# ASPHER welcomes European Medicines Agency judgement on the safety of AstraZeneca Covid-19 vaccine.

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Prepared on behalf of ASPHER by Jean-Philippe Naboulet and Laurent Chambaud, EHESP, Rennes, France

On Thursday 18 March, the European Medicines Agency (EMA)'s Pharmacovigilance Risk Assessment Committee (PRAC) issued its opinion on new unexpected cases of severe cerebral venous thrombosis associated with platelet deficiency (thrombocytopenia) and bleeding detected in several European countries, following vaccination with the AstraZeneca (AZ) COVID-19 Vaccine. The data reported concern 25 cases identified as of 15 March (7 cases of blood clots and 18 cases of thrombocytopenia, including 3 deaths)[1,2] for 20 million people vaccinated with this vaccine in Europe and the United Kingdom[3]. Two deaths potentially linked to the AZ vaccine were also reported on 18 March in Norway[4]. Furthermore, the EMA notes that these adverse events have been reported in women under 55 years of age.

The evaluation requested by the Member States from the EMA is part of the reinforced surveillance of these vaccines[4]. As these vaccines are authorised under the conditional authorisation regime[5], there is an obligation to monitor the detection of adverse effects not identified during clinical trials. It is therefore understandable that the health authorities of some twenty countries[6], faced with the presentation of cases of potentially serious adverse reactions following the administration of the AZ vaccine, have requested a suspension of its use while the EMA analyses these new reports and determines whether a direct causal relationship can be demonstrated.

Finally, the assessment carried out by the EMA experts shows that, while it cannot be totally excluded that very rare cases of unusual blood clots associated with thrombocytopenia may be related to the vaccination[7], their frequency appears at this stage to be very rare. Thus, the EMA, like the World Health Organisation and the Medicines and Healthcare products Regulatory Authority (MHRA) in the UK, considers that these extremely rare adverse events do not call into question the benefit-risk balance of AZ vaccine.

In addition, as a further precaution, the EMA plans to amend the SmPC and package leaflet of this vaccine to include information on these cases of blood clots and thrombocytopenia.

[1] EMA Press release 18/03/2021

[2] Paul-Ehrlich-Institut, FAQ - Temporary suspension of COVID-19 vaccine AstraZeneca, 16 March 2021

[3] As of 16 March 2021 - EMA Press release 18/03/2021

[4] Obligation to conduct a Risk Management Plan (RMP)

[5] EPAR - COVID 19 Vaccine Astra Zeneca

[6] Suspension of vaccination: Thursday 11/03: Denmark, Iceland, Norway, Bulgaria. Sunday 14/03: Ireland and the Netherlands. Monday 15/03: Germany, Spain, France, Italy, Portugal and Slovenia, Tuesday 16/03: Sweden, Luxembourg and Cyprus.
Suspension of the use of specific batches of AstraZeneca vaccine: Austria, Estonia, Lithuania, Latvia and Romania

[7] EMA Press release 18/03/2021

The EMA also recommends that health professionals and vaccinated individuals monitor for any signs of thromboembolism that may occur following vaccination[8].

The Association of Schools of Public Health in the European Region (ASPHER) welcomes the EMA judgement on the safety of the AZ vaccine. We agree with the need for transparency, and believe the citizens of Europe can be assured of the diligent vaccination surveillance programme. Moreover, this episode highlights the quality of the European pharmacovigilance system and the capacity of the various States to take strong decisions if the slightest risk were to call into question the benefit and safety of the vaccination campaign currently underway. All these elements contribute to the creation of a relationship of trust between the authorities and the public.

However, ASPHER regrets that the different countries did not coordinate to present a common position when the first cases of thromboembolism were announced. Without calling into question the competence of each country, such differences in the decisions taken can only be a source of misunderstanding by the public.

On the basis of the assessments made by the WHO, the EMA and the MHRA, considering the extremely favourable benefit/risk ratio, the performance of the system for monitoring the effects of vaccines, taking into account the additional information provided on the SmPC and the package leaflet, and noting the capacity of the States to take the necessary decisions, ASPHER recommends the continuation of vaccination programmes with authorised vaccines, including AZ vaccine. Furthermore, the difficulties in producing and supplying the various vaccines show the importance of working at European level with several manufacturers. ASPHER therefore supports the policy of vaccination with all products that have been positively evaluated by the EMA.

Professor John Middleton, President of ASPHER said ‘many of our members are reporting substantial damage to public confidence in COVID-19 vaccination. This is a major concern for us in the fight against this deadly disease. Experience in Israel, the USA and UK is showing the dramatic lifesaving power of these vaccines so we must encourage all our citizens to be vaccinated. We will not be free of the virus till everyone is free and we must call on all governments to work together to maintain and increase confidence in the vaccination for our collective safety and health.

For further information contact:
John Middleton john.middleton@aspher.org; Robert.otok@aspher.org

[8] Ibid.