged; the intent of the email was to reiterate the information in the Powis letter regarding reimbursement for the reasons stated above and it was sent to all existing customers, not just those in the complainant's area

As the email did not disparage health professionals, undermine the special nature of medicines or the professional standing of the audience and was not related to representative activity, Sanofi denied breaches of Clauses 2, 8.2, 9.2 and 15.2.

Sanofi determined that the email should have provided more information when referring to the Powis letter and should have been reviewed via the Sanofi approval system in accordance with the SOP. Sanofi thus accepted a breach of Clause 9.1.

Email from named Sanofi manager

Sanofi submitted that after feedback from representatives that several practices were cancelling orders of QIVe as a result of local interpretation of the Powis letter, the Sanofi manager reached out independently to the NHS team in the complainant's area on 17 February 2021. This was to clarify his/her understanding of why the team had advised surgeries that QIVe was not reimbursable which did not seem to align with the information in the Powis letter. Following this, the manager then telephoned the email recipient [an NHS manager] to discuss the evident confusion around reimbursement, the timeline of flu vaccine manufacture and the risk of delaying ordering vaccine until September, which could result in orders not being fulfilled and a subsequent shortage of flu vaccine for the vulnerable population. The NHS manager asked that the conversation be captured in an email which was now the subject of the complaint. Sanofi responded to each concern raised by the complainant as follows:

1 *Some CCGs within the [area] are threatening Practices with Non-reimbursement if QIVe is ordered/not cancelled.'*

Complainant's comments

'To be clear, the decisions regarding vaccine reimbursement are made at a national level, taking on the advice of the JCVI. NHSE/I Regional Commissioners for the [area] have clarified their definition of what is meant by "not available". To describe this as CCGs threatening Practices is inaccurate, defamatory and insulting.'

Response

The intent of this sentence was not to defame or insult the CCGs but rather to convey the understanding that the perceived uncertainty at practice level would be causing anxiety. Sanofi considered that the use of the term 'threatening' was poorly chosen.

2 *This should be of concern to yourselves from an implementation process and also a contractual process.*

Complainant's comments

The NHS manager was not responsible for the implementation process or the contractual processes involved in flu and so the complainant questioned why Sanofi's manager had engaged with the NHS manager whose role was to support the implementation of the agreed commissioning policies and to ensure practices complied with the flu specification to the expected quality and standards.

Response

The Sanofi manager's perspective was, in agreement with the complainant's, that the recipient of the email had a role that involved the 'support of implementation of the agreed policies and to ensure practices complied… to the expected quality and standards'. As such, the Sanofi manager believed it was important to communicate that a possible misunderstanding about the relationship between flu ordering and availability could jeopardise the expected standard of a flu vaccination programme by potentially resulting in a shortfall in available doses for the 2021/22 season.

3 *The JCVI Flu advice for this year is absolutely clear, and subsequently the Powis letter (3rd February) that QIVe will be reimbursed. We have yet to see the final Tripartite letter for confirmation of cohorts.*

Complainant's comments

The letter was clear that QIVe should only be used as an alternative to QIVc if QIVc was not available. At this stage of the flu season, when vaccine orders were being placed, QIVc was available. Clearly in order to ensure patients got the most effective vaccine, orders needed to be placed now. Regional commissioners were working hard with practices and CCGs to ensure sufficient volumes of the most effective vaccine were ordered by practices. It was not acceptable behaviour for Sanofi's flu team to encourage practices to act contrary to that advice and to place orders for the alternative vaccine when QIVc was widely available

Response

A communication from an NHS manager in commissioning dated 5 February 2021 (copy provided) stated that QIVe (used when QIVc was not available) 'will be reimbursed in line with the Powis letter'. The communication then closed by saying 'Manufacturers will start to produce volumes of vaccines shortly based on the orders they have received. You should submit your order as soon as possible to ensure sufficient supply'. Sanofi stated that its manager believed his/her email to the recipient was communicating the same message, rather than contradicting the advice given by local commissioning bodies, as no information was contained in that email that suggested orders of QIVe should be delayed. In fact, the email made it clear that because manufacturing would begin to occur soon, orders must be placed as soon as possible.

