# COVID-19 Vaccine AstraZeneca: Risk of thrombocytopenia and coagulation disorders

Dear Healthcare Professional,

AstraZeneca AB in agreement with the European Medicines Agency and the <National Competent Authority > would like to inform you of the following:

## *Summary*


- **COVID-19 Vaccine AstraZeneca: benefits outweigh the risks despite possible link to very rare blood clots with low blood platelets.**
- **A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with COVID-19 Vaccine AstraZeneca.**
- **Healthcare professionals should be alert to the signs and symptoms of thromboembolism and or thrombocytopenia.**
- **Those vaccinated should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg swelling, persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms including severe or persistent headaches and blurred vision after vaccination, or who experiences skin bruising (petechia) beyond the site of vaccination after a few days, should seek prompt medical attention.**


## *Background on the safety concern*

COVID-19 Vaccine AstraZeneca is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older.

Cases of thromboembolic events have been reported following administration of COVID-19 Vaccine AstraZeneca in several EEA countries, some leading to local suspensions of specific batches or to the use of the vaccine itself.

A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with COVID-19 Vaccine AstraZeneca. This includes severe cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, mesenteric vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. The majority of these cases occurred within the first seven to fourteen days following vaccination and occurred in women under 55 years of age, however this may reflect the increased use of the vaccine in this population. Some cases had a fatal outcome.

Based on these events, the PRAC has initiated signal procedure in order to further investigate the issue.

The PRAC has performed a full investigation under accelerated timetable including a careful review of EudraVigilance case reports of blood clots and thrombocytopenia in individuals who received the vaccine paying special attention to the information on the sex, age, risk factors, COVID-19 diagnosis (if available), time-to-onset, outcome, and clinical entity.
The investigation has also included a related literature review and an observed to expected analysis conducted with EudraVigilance case reports.

While further evidence is being collected, the PRAC has recommended an update to the product information of the COVID-19 Vaccine AstraZeneca suspension for injection to reflect the current knowledge of the safety issue.

## Call for reporting

Healthcare professionals should report any suspected adverse reactions associated with the use of COVID-19 Vaccine AstraZeneca in accordance with the national spontaneous reporting system *<include the details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system>*.

## Company contact point

*<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address (company contact point in the concerned EU MS should be included, respectively)>*

Yours Faithfully

Medical Director of AstraZeneca AB

## Communication Plan for Direct Healthcare Professional Communication

| DHPC COMMUNICATION PLAN | |
|---|---|
| **Medicinal product(s)/active substance(s)** | COVID-19 Vaccine AstraZeneca suspension for injection (ChAdOx1-S [recombinant]) |
| **Marketing authorisation holder(s)** | AstraZeneca AB |
| **Safety concern and purpose of the communication** | Risk of thrombocytopenia and coagulation disorders |
| **DHPC recipients** | General practitioners and vaccination centres.<br>The target group should be further defined at national level, in agreement with the respective national competent authority. |
| **Member States where the DHPC will be distributed** | All EU member states where COVID-19 Vaccine AstraZeneca is marketed. |

| Timetable | Date |
|---|---|
| **DHPC and communication plan (in English) agreed by PRAC** | 18/03/2021 |
| **DHPC and communication plan (in English) agreed by CHMP** | 19/03/2021 |
| **Submission of translated DHPCs to the national competent authorities for review** | 22/03/2021 |
| **Agreement of translations by national competent authorities** | 23/03/2021 |
| **Dissemination of DHPC** | 24/03/2021 |