

December 2021

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Brexit Update

In mid-December, the European Commission (EC) published its unilateral [proposal](#) to maintain a steady supply of medicines to Northern Ireland (NI), as well as other historically dependent markets (Cyprus, Ireland and Malta), while talks on post-Brexit trade rules continue and will be renewed in January 2022. The proposal includes a [document](#) - amending EU Directives [2001/20/EC](#) and [2001/83/EC](#) – and a [document](#) amending EU Delegated Regulation [2016/161](#) regarding the serialisation requirements. The EC confirmed that the existing arrangements, due to end on 1 January 2022, will continue until the end of 2022 unless the legislative procedure is finalised sooner. The EC's proposal reflects the main priorities of the BMA's extensive lobbying, which includes a letter to David Frost and to EC Vice-President Maroš Šefčovič, supported by our European partners (as reported in the [September](#) European Brief).

The proposal states that companies can continue to choose whether to license generic medicines either through the EU's Mutual Recognition/Decentralised (MR/DCP) Procedure or using the UK-wide national process. It would mean that companies would be able to use regulatory functions such as a Marketing Authorisation (MA) holder or Qualified Person (QP) based in Great Britain (GB) for EU MR/DCP applications for NI. Consequently, products could be approved for the NI market independent of the EU's MR/DCP process.

For innovative medicines, the EC's proposal would mean that companies are able to make use of a new bridging mechanism to ensure their product is licensed for the whole of the UK if the Medicines and Healthcare products Regulatory Agency (MHRA) licences a product before the European Medicines Agency (EMA) does. Once the EMA licence is in place, this licence would be used to supply NI, and the NI part of the UK licence would fall away. The MHRA is expected to publish further guidance in due course.

The EC has also opened a [public consultation](#), with the deadline on 2 March, on its proposal for amending the aforementioned EU Directives 2001/20/EC and 2001/83/EC, to which the BMA will send its response.

The UK government's initial [judgement](#) is that the EC's proposal could constitute a constructive way forward but it maintains its proposal to remove medicines from the NI Protocol.

On 16 December 2021, the UK government already tabled [the Human Medicines \(Amendment\) \(Supply to Northern Ireland\) Regulations 2021](#) which entered into force on 1 January 2022. It makes amendments to the Human Medicines Regulations 2012, as amended, to establish the NI MHRA Authorised Route (NIMAR) for the lawful supply of prescription-only medicines from GB to NI where licenced alternatives are not available in NI. Medicines will only be supplied under the NIMAR if they are a 'listed NIMAR product', which are prescription-only products with a UKMA(UK) or UKMA(GB) marketing authorisation from the MHRA, as detailed in a Department of Health and Social Care (DHSC) [guidance](#).

Early December, the UK Health Security Agency (UKHSA) and the European Centre for Disease Prevention and Control (ECDC) recently signed the [MoU](#) on health security collaboration. It is intended to strengthen collaboration between the two agencies and will create an overarching framework and principles that govern future cooperation between ECDC and the UKHSA. It will also identify a number of key topics where technical collaboration is considered important, such as on COVID-19, influenza and vaccination/immunisation. This will cover:

- Exchange of information
- Mutual consultation in the event of an emerging health threat
- Possible exchange of personnel and liaison officers

On 1 November 2021, the [UK-Swiss Convention](#) on Social Security Coordination, which includes reciprocal healthcare, entered into force and states the following:

'ensures that where the UK or Switzerland is responsible for an individual's healthcare and they fall within the full personal scope of the Convention, and that individual holds UK, Swiss or EU nationality or is the family member of someone who does, or is a stateless person or a refugee, that individual will be entitled to reciprocal healthcare cover in the other State. This includes healthcare cover for state pensioners, those exporting maternity allowance, and certain categories of cross-border workers, as well as necessary and emergency healthcare cover for people visiting Switzerland or the UK. Planned treatment in the other State will continue to be covered, including for maternity care.'

In addition, since February 2021, the UK government is also holding talks on a new agreement on social security coordination with Norway, Iceland and Liechtenstein but no timeline for concluding such agreement is available at this stage.

COVID-19 Response

The BMA has led on a [joint statement on global vaccine equity](#) with other Royal Colleges and unions, published on [Sky](#) news and [BBC](#), of almost 100 countries low-income missing the World Health Organisation (WHO) target for vaccinating 40% of their populations (please see [press release](#)). The statement follows the BMA letters to the Prime Minister in [September](#) and again in [December](#) on the first anniversary of the UK's Covid-19 vaccine programme being delivered. Today's joint statement calls for the government to:

- raise its ambition and commitment to expedite vaccines reaching those most in need
- increase its overall commitment to COVAX, as well as urgently swapping places with COVAX in vaccine manufacturing and delivery queues
- publish a schedule for reallocation of doses to support COVAX
- support a TRIPS waiver at the World Trade Organisation during this global crisis
- encourage other G7 and G20 countries to increase their commitments to global vaccine equity

The BMA will continue to press the case in the new year, particularly in light of WHO [projections](#) that there will be sufficient vaccine stock in circulation to fully vaccinate the entire adult population globally, and deliver booster doses to high risk populations, by the first quarter of 2022.

