War Room/DailyClout Pfizer Document Analysis

Post-Marketing Team Micro-Report 4:

Liver (Hepatic) System Organ Class (SOC) 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."

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

SEQUELAE: an abnormal condition resulting from a previous disease, injury, or other trauma

AGE GROUPS defined in 5.3.6 (p. 25 footnote) :

Adult	18 - 64
Elderly	≥ 65
Child	2 - 11
Adolescent	12 - < 18
Infant	1 – 23 months

Hepatic AESIs *Search criteria: Liver related investigations, signs and symptoms (SMQ) (Narrow and Broad) OR PT Liver injury*	• Number of cases: 70 cases (0.2% of the total PM dataset), of which 54 medically confirmed and 16 non-medically confirmed; • Country of incidence: UK (19), US (14), France (7), Italy (5), Germany (4), Belgium, Mexico and Spain (3 each), Austria, and Iceland (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (43), male (26) and unknown (1); • Subjects' age group (n=64): Adult (37), Elderly (27);

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BNT162b2
5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Number of relevant events: 94, of which 53 serious, 41 non-serious; • Most frequently reported relevant PTs (≥3 occurrences) include: Alanine aminotransferase increased (16), Transaminases increased and Hepatic pain (9 each), Liver function test increased (8), Aspartate aminotransferase increased and Liver function test abnormal (7 each), Gamma-glutamyltransferase increased and Hepatic enzyme increased (6 each), Blood alkaline phosphatase increased and Liver injury (5 each), Ascites, Blood bilirubin increased and Hypertransaminasaemia (3 each); • Relevant event onset latency (n = 57): Range from <24 hours to 20 days, median 3 days; • Relevant event outcome: fatal (5), resolved/resolving (27), resolved with sequelae (1), not resolved (14) and unknown (47). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue

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This event category was comprised of abnormal laboratory tests and not defined under any specific disease designations. There was no further categorization or classification under medically recognized diseases such as hepatitis or hepatobiliary (gallbladder or bile duct) conditions, though the lab tests cited often point to different disease entities. The common terms normally used, such as hepatitis, gallstones, and others, were not included in the search terms for patient cases in this document.

There were nine reports of "hepatic pain," three reports of ascites (fluid free within the abdominal cavity) and three cases of high bilirubin, which is the chemical that causes jaundice. **Pfizer chose to specify only those events with three or more occurrences.** All of the specific reported adverse events were elevated levels of proteins reflective of hepatocyte (the major type of liver cell) injury, bile processing system cell injury, symptoms, or physical findings.

Of those patients with age reported, 37 were categorized as adult and 27 as elderly. There were reports from 18 countries.

- **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.**
- **There were 70 cases with 94 adverse events reported in the hepatic SOC category.**
- **The hepatic adverse events were defined as "liver-related investigations, signs and symptoms" or reported as "liver injury."**

The time reported from vaccine injection to adverse event ranged from within 24 hours to 20 days, **with half occurring within three days.**

There were **five deaths (7% of the patients)**. Of the reported events that were not fatal, 27 (30%) were resolved or resolving, although the figures in these two outcome categories were not independently provided. One (1%) was "resolved with sequelae," 14 (15%) were unresolved, and 47 (50%) were unknown. Given the imprecise method of outcome reporting, combined with the lack of long-term follow-up, the stated fatality rate is questionable and may be much higher.

This report is unique compared to other SOC categories under review by the Post-Marketing Team, in that the data presented by Pfizer largely consists of laboratory abnormalities, rather than clinical disease descriptions. No justification is offered to explain this inconsistency in data collection and reporting.

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Pfizer presents this SOC data as single, abnormal lab results rather than diseases or conditions. Liver injury, short of catastrophic acute liver failure, requires complex assessment of multiple lab and other diagnostic studies performed over time. For example, fluid in the abdomen (ascites), which was found in three patients with abnormal liver enzymes, suggests a potentially severe liver condition. One test or a panel of enzyme tests at a single point in time are not sufficient data to evaluate safety or predict future liver health. Pfizer's own data show they have no follow-up information on over 50% of the patients in this SOC. Given the biochemical mixture in this novel genetic product, which includes mRNA plus lipid nanoparticles and other chemicals, the impact on the liver should have been of the highest safety monitoring priority.

Five deaths, and numerous other patients demonstrating serious enzyme elevations, demand further evaluation beyond Pfizer's dismissive conclusion published at the end of the hepatic SOC section, which reads:

"This cumulative case review does not raise new safety issues. Surveillance will continue."

Pfizer's inadequate assessment of the hepatic AEs, in terms of complete disregard of the safety signals revealed in this data set, foretells the overarching summary conclusion in Pfizer's 5.3.6 Post Marketing Adverse Events document which proclaims a "favorable benefit risk profile" of their investigational product:

> 4. DISCUSSION
> Pfizer performs frequent and rigorous signal detection on BNT162b2 cases. The findings of these signal detection analyses are consistent with the known safety profile of the vaccine. This cumulative analysis to support the Biologics License Application for BNT162b2, is an integrated analysis of post-authorization safety data, from U.S. and foreign experience, focused on Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in the Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). The data do not reveal any novel safety concerns or risks requiring label changes and support a favorable benefit risk profile of to the BNT162b2 vaccine.
>
> 5. SUMMARY AND CONCLUSION
> Review of the available data for this cumulative PM experience, confirms a favorable benefit: risk balance for BNT162b2.
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It is important to note, since the end of the 5.3.6 reporting period (February 28, 2021), Pfizer has not voluntarily released any publicly available data to support their pledge to continue safety surveillance on the company's novel COVID-19 experimental product. Ongoing surveillance by Pfizer was a condition of the vaccine approval granted Pfizer by the FDA (August 2021). Furthermore, as of the date of this Post-Marketing Team report (January 8, 2023), there is no indication that the FDA has enforced this surveillance mandate.

The FDA's dereliction of regulatory duty is stunning given the fact that Pfizer's own 5.3.6 data reveal no definitive outcome or follow-up information on over half of the patients in the hepatic adverse events category.

Post-Marketing Team's CONCLUSION:
WHAT DOES IT TAKE?

How many serious **ADVERSE EVENTS** does it take?
How many **UNRESOLVED and UNKNOWN** outcomes does it take?
How many **DEATHS** does it take?

What does it take to **RECALL PFIZER'S UNSAFE "VACCINE"?**

Post Marketing Team