



Guidelines in relation to the COVID-19 pandemic

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### **Revision record**

Issue	Date of issue	Summary of changes
01	12.05.2021	Initial issue



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# 1. Purpose of these Guidelines

This document provides guidance for National Competent Authorities (NCAs), Air Navigation Service Providers (ANSPs) and Air traffic controllers.

#### 2. Abreviations

AeMC - Aero-medical centre

AME - Aero-medical examiner

ANSP - Air Naviagation Service Provider

ATCO - Air traffic controller

EASA – European Union Aviation Safety Agency

ECDC – European Centre for Disease Prevention and Control

EMA – European Medicines Agency

ICAO – International Civil Aviation Organisation

NCA - National Competent Authority

SMS – Safety Management System

WHO - World Health Organisation

#### 3. Background

Following the evolution of the SARS-CoV-2 outbreak causing COVID-19 disease, on March 11, 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 December 27, 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 ATCOs and other operational aeronautical personnel, in phase 3 of the vaccination campaigns, 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 aviation personnel, some of whom may have already received one dose of vaccine prior to the issuance of these Guidelines .

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 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 persons with multiple allergies and tend to appear immediately, in the first 30 minutes following the vaccination. Side effects were also reported more frequently and with a slightly



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increased severity following the second dose of the ARNm type COVID-19 vaccines, while for adenovirus vectored vaccines such side effects seem to be more frequent following the first dose

Recently thromboembolic events have been described in relation with the vaccines using adenovirus as a vector, mostly in patients below the age of 60. Several EU Member States decided to adjust their national vaccination strategies to make use of these vaccines only for individuals within certain age groups. Although these events are very rare compared with the number of doses administered and have not been linked with any particular risk factor, attention should be given to the association of additional risk factors for thromboembolic events such as smoking, sedentarism and birth control medication.

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, ICAO, and the European Commission (EC), in particular the 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 document.

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 influence the ability of operational staff such as ATCOs to perform their safety tasks in a safe manner.

At this time, no evidence is available regarding the impact of working conditions on the severity of the side effects, nor on the resulting impact on the performance of the ATCOs 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 and EUROCONTROL issued these recommendations to draw the aviation community's attention to information and guidelines provided by EASA, WHO, EMA, ECDC and ICAO on vaccination of ATCOs.

#### 4. Recommendations:

EASA and EUROCONTROL recommend the following:

- 1. Due to their safety relevant functions, it is recommended that ATCOs, as essential workers, receive the COVID-19 vaccine as soon as it becomes available in accordance with the national COVID-19 vaccine rollout plan.
- 2. ATCOs and the ANSPs should consider a waiting period of 48 hours after each dose of COVID-19 vaccine, before the ATCO should be engaged in any operational related tasks in accordance with the privileges of their licence.
- 3. ATCOs are advised to consult with their AME or AeMC in case side effects persist for more than 48 hours following the vaccination and, in consultation with the AME or AeMC, extend the waiting period until the time when the side effects completely disappear.
- 4. ATCOs are reminded to give proper consideration to the requirements of ATCO.MED.A.020(a)-Decrease in medical fitness and the corresponding GM1 ATCO.MED.A.020.
- 5. AMEs and AeMCs performing medical examinations of ATCOs should encourage consultation regarding the indication and side effects of vaccination.



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6. NCAs and ANSPs should avoid implementing different waiting periods between ATCO vaccination and operational 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 to the implementation of different waiting periods.

7. NCAs are advised to consider the above-mentioned recommendations in the context of their oversight activities.

#### What can you do as an ANSP?

- ANSPs should be prepared to enable flexibility in the management of the ATCO rostering to accommodate such cases, in order to prevent operational negative effects e.g.:
  - Organise shift patterns with a sufficient break, which would allow ATCOs to take sufficient rest, as much as possible without disclosing information on vaccination
- Implement a reporting system for ATCOs not only to AMEs to address vaccination issues (restriction
  due to medical aspect of being vaccinated). This would allow tactical rostering in case of being
  vaccinated or received an invitation for a vaccination. The content of the report should be treated in
  line with medical confidentiality requirements.
- Review and adjust, if needed, the procedure required by ATCO.A.015 (d) regarding provisional inability to ensure it is fit for purpose
- ANSPs should perform a risk assessment in accordance with their SMS to identify whether the
  recommendation made in this document should also be extended to their operational personnel on
  shift undertaking safety related tasks as per SMS of the ANSP

#### What can you do as an ATCO?

- 1. It is recommended to provide certain information (e.g. scheduled for a vaccination) to the ANSP to allow a proper rostering
- 2. Use the established process within the ANSP (e.g.: provisional inability) in case of encountering any issues with vaccination
- 3. Consult with your AME/AeMC if you are suffering from vaccination side effects for more than 48 hours.



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#### 5. Reference

- 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.
- EMA: Comirnaty EPAR -public assessment report.
- EMA <u>Comirnaty Procedural steps taken and scientific information after the authorisation.</u>
- EMA: COVID-19 vaccine Moderna- EPAR-public assessment report.
- EMA: COVID-19 vaccine AstraZeneca EPAR-public assessment report.
- WHO: <u>Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines.</u>
- WHO: COVID-19 vaccines technical documents
- EASA: <u>Guidelines for Aero-Medical Centres and Aeromedical Examiners regarding the examination and assessment of applicants</u>
- Research Square: <u>Towards Understanding ChAdOx1 nCov-19 Vaccine-induced Immune</u> <u>Thrombotic Thrombocytopenia (VITT)</u>