War Room/DailyClout Pfizer Document Analysis

Post-Marketing Team Micro-Report 18:

Vaccine Effectiveness Review of 5.3.6

SOURCE

https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf

5.3.6 AE REPORTING PERIOD:

"Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021."

Adverse Events were reported to Pfizer during a 90-day period, following the December 1, 2020, public rollout of its COVID-19 experimental "vaccine" product.

In the Pfizer 5.3.6 document, these AEs were categorized by System Organ Classes (SOC) – in other words, by systems in the body.

ABBREVIATIONS:

5.3.6 : Pfizer source document

SOC : System Organ Class

AE : Adverse Event

AESI : Adverse Event of Special Interest

EUA : Emergency Use Authorization by FDA

PM : Post-Marketing

BNT162b2 : Pfizer's mRNA COVID-19 vaccine

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09Oct23

Pfizer identified three categories of **Safety Concerns** in Table 3. These were:

1) Important identified risks: Anaphylaxis (Table 4)
2) Important potential risks: Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD) (Table 5)
3) Missing Information: Use in Pregnancy and Lactation, Use in Paediatric Individuals < 12 years of Age, and **Vaccine Effectiveness** (Table 6)

Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)
Total Number of Cases in the Reporting Period (N=42086)

1st dose (day 1-13)	From day 14 post 1st dose to day 6 post 2nd dose	Day 7 post 2nd dose
Code only the events describing the SARS-CoV-2 infection	Code "Drug ineffective"	Code "Vaccination failure"
Scenario Not considered LOE	Scenario considered LOE as "Drug ineffective"	Scenario considered LOE as "Vaccination failure"

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In this section of 5.3.6, Pfizer reported 1,665 cases submitted with the diagnosis of "lack of efficacy" (LOE). They are broken into two categories:

1. Drug ineffective
2. Vaccination failure.

It takes time for the body to develop immunity to any vaccination. Pfizer asserted that the immune system needed a full 13 days to "respond" to the vaccine. That is why Pfizer did not consider it to be lack of efficacy if COVID-19 infection occurred within that 13-day period following the first injection. In Table 6, these cases are described simply as "COVID-19," and it appears that there were 383 of them (155 suspected and 228 confirmed).

Beginning 14 days after the first shot through Day Six after the second shot, Pfizer termed LOE as "drug ineffective." For BNT162b2 to be "ineffective," the Pfizer definition required that an individual must have received both doses of the vaccine with a documented COVID-19 infection developing seven days or longer after the second shot.

The cases represented in 5.3.6 were collected from multiple countries during the 90-day period (December 1, 2020, through February 28, 2021). **Interestingly, the coding conventions (or criteria) for the drug ineffective and vaccination failure categories were revised on February 15, 2021.** No information is supplied in 5.3.6 regarding the specific content of the ***initial*** coding conventions.

Why were the coding conventions changed?

What were the outcomes in the 1,665 individuals with lack of efficacy?

65 deaths (3.9%)

165 *resolved/resolving* **205 *not resolved*** **1230 *outcome unknown***