The EMA's human medicines committee (CHMP) has [concluded](#) that a booster dose of the Covid-19 vaccine Janssen may be considered at least two months after the first dose in people aged 18 and above. The risk of thrombosis in combination with thrombocytopenia (TTS) or other very rare side effects after a booster is not known and is being carefully monitored. The CHMP also concluded that such a booster dose may be given after two doses of one of the Messenger RNA (mRNA) vaccines authorised in the EU (Comirnaty or Spikevax).

EMA has also [published](#) updated results showing that Lagevrio (molnupiravir) reduced the risk of hospitalisation or death in people with COVID-19 who were at higher risk of severe disease from 9.7% in the placebo group to 6.8% in the Lagevrio group. Earlier interim recommendations to support national authorities who may decide on early use of Lagevrio prior to marketing authorisation remain unchanged.

The ECDC [published](#) the eighteenth update of its rapid risk assessment. The probability of further spread of the Omicron variant in the EU/EEA was deemed very high. The overall level of risk to public health associated with the further emergence and spread of the SARS-CoV-2 Omicron VOC in the EU/EEA was also assessed as very high. The ECDC called for immediate planning for an increasing health care capacity to treat the expected higher number of cases.

The Omicron variant is driving an unprecedented wave of coronavirus infection in Europe that, because it is so contagious, means it will be difficult for most people to avoid exposure to the disease. Even if Omicron is less deadly than earlier versions of the Sars-CoV-2 virus, hospitals and other critical services still face enormous strain in the weeks ahead as staff are infected or have to isolate. Some scientists say that the current surge heralds an 'exit wave' from the two-year-old pandemic and a transition to a new, less dangerous, endemic phase where societies will have to learn to live with the virus. Others call this wishful thinking and warn that, with more people infected than ever, risks will only grow of a new, and more dangerous, strain emerging.

The Omicron wave has been compared by political leaders to a tidal wave. France currently reached [270,000 new cases](#), while countries including [Greece](#), [Italy](#), and [Spain](#) are also setting infection records. Eastern European countries are now

detecting their [first](#) Omicron cases. But health experts agree that, unlike this time last year, intensive care units aren't at risk of being overrun. While Omicron can sidestep prior immunity, studies point to vaccines and previous infections still protecting against the worst outcomes.

In the UK new infections recently crossed the threshold of [200,000](#) and hospitalisations are increasing. But the number of patients being mechanically ventilated remains [flat](#) despite the surge in infections. This is considered as a positive signal for the rest of Europe.

Scientists are starting to speak of a possible end to the pandemic, with the virus becoming 'endemic', circulating freely but posing less of a threat to societies. That is the view of epidemiologist Maria Van Kerkhove, the WHO's technical lead on Covid-19. Speaking last December, she predicted a [long transition](#) before the end of the pandemic: *endemic doesn't mean that it's not dangerous.*

But there is no consensus on just how the pandemic will evolve, or even what living with an endemic virus will be like. Masks, for example, are likely to remain a common feature in Europe, as they already were in Asia throughout the flu season, said Martin McKee, professor of public health at the London School of Hygiene & Tropical Medicine. Professor McKee is a signatory of a letter co-authored by a number of different public health experts advocating for a '[vaccine plus](#)' strategy that focuses both on vaccines and public health measures, including tighter restrictions if needed. He added that the focus should continue to be on suppressing the virus, which can still pose a risk for the most vulnerable and there is no scientific consensus on whether the coronavirus will remain less deadly: *it could continue to evolve and again become more dangerous.* A group of Swedish-based scientists [shares](#) that fear: '*Letting large amounts of infection circulate is like opening Pandora's box. We should expect more unpleasant surprises to come. We have hardly seen the last variant.*'

Updates on the BMA's extensive work and guidance on this area can be found [here](#) with updates on the EU's response [here](#), from the ECDC [here](#) and from WHO Europe [here](#).

New report on UK doctors with EEA qualifications

The General Medical Council (GMC) recently published its annual data [report](#) on doctors who hold a primary medical qualification from the EEA. The analysis of the data shows that in the UK, 9% of all licensed doctors in 2021 were EEA graduates but this figure was slightly higher for specialist doctors (13%) and higher still for some specific specialisms. The number of licensed EEA graduates has remained constant over the last four years and the GMC data shows that fewer EEA graduates left UK medical practice in 2020 than in any year since 2012.

In addition, the GMC recently published a piece of [research](#) on the drivers of international migration of doctors to and from the UK. The research, carried out by the University of Plymouth, was commissioned to help understand what is driving the migration of doctors to better anticipate and respond to emerging trends affecting recruitment and retention. The research finds that:

- the decision for a doctor to migrate is multi-layered and is often a complex balance of these different factors
- reasons for overseas qualified doctors coming to work in the UK include perceived better employment opportunities and working conditions, more training and development opportunities, and a better overall quality of life
- the barriers to migration to the UK include stricter immigration policies, the complexities of the registration process, and perceiving the healthcare system as difficult to enter. Professional and personal concerns include worries about a new working environment, lack of support and language difficulties
- despite career progression being one of the key drivers for joining the UK workforce, migrating doctors report finding it difficult to progress within the UK healthcare system
- many of the key drivers of migration to the UK, for example better working conditions, were also factors driving migration from the UK and into other countries
- reasons for doctors leaving the UK include poor working conditions in the NHS, feeling professionally undervalued, and the desire for a better quality of life
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