War Room/DailyClout Pfizer Document Analysis

Post-Marketing Team Micro-Report 10:

Anaphylaxis – Important Identified Risk 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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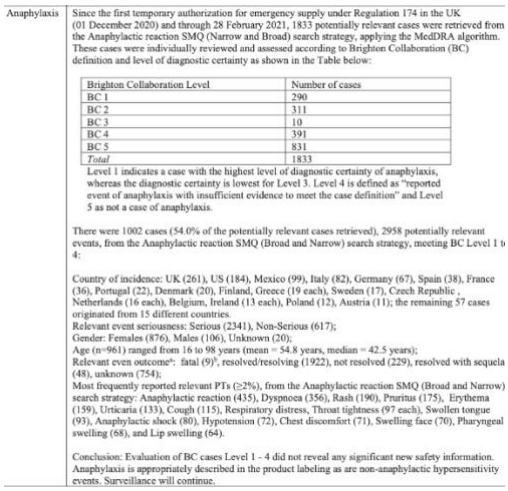
27Mar23



Anaphylaxis	Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 1833 potentially relevant cases were retrieved from the Anaphylactic reaction SMQ (Narrow and Broad) search strategy, applying the MedDRA algorithm. These cases were individually reviewed and assessed according to Brighton Collaboration (BC) definition and level of diagnostic certainty as shown in the Table below:

Brighton Collaboration Level	Number of cases
BC 1	290
BC 2	311
BC 3	10
BC 4	391
BC 5	831
Total	1833

Level 1 indicates a case with the highest level of diagnostic certainty of anaphylaxis, whereas the diagnostic certainty is lowest for Level 3. Level 4 is defined as "reported event of anaphylaxis with insufficient evidence to meet the case definition" and Level 5 as not a case of anaphylaxis.

There were 1002 cases (54.0% of the potentially relevant cases retrieved), 2958 potentially relevant events, from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy, meeting BC Level 1 to 4:

Country of incidence: UK (261), US (184), Mexico (99), Italy (82), Germany (67), Spain (38), France (36), Portugal (22), Denmark (20), Finland, Greece (19 each), Sweden (17), Czech Republic , Netherlands (16 each), Belgium, Ireland (13 each), Poland (12), Austria (11); the remaining 57 cases originated from 15 different countries.
Relevant event seriousness: Serious (2341), Non-Serious (617);
Gender: Females (876), Males (106), Unknown (20);
Age (n=961) ranged from 16 to 98 years (mean = 54.8 years, median = 42.5 years);
Relevant even outcome[a]: fatal (9)[b], resolved/resolving (1922), not resolved (229), resolved with sequela (48), unknown (754);
Most frequently reported relevant PTs (≥2%), from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy: Anaphylactic reaction (435), Dyspnoea (356), Rash (190), Pruritus (175), Erythema (159), Urticaria (133), Cough (115), Respiratory distress, Throat tightness (97 each), Swollen tongue (93), Anaphylactic shock (80), Hypotension (72), Chest discomfort (71), Swelling face (70), Pharyngeal swelling (68), and Lip swelling (64).

Conclusion: Evaluation of BC cases Level 1 - 4 did not reveal any significant new safety information. Anaphylaxis is appropriately described in the product labeling as are non-anaphylactic hypersensitivity events. Surveillance will continue.

https://www.phmpt.org/wpcontent/uploads/2022/04/reissue_5.3.6-postmarketiexperience.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 gender specified, 876 (89%) were female, 106 (11%) were male.**
- **The reported age range was 16 to 98 years old with half being less than 43.5 years old.**

Anaphylaxis is a condition most often referred to as a "severe allergic reaction" and is triggered by latex, foods such as peanuts, bee stings, or medications (injected or taken by mouth), among other things. Immunoglobulin E (IgE, a human antibody) is involved in this dangerous and explosive reaction. It causes mast cells to immediately release histamine and other chemicals.

The life-threatening symptoms that follow can include swelling such as hives, respiratory difficulties, drop in blood pressure and rapid heart rate, and abdominal symptoms such as pain, nausea and vomiting. These symptoms are typically rapid in both onset and progression. Treatment similarly has to be rapid (e.g., Epi-Pen) and often requires emergency room or hospital treatment.

Pfizer has used a tool, the Brighton Collaboration (BC), to assess whether the symptoms of a patient are correctly identified as anaphylaxis. In the three-month data collection, there were 1,833 potential anaphylaxis patients reported; but, after screening, 831 did not meet criteria, leaving 1,002 cases reported in this time period. Pfizer reported 2,958 "potentially relevant events" from those 1,002 individuals that included the signs and symptoms of anaphylaxis.

Pfizer reported only the most frequent anaphylaxis signs and symptoms: anaphylactic reaction (435), shortness of breath (356), rash (190), redness of the skin (159), hives (133), cough (115), **respiratory distress (97),** throat tightness (97), swollen tongue (93), low blood pressure (72), **low blood pressure severe enough to threaten organ function (shock) (80)**, chest discomfort (71), swelling face (70), throat swelling (68), and lip swelling (64).

The events were rated as **serious in 2,341 (79%)** and non-serious in 617 (21%).1922 events were reported as resolved or resolving (65%), 229 not resolved (8%), 48 resolved with sequelae (1.6%), and 754 had no outcome known (25%).

There were nine deaths reported.

IMPORTANT NOTE:

There are **831 patients, 45% of the total 1,833,** who were determined not to be anaphylaxis and dropped from this category. Where did those patients and their adverse events go?