PHARMACIST v SEQIRUS

Promotion of Fluad

A clinical commissioning group (CCG) lead prescribing support pharmacist complained about a promotional email for Fluad (influenza vaccine, adjuvanted) headed 'New guidance issued on adult flu vaccines' sent from Seqirus UK.

The complainant alleged that the email implied that the Joint Committee on Vaccination and Immunisation (JCVI) had changed its recommendations for 2018/19 such that Fluad should be used for everyone over 65 years, which was not so. Unless readers delved deeper, they would think this was a national recommendation and change in policy.

The complainant stated that if Fluad was adopted by CCGs for those aged over 65 years, it would have a huge cost implication for prescribing budgets, even though it was claimed to be cost effective. The complainant added that the evidence showed that Fluad was most cost effective in those aged over 75 years. The complainant alleged that the email was misleading.

The detailed response from Seqirus is given below.

The Panel noted that according to its summary of product characteristics (SPC) Fluad was indicated for active immunisation against influenza in the elderly (65 years of age and over) especially for those with an increased risk of complications and its use should be based on official recommendations.

The Panel noted that the email in question included a prominent highlighted blue box that read 'Important: Influenza vaccine policy change affecting your order for 2018/19'. Readers were told to make sure that their elderly patients received the suitable flu vaccine for them in 2018/2019. Under a subheading 'Improved influenza vaccines needed for people aged 65 years and over' it stated that according to the draft JCVI October 2017 meeting minutes the 2016/2017 season showed significant effectiveness against all laboratory confirmed influenza and specially the A(H3N2) virus in 18-64 year olds but non-significant vaccine effectiveness (VE) in the 65 years.

The email also stated that Fluad was a flu vaccine that specifically protected those aged 65 years and over and quoted the draft JCVI October 2017 meeting minutes referring to 'low influenza vaccine effectiveness seen in the over 65-74 year olds over several A(H3N2) dominated seasons and non-significant VE for all types of influenza in the over 75s' and 'use of aTIV [adjuvanted trivalent influenza vaccine] in those aged 65 years and over would be more effective than the non-adjuvanted vaccines currently in use, and also cost-effective'.

The Panel considered that the email made it clear from the outset and throughout that its quotations were from a draft JCVI minute. A highlighted prominent box towards the end of the email noted that the JCVI agreed that using Fluad in patients aged 65 years and over would be more effective than non-adjuvanted vaccines currently in use, as well as more cost-effective. The text in the box concluded by stating on the basis of clinical and cost-effective evidence and recent JCVI guidance encourage your GP to act now by ordering Fluad for their patients aged 65 years and over. The draft JCVI minutes were reflected in the NHS Green Book and thus it was not unreasonable to describe the subject matter of the email as a policy change. The source, and draft status of the JCVI minute was prominent and clear from the outset. In the Panel's view, the email in question was not misleading nor incapable of substantiation on this point as alleged. No breaches of the Code were ruled.

The Panel noted that the email at issue quoted the JCVI's draft minutes stating that the committee agreed that the available evidence indicated adjuvanted influenza vaccines were more effective in those over 65 years of age, compared with influenza vaccines currently used in the UK and mathematical modelling indicated that, under quite conservative estimates of effectiveness, the adjuvanted vaccine would be highly cost-effective in both the 65-75 and 75 and over age groups. The Panel did not consider that the complainant had established that the email was misleading with regards to this comparison and ruled no breach of the Code.

The Panel noted the complainant's allegation that it was misleading to state that Fluad was cost effective as there would be a huge cost implication for prescribing budgets and money saved would be elsewhere and not from the prescribing budget. The Panel noted that the email did not state how the cost-effectiveness would be achieved within the NHS but referenced the JCVI's own assessment based on Public Health England's modelling. The Panel did not consider that the email was misleading on the narrow ground alleged. There was no implication that cost effectiveness savings would mean that there was no negative impact on prescribing budgets as inferred by the complainant and no breach of the Code was ruled on this point. The Panel considered that the complainant had not provided evidence to show that the claim for cost-effectiveness was not capable of substantiation and no breach of the Code was ruled.

The Panel noted the relevant comments about cost-effectiveness in the draft JCVI minute above. The Panel noted that the email in question did not differentiate as to the cost-effectiveness across different age groups above 65 years and

therefore ruled no breach of the Code in relation to the complainant's allegation that the email was misleading because the evidence showed that Fluad was most cost effective in those aged over 75 years.

