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UK asserts its independence with first Covid-19 vaccine nod

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The UK's swift authorisation of Biontech and Pfizer's Covid-19 shot has attracted both praise and concern.

It is an inconvenient truth for Brexit-backing UK politicians that the country's swift authorisation of the first Covid-19 vaccine was in no way facilitated by the ongoing divorce from the European Union – not that this has prevented such claims being made.

For those more concerned with scientific rigour, it was the speed of the decision that raised eyebrows, rather than political boasts. But in reality the UK's move will only look controversial should regulators in the US or Europe come to a different conclusion – and that seems extremely unlikely.

True, opposing decisions cannot be completely ruled out, particularly as the only data released so far on the vaccine, BNT162b2 from Biontech and Pfizer, have come via a brief press release. But after incredibly upbeat comments from the companies and high-profile government scientists, anything other than green lights from across the globe would be very surprising.

The world will not have long to wait to hear these other opinions. The US FDA is likely to rule on emergency use authorisation soon after a December 10 advisory committee review. Europe's EMA has required developers to file for conditional approval, and has said a verdict will be reached on BNT162b2 by the end of the year.

The UK is still operating under EU law until January 1, 2021; however, the country's regulator, the MHRA, was able to diverge from the EMA's process under emergency regulations that have been in place for years, and which any EU member country could choose to adopt. This allowed BNT162b2 to be granted temporary authorisation for emergency use in the UK.

In a surprisingly frank exchange, the EMA told Reuters that the conditional approval process was "more appropriate" than the UK's chosen route because it was based on more evidence and required more checks. The statement can probably be read as both a criticism of the MHRA and a defence of the length of time that the EMA intends to take on making a decision.

Both of these assessments, as well as the one by the FDA, will represent remarkably quick turnarounds, of course. It is not unreasonable to question whether any medicine regulator is able to do a thorough review of huge reams of data in such a short space of time.

Only with hindsight will it be known whether these early projects should have been afforded greater scrutiny.

But with Covid-19 death rates still high in many regions, health services creaking under the strain of the pandemic and global economies crippled, “taking our time” is not a phrase governments are reaching for right now.

Pressure from those beleaguered politicians is another important factor to bear in mind here. The White House’s ominous presence around some controversial FDA emergency use authorisations has been well documented. And in the UK, it is not impossible that the government strongly encouraged the MHRA to beat an independent path.

Perhaps a more important question is whether the public can be assured that very high standards are being met here. Vaccine hesitancy could be a real problem in the coming months among populations that have repeatedly been told that these products have never before been developed so quickly.

Still, for those worried about BNT162b2 in particular, this vaccine is expected to be swiftly superseded by products with less onerous storage requirements. Which vaccines get the nod next depends on data yet to emerge, although Moderna’s mRNA-1274 also looks likely to win swift approvals in the coming weeks. At that point the same concerns about speed and rigour will arise once again.