DAILYCLOUT

War Room/DailyClout Pfizer Document Analysis

Post-Marketing Team Micro-Report 13:

Other Adverse Events of Special Interest Review of 5.3.6

Death was the "relevant event outcome" for 96 individuals, which is 7.8% of 1,223 deaths from all causes reported in this 90-day report.

Other AESIs	
Search criteria: Herpes viral infections (HLT) (Primary Path) OR PTs Adverse event following immunisation; Inflammation; Manufacturing laboratory analytical testing issue; Manufacturing materials issue; Manufacturing production issue; MERS-CoV test; MERS-CoV test negative; MERS-CoV test positive; Middle East respiratory syndrome; Multiple organ dysfunction syndrome; Occupational exposure to communicable disease; Patient	• Number of cases: 8152 (19.4% of the total PM dataset), of which 4977 were medically confirmed and 3175 non-medically confirmed; • Country of incidence (> 20 occurrences): UK (2715), US (2421), Italy (710), Mexico (223), Portugal (210), Germany (207), France (186), Spain (183), Sweden (133), Denmark (127), Poland (120), Greece (95), Israel (79), Czech Republic (76), Romania (57), Hungary (53), Finland (52), Norway (51), Latvia (49), Austria (47), Croatia (42), Belgium (41), Canada (39), Ireland (34), Serbia (28), Iceland (25), Netherlands (22). The remaining 127 cases were from 21 different countries; • Subjects' gender (n=7829): female (5969), male (1860); • Subjects' age group (n=7479): Adult (6330), Elderly (1125), Adolescent, Child (9 each), Infant (6);

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
isolation; Product availability issue; Product distribution issue; Product supply issue; Pyrexia; Quarantine; SARS-CoV-1 test; SARS-CoV-1 test negative; SARS-CoV-1 test positive	• Number of relevant events: 8241, of which 3674 serious, 4568 non-serious; • Most frequently reported relevant PTs (≥6 occurrences) included: Pyrexia (7666), Herpes zoster (259), Inflammation (132), Oral herpes (80), Multiple organ dysfunction syndrome (18), Herpes virus infection (17), Herpes simplex (13), Ophthalmic herpes zoster (10), Herpes ophthalmic and Herpes zoster reactivation (6 each); • Relevant event onset latency (n =6836): Range from <24 hours to 61 days, median 1 day; • Relevant events outcome: fatal (96), resolved/resolving (5008), resolved with sequelae (84), not resolved (1429) and unknown (1685). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue

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

- **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 with known age, 1,125 were elderly; 6,330 were non-elderly adult; nine were adolescents; nine were children; and six were infants.**
- **Of those whose gender was known (7,829), 5,969 (76%) were female and 1,860 (24%) were male with a ratio of 3.2:1 female to male.**

IMPORTANT NOTE:

This category of AESIs is not related to a particular set of medical conditions or a specific organ of the body. The search criteria range from medical conditions (Herpes virus infections, Middle East Respiratory Syndrome, Multiple Organ Dysfunction Syndrome) to symptoms (fever, inflammation) to non-medical-related issues (manufacturing laboratory analytical testing issues, manufacturing production issues). The Pfizer report only specifically identified those conditions that had **six or more occurrences.**

This SOC included 8,152 patients, 19.4% of the total cases/patients in the 90-day period of this report. The cases were reported from 48 countries. In this total group of patients, there were 8,241 adverse events of which **3,674 (45%) were serious** and 4,568 (55%) were non-serious.

Fever was the most common event (7,666). **Herpes virus infection, including shingles, herpetic eye infections, and non-shingles herpes infections, comprised 391 events.** Inflammation was listed with 132 events, but these were not defined further as to type or bodily location. **Multiple organ dysfunction syndrome had 18 events.**

Death was the "relevant event outcome" for 96 individuals, which is 7.8% of 1,223 deaths from all causes reported in this 90-day report and for 1% of the patients in this SOC. Of the 8,241 total events, outcomes of "resolved/resolving" were listed for 5,008 events (61%), "resolved with sequelae" for 84 (1%), "not resolved" for 1,429 (17%), and "unknown" for 1,685 (20%). **The time from injection to adverse event onset was from within 24 hours to 61 days with half occurring within one day.**

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

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22May23