The Panel noted that each quotation used in the email gave the source as the JCVI meeting draft minutes October 2017 and each quote was faithfully reproduced. The Panel therefore ruled no breach of the Code.

The Panel noted its rulings above and considered that Seqirus had not failed to maintain high standards. The Panel ruled no breach of the Code.

A clinical commissioning group (CCG) lead prescribing support pharmacist complained about a promotional email (ref UK/FLUD/0917/0026c) for Fluad (influenza vaccine, adjuvanted) sent on 11 December 2017 from Seqirus UK Limited. The subject heading of the email was 'New guidance issued on adult flu vaccines'.

COMPLAINT

The complainant noted the email subject heading and alleged that the email implied that the Joint Committee on Vaccination and Immunisation (JCVI) had changed its recommendations for 2018/19 such that Fluad should be used for everyone over 65 years, which was not the case. Unless readers delved deeper, they would think this was a national recommendation and change in policy; the complainant was sure that practice managers might think so.

The complainant submitted that if Fluad was adopted by CCGs for those aged over 65 years, it would have a huge cost implication for prescribing budgets, even though it was claimed to be cost effective. Money saved would be elsewhere and not from the prescribing budget and therefore CCGs would need to discuss with commissioners action to be taken.

The complainant added that the evidence showed that Fluad was most cost effective in those aged over 75 years.

The complainant alleged that the email was misleading.

When writing to Seqirus, the Authority asked it to consider the requirements of Clauses 7.2, 7.3, 7.4, 9.1 and 10.2.

RESPONSE

With regard to the accuracy of the claims made in the email, Seqirus referred to the JCVI draft minute for the meeting of 4 October 2017 and Chapter 19 (on influenza vaccines) of The Green Book published by Public Health England which was most recently updated on 1 December 2017. Seqirus considered that these documents demonstrated the accuracy and balance of the claims in the email with which the complainant took issue, namely that:

a) there had been a change in guidance;

b) current guidance was now that Fluad was both more effective and cost-effective in those aged 65 years and over compared with non-adjuvanted vaccines already in use; and

c) the claims regarding cost-effectiveness in the email were not misleading.

To take point (a) first, the October 2017 JCVI meeting minute effectively started a directive cascade leading to a change in guidance, which ultimately culminated on 1 December 2017 in the updating of The Green Book influenza chapter (Chapter 19). The Green Book constituted the Department of Health's up-to-date information to health practitioners on vaccination and immunisation practice based on the recommendations of the JCVI (its most recent publication was on 15 November 2017).

Seqirus also referred to the letter of 22 December 2017 from NHS England which updated all GPs and CCGs in England on the use of adjuvanted trivalent flu vaccine (ie Fluad) for the 2018-19 flu season. Although this was circulated after the email at issue, Seqirus noted that this was an objective and directive communication from NHS England to CCGs and GPs in England alerting them to the specific guidance changes in recommendations on vaccination which were found in the JCVI minute and The Green Book which had already occurred when the email was sent; in particular, the subject heading of the NHS England letter and the statement, "This ***update*** summarises ***recent advice*** *from the Joint Committee on Vaccination and Immunisation (JCVI) and the* ***latest update*** in the Green Book on adjuvanted trivalent flu vaccine ***that can support your decisions on optimal choice of influenza for the 2018/19 season"*** (emphasis added), reiterated the changes to The Green Book and the October 2017 JCVI draft minute (which were specifically identified in the email).

Seqirus stated that in its view, this amounted to a change in guidance in the form of expert bodies and policy makers reacting to new circumstances, ie that Fluad was now available to order for use in the 2018/19 influenza season, and was considered cost-effective in the 65 years and over age group, particularly when reviewed against the existing comparator non-adjuvanted vaccines that were currently being ordered and used which were in truth demonstrated to provide no proven significant vaccine effectiveness by Public Health England (Pebody *et al* 2017 and the JCVI Minute – copies provided).

Seqirus stated that it was aware that an increasing number of CCGs had acted upon the advice of the JCVI and the guidance in The Green Book and had incorporated the recommendations into their own guidance and policies (see further below). This illustrated that CCGs had also understood this was a change in policy.

