*NO BREACH OF THE CODE*

**CASE AUTH/3520/6/21**

# NHS COMMISSIONING MANAGER v SANOFI

## Promotion of flu vaccines

**An NHS commissioning manager complained about the promotion and availability of flu vaccines for the 2021/22 flu season by Sanofi Pasteur. The complainant had previously complained about the promotion of QIVe (quadrivalent influenza vaccine, egg-based) by Sanofi Pasteur in Case AUTH/3487/3/21 and now additionally complained about the company's promotion of QIVr (quadrivalent influenza vaccine, recombinant).**

**The complainant stated that he/she was still very concerned about the approach Sanofi Pasteur was taking in relation to the marketing of its QIVe and QIVr flu vaccines.**

**The complainant noted that, from his/her previous complaint (Case AUTH/3487/3/21), Sanofi Pasteur undertook an assertive marketing campaign ahead of the NHS England/Ireland (NHSE/I) announcement of vaccine reimbursement for 2021/22 flu season. As far back as September 2020, the company began to approach practices with significant discount offers as an inducement for GPs to place orders for the following flu season. This was well ahead of the publication of the Joint Committee on Vaccination and Immunisation (JCVI) advice which was the basis of NHSE/I funding decisions.**

**The complainant stated that earlier in 2021, in January/February, after the region had issued clarification of the recommended vaccine in the flu reimbursement letter, a number of practices which wanted to cancel their orders to switch to QIVc (quadrivalent influenza vaccine, cell-based) were prevented from doing so. The complainant submitted that it was that behaviour that led to his/her initial complaint (Case AUTH/3487/3/21).**

**The complainant stated that in March 2021, a member of the NHSE/I national team advised on a call that Sanofi had informed NHSE/I that it had a shortfall of around 1 million doses of QIVe and would struggle to fulfil its QIVe order book. As part of the discussions with the NHSE/I , Sanofi was advised to release practices from their orders to enable them to switch to QIVc. The complainant stated that he/she had personally checked that the manufacturer of QIVc was able to accept additional orders from new customers should those arise.**

**The complainant stated that on 1 April, a second flu reimbursement letter was issued by NHSE/I. This announced the extension to 50-64 year olds and in addition confirmed the inclusion of QIVr to the list of reimbursable vaccines for the under 65s. Practices were encouraged to order additional vaccines to support the age expansion for 50-64 year olds. The recommended vaccines were QIVc or QIVr with QIVe as an alternative if those were not available. The names of potential suppliers were listed for practices to approach including Seqirus for QIVc, Mylan for QIVe and Sanofi who also manufactured**

**QIVr. QIVr, which was not initially included in the list of reimbursable vaccines, cost £22 plus VAT (ie around 4 times the cost of QIVe).**

**The complainant explained that it was usual for GP practices to order vaccines and pay for them which meant that practices made a significant initial outlay on vaccines. NHSE/I later reimbursed practices for the vaccines used during the flu season based on the BNF (British National Formulary) price irrespective of the price they had paid therefore, for some medicines, practices made a small profit which they used to invest in their services. QIVr was not offered at a discounted price, this meant that the initial outlay for practices was considerably higher than for QIVe and there was no profit for GPs.**

**The complainant stated that he/she was advised that the order window for QIVc had been extended until Friday 7 May 2021 to give practices more time to increase their orders.**

**The complainant stated that on 13 May, he/she and a named colleague received emails from a number of practices stating that they had received an email from Sanofi Pasteur, advising an automatic 30% reduction of their QIVe order. In response, practices had tried to increase their orders of QIVe from other suppliers or QIVc. These options were in preference to QIVr mainly due to affordability of the initial outlay. Although for some the loss of profit on the 30% and inability to replace that through similar deals was a consideration.**

**The complainant stated that later that same day he/she was contacted by a named Sanofi Pasteur representative who was following up on the communications issued by the company. The representative stated that the reason for the 30% reduction was due to insufficient global supplies of QIVe due to unprecedented demand in the Northern hemisphere; as a company, Sanofi only had a certain amount of vaccine allocated to each country and that the UK allocation was over-subscribed and could not be increased. The complainant had met with the representative and his/her manager less than two weeks before on 30 April to discuss the flu second reimbursement letter and the positioning of QIVr, so he/she was really surprised that the issue had not been mentioned by them then.**

