CASE AUTH/3519/5/21

MEMBER OF THE PUBLIC v PFIZER

Misleading press release

A complaint was made about a press release issued by Pfizer Limited and BioNTech dated 2 December 2020.

The complainant provided a link to a recent peer reviewed article in the Lancet which pointed out that the efficacy claims being made for the Covid-19 vaccines were based on relative risk reduction (RRR) and not absolute risk reduction (ARR) which was a vastly smaller number.

The complainant provided links to two UK press releases including one from Pfizer in which efficacy results from its study were discussed. The complainant noted that only the RRR results were presented, with no mention of ARR in breach of the Code which specifically required that any discussion of RRR must include presentation of ARR results too. The complainant further alleged that this was information to the public which had not been presented in a factual and balanced way.

The complainant believed the relevant ARR results were in the order of 0.84% for the Pfizer study.

The detailed response from Pfizer is given below.

The Panel noted Pfizer's submission that it recognised that absolute risk reduction could be helpful when individuals were considering if they wanted/needed to be vaccinated or not. Nonetheless, the Panel also noted Pfizer's submission that the development of its vaccine BNT162b2, presented a unique issue; the key efficacy trial took place over a period of approximately 3.5 months at sites in six different countries (USA, Argentina, Brazil, South Africa, Germany, Turkey) when the second wave of the SARS-CoV-2 pandemic was beginning with the epidemic curve rapidly rising. At the time, the risk of an unvaccinated person acquiring the virus was therefore dynamic and increasing with time (and continued to increase after the trial concluded). Furthermore, the risk of acquiring the virus also varied between countries participating in the trial, depending on the extent to which local lockdowns were enforced and specific containment strategies used. It was therefore challenging to attribute a meaningful risk of acquiring COVID-19 for unvaccinated participants in the context of the trial and could be misleading at a time of a global pandemic with continuously changing epidemiology.

Whilst noting Pfizer's submission about the difficulties associated with the calculation and inclusion of ARR, the Panel considered that the relevant supplementary information, 'reference to absolute and relative risk', and compliance with it should be interpreted in light of its associated clause which required that materials etc should not be, *inter alia*, misleading and material must be sufficiently complete to enable the recipient to form their own opinion of the therapeutic values of the medicine.

In the Panel's view, whilst noting Pfizer's submission that the press release included reference to the absolute number of events upon which the first primary objective analysis was based and, as such, provided context to the scale of the trial and the vaccine efficacy data, the Panel considered that further details, such as the number of cases and subjects in each arm, would help certain sectors of the ultimate audience to interpret the absolute risk and form their own opinion of the efficacy of the medicine. In addition, the Panel noted that the status of the ultimate audience was relevant and it was particularly important to be clear about such matters in circumstances where the ultimate audience might include members of the public. The Panel considered that, in the absence of any explanation in the press release, some readers such as members of the public might assume that the efficacy rate was, in effect, an absolute rate and that was not so. A breach of the Code was ruled.

The Panel noted that the press release explained that Pfizer's Covid-19 vaccine had been granted a temporary authorisation in the UK to permit its supply, the vaccine had not been granted a marketing authorisation and so had not been legally classified as a prescription only medicine when the press release was issued. The Panel noted that Clause 26.2 only applied to prescription only medicines and on that very narrow technical point, no breach of the Code was ruled.

The Panel noted its comments and rulings above and consequently ruled a breach of the Code as high standards had not been maintained.

The Panel noted the unique circumstances of the Covid-19 pandemic and the trial and therefore did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and was reserved for such use and no breach was ruled.

A complaint was made about a press release issued by Pfizer Limited and BioNTech dated 2 December 2020.

COMPLAINT

The complainant referred to a recent peer reviewed article in the Lancet which pointed out that the efficacy claims being made for the Covid-19 vaccines were based on relative risk reduction (RRR) and not absolute risk reduction (ARR) which was a vastly smaller number.

