On 12 April, the European Council adopted a directive and a regulation to ensure continued supply of medicines to Northern Ireland (NI), and to Cyprus, Ireland and Malta. These texts will enter into force in the next few days after the official publication in the Official Journal of the European Union and the measures will apply retroactively from 1 January 2022. The aim of the directive is to preserve the uninterrupted supply of medicinal products for human use in NI post-Brexit, under the Northern Ireland Protocol. It will also, exceptionally and for a transitional period of three years, allow medicinal products from the Great Britain (GB) to be placed on the market in Ireland, Malta and Cyprus under derogations from the requirement for authorisation-holders to be established in the EU. The regulation is closely linked to the directive and is aimed at ensuring the supply of investigational medicinal products to the same markets.

The newly adopted EU legislation allows for companies to continue choosing whether to license generic medicines either through the EU’s Mutual Recognition/Decentralised (MR/DCP) Procedure or using the UK-wide national process. It also confirms that, for innovative medicines, companies can 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.

As the derogations on the Qualified Person, Marketing Authorisation Holder and batch-testing apply permanently to NI, the BMA responded to an earlier consultation to prepare the new legislation, in which we requested the EU consider extending such derogations to Ireland and that the proposed three-year time limit from the Falsified Medicines Directive (FMD) be removed and permanent derogations applied. The BMA reiterated that any shortages in medicines supply risks patients’ needs not being met and could result in physicians prescribing medicines that are less than optimal for their patients. The situation could be worsened by the inability to access any alternative medication. The BMA’s response concluded that, in order to avoid such scenarios and provide permanent solutions for the medical profession so they can continue treating their patients to the highest possible safety levels, the EU should consider removing medicines from the scope of the NI Protocol or, as the bare minimum, remove NI from the requirements of the FMD.

As the adopted EU legislation provides some temporary solutions, both parties are continuing with their talks on the wider implementation of the NI Protocol. The BMA is monitoring the ongoing discussions and will intervene when appropriate to secure permanent solutions for an uninterrupted medicines supply to NI.

The framework that governs all the aspects of the UK-EU Trade and Cooperation Agreement (TCA) requests both parties to establish their Domestic Advisory Groups (DAG) and Civil Society Forum (CSF), through which they will regularly consult civil society organisations on the implementation of the TCA. On 31 March the UK Foreign, Commonwealth and Development Office appointed 42 members of the UK DAG as a consultative body to give the government input from sectors most affected by Brexit.

Last October, the government launched an Expression of Interest (EoI) campaign to determine membership of these bodies, the BMA submitted a successful application and got selected as a DAG member. In its EoI the BMA advised that, within the DAG/CSF, particular attention should be given to health security, medical research, the free flow of data, continued medicine supply, labour and environmental standards, labour rights and medical workforce issues. The engagement of health professionals across all UK nations is therefore essential for providing expertise in these fields and insight into the health
implications of any future breach of the TCA. The DAG, which is intended to meet twice a year, will hold its first meeting on 28 April in London.

In addition, the UK is currently discussing with the European Commission (EC) the date for the first meeting of the CSF - which the BMA also expressed its interest in being a member of - but its membership rules of engagement have not yet been announced.

COVID-19 Response

The European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC) has issued a joint statement advising that current data does not demonstrate the need for a fourth dose of coronavirus mRNA vaccines for people under 80 years of age, however it might become advisable in the future. The statement adds that there is no evidence of any added value in a fourth dose for adults below 60 years of age, while a fourth dose for those with a compromised immune system is already recommended. The EU agencies said that data from Israel (which approved a fourth dose for Israelis aged 60 and over last January) suggested that a fourth dose could restore antibody levels to those reached with a first booster without additional safety risks. At a recent meeting of EU health ministers, the German minister Karl Lauterbach called for an extra booster shot to be made available to the over-60s in the EU, citing Israel’s positive experience. The ECDC and the EMA said that a re-vaccination campaign may start in the autumn, and that vaccines modified for the latest variants could be used in this case. Both BioNTech/Pfizer and Moderna are developing vaccines adapted for the Omicron variant that is now dominant in Europe. The EMA advised its authorisation could happen during the summer. In addition, the World Health Organisation (WHO) has tasked an independent advisory group to recommend whether a new approach to vaccinating against COVID-19 is needed and, if so, what the composition of new vaccines should be.