**The complainant stated that he/she had asked a number of questions which unsurprisingly, the representative was unable to respond to.**

**The complainant stated that that he/she was really concerned that the cancellation was so soon after the order window for QIVc had closed. Also, given the national team had flagged a potential shortfall as far back as March, notification could have been given much earlier. The complainant questioned if it was a coincidence that Sanofi had a substitution available that cost on average 4 times the price of the standard vaccine.**

**The complainant stated that as part of his/her regional assurance process, he/she contacted all practices to ensure that if their orders had been reduced, they took action to ensure that they had enough flu vaccine on order to supply the potential demand for 2021/22 flu season; the complainant knew that over 450 practices in the area had ordered QIVe instead of the preferred QIVc vaccine for the under 65s, although he/she did not know which manufacturer they had ordered from. The complainant stated that to date, he/she had received over 200 emails from practices which had had their orders automatically cut by 30% and had tried to order replacement vaccine.**

**The complainant noted that the situation had caused enormous inconvenience to practices trying to replenish their stocks. Some had ordered QIVe from another supplier which begged the question was there really a global shortage of QIVe. Some had ordered QIVc from Seqirus which kindly considered some small additional orders, some had reluctantly ordered QIVr from Sanofi given the additional cost and loss of profit/income and some had done nothing and were facing a potential vaccine shortage for their under 65s.**

**The complainant noted that a number of practice managers had commented on both the timing of the 30% reduction ie after the QIVc order window closed, and also the fact that the only supplier of QIVe to be affected by the 'global shortage' was the only one with an alternative vaccine that costs 4 times the price.**

**The complainant stated that again, the actions of Sanofi Pasteur had done nothing to enhance its own reputation or that of the pharmaceutical industry.**

**The detailed response from Sanofi is given below.**

**The Panel noted the complainant's allegation that in September 2020, well before guidance had been issued as to which flu vaccines would be used in the 2021/22 flu season, Sanofi had assertively promoted its flu vaccine and had offered significant discounts as an inducement for GPs to order QIVe. The Panel further noted that flu vaccine was not generally procured centrally; GP practices ordered their own supplies and the difference between the price that they paid vs the amount that NHSE/I later reimbursed for the vaccine doses used, might mean that some practices would make a profit which could be reinvested in service provision.**

**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. In summary, the letter stated 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 aged 18 to less than 65 years and pregnant women; 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 the complainant's submission that some practices had ordered QIVe ahead of the Powis letter and that as a result of clarification issued by the local health region (January/February) as to the recommended vaccine in the flu reimbursement letter, practices which wanted to cancel their QIVe orders to switch to QIVc were prevented from doing so. Sanofi denied that it had prevented any requests for cancellation of orders and in that regard noted its briefing material which stated 'The Sanofi Pasteur customer facing team are advised to accept all customer cancellations reactively based on this guidance'.**

**The Panel noted that in March 2021, the complainant became aware that Sanofi had informed NHSE/I that there was a shortfall of around 1 million doses of QIVe; according to Sanofi's submission it appeared that, at the time, that shortfall and the potential solutions to it were the subject of confidential discussions between Sanofi and government teams.**

**The Panel noted the second letter from the NHS (Powis letter dated 1 April 2021) which updated the advice regarding the vaccines to be reimbursed in 2021 and 2022. . An additional cohort of patients had been included (those aged 50-64 years) and QIVr would now be reimbursed for certain age groups as an alternative to QIVc. This meant that Sanofi Pasteur's vaccine, QIVe, was now recommended only for third-line use in the at-risk population and those aged 50-64 years when neither QIVc nor QIVr were available.**

**The Powis letter, dated 1 April, included information from manufacturers about additional vaccine availability. In relation to Sanofi Pasteur, the letter stated that the company would be fulfilling current orders for the 2021/2022 season with QIVe or QIVr.**

