



War Room/DailyClout Pfizer Document Analysis

Post-Marketing Team Micro-Report 14: Musculoskeletal Adverse Events of Special Interest 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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<p>Musculoskeletal AESIs <i>Search criteria: PTs: Arthralgia; Arthritis; Arthritis bacterial; Chronic fatigue syndrome; Polyarthritides; Polyneuropathy; Post viral fatigue syndrome; Rheumatoid arthritis</i></p>	<ul style="list-style-type: none"> • Number of cases: 3600 (8.5% of the total PM dataset), of which 2045 medically confirmed and 1555 non-medically confirmed. • Country of incidence: UK (1406), US (1004), Italy (285), Mexico (236), Germany (72), Portugal (70), France (48), Greece and Poland (46), Latvia (33), Czech Republic (32), Israel and Spain (26), Sweden (25), Romania (24), Denmark (23), Finland and Ireland (19 each), Austria and Belgium (18 each), Canada (16), Netherlands (14), Bulgaria (12), Croatia and Serbia (9 each), Cyprus and Hungary (8 each), Norway (7), Estonia and Puerto Rico (6 each), Iceland and Lithuania (4 each); the remaining 21 cases originated from 11 different countries; • Subjects’ gender (n=3471): female (2760), male (711); • Subjects’ age group (n=3372): Adult (2850), Elderly (515), Child (4), Adolescent (2), Infant (1); • Number of relevant events: 3640, of which 1614 serious, 2026 non-serious; • Reported relevant PTs: Arthralgia (3525), Arthritis (70), Rheumatoid arthritis (26), Polyarthritides (5), Polyneuropathy, Post viral fatigue syndrome, Chronic fatigue syndrome (4 each), Arthritis bacterial (1); • Relevant event onset latency (n = 2968): Range from <24 hours to 32 days, median 1 day;
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The category of musculoskeletal adverse events of special interest (AESI) is made up of these different diagnoses: arthralgia (joint pain), arthritis (joint inflammation), arthritis/bacterial, chronic fatigue syndrome, polyarthritides (inflammation of multiple joints), post viral fatigue syndrome, and rheumatoid arthritis.

Fibromyalgia is not included in this report but was listed under the category of “Neurological AESIs.” Polyneuropathy (symmetrical damage to peripheral nerves) is included in this report rather than under “Neurological AESIs.”

3,600 cases were reported, **8.5% of the post-marketing data set** of 42,086 cases. These 3,600 individuals reported 3,640 events. **1,614 (44%) were classified as serious.** The most common adverse event was **arthralgia (3,525 or 97%)**, followed by 70 arthritis (2%), 26 rheumatoid arthritis (<1%) and 5 (<1%) polyarthritides.

- 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.

The time from administration to adverse event ranged from < 24 hours to 32 days. **50% of the events started within the first 24 hours.**

Of the cases where gender was reported, 2,760 individuals were female, and 711 were male. Once again, the pattern from 5.3.6 SOC’s continues, with an almost **4:1 ratio of female to male.**

Age distribution was predominantly adult (2,850, 85%), with 515 (15%) elderly, two adolescents, four children, and one infant. During these dates, BNT162b2 was not approved for use in children or infants. Approval was only for adolescents 16 and above (not clarified by Pfizer).

Outcomes were reported for 3,662 events: 1,801 (49%) resolved or resolving, **959 (26%) not resolved**, 49 (1%) resolved with sequelae, and **853 (23%) were unknown.**

Pfizer’s Conclusion:

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

Note: As of the date of this team report, no follow-up safety surveillance data have been publicly released.



RECALL

this unsafe “vaccine.”