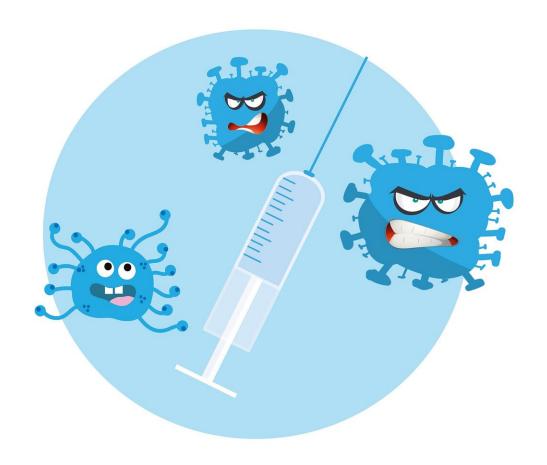


EU set to decide on COVID boosters next month

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The EU's drug watchdog said Thursday it expected to decide in early October whether to approve boosters of the Pfizer/BioNTech COVID-19 vaccine for over 16s.

A decision on further jabs of both the Pfizer and Moderna vaccines for at-risk people and the elderly is due at the same time, the European Medicines Agency (EMA) said.

Protection against coronavirus is shown to decrease in the months following the first jabs, the Amsterdam-based regulator's head of <u>vaccine</u> strategy Marco Cavaleri told a news conference.

"The available data are showing that immunity against COVID-19 from initial vaccination wanes over time, and the protection from infection and symptomatic disease is decreasing in different parts of the world," Cavaleri said.

As a result, the EMA is now evaluating Pfizer's application for the use of a third booster dose at least six months after the second dose in people aged 16 or older.

"The outcome of this evaluation is expected in early October unless supplementary information is needed," Cavaleri said.

The EMA expert also said the "evidence was becoming clearer" on the need for boosters shortly after the first jabs for people with weakened immune systems who "respond poorly" to the initial vaccination.

Hospitalisation rates in the elderly were starting to rise as the initial jabs wore off, Cavaleri said.

The watchdog would "consider by early October if any specific recommendation can be included in product information" for the



Moderna and Pfizer vaccines for such people, Cavaleri said.

Some EU countries were starting to give boosters to at-risk people ahead of a possible winter spike in COVID cases ahead of authorisation, Cavaleri said.

The EMA "acknowledged and understood" this decision, he added.

The watchdog meanwhile expects to make decisions on approving COVID vaccines for <u>younger children</u> in coming months.

Pfizer is due to submit data on trials for children aged 5-11 in early October, and Moderna in November, with decisions likely four weeks afterwards in each case, Cavaleri said.

The regulator has currently approved four vaccines for use in the 27-nation EU: Pfizer and Moderna, which use messenger RNA technology, and AstraZeneca and Johnson & Johnson, which use viral vector technology.

Only Pfizer and Moderna are so far approved for use in children aged 12 and up.

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