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Europe backs Pfizer/Biontech Covid-19 vaccine's broad applicability

Jacob Plieth

An extraordinary meeting of the EU CHMP recommends conditional approval of Pfizer/Biontech's Covid-19 vaccine.

With the US as of last week boasting two Covid-19 vaccines approved for emergency use, the European regulator has moved to make the first, Pfizer/Biontech's BNT162b2, available throughout the EU.

At an extraordinary meeting today the CHMP recommended conditional marketing authorisation of the jab, under the name Comirnaty. Of course, under a separate procedure the UK has already approved BNT162b2, and EMA officials offered the UK some good news, saying there was no evidence suggesting that this vaccine should not work in the new variant Covid-19.

It is in parts of the UK that this new variant has caused a surge in infections in recent weeks, leading the government to implement new regional lockdowns over the Christmas period. That the coronavirus should mutate is a logical consequence of natural selection, but its properties and susceptibility to vaccination are still not clear.

Neutralising antibodies

"We have quite a broad knowledge around the fact that this vaccine is capable of generating antibodies that can neutralise different [Covid-19] variants with mutations in the receptor-binding domain," Marco Cavaleri, chair of the EMA's Covid-19 pandemic task force, told a press briefing today.

"Even if we don't have full confirmation yet, we think it is very likely that the vaccine will retain protection also against this new variant." But he stressed that there was no direct evidence yet as to whether the new Covid-19 strain was susceptible to the antibodies elicited by BNT162b2.

Pfizer/Biontech's 43,000-patient study showed that the vaccine conferred 95% protection against Covid-19 versus placebo, but it is unlikely that many of its participants would have been exposed to the latest strain of the virus.

The EMA spent much of the briefing highlighting its review of the risk/benefit arising from this trial, stressing that conditional authorisation required ongoing review of data as they emerged, and ruling out the possibility of any political pressure. Formal approval for Comirnaty should come within days.

The CHMP's recommendation is specifically in people aged 16 and above. The agency said that because of low

study participant numbers it could not draw firm conclusions effects on pregnant women, and thus recommended a case-by-case approach in this population.

Anaphylaxis

It also accepted that allergic reactions were an emerging adverse effect that a small number of patients had experienced in countries, like the UK, that had already approved BNT162b2 and had begun national vaccination campaigns.

As a result, the EMA recommends close observation of patients for at least 15 minutes after vaccination, and says the second dose of Comirnaty should not be given to those who have experienced anaphylaxis after the first.

The agency was the first to start a rolling review of the Pfizer/Biontech vaccine, and is similarly reviewing Moderna's mRNA-1273 and Astrazeneca's ADZ1222. It had initially set December 29 as the date for the CHMP's extraordinary meeting, but brought this forward by a week in light of additional data received from Pfizer/Biontech on December 14.

It said it would continue monitoring emerging side effects, and has commissioned independent studies to monitor Covid-19 vaccine safety in addition to data from company-sponsored trials.