



11 July 2022 EMA/635144/2022

ECDC and EMA update recommendations on additional booster doses of mRNA COVID-19 vaccines

The European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) are recommending that second booster doses of mRNA COVID-19 vaccines be considered for people between 60 and 79 years old and people with medical conditions putting them at high risk of severe disease.

In <u>April 2022</u>, both agencies recommended that people over 80 years of age be considered for a second booster. However, the agencies noted at the time that it might be necessary to consider second boosters in people between 60 and 79 years old and vulnerable persons of any age if there was a resurgence of infections.

Second boosters for people above 60 years and vulnerable persons

As a new wave is currently underway in Europe, with increasing rates of hospital and intensive care unit (ICU) admissions, it is critical that public health authorities now consider people between 60 and 79 as well as vulnerable persons of any age for a second booster. These could be administered at least four months after the previous one, with a focus on people who have received a previous booster more than 6 months ago. Currently authorised vaccines continue to be highly effective in reducing COVID-19 hospitalisations, severe disease and deaths in the context of emerging SARS-CoV-2 variants.

Stella **Kyriakides**, the European Commissioner for Health and Food Safety said that 'Our COVID-19 vaccines work, and offer good levels of protection against severe illness and hospitalisation. With cases and hospitalisations rising again as we enter the summer period, I urge everybody to get vaccinated and boosted as quickly as possible. There is no time to lose.

'I call on Member States to roll-out second boosters for everyone over the age of 60 as well as all vulnerable persons immediately and urge everyone eligible to come forth and get vaccinated. This is how we protect ourselves, our loved ones and our vulnerable populations.'

'We are currently seeing increasing COVID-19 case notification rates and an increasing trend in hospital and ICU admissions and occupancy in several countries mainly driven by the BA 5 sublineage of Omicron,' said Dr Andrea **Ammon**, the Director of ECDC.

'This signals the start of a new, widespread COVID-19 wave across the European Union. There are still too many individuals at risk of severe COVID-19 infection whom we need to protect as soon as possible. We need to remind people of the importance of vaccination from the very first shot to the second booster. We have to start today.



'We expect that adults 60 years and older and medically vulnerable populations will need a second booster dose. These are the groups most at risk of severe disease and giving a second booster to those groups now will avert a significant number of hospitalisations and deaths from COVID-19.

'I am aware that it requires a significant effort from public health authorities and society at large to achieve this goal. But now at the beginning of a new wave is the time to make the extra effort. We have several safe and effective vaccines available, and every single COVID-19 infection prevented now is a potential life saved.'

Second boosters in the wider population

At the moment, there is no clear evidence to support giving a second booster dose to people below 60 years of age who are not at higher risk of severe disease. Neither is there clear evidence to support giving early second boosters to healthcare workers or those working in long-term care homes unless they are at high risk.

However, residents at long-term care homes are likely to be at risk of severe disease and should be considered for booster doses in line with national recommendations.

ECDC and EMA have called on public health authorities across the EU to plan for additional boosters during the autumn and winter seasons for people with highest risk of severe disease, possibly combining COVID-19 vaccinations with those for influenza.

National Immunisation Technical Advisory Groups (NITAGs) will ultimately make national decisions on who should get second boosters, taking into account the situation in their countries.

Adapted vaccines

The latest ECDC/EMA advice comes amid work to adapt vaccines for the Omicron variants of concern.

'We are working towards possible approvals of adapted vaccines in September,' said EMA's Executive Director, Emer **Cooke**, noting that 'our human medicines committee is currently reviewing data for two adapted vaccines.'

'In the meantime, it is important to consider using currently authorised vaccines as second boosters in people who are most vulnerable. Authorised vaccines in the EU continue to be effective at preventing hospitalisations, severe disease and deaths from COVID-19, even as new variants and subvariants continue to emerge.'

She added that 'Authorities in the EU are working closely with the World Health Organization and international partners on policies concerning adapted vaccines.'

ECDC and EMA will continue to closely evaluate emerging vaccine effectiveness and epidemiological data and will update their recommendations accordingly. Further details about the latest advice on second booster doses is available in the ECDC/EMA joint statement.