**The Panel noted that the complainant had provided a copy of an email he/she had received on 13 May to which was attached 'logistical' email of the same date from Sanofi informing readers that, due to an increase in global demand, orders from Sanofi Pasteur for QIVe would be automatically reduced by 30%. Readers were told that in order to meet their flu vaccine needs they might wish to consider contacting another supplier or contacting Sanofi Pasteur to source an alternative flu vaccine as recommended in the NHS guidance. Given that email, the complainant was surprised in retrospect that at a meeting with Sanofi representatives on 30 April, nothing had been said about the 30% reduction in QIVe orders. The Panel noted Sanofi's submission that that information was still confidential at that time and would not have been known to the representative. In that regard, the Panel thus did not consider that there was any evidence to show that the representative had not maintained a high standard of ethical conduct or had been misleading about the supply of QIVe. No breaches of the Code were ruled.**

**The Panel noted Sanofi's submission that it was first made aware on 4 March by global colleagues that the UK supply of QIVe would be affected by a dose volume reduction; the company submitted that it had not oversold doses. The company submitted that there would be centrally procured stock to support the vaccination programme although the complainant would not have known that when he/she submitted the complaint.**

**The Panel noted that the briefing document, used by the representative in discussions with the complainant on 13 May, set out the content of the 'logistical' email referred to above which stated that due to an increase in global demand, orders from Sanofi Pasteur for QIVe had to be reduced by 30%. The document provided a list of questions and answers including that the number of doses had to be reduced and that Sanofi Pasteur could supply doses of QIVr. In relation to a question about why Sanofi was reducing the number of QIVe doses, when Seqirus was not, the answer referred to the surge in demand which outstripped Sanofi's current Northern hemisphere capacity and that for the UK, the company had worked with the NHS to provide a limited number of QIVr doses to help cover the shortfall of QIVe.**

**The Panel noted that the manufacture, and thus supply of flu vaccine, was not straightforward. According to Sanofi, the strain of flu to be used in the Northern**

**hemisphere had been released on 26 February 2021 to allow vaccine manufacturers to begin production in March and deliver from September as the flu season commenced. Further, flu vaccines took several months to produce; the strict quality control measures required at each step of the process accounted for most of the total production time between March and September.**

**The Panel further noted that on 3 February, national guidance had been issued regarding which flu vaccines should be used for the over 65s and the at-risk population; this guidance was updated in April with the addition of another patient cohort (50-65 years) and the inclusion of Sanofi's QIVr which would be reimbursed. In the meantime, Sanofi had been advised by its global colleagues that there would be a shortfall in the UK supply of QIVe which many practices had already ordered. That situation had led to confidential discussions with Sanofi and government teams about possible solutions which, given the commercial confidentiality of such matters, had not been made generally known until May. The Panel considered that the timing of events was unfortunate.**

**The Panel noted the extreme dissatisfaction that was generally required before an individual was moved to complain, and it had some sympathy for the complainant's position. It considered that the 'logistical' email of 13 May could have set out more clearly that the demand for QIVe had outstripped Sanofi's capacity and in that regard, it appeared that the shortfall was limited to Sanofi and was not a global issue as such. Nonetheless, as acknowledged by the complainant, the email did encourage readers to order supplies of vaccine from other manufacturers and in response, practices had tried to increase their orders of QIVe from other suppliers or QIVc. Readers had also been told that they could contact Sanofi Pasteur to source an alternative flu vaccine.**

**Overall, it appeared to the Panel that circumstances had changed rapidly in the early part of the year and that some of the resultant discussions between Sanofi and government teams had necessarily been confidential; Sanofi was thus not able to share details and the position was unknown to the complainant until discussions were completed. While the shortfall in the supply of QIVe from Sanofi might leave some practices short of stock, there nonetheless appeared to be supplies of vaccines from other manufacturers; there was no evidence that Sanofi had influenced the supply of its QIVe such as to preferentially sell the higher priced QIVr as alleged. It appeared that both parties were caught up in a situation which did not seem to be of their own making at a time when practices had to act quickly to secure sufficient supplies of the flu vaccine for the coming flu season. The Panel understood why the complainant might question Sanofi's conduct and motives, but it did not consider that there was evidence to show that the company had been misleading about the arrangement nor that it had not maintained high standards. No breaches of the Code were ruled including Clause 2.**

An NHS commissioning manager complained about the promotion and availability of flu vaccines for the 2021/22 flu season by Sanofi Pasteur. The complainant had previously complained about the promotion of QIVe (quadrivalent influenza vaccine, egg-based) by Sanofi Pasteur in Case AUTH/3487/3/21 and now additionally complained about the company's promotion of QIVr (quadrivalent influenza vaccine, recombinant).