The complainant provided links to two UK press releases one from Pfizer and one from another company in which efficacy results from their studies were discussed. The complainant noted that in the Pfizer press release only the relative risk reduction results were presented, with no mention of absolute risk reduction. This was a breach of Clause 7.2 of the Code which specifically required that any discussion of RRR must include presentation of ARR results too. As this was information to the public which had not been presented in a factual and balanced way, the complainant also alleged a breach of Clause 26.2. If companies were found to have breached the Code in this regard then surely any sanction must include them being required to issues a further press statement pointing out this 'error' and including the relevant ARR results which he/she believed were in the order of 0.84% for the Pfizer study.

When writing to Pfizer, the Authority asked it to consider the requirements of Clauses 2, 9.1, 7.2 and 26.2 of the Code.

RESPONSE

Pfizer stated that it took its commitment to working within the framework of the Code very seriously and was very concerned by the allegations associated with this complaint. Pfizer provided a detailed response below.

Clause 7.2 Misleading Information, Claims and Comparisons

Pfizer stated that it recognised the requirement and importance of presenting the ARR alongside any RRR claims included in the materials it issued. This would normally form an essential part of any data the company presented to ensure that the reader could appropriately assess the clinical impact of the medicine. However, estimates of vaccine efficacy (using data from randomised clinical trials) and vaccine effectiveness (using data from real world observational studies) were always expressed as relative risk reduction. This was the case in the Regulation 174 Information for Health Professionals on Pfizer/BioNTech COVID-19 vaccine published by the Medicines and Healthcare products Regulatory Agency (MHRA) and also in vaccine effectiveness publications for COVID-19 by Public Health England.

Pfizer stated that RRR informed the individual in an intuitive and easily understandable way the extent to which the vaccine was estimated to reduce the risk of acquiring the disease the vaccine was targeting. However, it did not inform individuals about their risk of acquiring the disease whilst unvaccinated. Pfizer stated that it recognised that this information could be helpful when individuals were considering if they wanted/needed to be vaccinated or not.

The risk of acquiring an infectious disease (diseases against which vaccines were often developed) was rarely constant over time. This would often fluctuate with time (eg the disease was associated with a seasonality and/or an epidemic cycle) with risk of acquisition also varying by age group and other demographic factors that influenced contact patterns and transmission pathways. Clinical trials often had to run over extended periods of many months or even years to recruit the required number of cases so it might be more reasonable in these circumstances to consider an average risk of exposure.

However, the development of Pfizer's vaccine BNT162b2, presented a unique issue. The key efficacy trial took place over a period of approximately 3.5 months from 27 July 2020 to 14 November 2020 at sites in six different countries (USA, Argentina, Brazil, South Africa, Germany, Turkey). This reflected the period when the second wave of the SARS-CoV-2 pandemic was beginning with the epidemic curve rapidly rising. At the time the risk of an unvaccinated person acquiring the virus was therefore dynamic and increasing with time (and continued to increase after the trial concluded). Furthermore, the risk of acquiring the virus also varied between countries participating in the trial depending on the extent to which local lockdowns were enforced and specific containment strategies used. It was therefore challenging to attribute a meaningful risk of acquiring COVID-19 for unvaccinated participants in the context of this trial and could be misleading at a time of a global pandemic with continuously changing epidemiology.

The press release included reference to the absolute number of events upon which the first primary objective analysis was based (the first primary objective analysis was based on 170

cases of COVID-19 in participants without prior SARS-CoV-2 infection as specified in the protocol) and as such Pfizer submitted it provided context to the scale of the trial and the vaccine efficacy data.

For these reasons Pfizer did not believe that the press release was misleading. The information presented was fair, balanced and consistent with the approach taken by the MHRA and Public Health England. Pfizer therefore denied a breach of Clause 7.2.

Clause 26.2 Relations with the Public and the Media

Pfizer stated that it believed that the information provided was factual, presented in a balanced way and accurately reported the primary objective of the phase 3 clinical trial. The press release was consistent with the Regulation 174 information for Healthcare Professionals published by the MHRA and did not raise unfounded hopes of successful treatment. The press release was not designed to encourage members of the public to ask their health professional to prescribe a specific prescription only medicine; vaccines for the COVID-19 national vaccination programme were centrally procured and implemented by government with no option for clinicians or individuals to request a specific vaccine.

