War Room/DailyClout Pfizer Document Analysis

Post-Marketing Team Micro-Report 11:

Immune-Mediated/Autoimmune AESIs Review of 5.3.6

SOURCE:
https://www.phmpt.org/wp-content/uploads/2022/04/reissue5.3.6-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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Immune-Mediated/Autoimmune AESIs	
Search criteria: Immune-mediated/autoimmune disorders (SMQ) (Broad and Narrow) OR Autoimmune disorders HLGT (Primary Path) OR PTs Cytokine release syndrome; Cytokine storm; Hypersensitivity	• Number of cases: 1050 (2.5 % of the total PM dataset), of which 760 medically confirmed and 290 non-medically confirmed; • Country of incidence (>10 cases): UK (267), US (257), Italy (70), France and Germany (69 each), Mexico (36), Sweden (35), Spain (32), Greece (31), Israel (21), Denmark (18), Portugal (17), Austria and Czech Republic (16 each), Canada (12), Finland (10). The remaining 74 cases were from 24 different countries. • Subjects' gender (n=682): female (526), male (156). • Subjects' age group (n=944): Adult (746), Elderly (196), Adolescent (2). • Number of relevant events: 1077, of which 780 serious, 297 non-serious. • Most frequently reported relevant PTs (>10 occurrences): Hypersensitivity (596), Neuropathy peripheral (49), Pericarditis (32), Myocarditis (25), Dermatitis (24), Diabetes mellitus and Encephalitis (16 each), Psoriasis (14), Dermatitis Bullous (13), Autoimmune disorder and Raynaud's phenomenon (11 each); • Relevant event onset latency (n = 807): Range from <24 hours to 30 days, median <24 hours. • Relevant event outcome[1]: resolved/resolving (517), not resolved (215), fatal (12), resolved with sequelae (22) and unknown (312). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue

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This category comprises the numerous diseases resulting from disordered immune attacks against tissues of any of the body's organs. Pfizer has grouped some conditions in a very general way, such as "hypersensitivity." This is defined as an exaggerated response of the normal immune system. However, anaphylaxis, another hypersensitivity reaction, has its own separate SOC report.

Autoimmune diseases attacking nerve tissue (Guillain-Barré, multiple sclerosis, polyneuropathy, and others) are not in this SOC but are found under the Neurological and Musculoskeletal SOC reports. However, dermatitis (skin hypersensitivity) is listed here.

Only diseases or conditions with over 10 cases are described with a diagnosis or symptom. Hypersensitivity had 596 (55%) of the adverse events. The conditions in this large grouping are not further defined in the report. Peripheral neuropathy had 49 events (5%) though, and, as discussed above, other neuropathies are separately listed and presumably different patients. There are **32 diagnosed pericarditis events (3%)** with inflammation of the lining around the heart. **Myocarditis (immune attack against the heart muscle itself) had 25 events (2%)**.

- **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.**
- **Of those whose sex was specified, 526 (77%) were female, and 156 (23%) were male (a ratio of 3.4 to 1).**
- **Age was listed as elderly 196 (19%), adult 746 (71%), adolescent 2 (<1%), and not reported 106 (10%).**

There were 1,077 events reported with **780 (72%) serious** and 297 (28%) non-serious.

12 (1.1%) AEs were fatal.

The time from vaccination to adverse event onset was defined in 807 (75%) of the 1,077 events with a range of within 24 hours to 30 days. **Half of the adverse events started within 24 hours of the injection**. 517 (48%) had outcomes reported as "resolved" or "resolving." **215 events (20%) were not resolved**, **22 (2%) resolved with sequelae**, and **312 (29%) had unknown outcome**.

Further observation regarding autoimmune events:

There was no mention of immune rejection of transplanted organs. It is unknown whether Pfizer found none, or whether there were 10 or fewer and thus not listed explicitly.

There is a VAERS report of a 17-year-old male who was vaccinated 1/19/2021 and was hospitalized mid-May 2021 with heart transplant rejection and heart failure.