PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

COMIRNATY LP.8.1 (COVID-19 MRNA VACCINE)

Marketing Authorization Numbers:

70403

Dispersion for injection in a pre-filled syringe 30 micrograms/dose

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LIST OF ABBREVIATIONS

Abbreviation	Definition of Term
COPD	chronic obstructive pulmonary disease
CoV	coronavirus
COVID-19	coronavirus disease 2019
EMA	European Medicines Agency
EPAR	European Public Assessment Report
EU	European Union
mRNA	messenger ribonucleic acid
PSUR	Periodic Safety Update Report
RMP	Risk Management Plan
RNA	ribonucleic acid
SARS	severe acute respiratory syndrome
SmPC	Summary of Product Characteristics (European Union)
VAC4EU	Vaccine monitoring Collaboration for Europe

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OVERVIEW

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them. The RMP summary for Comirnaty LP.8.1 is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g., by mentioning risks occurring in populations or indications not included in the Swiss marketing authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Comirnaty LP.8.1 in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorised by Swissmedic. Pfizer is fully responsible for the accuracy and correctness of the content of the published RMP summary of Comirnaty LP.8.1.

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SUMMARY OF RISK MANAGEMENT PLAN

Summary of risk management plan for Comirnaty

This is a summary of the risk management plan (RMP) for Comirnaty. The RMP details important risks of Comirnaty, how these risks can be minimised, and how more information will be obtained about Comirnaty's risks and uncertainties (missing information).

Comirnaty summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Comirnaty should be used.

This summary of the RMP for Comirnaty should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Comirnaty's RMP.

I. The Medicine and What It Is Used For

Comirnaty is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people from the age of 6 months.

The originally authorised Comirnaty contains tozinameran, a messenger RNA (mRNA) molecule with instructions for producing a protein from the original strain of SARS-CoV-2, the virus that causes COVID-19.

Comirnaty is currently available as four adapted vaccines:

- Comirnaty Omicron XBB.1.5 contains raxtozinameran, an mRNA molecule with instructions for producing a protein from the Omicron XBB.1.5 subvariant of SARS-CoV-2.
- Comirnaty JN.1 contains bretovameran, an mRNA molecule with instructions for producing a protein from the Omicron JN.1 subvariant of SARS-CoV-2.
- Comirnaty KP.2 contains an mRNA molecule with instructions for producing a protein from the Omicron KP.2 subvariant of SARS-CoV-2.
- Comirnaty LP.8.1, the most recent version, contains an mRNA molecule with instructions for producing a protein from the Omicron LP.8.1 subvariant of SARS-CoV-2.

Comirnaty does not contain the virus itself and cannot cause COVID-19.

Further information about the evaluation of Comirnaty’s benefits can be found in Comirnaty’s EPAR, including in its plain-language summary, available on the EMA website, under the medicine’s webpage www.ema.europa.eu/en/medicines/human/EPAR/comirnaty.

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II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Comirnaty together with measures to minimise such risks and the proposed studies for learning more about Comirnaty's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific Information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Comirnaty is not yet available, it is listed under 'missing information' below.

II.A. List of Important Risks and Missing Information

Important risks of Comirnaty are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Comirnaty. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g., on the long-term use of the medicine).

Table 1. List of Important Risks and Missing Information

Important identified risks	Myocarditis and Pericarditis
Important potential risks	None
Missing information	Use in pregnancy and while breast feeding
	Use in immunocompromised patients
	Use in frail patients with co-morbidities (e.g., chronic obstructive pulmonary disease [COPD], diabetes, chronic neurological disease, cardiovascular disorders)
	Use in patients with autoimmune or inflammatory disorders
	Long term safety data

II.B. Summary of Important Risks

The safety information in the Product Information is aligned to the reference.

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Table 2. Important Identified Risk: Myocarditis and Pericarditis

Evidence for linking the risk to the medicine	Events of Myocarditis and Pericarditis have been reported.
Risk factors and risk groups	Post-authorization reports have been reported more frequently in adolescent and young adult male patients following the second dose of vaccine; however, reports have been received for adult males and females of broader age range and following the first vaccination also.
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.4. and 4.8. Additional risk minimisation measures: DHCP letter and communication plan*
Additional pharmacovigilance activities	C4591036 (former Pediatric Heart Network study) C4591009 C4591021 (former ACCESS/VAC4EU) C4591038 (former C4591021 sub-study) C4591052 See Section II.C of this summary for an overview of the post-authorisation development plan.