**COMPLAINT**

The complainant stated that he/she was still very concerned about the approach Sanofi Pasteur was taking in relation to the marketing of QIVe and more recently its QIVr flu vaccine.

The complainant noted that from his/her previous complaint (Case AUTH/3487/3/21), Sanofi Pasteur undertook an assertive marketing campaign ahead of the NHS England/Ireland (NHSE/I) announcement of vaccine reimbursement for 2021/22 flu season. As far back as September 2020 the company began to approach practices with significant discount offers as an inducement for GPs to place orders for the following flu season. This was well ahead of the publication of the Joint Committee on Vaccination and Immunisation (JCVI) advice which was the basis of NHSE/I funding decisions.

Earlier this year, (January/February) after the region had issued clarification of the recommended vaccine in the flu reimbursement letter, a number of practices which wanted to cancel their orders to switch to QIVc (quadrivalent influenza vaccine, cell-based) were prevented from doing so. The complainant submitted that it was that behaviour that caused him/her enough concern to raise his/her initial complaint (Case AUTH/3487/3/21).

The complainant stated that in March 2021, he/she was on a call when a member of the NHSE/I National Team advised that Sanofi had informed NHSE/I that it had a shortfall of around 1 million doses of QIVe and would struggle to fulfil its QIVe order book. As part of the discussions with the NHSE/I National Team, Sanofi was advised to release practices from their orders to enable them to switch to QIVc. The complainant stated that he/she had personally checked that the manufacturer of QIVc was able to accept additional orders from new customers should those arise.

The complainant stated that on 1 April, a second flu reimbursement letter was issued by the National Team. This announced the extension to 50-64 year olds and in addition confirmed the inclusion of QIVr to the list of reimbursable vaccines for the under 65s. Practices were encouraged to order additional vaccines to support the age expansion for 50-64 year olds. The recommended vaccines were QIVc or QIVr with QIVe as an alternative if those were not available. The names of potential suppliers were listed for practices to approach. This included Seqirus for QIVc, Mylan for QIVe and Sanofi who also manufactured QIVr. QIVr, which was not initially included in the list of reimbursable vaccines, cost £22 plus VAT (ie around 4 times the cost of QIVe).

The complainant explained that it was usual for GP practices to order vaccines and pay for them which meant that practices made a significant initial outlay on vaccines. NHSE/I later reimbursed practices for the vaccines used during the flu season based on the published BNF (British National Formulary) price irrespective of the price they had paid therefore, for some medicines, practices made a small profit which they used to invest in their services. QIVr was not offered at a discounted price, this meant that the initial outlay for practices was considerably higher than for QIVe and there was no profit for GPs.

The complainant stated that he/she was advised that the order window for QIVc had been extended until Friday 7 May 2021 to give practices more time to increase their orders.

The complainant stated that on 13 May around 11am, he/she and a named colleague started to receive emails from a number of practices stating that they had received an email from Sanofi Pasteur, advising them of an automatic 30% reduction of their QIVe order. Practices were advised that they could order supplies of vaccine from other manufacturers. In response,

practices had tried to increase their orders of QIVe from other suppliers or QIVc. These options were in preference to QIVr mainly due to affordability of the initial outlay. Although for some the loss of profit on the 30% and inability to replace that through similar deals was a consideration.

The complainant stated that later that same day he/she was contacted by a named Sanofi Pasteur representative who was following up on the communications issued by the company. The representative stated that the reason for the 30% reduction was due to insufficient global supplies of QIVe due to unprecedented demand in the Northern hemisphere. The complainant stated that he/she was told that as a company Sanofi only had a certain amount of vaccine allocated to each country and that the UK allocation was over-subscribed and could not be increased. The complainant noted that he/she had met with the representative and his/her manager less than two weeks before on 30 April to discuss the flu second reimbursement letter and the positioning of QIVr, so he/she was really surprised that the issue had not been mentioned by them then.

