UK drugs regulator defends fast pace of vaccine approval

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Britain's medicines regulator insisted Friday its world-first approval of the Pfizer-BioNTech coronavirus vaccine met all safety standards, after officials in Europe and the United States queried the rapid process.

The Medicines and Healthcare products Regulatory Agency (MHRA) on

Wednesday announced emergency approval for the vaccine's general use against COVID-19, and the government plans to start rolling it out next week.

Any vaccine "must undergo robust clinical trials in line with international standards", the MHRA said in a statement.

"No vaccine would be authorised for supply in the UK unless the expected standards of safety, quality and efficacy are met."

Leading US infectious disease scientist Anthony Fauci on Thursday said the MHRA had "rushed through that approval", but later apologised.

"I have a great deal of confidence in what the UK does both scientifically and from a regulator standpoint," Fauci, who leads the US National Institute of Allergy and Infectious Diseases, told the BBC.

"Our process is one that takes more time than it takes in the UK. And that's just the reality," he said. "I did not mean to imply any sloppiness even though it came out that way."

MHRA chief executive June Raine previously insisted that "no corners had been cut" in vetting the Pfizer-BioNTech vaccine.

With Britain transitioning out of the European Union, the UK regulator obtained an exemption from the EU's medicines agency, which has stressed it prefers to wait for further review and consultations across the 27-nation bloc.

Britain plans to distribute an initial batch of 800,000 doses starting next week, prioritising care homes.

Vaccine nationalism

The MHRA said it was able to move quickly after launching a rolling review of data provided by Pfizer and BioNTech as human trials proceeded, rather than waiting for all the data to be compiled at the end of the trials.

"COVID-19 vaccines, including this one, are being developed in a coordinated way that allows some stages of this process to happen in parallel to condense the time needed, but it does not mean steps and the expected standards of safety, quality and effectiveness have been bypassed," it said.

Approval is expected this month by both the US Food and Drug Administration and the European Medicines Agency.

England's deputy chief medical officer Jonathan Van-Tam has also hit back at critics, suggesting sour grapes on the part of regulators who are bound by more bureaucracy.

"If you're a regulator who's slightly further behind, what do you say to justify your position that you are further behind? Words such as the ones we've heard perhaps," he told the BBC on Thursday.

Some British ministers have strayed into anti-EU jingoism after London beat Brussels to approving the Pfizer-BioNTech jab. Education Secretary Gavin Williamson said the UK was first because it was "a better country".

But Van-Tam also stressed the cross-border nature of scientific collaboration. Another government scientific adviser, Peter Openshaw of London's Imperial College, decried the "unfortunate international competition being set up".

"This is really us against the virus, it's not us against the Americans, us

against the Europeans," the professor in respiratory and immunology medicine said on BBC television Thursday.

Openshaw also defended the MHRA's green light for the vaccine: "It's quite clear this has been very, very carefully scrutinised and I have no concerns about it."