4 *This is subject to when QIVc is unavailable. This has not been defined adequately or with any regards to pragmatically implementing the National Flu Programme.*

Complainant's comments

The complainant's area commissioners had defined what they interpreted as 'unavailable' and had issued clear clarification to GP practices and CCGs. As commissioners, they had a responsibility to ensure patients got access to the most effective vaccine. If sufficient volumes of aQIV and QIVc were ordered now there was a greater likelihood of patients receiving the most effective vaccine.

Response

The manager's email did not intend to question the comparative efficacies of vaccines or the advice of the JCVI or regional commissioners. His/her intent was to communicate the likelihood that if the appraisal of 'lack of availability' was left until the start of the flu season, there was a higher likelihood that there could be insufficient QIVe produced to offset that shortfall. This was in line with the above-mentioned communication from the NHS manager in commissioning dated 5 February 2021. Sanofi accepted that this could have been worded more constructively.

5 *There is an attempt to define this as September 2021. This demonstrates a complete lack of understanding of the Flu manufacturing and Northern Hemisphere flu dose*

distribution process. Once any orders with SP are cancelled this becomes visible to our Industrial Affairs global manufacturing team and will be re-distributed to other markets with no chance of recovery if required at a later stage. Demand currently outstrips supply by some way again for the next season.

Complainant's comments

The complainant considered that this was a very insulting comment. He/she was well aware of the flu manufacturing process and Northern Hemisphere flu dose distribution. Vaccines were ordered now for delivery in Autumn. Deliveries commenced in September and were usually phased. Clearly, if sufficient stocks were ordered there would be availability until well into the flu season before additional supplies were required. Official advice to practices was to reorder QIVc if additional stocks were required. Until the point that QIVc was unavailable, orders of QIVe were not expected to be necessary. The second part of the sentence was a blatant threat. 'If you cancel your orders they will be distributed to other markets and not available to the UK market.' Clearly this demonstrated that Sanofi's manager was more bothered about Sanofi's UK market share than doing what was best for patients or upholding the ABPI Code in spirit or letter! This latter point was clearly an attempt to manipulate the NHS manager and it caused him/her to worry about the risk and to forward his/her email to the complainant to question the local approach.

The complainant stated that this was certainly not an example of the type of behaviour he/she would expect and was not the experience he/she had had working with pharmaceutical representatives from other companies. This fell below the standard of professions, or ethical behaviour he/she would expect.

Response

Sanofi submitted that the intent of the comment was not to be insulting, although, in retrospect the use of the phrase 'demonstrates complete lack of understanding of the flu manufacturing [process]' could have been phrased more constructively. The complainant's explanation that '…there will be availability until well into the flu season before additional supplies are required' reiterated the concern that as manufacturing was planned well ahead of the season, any orders placed at the start of, or during, the season itself might be less likely to be filled (due to the manufacturing process) and this might result in a shortfall of doses. Sanofi noted that pre-orders for the following season began to be taken at that time, so helping manufacturing plan for the following year (as described above). Sanofi submitted that its manager was intent on helping ensure the best possible uptake of flu vaccination, in order to support the wider public health need. The intent was not to manipulate the NHS manager but to highlight that doses ordered 'well into the flu season' might not be available for the reasons already stated. Both Sanofi and its manager accepted that the wording was not as constructive or as sensitive as it could have been, but the intention was to inform and not to manipulate the recipient.

6 *There is a high expectation in the system that the VCRs achieved this year will be achieved potentially using a single supplier, and any future cohorts to be defined. This carries considerable assurance risk.*

Complainant's comments

The complainant stated he/she hoped that the VCRs would be higher in 2021/22 than in 2020/21; there would be specific action to encourage uptake. That was also the reason for encouraging practices to order sufficient volumes of the most effective vaccine. The decision to recommend aQIV and QIVc was a national decision based on JCVI advice. The fact that both vaccines were manufactured by the same company would not have escaped its notice. If any future cohorts were defined, this would be accompanied by a national procurement of vaccine supplies as it was this year. It was unclear what Sanofi's manager hoped to achieve by suggesting that the NHS manager should be concerned by the 'perceived risk' he/she had highlighted. The NHS manager was not a prescriber, commissioner or decision maker and did not directly impact on local policy decisions. In any case that would still not constitute a valid reason for practices to order QIVe.