Additionally, the Chief Medical Officer for Wales also referred to the updated advice and JCVI guidance in his letter of 29 November 2017 addressed to all GPs, Health Boards/Trusts, and pharmacists in Wales

(copy provided). This letter referred to the '***updated advice from the JCVI*** on the cost-effectiveness of particular vaccines' and also stated ***'updated guidance ...*** has been published in the Green Book' (emphasis added). Seqirus stated that in its view, this quite clearly demonstrated there had been a widely accepted change in guidance.

As to point (b), both the JCVI minute and The Green Book stated that Fluad was both more effective and more cost-effective in those 65 years and over than the non-adjuvanted vaccines already in use. Seqirus did not agree that the JCVI guidance recommendation was only for those aged 75 years and over (as the complainant insinuated). The JCVI minute and The Green Book additionally identified that use of Fluad should be a priority in the over 75 years age group (due to current vaccines not being effective in that age group); and moreover, the JCVI clearly stated that Fluad was highly cost-effective in all those aged 65-74 years old.

Seqirus noted the complainant's comments that the evidence showed that Fluad was most cost effective in those aged over 75 years. This did not seem relevant to the email given that it did not differentiate as to the effectiveness across different age groups above 65 years. Neither the JCVI minute nor The Green Book dealt with the differential effectiveness of Fluad in those aged 65-74 years and those aged 75 years and over. Rather these documents merely stated that it was a priority to use Fluad in the 75 and over age-group and this did not exclude use in those aged 65-74.

As noted above, an increasing number of CCGs had already reacted positively to the change in guidance and had incorporated this guidance for the 65-74 years age group into their own policies as well as for the 75 years and older. A specific named CCG example was given in which the CCG had incentivised the use of Fluad for patients aged 65 years and over. Although this communication post-dated the email in question, it clearly demonstrated that the JCVI guidance changes had been clearly and unambiguously understood as recommendations regarding the cost-effectiveness in the 65 years and over age group and not just in the over 75 years age group. Furthermore, in the letter, the named CCG additionally incentivised its GPs to order Fluad for their adults aged 65 years and over, which reinforced the accepted expert opinion that Fluad was highly cost-effective in adults aged 65 years and over. A not too dissimilar approach could also be seen in another named CCG's 'position statement on influenza vaccine for 2018/19 season' dated November 2017 (ie pre-dating the email), which stated that 'Patients aged 65 years and over should be offered the adjuvanted trivalent vaccine (Fluad)' (copy enclosed).

As to point (c), Seqirus submitted that the complainant seemed to imply that claims were misleading as the savings would not, in his/her view, necessarily be felt by an individual CCG when he or she stated that if [Fluad] was adopted by CCGs for over 65 years, it would have a huge cost implication for prescribing budgets, although it is claimed to be cost effective and that 'money saved would be elsewhere'. The complainant thus appeared to acknowledge that savings would be made overall so it was not entirely clear what criticism was made here.

Seqirus stated that the email did not contain any claim as to where or how the cost-effectiveness would be achieved within the NHS but simply referenced the JCVI's own assessment based on Public Health England's modelling, which likewise did not make any assessment as to where or how cost-effectiveness would be achieved within the NHS. Indeed, the JCVI minute stated that the Committee received not only a cost-effectiveness analysis of Fluad from Seqirus but also used and reviewed their own independent cost-effectiveness analysis, and in both models - which used the NHS List price of Fluad – stated that, 'Both models indicated ***a programme in the 65 years upwards age group would be cost-effective at the list price*** of the vaccine', and even 'under quite conservative estimates of effectiveness, [***Fluad] would be highly cost-effective in both the 65-74*** and 75 and over age-groups'
(emphasis added).

From the various headings and attributions contained in the email, Seqirus submitted that it was clear that the claims were based upon the minuted assessment of a national expert panel and were references as to cost-effectiveness for the NHS overall, and did not amount to implied claims concerning cost-effectiveness at an individual CCG level.

Seqirus denied any breach of Clause 7.2, it did not consider that the statements in the email were misleading; they were accurate, balanced, fair and objective and based on the opinions of a national expert body.

