War Room/DailyClout Pfizer Document Analysis

Post-Marketing Team Micro-Report 12:

Vasculitis 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."

5.3.6 AE CASES/EVENTS:

TOTAL AE CASES: 42,086

TOTAL AE EVENTS: 158,893

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

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Vasculitic Events *Search criteria: Vasculitides HLT*	• Number of cases: 32 cases (0.08% of the total PM dataset), of which 26 medically confirmed and 6 non-medically confirmed; • Country of incidence: UK (13), France (4), Portugal, US and Spain (3 each), Cyprus, Germany, Hungary, Italy and Slovakia and Costa rica (1 each); • Subjects' gender: female (26), male (6); • Subjects' age group (n=31): Adult (15), Elderly (16); • Number of relevant events: 34, of which 25 serious, 9 non-serious; • Reported relevant PTs: Vasculitis (14), Cutaneous vasculitis and Vasculitic rash (4 each), (3), Giant cell arteritis and Peripheral ischaemia (3 each), Behcet's syndrome and Hypersensitivity vasculitis (2 each) Palpable purpura, and Takayasu's arteritis (1 each); • Relevant event onset latency (n = 25): Range from <24 hours to 19 days, median 3 days; • Relevant event outcome: fatal (1), resolved/resolving (13), not resolved (12) and unknown (8). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue

https://www.phmpt.org/wpcontent/uploads/2022/04/reissue_5.3.6-postmarketiexperience.pdf

The search criterion for this SOC was Vasculitides. **Vasculitis means an inflammation of blood vessels. The inflammation can be related to a direct immune attack on the cells of the blood vessel or to deposits of complexes of antibody and an antigen (virus or other protein) that is not part of the blood vessel itself.** Sometimes small blood vessels are involved, and other times large vessels are involved. Symptoms vary, depending on which organ the inflamed blood vessels feed.

Thirty-four adverse events were reported. Fourteen cases of unspecified vasculitis were recorded. Without further detail, it is impossible to draw conclusions about these 14 events, except to say that systemic vasculitis is not easy to treat and often cannot be cured but, instead, has to be **permanently** medicated to control. The 32 individuals had 34 relevant adverse events, with **25 (74%) classified as serious**.

Eleven AEs were related to skin rashes which were vasculitic in nature. These include: cutaneous vasculitis, vasculitic rash, hypersensitivity vasculitis, and palpable purpura. A vasculitic rash is often described as "palpable purpura," a slightly elevated bluish-red rash, often on the legs, related to disruption of small vessels.

- **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.**
- **32 cases were found, from multiple countries. 26 (81%) were female and 6 (19%) were male.**
- **15 were non-elderly adults, and 16 were elderly.**

One event was fatal.

Thirteen AEs are described as "resolved/resolving" but not broken down any further. **Twelve were "not resolved,"** and eight were outcome "unknown."

No mention is given for the outcome category of "resolved with sequelae," which appears in most of the other SOC outcome lists. Does this suggest some severe sequelae for this serious set of diseases?

The time from injection to symptom onset was noted for 25 adverse events.

This time ranged from < 24 hours to 19 days, **with half of AEs occurring within three days.**