* In a decision dated 30 July 2021, Swissmedic agreed to a distribution of a DHPC to address myocarditis and pericarditis. As agreed with Swissmedic the DHPC was distributed 12 August 2021. The corresponding additional risk minimization measure listed in Part V.2 of the EU RMP is therefore considered fulfilled and no longer applicable for Switzerland. Therefore, no additional risk minimisation activities are currently planned to be undertaken in Switzerland.

Table 3. Missing Information: Use in Pregnancy and while Breast Feeding

Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.6; PL section 2. Additional risk minimisation measures: None.
Additional pharmacovigilance activities	C4591022[a] C4591009[a] C4591021 (former ACCESS/VAC4EU)[a] C4591052[a] See Section II.C of this summary for an overview of the post-authorisation development plan.

a. Please note that studies C4591009, C4591021 (former ACCESS/VAC4EU), C4591022 and C4591052 address only "Use in pregnancy" and not "Breast feeding".

Table 4. Missing Information: Use in Immunocompromised Patients

Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.4 and 5.1. Additional risk minimisation measures: None.
Additional pharmacovigilance activities	C4591009 C4591021 (former ACCESS/VAC4EU) C4591052 See Section II.C of this summary for an overview of the post-authorisation development plan.

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Table 5. Missing Information: Use in Frail Patients with Co-morbidities (eg. chronic obstructive pulmonary disease (COPD), diabetes, chronic neurological disease, cardiovascular disorders)

Risk minimisation measures	Routine risk minimisation measures: SmPC section 5.1. Additional risk minimisation measures: None.
Additional pharmacovigilance activities	C4591021 (former ACCESS/VAC4EU) C4591052 See Section II.C of this summary for an overview of the post-authorisation development plan.

Table 6. Missing Information: Use in Patients with Autoimmune or Inflammatory Disorders

Risk minimisation measures	Routine risk minimisation measures: None. Additional risk minimisation measures: None.
Additional pharmacovigilance activities	C4591021 (former ACCESS/VAC4EU) C4591052 See Section II.C of this summary for an overview of the post-authorisation development plan.

Table 7. Missing Information: Long Term Safety Data

Risk minimisation measures	Routine risk minimisation measures: None. Additional risk minimisation measures: None.
Additional pharmacovigilance activities	C4591009 C4591021 (former ACCESS/VAC4EU) C4591038 (former C4591021 substudy) C4591036 (former PHN) C4591052 See Section II.C of this summary for an overview of the post-authorisation development plan.

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II.C. Post-Authorisation Development Plan

II.C.1 Studies which are Conditions of the Marketing Authorisation

None.

II.C.2 Other Studies in Post-Authorisation Development Plan

Study	Purpose of the study
C4591009	To assess the occurrence of safety events of interest, including myocarditis and pericarditis, in the general US population (all ages), pregnant women, the immunocompromised and persons with a prior history of COVID-19 within selected data sources participating in the US Sentinel System.
C4591021 (former ACCESS/ VAC4EU)	Assessment of potential increased risk of adverse events of special interest (AESI) among individuals (all ages) after being vaccinated with COVID-19 mRNA vaccine, including individuals less than 12 years of age. Estimating the time trend, in relation to DHPC letter dissemination, of the proportion of individuals who received real-world clinical assessments for myocarditis/pericarditis following Comirnaty vaccination.
C4591038 (former C4591021 substudy)	To describe clinical course (treatment, survival, hospitalisations, long-term cardiac outcomes) of myocarditis and pericarditis among individuals diagnosed with myocarditis and/or pericarditis after receiving at least 1 dose of the Pfizer-BioNTech COVID-19 vaccine and among individuals diagnosed with myocarditis and/or pericarditis who had no prior COVID-19 vaccination, using a cohort. study.
C4591022	To assess whether pregnant women receiving BNT162b2 experience increased risk of pregnancy and infant safety outcomes, including major congenital malformations, spontaneous abortion, stillbirth, preterm delivery, small for gestational age, and small for age postnatal growth to one year of age relative to pregnant women who received no COVID-19 vaccines during pregnancy.
C4591036 (former Pediatric Heart Network study)	To characterize the clinical course, risk factors, long-term sequelae, and quality of life in children and young adults <21 years with acute post-vaccine myocarditis including myocarditis after the bivalent Omicron modified vaccine.
C4591048	To investigate the safety, tolerability, and immunogenicity of variant BNT162b2 RNA-based vaccine candidate(s) in healthy children.
C4591052	To ensure comprehensive understanding of real-world safety of the Pfizer-BioNTech COVID-19 bivalent Omicron-modified vaccine in large samples of general EU populations.

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