Seqirus stated that in its view all of the comparative claims in the email satisfied the requirements of Clause 7.3. The claims were either direct quotations from, or closely based upon, the JCVI minute of the October 2017 meeting. The JCVI represented and reflected the opinion of the national expert body which directly advised the Department of Health. The comparative claims were therefore clearly substantiated by the evidence and could not be considered misleading. Moreover, the comparative claims assessed medicines for the same needs or intended for the same purposes and also compared material, relevant, substantiable and representative features of the products, in particular both effectiveness and cost-effectiveness, which were key factors for vaccine purchasing decisions. Seqirus denied a breach of Clause 7.3.

As noted above, the claims questioned by the complainant were direct quotations from, or were closely based on, the JCVI minute. They were described as guidance and reflected the assessments made on the evidence by the national expert body in this area. Seqirus thus considered these claims had been substantiated.

With regards to the statement 'FLUAD is a flu vaccine that specifically protects those aged 65 years and over', Seqirus submitted that the Fluad SPC which demonstrated that Fluad was specifically therapeutically indicated for the 65 years and over

age group. Seqirus thus considered that this was an accurate statement, substantiated by the SPC.

With regards to substantiating whether there has been a change in the guidance, Seqirus referred to its analysis above in respect of Clause 7.2 for point (a) therein. The company considered that it was clear that the JCVI minute and the changes to The Green Book amounted to a change in the guidance, as they amounted to a positive reaction to the new circumstance of Fluad becoming licensed in the UK for order to be used in the 2018/19 influenza season as well as the associated evidence on Fluad's effectiveness and cost-effectiveness.

Seqirus submitted that the email did comply with the Code and that high standards had been maintained. The email was accurate and did not mislead; it was a responsible communication which highlighted relevant expert opinion regarding Fluad's efficacy, effectiveness, and cost-effectiveness. Seqirus again noted that that various NHS bodies had similarly disseminated equivalent and more directive guidance to GP practices and prescribers.

Seqirus submitted that each quotation in the email satisfied the requirements of Clause 10.2 in that for each one the precise source had been identified, each was faithfully reproduced and was not taken out of context (ie there was nothing which significantly qualified the quotations elsewhere in the minute). The quotations accurately reflected the meaning of the author, ie the JCVI.

PANEL RULING

The Panel noted that according to its SPC Fluad was indicated for active immunisation against influenza in the elderly (65 years of age and over) especially for those with an increased risk of complications and its use should be based on official recommendations.

The Panel noted that the subject line of the email in question read 'New guidance issued in adult flu vaccines'. A prominent highlighted blue box at the beginning of the email read 'Important: Influenza vaccine policy change affecting your order for 2018/19'. Readers were told to make sure that their elderly patients received the suitable flu vaccine for them in 2018/2019. Under a subheading 'Improved influenza vaccines needed for people aged 65 years and over' it stated that according to the draft JCVI October 2017 meeting minutes the 2016/2017 season showed significant effectiveness against all laboratory confirmed influenza and specially the A(H3N2) virus in 18-64 year olds but non-significant vaccine effectiveness (VE) in the 65 years.

A prominent subheading then stated that Fluad was a flu vaccine that specifically protected those aged 65 years and over and quoted a number of statements from the draft JCVI October 2017 meeting minutes referring to 'low influenza vaccine effectiveness seen in the over 65-74 year olds over several A(H3N2) dominated seasons and non-significant VE for all types of influenza in the over 75s' and 'use of aTIV in those aged 65 years and over would be more effective than the non-adjuvanted vaccines currently in use, and also cost-effective'.

The Panel noted that the JCVI advised UK health departments on immunisation. The Panel noted that the draft JCVI minute referred to a Public Health England analysis of pooled primary care data since 2005/06 stratified by 65-74, 75-84 and 85 years upwards showing significant vaccine effectiveness in the 65-74 age group for all influenza A (H1N1) pdm09 and influenza B and evidence of protection against A(H3N2). Above the age of 75 years pooled estimates of VE were non-significant against all influenza virus types.

The Panel noted the conclusions of the JCVI in the draft minute that adjuvanted influenza vaccines were more effective in those over 65 years compared to currently used vaccines. The Panel also noted its agreement that if a change in approach were to be considered switching vaccination of the 75 years and over age group to adjuvanted vaccine would be given the first priority given the non-adjuvanted inactivated vaccine showed no significant effectiveness in this group. The JCVI asked the Department of Health, Public Health England and NHS England to give consideration to the evidence on provision of adjuvant influenza vaccine to those aged 65 years and over whilst recognising practical considerations such as procurement arrangements.

