CASE AUTH/3157/2/19

VOLUNTARY ADMISSION BY ASTRAZENECA

Substantiation of a claim for Fluenz Tetra

AstraZeneca voluntarily admitted that a claim on the Fluenz Tetra (live attenuated influenza vaccine (LAIV)) website (fluenztetra.co.uk) could not be substantiated by the reference cited.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint the matter was taken up with AstraZeneca.

The detailed response from AstraZeneca is given below.

The Panel noted the statement at issue, 'Approximately 125.6 million doses of nasal spray flu vaccine (trivalent and quadrivalent) have been distributed worldwide since the 2003/04 flu season until the end of the 2017/18 flu season [data on file], and there have been no laboratory-confirmed reports of LAIV virus transmission or illness associated with LAIV virus transmission [Izurieta *et al* 2005]', appeared on the Fluenz Tetra nasal spray website and in a Q&A booklet aimed at health professionals.

The statement was part of a response to the question 'What is the transmission risk?' on the website.

The Q&A document question 'Is there a risk of transmitting Fluenz Tetra viruses?' was followed by 'Vaccine recipients should be informed that Fluenz Tetra is a live attenuated influenza vaccine and has the potential for transmission to immunocompromised contacts'. This was followed by the statement at issue.

The Panel noted AstraZeneca's submission that the impression given by the statement at issue could not be supported by the references given and that, to date, there had been few published or documented cases of secondary transmission from vaccinated individuals to no-vaccinated individuals; whilst the numbers were very small, there had been cases.

The Panel considered that the claim was misleading and could not be substantiated and breaches of the Code were ruled including that AstraZeneca had failed to maintain high standards as acknowledged by AstraZeneca.

AstraZeneca voluntarily admitted that a claim on the Fluenz Tetra (live attenuated influenza vaccine (LAIV)) website (fluenztetra.co.uk) could not be substantiated by the reference cited.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with AstraZeneca.

VOLUNTARY ADMISSION

AstraZeneca explained that it had potentially breached Clauses 7.2, 7.4 and 9.1 of the 2016 Code with regard to the health professional section of Fluenz Tetra nasal spray website and a questions and answers (Q&A) booklet, also aimed at health professionals.

AstraZeneca stated that it discovered the potential breaches on 6 December 2018, after a member of the public enquired about transmission data on the Fluenz Tetra website. This was a promotional website for health professionals only, which contained learning modules on Fluenz. To access the modules, visitors had to declare whether they were a health professional or member of public; no access was granted to members of the public.

The enquiry centred on why transmission information contained in the US prescribing information was not on the UK website. The particular information in question was not included in the EU approved Quality Review of Documents (QRD) and subsequently the UK summary of product characteristics (SPC) in line with the assessment by the European Medicines Agency (EMA).

During the investigation it was noticed that in the section on the website about the risk of transmission of the live attenuated virus from a recipient to an immunocompromised individual, there was a subsequent page that discussed transmission from vaccine recipients to healthy individuals. This statement also appeared in the Q&A booklet.

The statement read as follows:

> 'Approximately 125.6 million doses of nasal spray flu vaccine (trivalent and quadrivalent) have been distributed worldwide since the 2003/04 flu season until the end of the 2017/18 flu season [data on file], and there have been no laboratory-confirmed reports of LAIV virus transmission or illness associated with LAIV virus transmission [Izurieta *et al* 2005].'

AstraZeneca stated that the claim suggested that all reported cases of influenza were investigated to exclude transmission from other sources than the wild type form of the virus. This was not the case and could not be substantiated by the two references cited.

AstraZeneca stated that, to date, there had been few published or documented cases of secondary transmission from vaccinated individuals to no-vaccinated individuals but the fact remained whilst the numbers were very small there had been cases.

AstraZeneca stated that it was committed to ensuring it upheld the highest of standards and therefore it had: removed the statement in question and associated pages from the website on 12 December 2018; recalled the Q&A booklet on 13 December 2018; and retrained the individuals involved.

The material had been certified in line with standard operating procedures. AstraZeneca was disappointed that the company's normal attention to detail was not demonstrated when these items were reviewed.

AstraZeneca stated that the claim was in breach of Clauses 7.2 and 7.4 of the Code and that the company, in this instance, had not maintained high standards in line with its values and therefore had also breached Clause 9.1.

RESPONSE

AstraZeneca stated that the website and Q&A document were used as support material for health professionals for the 2018/19 flu season. The webpages at issue were part of an online training module. The Q&A booklet was for use by health professionals to support use of Fluenz, which was part of the childhood flu immunisation programme.

PANEL RULING

The Panel noted the statement at issue: 'Approximately 125.6 million doses of nasal spray flu vaccine (trivalent and quadrivalent) have been distributed worldwide since the 2003/04 flu season until the end of the 2017/18 flu season [data on file], and there have been no laboratory-confirmed reports of LAIV virus transmission or illness associated with LAIV virus transmission [Izurieta *et al* 2005]', which appeared on the Fluenz Tetra nasal spray website and in a Q&A booklet aimed at health professionals. The statement was part of a response to a question on the website 'What is the transmission risk?'. The Q&A document question 'Is there a risk of transmitting Fluenz Tetra viruses?' was followed by 'Vaccine recipients should be informed that Fluenz Tetra is a live attenuated influenza vaccine and has the potential for transmission to immunocompromised contacts'. This was followed by the statement at issue. The Panel noted AstraZeneca's submission that the impression given by the statement at issue could not be supported by the references given and that, to date, there had been few published or documented cases of secondary transmission from vaccinated individuals to no-vaccinated individuals; whilst the numbers were very small, there had been cases.

The Panel considered that the claim was misleading and could not be substantiated and ruled a breach of Clauses 7.2 and 7.4 as acknowledged by AstraZeneca.

The Panel considered that AstraZeneca had failed to maintain high standards and a breach of Clause 9.1 was ruled as acknowledged by AstraZeneca.

Complaint received **12 February 2019**

Case completed **8 May 2019**