This was an unprecedented time of global emergency and there was widespread coverage of all clinical development programmes for COVID-19 vaccines and treatments. Pfizer stated that it believed that in these unique circumstances, the reporting of the primary objective in the pivotal clinical trial was balanced, factual and appropriate with reporting of data in line with public health agencies and regulators.

Pfizer submitted that the press release met all of the requirements of Clause 26.2 and Pfizer therefore denied a breach of the Code.

Clause 9.1 and Clause 2 Maintaining High Standards and Confidence in the Industry

Pfizer strongly refuted the suggestion that this press release was not fair and balanced and that it might have misled the recipients or members of the public. The press release accurately reported the decision of the MHRA to grant a temporary supply authorisation for the vaccine and summarised the data that this decision was based upon in a fair and balanced way. Pfizer stated that it believed that the press release was of a high standard and in no way brought discredit upon, or reduced confidence in, the industry.

In response to a request for further information, Pfizer provided a copy of the approved press release and relevant final form certificate.

PANEL RULING

The Panel noted that Clause 7.2 of the 2019 Code stated that information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis. Material must be sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicine.

The supplementary information to Clause 7.2 highlighted areas where particular care should be taken by companies including, *inter alia*, reference to absolute risk and relative risk. It stated that referring only to relative risk, especially with regard to risk reduction, could make a medicine appear more effective than it actually was. In order to assess the clinical impact of an outcome, the reader also needed to know the absolute risk involved. In that regard, relative risk should never be referred to without also referring to the absolute risk. Absolute risk could be referred to in isolation.

The Panel noted Pfizer's submission that it recognised that this information [absolute risk reduction] could be helpful when individuals were considering if they wanted/needed to be vaccinated or not. Nonetheless, the Panel also noted Pfizer's submission that the development of its vaccine BNT162b2, presented a unique issue; the key efficacy trial took place over a period of approximately 3.5 months at sites in six different countries (USA, Argentina, Brazil, South Africa, Germany, Turkey) when the second wave of the SARS-CoV-2 pandemic was beginning with the epidemic curve rapidly rising. At the time, the risk of an unvaccinated person acquiring the virus was therefore dynamic and increasing with time (and continued to increase after the trial concluded). Furthermore, the risk of acquiring the virus also varied between countries participating in the trial, depending on the extent to which local lockdowns were enforced and specific containment strategies used. It was therefore challenging to attribute a meaningful risk of acquiring COVID-19 for unvaccinated participants in the context of the trial and could be misleading at a time of a global pandemic with continuously changing epidemiology.

Whilst noting Pfizer's submission about the difficulties associated with the calculation and inclusion of absolute risk reduction, the Panel considered that the relevant supplementary information, 'reference to absolute and relative risk', and compliance with it should be interpreted in light of its associated clause, Clause 7.2, which required that materials etc should not be, *inter alia*, misleading and material must be sufficiently complete to enable the recipient to form their own opinion of the therapeutic values of the medicine.

In the Panel's view, whilst noting Pfizer's submission that the press release included reference to the absolute number of events upon which the first primary objective analysis was based and, as such, provided context to the scale of the trial and the vaccine efficacy data, the Panel considered that further details, such as the number of cases and subjects in each arm, would help certain sectors of the ultimate audience to interpret the absolute risk and form their own opinion of the efficacy of the medicine. In addition, the Panel noted that the status of the ultimate audience was relevant and it was particularly important to be clear about such matters in circumstances where the ultimate audience might include members of the public. The Panel considered that, in the absence of any explanation in the press release, some readers such as members of the public might assume that the efficacy rate was, in effect, an absolute rate and that was not so. A breach of Clause 7.2 was ruled.

The Panel noted that the press release explained that Pfizer's Covid-19 vaccine had been granted a temporary authorisation in the UK to permit its supply, the vaccine had not been granted a marketing authorisation and so had not been legally classified as a prescription only medicine when the press release was issued. The Panel noted that Clause 26.2 only applied to prescription only medicines and on that very narrow technical point, no breach of Clause 26.2 was ruled.

The Panel noted its comments and rulings above and consequently ruled a breach of Clause 9.1.

The Panel noted the unique circumstances of the Covid-19 pandemic and the trial and therefore did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and was reserved for such use and no breach was ruled.

Complaint received	**27 May 2021**
Case completed	**19 February 2022**