The Panel further noted Seqirus' submission that the Green Book constituted the Department of Health's up-to-date information to health practitioners on vaccination and immunisation practice based on the recommendations of the JCVI. The Green Book reflected the advice in the draft October JCVI minute, noting, in particular, that priority for adjuvanted vaccine should be for those aged 75 years and above.

The Panel noted that the NHS England update letter dated 22 December 2017 on use of adjuvanted trivalent flu vaccine for 2018-2019 flu season stated that it summarised recent advice from the JCVI and the latest update in the Green Book on adjuvanted trivalent flu vaccine that could support decisions on optimal choice of influenza vaccine for the 2018/2019 season. The Panel noted that the NHS England letter was sent after the email in question.

The email made it clear from the outset and throughout that its quotations were from a draft JCVI minute. A highlighted prominent box towards the end of the email noted that the JCVI agreed that using Fluad in patients aged 65 years and over would be more effective than non-adjuvanted vaccines currently in use, as well as more cost-effective. The text in the box concluded by stating on the basis of clinical and cost-effective evidence and recent JCVI guidance encourage your GP to act now by ordering Fluad for their patients aged 65 years and over. The draft JCVI minutes were reflected in the NHS Green Book and thus in this regard it was not unreasonable to describe the subject matter of the email as a policy change. The source, and draft status of the JCVI minute was prominent and clear from the outset. In the Panel's view, the email in question was not misleading nor incapable of substantiation on this point as alleged. No breach of Clauses 7.2 and 7.4 were ruled.

The Panel noted that the email at issue quoted the JCVI's draft minutes stating that the committee agreed that the available evidence indicated adjuvanted influenza vaccines were more effective in those over 65 years of age, compared with influenza vaccines currently used in the UK and mathematical modelling indicated that, under quite conservative estimates of effectiveness, the adjuvanted vaccine would be highly cost-effective in both the 65-75 and 75 and over age groups. The Panel did not consider that the complainant had established that the email was misleading with regard to this comparison and ruled no breach of Clause 7.3.

The Panel noted the complainant's allegation that it was misleading to state that Fluad was cost effective as there would be a huge cost implication for prescribing budgets and money saved would be elsewhere and not from the prescribing budget. The Panel noted that the email did not state how the cost-effectiveness would be achieved within the NHS but referenced the JCVI's own assessment based on Public Health England's modelling, which likewise did not make any assessment as to where or how cost-effectiveness would be achieved. The draft JCVI minute stated that the Committee received not only a cost-effectiveness analysis of Fluad from Seqirus but also used and reviewed their own independent cost-effectiveness analysis and that, 'Both models indicated a programme in the 65 years upwards age group would be cost-effective at the list price of the vaccine', and even 'under quite conservative estimates of effectiveness, [Fluad] would be highly cost-effective in both the 65-74 and 75 and over age-groups'. The Panel did not consider that the email was misleading on the narrow ground alleged. There was no implication that cost effectiveness savings would mean that there was no negative impact on prescribing budgets as inferred by the complainant and no breach of Clause 7.2 was ruled on this point. The Panel considered that the complainant had not provided evidence to show that the claim for cost-effectiveness was not capable of substantiation and no breach of Clause 7.4 was ruled.

The Panel noted the relevant comments about cost-effectiveness in the draft JCVI minute above. The Panel noted that the email in question did not differentiate as to the cost-effectiveness across different age groups above 65 years and therefore ruled no breach of Clause 7.2 in relation to the complainant's allegation that the email was misleading because the evidence showed that Fluad was most cost effective in those aged over 75 years.

The Panel noted that Clause 10.2 required that quotations from medical and scientific literature or from personal communications must be faithfully reproduced (except where adaptation or modification is required in order to comply with the Code) and must accurately reflect the meaning of the author. The precise source of the quotation must be identified. The Panel noted that each quotation used in the email gave the source as the JCVI meeting draft minutes October 2017 and each quote was faithfully reproduced. The Panel therefore ruled no breach of Clause 10.2.

The Panel noted its rulings above and considered that Seqirus had not failed to maintain high standards. The Panel ruled no breach of Clause 9.1.

Complaint received **14 December 2017**

Case completed **10 May 2018**