Brexit threatens the UK's ability to respond to the novel coronavirus and future pandemics

The novel coronavirus 2019-nCoV pandemic could not have come at a worse time for the UK and its citizens. Just as UK government ministers are digging in for the really difficult part of Brexit, the negotiations on future relationships with the EU and the rest of the world, a new virus comes out of China that not only stops everyone in their tracks, but also reminds us of just why international co-operation is so important.

The obvious response, one might think, would be to do everything possible to safeguard those areas where the UK does collaborate, so as to reduce the threat of infectious disease. Obvious, but wrong. Instead, the UK has decided to self-isolate itself from European systems that have been built up over the past decade, many as a result of earlier problems exposed by the 2009 swine flu pandemic.

The UK's decision to leave the European Medicines Agency (EMA), an arm of the European Commission, has been discussed at length in the media. The EMA is responsible for overseeing clinical trials for new vaccines and medicines for pandemics, and deciding on marketing authorisations for them that apply across the EU. Much media attention has been on the damage that being outside the EMA will do to the British economy. This is both through lost activity among UK researchers and suppliers, and by making the UK a less attractive place for major pharmaceutical companies to do business.

However, the consequences of being outside the EMA go much further. The UK now lies outside the EMA's rapid authorisation mechanism for pandemic vaccines and medicines for treatment. Consequently, the UK could have to wait longer for these than EU member states. To make matters worse, the UK has also withdrawn from the EU's emergency bulk buying mechanism for vaccines and medicines, which allows EU member states to increase their market power and speed up access to vaccines and medicines during a crisis. Its exclusion could mean the UK will have to pay more to acquire these pandemic countermeasures.

It remains unclear what the UK's future relationship with the EU might be. The government could, if it wished, go for a much closer alignment, a choice made by Norway, Liechtenstein, and Iceland, which with the EU form the European Economic Area (EEA). Regulators in these countries are on the same footing as regulators in EU countries, although as non-member states they do not have a say in the EMA or wider EU decisions. However, the difference with the UK is that these countries are in the single market and have accepted its rules. Even Switzerland, which is outside the EEA, has bespoke arrangements with the EMA based on its alignment to EU rules. A future relationship modelled on the Ukrainian Association Agreement with the EU is another option. But each of these non-member states are outside the EU's bulk buying mechanism for vaccines and medicines. In any case, all of these models seem completely unacceptable to the current UK government.

Even if it continues to reject any alignment with EU rules, there other ways that the UK could mitigate the problems that come with being outside the EMA. One would be to copy Singapore, which has decided, unilaterally, to recognise automatically EMA marketing authorisations, as well as those issued by the US Food and Drug Administration, subject to a 60-day Verification Route. However, this would be contrary to the UK government's refusal to be a 'rule taker'.

Finally, the UK could also, at least in theory, create its own rapid marketing authorisation mechanism. The slight problem is that this would almost certainly be impossible in the short term, not least because of the need to attract skilled staff. Many staff would have to be recruited internationally, and they may well decide that the UK's harsh, and extremely expensive, immigration regime was less than welcoming. And even if a new UK mechanism did work, it would not necessarily

ensure swift access to medicines as UK standards may diverge from those in the EU, a real threat given the upcoming implementation of the recent EU clinical trials regulation.

Concerns about UK divergence have been exacerbated by the comment by Matt Hancock, Secretary of State for Health and Social Care in England, that the UK's medicines regulator could reduce bureaucracy, signifying an intention to diverge. Clinical trials data and marketing authorisations in the UK, especially when made on the basis of that data, may not satisfy the EMA. Some pharmaceutical companies may therefore opt to base clinical trials in the EU, or in third countries that apply EU-compliant standards, so as to ensure they obtain marketing approval through the EMA for the EU market.

Pharmaceutical companies with UK-based manufacturing plants, including AstraZeneca, have already established batch control sites and pharmacovigilance teams in EU member states. This is to ensure they can continue to lawfully supply medicines in the EU. Pharmaceutical companies, facing the very large administrative burden involved in obtaining marketing authorisation, are likely to prioritise the EU's single market over the UK's far smaller market, as already happens with Switzerland and Canada.

It is a Canada-style trade deal that the UK is now pursuing, although it has not ruled out what it describes as an 'Australia-style' deal, which is in effect code for no deal. Yet this could take upwards of eight or more years to agree and EU negotiators, with their much greater experience, are likely to drive a hard bargain. As with any deal with the US, itself very unlikely, this will demand that the UK make choices about who to align with.

For all of these reasons, if, as seems likely, a vaccine will be developed against the 2019-nCoV virus, the UK is likely to have to join the queue for access with other countries outside the EU, and to pay more than it otherwise would as an EU member state. Looking further ahead, this problem will not be limited to emergencies, and the UK can expect slower and more limited access to medicines, especially those for rare conditions or used to treat children, where the market is small.

So while, in one respect, the timing of the 2019-nCoV virus pandemic could not have been worse for the UK, in another it could provide an opportunity to reflect on whether the pursuit of an isolationist ideology really is such a good idea when the threats ignore borders. It has taken many years to build up the EU's systems of defences against infectious disease. In an ever more uncertain and interconnected world, is it really a good idea to withdraw from them?