REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

Press release

COVID-19 Vaccine AstraZeneca – Update on ongoing evaluation of blood clot cases

Last week, EMA's safety committee, PRAC, concluded its preliminary review of cases of blood clots, including very rare cases of blood clots with unusual features such as low numbers of platelets, in people vaccinated with COVID-19 Vaccine AstraZeneca. The committee confirmed that the vaccine is not associated with an increase in the overall risk of blood clots and that the benefits of the vaccine in combating the still widespread threat of COVID-19 continue to outweigh the risk of side effects. The committee recommended including more information and advice for healthcare professionals and the public in the vaccine's product information.

The amended product information and the associated direct healthcare professional communication are now available on the EMA website.

PRAC is continuing its assessment of the reported cases. In this context, EMA is convening an *ad hoc* expert group on 29 March to provide additional input into the assessment. External experts in haematology (thrombosis and haemostasis), cardiovascular medicine, infectious diseases, virology, neurology, immunology and epidemiology will meet to provide their views to PRAC on aspects such as any plausible mechanism of action, possible underlying risk factors and any additional data needed to gain a deeper understanding of the observed events and the potential risk. This expert group will also include two representatives from the public.

The outcome of the expert meeting, together with further analysis of the reported cases, will feed into PRAC's ongoing evaluation. The PRAC's updated

recommendation on the issue is expected during its April plenary meeting (6–9 April).

More about the procedure

The review of thromboembolic events with COVID-19 Vaccine AstraZeneca is being carried out in the context of a safety signal, under an accelerated timetable. A safety signal is information on a new or incompletely documented adverse event that is potentially caused by a medicine such as a vaccine and that warrants further investigation.

The review is being carried out by EMA's Pharmacovigilance Risk Assessment Committee (PRAC), the committee responsible for the evaluation of safety issues for human medicines. Once the review is completed, PRAC will make any recommendations necessary to minimise risks and protect patients' health.

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Ministry of Health

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