REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

Press release

EMA evaluating data on booster dose of COVID-19 Vaccine Janssen

EMA has started evaluating an application for the use of a booster dose of COVID-19 Vaccine Janssen to be given at least two months after the first dose to people aged 18 years and older.

EMA's human medicines committee (CHMP) will carry out an accelerated assessment of data submitted by the company that markets the vaccine. These data include results from more than 14,000 adults who received a second dose of COVID-19 Vaccine Janssen or placebo (a dummy treatment) two months after the initial dose.

The CHMP will recommend whether updates to the product information are appropriate. The outcome of this evaluation is expected within weeks, unless supplementary information is needed, and will be communicated by EMA.

COVID-19 Vaccine Janssen is a vaccine for preventing COVID-19. It is currently authorised for use in people aged 18 and older, with the primary vaccination consisting of a single dose. The vaccine is made up of another virus (of the adenovirus family) that has been modified to contain the gene for making a protein from SARS-CoV-2, the virus that causes COVID-19. COVID-19 Vaccine Janssen does not contain the virus itself and cannot cause COVID-19. The vaccine works by preparing the body to defend itself against SARS-CoV-2. More information about the vaccine is available.

The implementation of vaccination campaigns in the EU, including the use of booster doses, remains the prerogative of the national immunisation technical advisory groups (NITAGs) guiding the vaccination campaigns in each EU Member State. These bodies are best placed to take into account the local conditions, including the spread of the virus (especially any variants of concern), the availability of vaccines and the capacities of national health systems.

Ministry of Health

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