Response

Sanofi submitted that its manager did not intend to question decisions made at a national level. His/her intent was to highlight that there was a level of unpredictability with vaccine manufacture and that an alternative supplier helped reduce risk of there being insufficient stock available to meet vaccine uptake targets. Sanofi considered that this was reflected in the advice that QIVe would be reimbursed, as given in the Powis letter. As highlighted above, the recipient of the email (the NHS manager) had a role that involved the successful roll out of the flu program and as such, Sanofi's manager considered that it was important to communicate a possible risk of insufficient stock.

7 *The narrative from PHE/NHSE for years has been to spread manufacturing and delivery risk across multiple suppliers.*

Complainant's comments

The complainant stated that that was not so this year and asked if it was part of the Sanofi manager's role to attempt to undermine confidence in the national guidance.

Response

Sanofi's response to this point was similar to the one above. For the at-risk population, the national guidance had ensured that manufacturing was spread across two suppliers by stating that QIVe was reimbursable. The Sanofi manager intended to highlight that, wherever possible, ordering from multiple suppliers helped mitigate risk from unanticipated breaks in supply.

8 *Given the lack of confirmed Influenza in both the Southern and Northern Hemispheres this year the imminent WHO flu strain advice will be challenging. This increases the risk of mis-match. One way to counter this to a certain extent is to have a mixed supply of vaccines that utilise different manufacturing platforms and hence slightly differing seed wild flu strains to maximise yield.*

Complainant's comments

The complainant again asked if it was part of the Sanofi manager's role to create uncertainty and mistrust in national guidance and to persuade practices to order vaccines that were only to be used if the recommended vaccine was unavailable instead of ordering the most effective vaccine when it was widely available. Was the Sanofi manager trained

by Sanofi to generate concern, fear and mistrust in the guidance and potentially cause conflict between commissioners and GPs in relation to the reimbursement of vaccine orders? The complainant stated that he/she was confident that both the JCVI and the national team had taken all those factors into account when making their decisions. If Sanofi Pasteur had concerns it should voice them nationally and not leave managers to use tactics locally to encourage inappropriate ordering by practices.

Response

Sanofi submitted that although not in line with the approved briefing (copy provided), nor a company directed activity, the manager's intent was not to create uncertainty and mistrust in national guidance but rather to help ensure Sanofi's products were best used within that guidance for the benefit of public health. He/she was reacting to communications received by representatives from customers who were confused by the perceived reimbursement status of QIVe and he/she was trying to convey the importance of maintaining already placed orders for the reasons already described. The telephone call, and subsequent email, were meant to pass those concerns on to the relevant people. With respect to the statement that those concerns should have been raised by the company at a national level, Sanofi confirmed that this was the agreed approach by the company which was engaging with Public Health England and the Department of Health on the matter and field teams had not been instructed to discuss those matters.

With regard to the complainant's overall criticism of the Sanofi manager's conduct, Sanofi reiterated that the email was sent at the request of the recipient following a telephone conversation. Sanofi considered that as the recipient was a trained health professional (details provided) and someone whose remit included ensuring the successful local roll out of the flu vaccination programme, he/she was an appropriate person for the Sanofi manager to interact with. The email was not meant to be insulting, threatening or misleading, either in its tone or content. Sanofi acknowledged that some points could have been worded more constructively. The Sanofi manager had extensive experience in the pharmaceutical industry and a passion for helping support public health and this passion was evident in the email.

The job role, included supporting the successful implementation of Government recommended vaccination campaigns, including flu. Training for the role included ABPI representative training and relevant SOP/Code training. The email recipient had been identified for several seasons as someone whose job it was to ensure that the flu campaigns were run successfully in his/her area with success being measured by how many vulnerable people received vaccinations. The Sanofi manager was genuinely concerned that there would be insufficient vaccine to ensure a successful flu campaign if orders were cancelled, and so felt compelled to reach out to the email recipient (the NHS manager) to ensure his/her concerns were raised. The Sanofi manager did not intend to undermine confidence in the national programme, rather he/she was worried that a shortfall of vaccine would undermine the aims of the programme itself. However, the email was sent, albeit with the manager's best intentions, without discussion or agreement by Sanofi. The Sanofi manager regretted some of the phrasing of the email and reflected that this was the result of his/her passion for supporting public health.

