

# ОПЕРАТИВНО ОБАВЕШТЕЊЕ

**OAM** 

Број: 01/2021 Датум издавања: 25.03.2021

Наслов:

Обавештење о издавању и поступање према EASA SIB 2021-6

Врста ваздушног саобраћаја на које се примењује ОАМ:

🔀 јавни авио-превоз

🛮 посебне делатности из ваздуха 🖂 некомерцијално летење

Поштовани оператери,

обавештавамо вас да је Агенција Европске уније за безбедност ваздушног саобраћаја (EASA) издала SAFETY INFORMATION BULLETIN 2021-06 који се односи успостављање временског периода након вакцинације током кога летачко особље не може да обавља летачке дужности.

Позивају се оператери ваздухоплова да одредбе из овог документа примене приликом планирања летачких посада.

С поштовањем,

Директорат цивилног ваздухопловства Републике Србије

EASA SIB No.: 2021-06



# **Safety Information Bulletin**

**Operations** 

SIB No.: 2021-06

Issued: 25 March 2021

Subject: Vaccination of aircrew - Operational Recommendations

#### **Ref. Publications:**

- European Centre for Disease Prevention (ECDC) Overview of the implementation of COVID-19
  vaccination strategies and vaccine deployment plans in the EU/EEA.
- ECDC COVID-19 vaccination and prioritisation strategies in the EU/EEA.
- European Medicines Agency (EMA) Comirnaty EPAR -public assessment report.
- EMA Comirnaty Procedural steps taken and scientific information after the authorisation.
- EMA COVID-19 vaccine Moderna- EPAR-public assessment report.
- EMA COVID-19 vaccine AstraZeneca EPAR-public assessment report.
- World Health Organization (WHO) <u>Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines</u>.
- WHO COVID-19 vaccines technical documents.

#### **Applicability:**

National Competent Authorities (NCAs), aircraft operators, aero-medical centres (AeMCs), aero-medical examiners (AMEs) and aircrew members.

### **Description:**

Following the evolution of the SARS-CoV-2 outbreak causing COVID-19 disease, on 11 March 2020 the WHO assessed the current SARS-CoV-2 as a pandemic. Since December 2020, the first vaccines were authorised for emergency use in Europe following the assessment of the EMA, and other vaccines are pending assessment. Starting on 27 December 2020, the European States started their vaccination campaigns with the priority groups based on the WHO recommendations and the national assessment.

The WHO recommends to prioritise transport workers, which include aircrew, in phase 3 of the vaccination, unless they have additional risk factors, in which case they would be prioritised on an individual basis. Nevertheless, several States have included among their priority lists for phase 1 and/or phase 2 the crew members involved in helicopter emergency medical services and air ambulance services, some of whom may have already received one dose of vaccine prior to the issuance of this SIB.

In the documentation provided by the EMA, as part of the assessment process of the vaccine, as well as other published studies regarding the vaccines approved for use in Europe, it can be noticed that some adverse reactions can result following the vaccination. These side effects are generally mild and usually common to any type of vaccine, e.g. headache, mild fever, nausea, pain at the site of injection, dizziness, gastrointestinal disorders, lymphadenopathy, thromboembolic



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events, etc. These side effects have shown to be more frequent between 12 and 48 hours following the vaccination and, in isolated cases, with a potential extended duration of up to 7 days. Severe side effects are extremely rare and were cited to be more frequent among the persons with multiple allergies and tend to appear immediately, in the first 30 minutes following the vaccination. Side effects were also reported more frequent following the second dose of the vaccine.

EASA is closely monitoring developments related to the SARS-CoV-2 outbreak and the development and roll-out of vaccines, and is actively engaged with the WHO, International Civil Aviation Organization (ICAO), and the European Commission (EC), in particular EC Directorate General for Health and Food Safety and EC Directorate General Mobility and Transport. Accordingly, the latest guidance and recommendations issued by EASA, WHO, ECDC, EMA and ICAO should be considered in the context of this SIB.

Although the vast majority of side effects reported so far are mild and do not put into question in any way the safety of the approved vaccines, they may be further enhanced by in-flight conditions while at cruise level, such as lower air pressure and mild hypoxic environment.

At this time, no evidence is available regarding the impact of in-flight conditions on the severity of the side effects, nor on the resulting impact on the performance of the crew members during their safety related tasks. For these reasons, taking into account that these vaccines are new pharmacological products, and in order to ensure that the side effects described above do not interfere with the completion of any safety-related tasks, EASA issued this SIB to draw the aviation community's attention to information and guidelines provided by EASA, WHO, EMA, ECDC and ICAO on aircrew vaccination.

## **Recommendation(s):**

EASA recommends the following:

- 1. Due to their increased exposure, it is highly recommended for aircrew members to receive the COVID-19 vaccine as soon as they become available in accordance with the national COVID-19 vaccine roll-out plan.
- 2. Operators and aircrew members should consider a waiting period of 48 hours after each dose of COVID-19 vaccine, before aircrew members should be engaged in any flight-related tasks in accordance with the privileges of their flight crew licence or cabin crew attestation. This interval could be extended to 72 hours for aircrew members performing single crew operations.
- 3. Aircrew members are advised to consult with their AME in case side effects persist for more than 48 hours following the vaccination and, in consultation with the AME, extend the waiting period until the time when the side effects completely disappear.
- 4. Aircrew members are reminded to give proper consideration to the requirements of MED.A.020-Decrease in medical fitness and the corresponding GM1 MED.A.020.



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5. AMEs and AeMCs performing medical examinations of aircrew should encourage consultation regarding the indication and side effects of vaccination.

- 6. NCAs should avoid implementing different waiting periods between aircrew vaccination and flying duties, unless duly justified by medical publications regarding the COVID-19 vaccines' adverse reactions from EMA, WHO, ECDC or EASA. Furthermore, in such cases NCAs should consult EASA prior implementation different waiting periods.
- 7. NCAs are recommended to consider the above-mentioned recommendations in the context of their oversight activities.

# Contact(s):

For further information contact the EASA Safety Information Section, Certification Directorate, E-mail: ADs@easa.europa.eu.