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ECDC and EMA highlight considerations for additional and booster doses of COVID-19 vaccines

Based on current evidence, there is no urgent need for the administration of booster doses of vaccines to fully vaccinated individuals in the general population, according to a <u>technical report</u> issued today by the European Centre for Disease Prevention and Control (ECDC). The report also notes that additional doses should already be considered for people with severely weakened immune systems as part of their primary vaccination.

Evidence on vaccine effectiveness and duration of protection shows that all vaccines authorised in the EU/EEA are currently highly protective against COVID-19-related hospitalisation, severe disease and death, while about one out of three adults in the EU/EEA over 18 years is still currently not fully vaccinated. In this situation, the priority now should be to vaccinate all those eligible individuals who have not yet completed their recommended vaccination course. To complement vaccination efforts, it is also crucial to continue applying measures such as physical distancing, hand and respiratory hygiene, and using face masks where needed, in particular in high-risk settings such as long-term care facilities or hospital wards with patients at risk of severe COVID-19.

It is important to distinguish between booster doses for people with normal immune systems and additional doses for those with weakened immune systems. Some studies report that an additional vaccine dose can improve the immune response in immunocompromised individuals, such as organ transplant recipients whose initial responses to vaccination were low. In such cases, the option of administering an additional dose should be considered already now. Consideration could also be given to providing an additional dose, as a precautionary measure, to older frail individuals, in particular those living in closed settings such as residents of long-term care facilities.

The European Medicines Agency (EMA) is currently assessing data on additional doses and will consider whether updates to the product information are appropriate. EMA will also be assessing data on booster doses.

While EMA assesses relevant data, Member States may consider preparatory plans for administering boosters and additional doses.

Advice on how vaccinations should be given 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.

The ECDC will update its technical report as ECDC and EMA continue to work together to collect and assess data that are becoming available on boosters and additional doses. Close monitoring of vaccine effectiveness data and breakthrough infections, particularly among vulnerable groups at risk of severe COVID-19 and among those living in closed settings, should be continued. In the meantime, Member States need to prepare for possible adaptations to their vaccination programmes should a substantial decrease in vaccine effectiveness be noted in one or more population groups.