The complainant stated that he/she had asked a number of questions:

1. If Sanofi's UK supply was capped - why sell more vaccine that it was able to supply? Especially when that was contrary to the advice to await the JCVI letter and also to order QIVc as the preferred vaccine.
2. If Sanofi knew that it had a capped supply and a potential 1 million dose shortfall, why make it difficult for practice to cancel their orders in January? Especially when they were advised by the region to switch to QIVc?
3. Why, when the National Team was aware of 1million doses shortage of QIVe in March, did Sanofi wait until May to inform practices that their orders could not be fully met?
4. Why wait until 4 working days after the QIVc order window closed before taking that action – making it more difficult for practices to replace their stocks of vaccine?
5. Was it a coincidence that the global shortage of QIVe had only affected Sanofi Pasteur and not those other suppliers without an alternative vaccine available that was 4 times the price? Practice which had ordered QIVe from Mylan, Masta or other suppliers had not had their orders cut by 30%, only those with orders from Sanofi. In fact, practices had been able to order more QIVe from the other suppliers to replace the orders lost from Sanofi!
6. When a practice placed an order, it was effectively entering into a contract with Sanofi; Sanofi was effectively breaching the contract it had with practices by cancelling those orders and it should offer to provide QIVr as a substitution at the same cost of QIVe.

The complainant noted that, unsurprisingly, the representative was unable to respond to any of these questions.

The complainant stated that that he/she was really concerned that the cancellation was so soon after the order window for QIVc had closed. Sanofi Pasteur would be aware of that fact. Also, given the National Team had flagged a potential shortfall as far back as March, notification could have been given much earlier. Was it a coincidence that Sanofi had a substitution available that cost on average 4 times the price of the standard vaccine?

The complainant stated that as part of his/her regional assurance process, he/she contacted local practices to ensure that if their orders had been reduced they took action to ensure that they had enough flu vaccine on order to supply the potential demand for 2021/22 flu season (copy provided). The complainant stated that he/she knew from previous work that over 450 practices ihad ordered QIVe instead of the preferred QIVc vaccine for the under 65s although

he/she did not know which manufacturer they had ordered from. The complainant stated that to date, he/she had received over 200 emails from practices which had had their orders automatically cut by 30% and which had tried to order replacement vaccine.

The complainant noted that the situation had caused enormous inconvenience to practices trying to replenish their stocks. Some had ordered QIVe from another supplier which begged the question was there really a global shortage of QIVe. Some had ordered QIVc from Seqirus which kindly considered some small additional orders, some had reluctantly ordered QIVr from Sanofi given the additional cost and loss of profit/income and some had done nothing and were facing a potential vaccine shortage for their under 65s.

The complainant noted that a number of practice managers had commented on both the timing of the 30% reduction ie after the QIVc order window closed, and also the fact that the only supplier of QIVe to be affected by the 'global shortage' was the only one with an alternative vaccine that costs 4 times the price.

The complainant stated that again, the actions of Sanofi Pasteur had done nothing to enhance its own reputation or that of the pharmaceutical industry.

When writing to Sanofi, the Authority asked it to consider the requirements of Clauses 2, 7.2, 9.1 and 15.2 of the Code.

**RESPONSE**

Sanofi stated that it was sorry to see this complaint and that it took these matters very seriously. Sanofi acknowledged the complainant's concerns and stated that it had conducted a thorough investigation and interviewed relevant members of staff.

The complainant raised concerns regarding the conduct of the Sanofi flu team around QIVe dose volume reduction relating to pre-orders and conduct of a named Sanofi representative and information provided to customers.

**A Context and background to the nature of flu vaccine production and events related to this complaint**

Sanofi stated that the flu vaccine strains changed each year based on World Health Organization (WHO) sentinel surveillance of dominant circulating strains in the Southern and Northern hemispheres. The WHO released Northern hemisphere strains in January-February of each year (26 February in 2021) to allow flu vaccine manufacturers to begin production in March and deliver from September as the flu season commenced.

Flu vaccine production was complex, taking several months to produce; it involved antigen production, formulation, filling, packaging and quality release. Each of the process steps were carried out under cold chain control and required very strict quality control measures. The quality control steps accounted for 70% of the total production time between March and September.

In the UK there were additional complexities in that flu vaccine guidance, recommendation and reimbursement were distinct processes, separated in time, that began a year in advance of the next flu season. Flu vaccines for the adult programme were not generally centrally procured, so

practices were free to select the vaccines that met the needs of their population, based on guidelines.