Sanofi stated that it would not proactively cancel existing orders as this would neither be ethical nor supportive of public health. As described above, cancelling orders would mean that doses, previously allocated to the UK, would be re-allocated and any shortfall of vaccine in September could result in a danger to patient safety. However, the ongoing Sanofi policy, as evidenced by

the briefing document (copy provided), was that any decision by practices to cancel orders would be accepted.

Sanofi submitted that the Sanofi manager's email provided information beyond the remit of his/her role and should have been worded more constructively; on this rare occasion, he/she had not acted in line with the briefing documents provided. The manager had acknowledged that and regretted the distress caused. Sanofi accepted a breach of Clause 15.2.

The subject of the email related to ensuring adequate supply of vaccines to meet patient needs but did not disparage the clinical or scientific opinions of health professionals. Sanofi did not consider that this singular, undirected email, represented a breach of Clauses 9.1, 9.2, 8.2 or 2.

PANEL RULING

The Panel noted that the Powis letter (dated 3 February) sent, *inter alia*, to all GP practices set out the official NHS guidance about which flu vaccines would be reimbursed as part of the NHS 2021/22 flu vaccine programme for adults; the letter was signed by the national medical director for NHS England. The summary of the key points was clear that aQIV was to be used as the first-choice vaccine in patients 65 and over with QIVc to be used where aQIV was not available. QIVc was to be the vaccine of choice in at risk adults, including pregnant women, aged 18 to less than 65 years; the alternative QIVe was to be used where QIVc was not available. Sanofi Pasteur's vaccine, QIVe, was thus recommended only for second line use in the at-risk population. The letter advised providers to plan their vaccine ordering to at least equal the high levels of uptake achieved in 2020/21. The Panel considered that the official NHS letter implied that QIVe would only be reimbursed in circumstances where QIVc was not available.

The Panel noted that Sanofi's briefing material, issued February 2021 (certified 5 February), provided its customer facing teams with an understanding of the official NHS flu vaccine reimbursement letter. The material advised the Sanofi team to accept all customer cancellations *reactively* based on the guidance (emphasis added); it stated the cancellation should be in writing and sent to a named team to action. On 19 February, the Sanofi flu team sent an email to existing flu customers in which it was stated that 'your flu vaccine order remains fully reimbursable in line with NHS guidelines'. Noting the content of the official NHS letter sent earlier in the month, the Panel queried whether that was correct so early on in the season ie when QIVc could still be ordered. In that regard, the Panel noted from correspondence provided by the complainant, that the email had caused confusion amongst some of its recipients. The Panel noted Sanofi's submission that a link to its online ordering system 'Vaxishop' was provided so that customers could easily amend or cancel their orders, however it appeared that readers were only pointed in the direction of Vaxishop so that they could 'check' their orders. The Panel did not consider, given they had been told by Sanofi that their flu vaccine order for QIVe would be 'fully reimbursable', that the email would prompt customers to consider cancelling their order.

Further to the NHS letter of 3 February, clarification was sent from the complainant's NHS area on 5 February emphasising which flu vaccines would be reimbursed and urging readers to submit orders as soon as possible to ensure sufficient supplies. Further clarification was sent on 18 February advising practices to ensure that QIVc would be available and avoid the purchase of QIVe. It appeared to the Panel that practices in the complainant's remit should set out in February to order enough aQIV and QIVc to vaccinate their eligible populations to the level indicated by NHSE/I and to improve uptake in the at-risk group vs the 2020/21 uptake rates. It was made clear that practices were not expected to order QIVe before the flu vaccine

season started. If, however, later in the season and not before September, and as a result of higher than planned for vaccine uptake, further orders of QIVc were required but QIVc was no longer available, then it would be acceptable to order QIVe. In those circumstances practices would be reimbursed for the purchase of QIVe.

