



UK Regulator Finds Pfizer Guilty of Violating Three Sections of the British Pharmaceuticals Code of Practice

Description

A complaint against Pfizer pharmaceutical was filed to the UK's Prescription Medicines Code of Practice Authority (PMCPA), the regulator responsible for policing promotions of prescription medicines in the UK.

The complaint centered on an interview that was conducted by a medical editor at the BBC, in which Pfizer's CEO Albert Bourla made comments that were "misleading" about COVID shots for children. On December 2, 2021, this interview also appeared on the BBC website under the category "Health."

Children's Health Defense reported:

In the BBC interview, Bourla said it was up to the regulatory agencies to determine whether to approve and distribute vaccines to children under 11, but he thought that "immunising that age group in the UK and Europe would be a very good idea," according to the [PMCPA case report](#) published last week.

At the time, no COVID-19 vaccines had been approved by the U.K.'s [Medicines and Health products Regulatory Agency](#) (MHRA) for children under 12, so the panel found Bourla's comments were in breach of code.

Citing possible disruptions in schooling and the potential for [long COVID](#), Bourla also said, "So, there was no doubt in my mind that the benefits completely were in favour of doing it [vaccinating children against COVID-19]."

He added, "I believe it's a good idea."

The panel found these strong opinion statements could lead the public to infer there was no need to be concerned with potential side effects or that the benefits of vaccination outweigh the risks, which had not been determined by the health authorities.

The complaint was filed on Dec. 11, 2021 by Us For Them, “a parent-led campaign group calling for children’s needs to be prioritized during the Covid pandemic response.”

The Us For Them organization believes that children “must be placed front and center in all decisions impacting them. The wellbeing of children should be a guiding principle of public policy making.”

?? BREAKING:

UK regulator finds Pfizer boss guilty of misinformation — full case report published.

Read our inside story here.

??<https://t.co/87aSbyHnC8>

— UsForThemUK ? (@UsforThemUK) [February 2, 2023](#)

Read the case summary below:

The complainant made specific allegations about statements and claims made in the promotional piece relating to children:

1. ‘Immunising that age group [children under the age of 11] in the UK and Europe would be a very good idea.’

The complainant alleged that by recommending vaccinating healthy British children under the age of 11 against Covid-19, the Pfizer CEO was making a claim for the clinical efficacy and safety of Pfizer’s product and its risk/benefit balance, even though the vaccine had not yet been included in the emergency use temporary approval for use in children this young in the UK.

2. ‘Covid in schools was thriving’. ‘This was disturbing significantly the educational system and there were kids that would have severe symptoms.’

The complainant stated that severe Covid-19 was rare amongst children and school age in the UK and while the virus did circulate in schools, schools had typically reflected community transmission throughout the pandemic. Neither had Covid-19 itself had a significant impact on disturbing children’s education in the UK. The ‘disturbance’ to the UK educational system had resulted from political decisions made by governments, not the virus. Indeed, the complainant knew that the UK had the second highest rates of school closures in Europe, except for Italy – a result of political decisions.

The complainant stated that there was simply no evidence that healthy school children in the UK were at significant risk from the SARS COV-2 virus and to imply that they were was disgracefully misleading.

3. ‘So, there was no doubt in my mind that the benefits completely were in favour of doing it.’

The complainant alleged that this was probably the most egregiously false and misleading of the Pfizer’s CEO’s statements. It completely neglected to consider that there were potential risks to healthy children associated with administration of the Covid-19 vaccine. The complainant referred to a number of documents including a Pfizer leaflet listing side-effects; Latest government advice regarding myocarditis to healthcare workers detailing rates of myocarditis in hospitalised children; and Latest adverse events reported for Pfizer.

The complainant stated that the tone, content and means of dissemination of this article and the associated video were extremely promotional in nature. The complainant strongly believed that it was not appropriate for Pfizer to promote its product in this way. The complainant referred to three earlier cases against Pfizer for promoting its Covid-19 vaccine illegitimately online

The UK’s Prescription Medicines Code of Practice Authority (PMCPA) found Pfizer guilty of violating three sections of the pharmaceutical code. The final ruling was posted on its website on Jan. 27, 2023.

1. The Panel considered that the subsequent strong opinion statements, including ‘So, there was no doubt in my mind that the benefits completely were in favour of doing it [vaccinating children against Covid-19]’ and ‘I believe it’s a very good idea’ might infer to the ultimate audience, including members of the public, that there was no need to be concerned about potential side-effects which was not so. The Panel considered that this implication was incapable of substantiation and through phrases such as ‘no doubt’ and ‘completely in favour’, Pfizer’s CEO did not encourage the rational use of a medicine. **Breaches of the Code were ruled.** These rulings were appealed by Pfizer but were unsuccessful.

2. Whilst the Appeal Board noted the CEO’s statement that he/she ‘did not want to speak for the health authorities or the regulatory authorities of UK, it was up to them to approve it and use it or not’, the Appeal Board considered that the CEO’s opinion statements, including ‘So there is no doubt in my mind about the benefits completely are in favour of doing it’ might infer to the ultimate audience, including members of the public, that the benefits outweighed the risks when the UK regulatory authorities had not yet made any conclusions in relation to the vaccination of 5 to 11 year olds and the Appeal Board therefore upheld the Panel’s rulings of **breaches of the Code**. These rulings were appealed by Pfizer but were unsuccessful.

3. The Pfizer-BioNTech Covid-19 vaccine was not licensed in the UK in that age group when the article at issue was published and the Panel therefore **ruled breaches of the Code**. These rulings were appealed by Pfizer but were unsuccessful.

Pfizer has been found guilty of violating three sections of the British Pharmaceuticals Code of Practice?

This seems rather newsworthy.

I’m surprised it got so little media attention, especially given the recent concerns about

misinformation. <https://t.co/IUqN8Sb6SX> pic.twitter.com/zKEqIDy0cE

— Lion Advocacy (@LionAdvocacy) [February 5, 2023](#)

Breach clauses:

Clause 6.1 states:

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 recipients to form their own opinion of the therapeutic value of the medicine.

Clause 6.2 states:

Any information, claim or comparison must be capable of substantiation.

Companies must provide substantiation, following a request for it as set out in Clauses [14.3](#) and [18.2](#). In addition, when data from a clinical trial is used, companies must ensure that where necessary, that trial has been registered and the results disclosed in accordance with [Clause 4.6](#).

Clause 26.2 states:

Information about prescription only medicines which is made available to the public either directly or indirectly must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product.

Statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine.

by Jim Hoft

Category

1. Crime-Justice-Terrorism-Corruption
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3. Health-Wellness-Healing-Nutrition & Fitness
4. Main
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