War Room/DailyClout Pfizer Document Analysis

Post-Marketing Team Micro-Report 7:

Neurologic 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

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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Of the 542 neurological adverse events
95% were defined as serious**. 16** were fatal.

Neurological AESIs (including demyelination) *Search criteria: Convulsions (SMQ) (Broad and Narrow) OR Demyelination (SMQ) (Broad and Narrow) OR PTs Ataxia; Cataplexy; Encephalopathy; Fibromyalgia; Intracranial pressure increased; Meningitis; Meningitis aseptic; Narcolepsy*	• Number of cases: 501 (1.2% of the total PM dataset), of which 365 medically confirmed and 136 non-medically confirmed. • Country of incidence (≥9 cases): UK (157), US (68), Germany (49), Mexico (35), Italy (31), France (25), Spain (18), Poland (17), Netherlands and Israel (15 each), Sweden (9). The remaining 71 cases were from 22 different countries. • Subjects' gender (n=478): female (328), male (150). • Subjects' age group (n=478): Adult (329), Elderly (149); • Number of relevant events: 542, of which 515 serious, 27 non-serious. • Most frequently reported relevant PTs (>2 occurrences) included: Seizure (204), Epilepsy (83), Generalised tonic-clonic seizure (33), Guillain-Barre syndrome (24), Fibromyalgia and Trigeminal neuralgia (17 each), Febrile convulsion, (15), Status epilepticus (12), Aura and Myelitis transverse (11 each), Multiple sclerosis relapse and Optic neuritis (10 each), Petit mal epilepsy and Tonic convulsion (9 each), Ataxia (8), Encephalopathy and Tonic clonic movements (7 each), Foaming at mouth (5), Multiple sclerosis, Narcolepsy and Partial seizures (4 each), Bad sensation, Demyelination, Meningitis, Postictal state, Seizure like phenomena and Tongue biting (3 each); • Relevant event onset latency (n = 423): Range from <24 hours to 48 days, median 1 day; • Relevant events outcome: fatal (16), resolved/resolving (265), resolved with sequelae (13), not resolved (89) and unknown (161); Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue

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- **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.**
- **In the neurologic SOC, of those patients whose sex was reported, 69% were female and 31% were male.**
- **Of the 478 subjects with age reported, 329 were adult and 149 were elderly.**

Within each SOC, the adverse events are further classified as either "serious" or "non-serious." **Given the extremely high rate of "serious" neurological adverse events**, an understanding of the FDA's definition of this term is important. Below are excerpts from the official FDA website. Provided with this context, the full impact of the information presented in this report can be realized.

What is a Serious Adverse Event?

An adverse event is any undesirable experience associated with the use of a medical product in a patient. The event is serious and should be reported to FDA when the patient outcome is:

Death
Life-threatening
Hospitalization (initial or prolonged)
Disability or Permanent Damage
Congenital Anomaly/Birth Defect
Required Intervention to Prevent Permanent Impairment or Damage (Devices)
Other Serious (Important Medical Events)

https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event

This category includes conditions of altered function of the brain, spinal cord, or peripheral nerves (nerves that connect to the spinal cord and extend to the rest of the body). Also included are conditions resulting from direct damage to nerve tissue. Pfizer chose to report fibromyalgia in this category. However, those conditions categorized by Pfizer under the general term peripheral neuropathy (abnormal nerve function) are reported separately in the SOC of "Immune-related/Autoimmune" adverse events. "Polyneuropathy" (multiple nerve dysfunction) is categorized under the SOC "Musculoskeletal" adverse events. The distribution of these diagnoses into various other SOCs is medically debatable. Bell's palsy with facial nerve damage is summarized in its own report.