The complainant's view, as set out in an email dated 18 February to an NHS manager, was that the advice given to practices had been to wait until the national reimbursement letter (NHS letter of 3 February) was issued before placing any orders for vaccines. The complainant stated that reimbursement was agreed nationally based on the advice from the JCVI and following discussions with the Treasury and noted that orders placed before the national reimbursement guidance had been issued were at risk.

The Panel noted that both the complainant and Sanofi were concerned to ensure that sufficient vaccines were available for the forthcoming flu vaccination programme; the difference of opinion between the parties was about the status of QIVe and how late in the flu vaccination season practices could wait before they ordered QIVe with any confidence of those orders being fulfilled. The complainant's view was that there should be adequate supplies of aQIV and QIVc if practices ordered sufficient volumes, in excess of uptake figures from the previous flu season, at the outset. QIVe should only be ordered later in the year if more than expected QIVc was needed but was unavailable. The Panel considered that the complainant had in effect advocated that any early orders for QIVe should be switched in QIVc now so that there was unlikely to be a shortfall in the supply of that vaccine in September. However, The Panel considered that ordering in February and ensuring an adequate supply of vaccine doses once the flu vaccination season arrived was not straightforward as the manufacture and distribution of flu vaccines relied upon orders being received months in advance. It was important to Sanofi that practices and the complainant understood that, in the absence of early orders, it was unlikely that the company would have surplus supply of QIVe at the start or during the flu vaccine season and so if orders for QIVe, to be used instead of QIVc in the at risk group, were not placed before September then it was likely that they would not be filled. The email from the Sanofi manager had set out a number of reasons for that view.

Neither the email from customer services at Sanofi dated 19 February and sent to existing flu customers, which stated that 'We would like to reassure you that your flu vaccine order remains fully reimbursable in line with NHS guidelines', nor the email from the manager (19 February), referred to the advice that orders could be amended or cancelled. Neither email referred to the need for practices to have sufficient stock of alternative flu vaccine ordered prior to cancelling any orders for QIVe. The Panel noted that the email from the flu team to existing customers had been misclassified as a purchase-related logistical email and as such had been not formally reviewed as per the company's Review and Approval SOP. The email from the manager had also not been certified; it was sent without discussion or agreement by Sanofi.

The Panel considered that the email from the Sanofi flu team was misleading in that it appeared to guarantee that orders for QIVe already placed in February would be fully reimbursable when the official NHS letter implied that QIVe would only be reimbursable where QIVc was not available. In the Panel's view, it was not for Sanofi to appear to infer differently. Although the Panel did not consider that the email disparaged health professionals, and so in that regard ruled no breach of Clause 8.2, it did consider that high standards had not been maintained and so a breach of Clause 9.1 was ruled. Although noting its comment and rulings, the Panel did not consider that the email did not recognise the special nature of medicines nor the professional standing of the audience to whom it was directed. No breach of Clause 9.2 was ruled.

The Panel noted the content of the manager's email and considered that statements such as 'Some CCGs within the [area] are threatening Practices with Non-reimbursement if QIVe is ordered/not cancelled' and 'This demonstrates a complete lack of understanding of the Flu manufacturing and Northern Hemisphere flu dose distribution process' were disparaging. The Panel noted that both Sanofi and the manager recognised that some of the wording had been poorly chosen. A breach of Clause 8.2 was ruled. The Panel considered that high standards had not been maintained and that the email did not recognise the professional standing of the audience to whom it was directed. Breaches of Clauses 9.1 and 9.2 were ruled. The Panel further considered that the manager who had sent the email had not maintained a high standard of ethical conduct and a breach of Clause 15.2 was ruled.

With regard to Clause 2, the Panel was concerned that the emails from the flu team and from the Sanofi manager appeared to call in to question the official NHS guidance with regard to the reimbursement and choice of flu vaccines. The Panel noted the complainant's submission that both communications could have led to conflict between GP practices and commissioners. The Panel considered that such activity brought discredit upon the pharmaceutical industry and a breach of Clause 2 was ruled.

Complaint received **22 February 2021**

Case completed **12 August 2021**