Office of Biostatistics and Epidemiology/Division of Epidemiology
Periodic Safety Report Review Checklist

Completed by Reviewer

Product Name	COMIRNATY
Manufacturer	Pfizer-BioNTech
STN #	125742/31
DCC Login ID #	1480993
Submission Type	PAER ☐ PSUR ☐ PBRER ☑ PADER ☐
Submission Format	ELECTRONIC ☑ PAPER ☐
Reporting Period	FROM September 1, 2021 TO September 30, 2021
Date Received by FDA	October 15, 2021
Date Routed to Reviewer	October 15, 2021
Regulatory Information Specialist (RIS) - Name	Bridget Davis-Jones
Reviewer - Name	Christopher Jankosky, MD
Reviewer Signature (electronic signature)	Christopher J. Jankosky -S (Affiliate) Digitally signed by Christopher J. Jankosky -S (Affiliate) DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2003366003, cn=Christopher J. Jankosky -S (Affiliate) Date: 2021.11.02 10:19:55 -07'00'

COMMENTS

This is the 10th Summary Monthly Safety Report for Comirnaty (COVID-19 mRNA Vaccine).

Special population of age 12-15 year olds (Table 13) this reporting period:
- US 230 cases. Worldwide 1082 cases (539 medically confirmed).
- 4 Fatal cases (no cases from US).
- Most frequently reported PTs were pyrexia, headache, and fatigue.

Age-stratified breakdowns (Table 11) for:
(1) myocarditis: 1070 cases, including 103 level 1 (definitive), 934 level 4 (insufficient evidence), age 12-15 (14 female, 66 male, 1 unknown), age 16-17 (10 female, 87 male), age 18-30 (74 female, 286 male), age 31-50 (110 female, 144 male, 1 unknown), age 51-64 (41 female, 47 male, 2 unknown), age >65 (26 female, 28 male).
- 2 notable cases of death in 40 and 50 year old males (Sweden and Netherlands) assessed as level 1 (full narratives pg 54).
(2) pericarditis: 888 cases, including 10 level 1 (definitive), 858 level 4 (insufficient evidence), age 12-15 (9 female, 31 male), age 16-17 (7 female, 77 male), age 18-30 (101 female, 146 male, 3 unknown), age 31-50 (178 female, 191 male, 4 unknown), age 51-64 (55 female, 52 male), age >65 (24 female, 23 male).

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1. Countries where the product is licensed or authorized for distribution:

   Not Reported ☐ US ☑ Worldwide ☑

2. Estimated number of doses distributed by reporting period/cumulative:

   Not Reported ☐ US (b) (4)

   Not Applicable ☐ Worldwide 303,158,973 / 1,709,812,866

3. Does this report describe any actions taken by the manufacturer or other regulatory agency for this product (e.g. labeling changes)? Yes ☑ No ☐

4. Have there been any new safety issues identified by the reviewer in this PSUR? Yes ☐ No ☑

If YES, please provide pertinent information below AND notify/discuss safety issues with the Team Lead and/or Branch Chief.

During the current reporting period (September 2021), an EUA was granted in the US for a single booster dose of Comirnaty administered at least 6 months after completing the primary series in individuals: 65 years of age and older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19. The Core Data Sheet was updated; the ADRs observed after the vaccine booster dose (third dose), based on a clinical data subset from a Phase 2/3 Study, were added in Section 4.8 Undesirable effects and in the Appendices A and B.

There were no actions taken for safety reasons during the reporting period.

The following following signals were addressed during the reporting period: (1) appendicitis , (2) Herpes Zoster including Ophthalmic Herpes Zoster, (3) Multisystem Inflammatory Syndrome (MIS) in Adults (MIS-A) and Children (MISC), and (4) Uveitis. The sponsor concluded that none of these conditions were a risk, based on the totality of available data.

The MAH had been reviewing TTS on a monthly basis for several months, but has now considered this a closed signal. Regardless of this status, it will be reviewed and updated monthly until no longer warranted.

Rhabdomyolysis cases exceeded the background rate used (data from the 1990s) in the MAH's analysis. The MAH plans to continue to explore sources for a more recent study to support this background rate estimate. For SMSR 11, a review with an expanded MedDRA search criteria will be performed, with additional PTs of "myositis", "necrotising myositis" and "muscle necrosis" as requested by PRAC. (see pages 77, 78, 13225). MAH writes that no safety signals have yet emerged in this category.

Conclusions:

☑ The contents of this PSUR/PAER do not indicate a need for further regulatory action.

☐ Please see the following comments and recommendations:

Reference Documents (X:\DE\MEDICAL OFFICER\Guidance Documents):

1. E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs 1996
2. Addendum to E2C Safety Data Management: Periodic Safety Update Reports for Marketed Drugs 2004