The following is a summary of the main UK external steps for flu vaccine supply for 2020/21 season:

1 **December 2020: JCVI evaluated existing vaccines and efficacy from previous seasons and made recommendation for the next season**

On 8 December 2020 the JCVI published the minutes from its 27 October 2020 meeting recommendations for evaluation of the available flu vaccines, to inform and issue guidance for the next flu season 2021/22. As a result of that, two guidance documents were released (JCVI-Advice on influenza vaccines 2021/22 – Original version and JCVI – Advice on influenza vaccines 2021/22 – Revised version). The final advice was:

- Over 65s: The JCVI recommended aQIV (adjuvanted quadrivalent influenza vaccine) as first-line, followed by QIV-high dose (not available in UK), or by QIVc or QIVr as second-line.
- Under 65 at-risk groups: the JCVI recommended QIVc or QIVr as first-line; QIVe could be considered if first-line options were not available.

2 **February 2021 NHS Flu Reimbursement Letter ('Powis' letter – 3 February 2021)**

The NHS influenza reimbursement letter for the 2021/22 season (the Powis letter) was published on 3 February, 2021 and 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).

3 **1 April 2021 Achievements and Developments of the 2020/21 Flu season letter published by NHSE (annual flu letter – April 2021)**

Following the Powis letter, the flu reimbursement document 'annual flu letter' was published on 1 April which added QIVr as equivalent first-line in the under 65 adult group alongside QIVc, and confirmed reimbursement of QIVr.

Sanofi provided a confidential detailed timeline of its internal responses reacting to the external flu environment over the season, which highlighted the processes it had in place to rapidly changing external guidance.

**B Response to allegations**

**Events and conduct leading up to dose volume reduction on 13 May**

Sanofi noted that the complainant had raised two concerns:

- *Sanofi prevented cancellation of QIVe orders in January and February 2021*

Following the publication of the Powis letter in February 2021 Sanofi received several requests for cancellation of QIVe vaccine orders, which were fulfilled by Sanofi without restrictions. Also, 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 (ref MAT-GB-2100467 – Field force briefing on Powis letter) stated: 'The Sanofi Pasteur customer facing team are advised to accept all customer cancellations reactively based on this guidance' and in that regard Sanofi denied that it had prevented any requests for cancellation of orders.

- *Dose volume reduction process, timelines, and communication*

Sanofi stated that it was first made aware on 4 March 2021 by its global colleagues that the UK QIVe would be affected by a dose volume reduction, and as a result the original QIVe allocation would need to be reduced. Sanofi stated that it had not oversold doses beyond the original allocation; however, it did acknowledge that a mitigation process needed to be implemented urgently to protect customers and patients.

Sanofi stated that it worked with government teams to ensure the shortfall in QIVe was fulfilled via other solutions, including practices switching to QIVc and the central procurement of QIVr. Confidential details were provided. Sanofi requested that these were not included in the case report.

1. External communication of those discussions and supply were under the full direction of the Department of Health and Social Care (DHSC) and not Sanofi, as per the government discussions. Sanofi noted an initial article in the GP publication 'Pulse Today' on 10 August, where the DHSC had confirmed notification to GPs of a centrally procured stock to support the GP-led upcoming flu vaccination programmes.

Sanofi accepted the complainant would not have known about those discussions when he/she initiated this complaint.

2. On 12 May representatives were briefed and instructed to contact customers to offer support and solutions (ref MAT-GB-2102131 – Briefing on QIVe dose reduction emails). Sanofi stated that it also noted the complainant's submission that local practices were subsequently able to successfully order QIVe from other suppliers, and some QIVc from Seqirus following the notification of dose reduction. Sanofi acknowledged the inconvenience the dose reduction would have caused, and its flu team had, and continued to remain engaged with its customers to try to mitigate any impact that might have.

Sanofi stated that its priority was ensuring that health professionals could select the most appropriate vaccines for their patients whilst following the JCVI, NHS, and government guidance. Sanofi stated that it worked closely with the government authorities, as it did every year, to ensure that it could support the UK flu national immunisation programme ensuring timely communication of information while respecting the jurisdiction of DHSC. In addition, any requests for cancellation of orders were accepted unreservedly. As such, Sanofi did not believe any actions had misled, breached high standards or brought the industry into disrepute and it refuted breaches of Clauses 7.2, 9.1 and 2.

