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

Completed by Reviewer

Product Name	COVID-19 vaccine, mRNA (BNT162b2)
Manufacturer	Pfizer
STN #	19736.491
DCC Login ID #	Process track #907079
Submission Type	**PAER** ☐ **PSUR** ☐ **PBRER** ☑ **PADER** ☐
Submission Format	**ELECTRONIC** ☑ **PAPER** ☐
Reporting Period	**FROM** August 1, 2021 **TO** August 31, 2021
Date Received by FDA	September 15, 2021
Date Routed to Reviewer	September 15, 2021
Regulatory Information Specialist (RIS) - Name	Laura Gottschalk
Reviewer - Name	Deborah Thompson
Reviewer Signature (electronic signature)	Deborah L. Thompson -S Digitally signed by Deborah L Thompson -S DN: c=US o=U S Government ou=HHS ou=FDA ou=Peop e 0 9 2342 19200300 100 1 1=2002552931 cn=Deborah L Thompson -S Date: 2021 09 29 08:11:36 04 00

COMMENTS

This is the 9th Summary Monthly Safety Report for Comirnaty (COVID-19 mRNA Vaccine).

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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) / (b) (4)

   Not Applicable ☐ Worldwide 296,747,982 / 1,405,758,453

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 (August 12, 2021) an EUA was granted in the U.S. for a third dose of BNT162b2 administered at least 28 days following the two dose regimen in individuals 12 years and older who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered an equivalent level of immunocompromise. There were no actions taken for safety reasons during the reporting period.

The following signals were addressed or are under evaluation by the sponsor during the reporting period: uveitis is under evaluation; thrombosis with thrombocytopenic syndrome (TTS) underwent an updated review and the sponsor concluded the available data do not support a causal association with the vaccine; per the sponsor, available data do not support a risk for erythema multiforme, glomerulonephritis and nephrotic syndrome, myasthenia gravis, hypoesthesia/paraesthesia, and rhabdomyolysis.

The sponsor provided safety evaluation reports, including individual case reviews, observed to expected (O/E) analyses as applicable, and literature searches, for hypoesthesia/paraesthesia, rhabdomyolysis, rheumatoid arthritis, menstrual disorders, post-menopausal hemorrhages, myasthenia gravis, acute disseminated encephalopathy (ADEM), Guillain-Barre syndrome (GBS), capillary leak syndrome (CLS), and TTS. No new safety signals were identified based on the totality of data presented in the safety evaluation reports. Topics will continue to be monitored.

The sponsor is evaluating a new safety topic of uveitis based on a literature report that described a prospective multicenter study that investigated efficacy and safety of the 2-dose BNT162b2 regimen in adults with autoimmune inflammatory rheumatic diseases (AIIRD; n=686) compared to controls (n=121); two cases of uveitis were reported in AIIRD patients. An IR was sent asking the sponsor in the next SMSR to provide a descriptive summary of reports, literature search, O/E analysis, and assessment of causality and safety for the occurrence of uveitis following vaccination with Comirnaty.

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