***Conduct of, and information given by a named Sanofi representative***

Sanofi noted the complainant's question as to why the supply issue was not raised at a meeting on 30 April with a Sanofi representative and his/her manager. In that regard Sanofi noted that from the briefing document provided, dated 12 May, (ref MAT-GB-2102131 – Briefing on QIVe

dose reduction emails) that the representative had no prior knowledge of any potential shortfall due to the progressive and positive discussions with DHSC, PHE and NHS/I. As previously explained, ongoing and regular confidential discussions at government level with DHSC and NHSE/I required that Sanofi was not able to communicate any external messages in advance.

Once the representative knew about and recognised the critical importance of the dose volume reduction, he/she organised and held a meeting on 13 May with the complainant. The representative followed the approved briefing document and entered the meeting with objectives to update the complainant on the critically important information given the shortfall announcement and to offer potential solutions. The representative had been briefed and followed the briefing document and did not respond to questions that fell outwith the scope of that brief. No request was made for follow up to the questions during or after the call by the complainant, nor was a further meeting requested to address them. After the call the representative sent two further emails, as requested by the complainant, to provide detailed company order data for the local region in order to support the reactive request by the complainant. As such, Sanofi did not believe any actions had misled, breached any high standards or brought the industry into disrepute and it refuted breaches of Clauses 7.2, 15.2, 9.1 and 2.

In conclusion, Sanofi submitted that, while it had experienced an unfortunate supply issue which could occur in vaccines manufacturing, it and all employees had maintained an ethical approach throughout, supporting customers with alternative solutions as well as following the normal influenza supply processes in place annually with the government bodies. Sanofi denied any breach of Clauses 7.2, 15.2, 9.1 and 2.

**PANEL RULING**

The Panel noted the complainant's allegation that in September 2020, well before guidance had been issued as to which flu vaccines would be used in the 2021/22 flu season, Sanofi had assertively promoted its flu vaccine and had offered significant discounts as an inducement for GPs to order QIVe. The Panel further noted that flu vaccine was not generally procured centrally; GP practices ordered their own supplies and the difference between the price that they paid vs the amount that NHSE/I later reimbursed for the vaccine doses used, might mean that some practices would make a profit which could be reinvested in service provision.

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. In summary, the letter stated 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 aged 18 to less than 65 years and pregnant women; 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 the complainant's submission that some practices had ordered QIVe ahead of the Powis letter and that as a result of clarification issued by the local health region (January/February) as to the recommended vaccine in the flu reimbursement letter, practices

which wanted to cancel their QIVe orders to switch to QIVc were prevented from doing so. Sanofi denied that it had prevented any requests for cancellation of orders and in that regard noted its briefing material which stated 'The Sanofi Pasteur customer facing team are advised to accept all customer cancellations reactively based on this guidance'.

The Panel noted that in March 2021, the complainant became aware that Sanofi had informed NHSE/I that there was a shortfall of around 1 million doses of QIVe; according to Sanofi's submission it appeared that, at the time, that shortfall and the potential solutions to it were the subject of confidential discussions between Sanofi and government teams.

The Panel noted the second letter from the NHS (Powis letter dated 1 April 2021) which updated the advice regarding the vaccines to be reimbursed in 2021 and 2022; the differences between the Powis letter of 3 February and that of 1 April are highlighted in bold in the table below. An additional cohort of patients had been included (those aged 50-64 years) and QIVr would now be reimbursed for certain age groups as an alternative to QIVc. This meant that Sanofi Pasteur's vaccine, QIVe, was now recommended only for third-line use in the at-risk population and those aged 50-64 years when neither QIVc nor QIVr were available.

| Those aged 65 years and over | **Those aged 50 to 64 years** | At-risk adults, including pregnant women, aged 18 to less than 65 years |
|---|---|---|
| • aQIV<br>• QIVc (where aQIV not available) | • **QIVc/QIVr**<br>• **QIVe (where QIVc or QIVr is not available)** | • QIVc/**QIVr**<br>• QIVe (where QIVc or **QIVr** is not available |

The Powis letter, dated 1 April, included information from manufacturers about additional vaccine availability. In relation to Sanofi Pasteur, the letter stated that the company would be fulfilling current orders for the 2021/2022 season with QIVe or QIVr.

The Panel noted that the complainant had provided a copy of an email he/she had received on 13 May to which was attached 'logistical' email of the same date from Sanofi informing readers that, due to an increase in global demand, orders from Sanofi Pasteur for QIVe would be automatically reduced by 30%. Readers were told that in order to meet their flu vaccine needs they might wish to consider contacting another supplier or contacting Sanofi Pasteur to source an alternative flu vaccine as recommended in the NHS guidance. Given that email, the complainant was surprised in retrospect that at a meeting with Sanofi representatives on 30 April, nothing had been said about the 30% reduction in QIVe orders. The Panel noted Sanofi's submission that that information was still confidential at that time and would not have been known to the representative. In that regard the Panel thus did not consider that there was any evidence to show that the representative had not maintained a high standard of ethical conduct or had been misleading about the supply of QIVe. No breach of Clauses 15.2 and 7.2 was ruled.

The Panel noted Sanofi's submission that it was first made aware on 4 March by global colleagues that the UK supply of QIVe would be affected by a dose volume reduction; the company submitted that it had not oversold doses. The company submitted that there would be centrally procured stock to support the vaccination programme although the complainant would not have known that when he/she submitted the complaint.

The Panel noted that the briefing document, used by the representative in discussions with the complainant on 13 May, set out the content of the 'logistical' email referred to above which stated that due to an increase in global demand, orders from Sanofi Pasteur for QIVe had to be reduced by 30%. The document provided a list of questions and answers including that the number of doses had to be reduced and that Sanofi Pasteur could supply doses of QIVr. In relation to a question about why Sanofi was reducing the number of QIVe doses, when Seqirus was not, the answer referred to the surge in demand which outstripped Sanofi's current Northern hemisphere capacity and that for the UK, the company had worked with the NHS to provide a limited number of QIVr doses to help cover the shortfall of QIVe.

The Panel noted that the manufacture, and thus supply of flu vaccine, was not straightforward. According to Sanofi, the strain of flu to be used in the Northern hemisphere had been released on 26 February 2021 to allow vaccine manufacturers to begin production in March and deliver from September as the flu season commenced. Further, flu vaccines took several months to produce; the strict quality control measures required at each step of the process accounted for most of the total production time between March and September.

The Panel further noted that on 3 February, national guidance had been issued regarding which flu vaccines should be used for the over 65s and the at-risk population; this guidance was updated in April with the addition of another patient cohort (50-65 years) and the inclusion of Sanofi's QIVr which would be reimbursed. In the meantime, Sanofi had been advised by its global colleagues that there would be a shortfall in the UK supply of QIVe which many practices had already ordered. That situation had led to confidential discussions with Sanofi and government teams about possible solutions which, given the commercial confidentiality of such matters, had not been made generally known until May. The Panel considered that the timing of events was unfortunate.

The Panel noted the extreme dissatisfaction that was generally required before an individual was moved to complain, and it had some sympathy for the complainant's position. It considered that the 'logistical' email of 13 May could have set out more clearly that the demand for QIVe had outstripped Sanofi's capacity and in that regard, it appeared that the shortfall was limited to Sanofi and was not a global issue as such. Nonetheless, as acknowledged by the complainant, the email did encourage readers to order supplies of vaccine from other manufacturers and in response, practices had tried to increase their orders of QIVe from other suppliers or QIVc. Readers had also been told that they could contact Sanofi Pasteur to source an alternative flu vaccine.

Overall, it appeared to the Panel that circumstances had changed rapidly in the early part of the year and that some of the resultant discussions between Sanofi and government teams had necessarily been confidential; Sanofi was thus not able to share details and the position was unknown to the complainant until discussions were completed. While the shortfall in the supply of QIVe from Sanofi might leave some practices short of stock, there nonetheless appeared to be supplies of vaccines from other manufacturers; there was no evidence that Sanofi had influenced the supply of its QIVe such as to preferentially sell the higher priced QIVr as alleged. It appeared that both parties were caught up in a situation which did not seem to be of their own making at a time when practices had to act quickly to secure sufficient supplies of the flu vaccine for the coming flu season. The Panel understood why the complainant might question Sanofi's conduct and motives, but it did not consider that there was evidence to show that the company had been misleading about the arrangement nor that it had not maintained high standards. No breaches of Clauses 7.2 and 9.1 were ruled.

The Panel noted it rulings and comments above and ruled no breach of Clause 2.

**Complaint received** **2 June 2021**

**Case completed** **28 September 2021**