The WHO recently published a guide on Strengthening COVID-19 vaccine demand and uptake in refugees and migrants through a range of strategies, actionable recommendations and good practices for understanding and addressing barriers. The guide identifies seven priority action areas for policymakers, planners, and all stakeholders responsible for COVID-19 vaccine rollout to these populations.

The EMA has launched a rolling review of the protein-based COVID-19 Vaccine HIPRA developed by HIPRA Human Health S.L.U as a booster vaccine for adults who have already been fully vaccinated with a different COVID-19 vaccine.

The EU, South Africa, India and the US have reached a compromise in long-running negotiations around a waiver on intellectual property (IP) rights for coronavirus products. Under the compromise, which currently only covers vaccines, developing countries that have exported less than 10% of the world’s coronavirus vaccine doses in 2021 would be able to authorise the use of a patented coronavirus vaccine without the owner of the patent’s consent. China is therefore ineligible. The solution is much broader than compulsory licensing, allowing countries to use means such as executive orders to elevate production of a vaccine. This development could signal the start of a resolution to the debate that has been halted at the World Trade Organisation (WTO) since October 2019, but it still needs agreement from EU member countries as well as other WTO members.

The compromise applies to coronavirus vaccines, ‘with a commitment to decide on the extension of the solution to therapeutics and diagnostics within 6 months from the date of the decision on vaccines.’ There are two options for the duration — three or five years. The text states that a country wouldn’t need to try to secure authorisation from the holder of the patent before undertaking this process. Rather than being limited to compulsory licensing, it ‘includes other acts, such as executive orders, emergency decrees, and judicial or administrative orders. It would also bundle together all patents necessary to produce a product. Furthermore, the compromise waives the need for the product to be predominantly for the domestic market, thereby enabling exports of the vaccine to other eligible countries.

The compromised sparked mixed responses, including criticisms that the proposal undermines IP rights or should be expanded to include COVID-19 tests and treatments. In the UK, both the Scottish Government and the Labour Party have backed a waiver on vaccine rights arguing that this will help boost global manufacturing and reduce the risk of new variants of concern developing.

As of 4 April 2022, 12% of people in low-income countries have been fully vaccinated, compared to 74% in high-income states. Africa continues to be the continent with the lowest vaccination rates. In March 2022, less than 15% of its population was fully vaccinated.
Health campaigners have called on the EC to convert its promised vaccine donations to cash as supply is no longer a constraining factor. The Pandemic Action Network and the ONE Campaign are lobbying the EC to turn its commitment of €1.3bn to purchase 200 million doses into a purely financial contribution. The appeal comes ahead of a summit hosted by Gavi, the Vaccine Alliance, Germany, Indonesia and Senegal, held on 8 April, that aims to raise $3.8bn for the vaccination mechanism COVAX. Most recently, COVAX and the African Union declined options they held to purchase additional doses of Moderna’s coronavirus vaccine.

While supply is no longer a constraint, much of the African continent remains unvaccinated. Hesitancy, in-country logistics and distribution bottlenecks have been cited as reasons for the slow uptake. The ONE Campaign and the Pandemic Action Network argue that if the EC gave cash instead of doses to low- and middle-income countries, it 'would ensure greater impact, while demonstrating that leaders are in tune with the changing realities on the ground.'

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, from EMA here and from WHO Europe here.

Humanitarian crisis Following the War in Ukraine

Speaking at the European Parliament (EP) plenary (full session), the President of the European Council, Charles Michel, stated: ‘We will continue to provide Ukraine with political, financial, humanitarian and material support. This war is a human tragedy. Over 10 million people have fled the war in Ukraine. More than six million are internally displaced, while over four million have fled to the EU, mostly women and children. We are welcoming them with dignity and with solidarity because the Ukrainian people deserve our support. We will continue to offer them any assistance they need, including housing, education and healthcare. And we will pay particular attention to the most vulnerable women and children who could fall prey to traffickers.’

The EU has agreed to activate the Temporary Protection Directive, in order to offer quick and effective assistance to people fleeing the war in Ukraine. Everyone fleeing must be granted access to the EU. Those eligible will be granted temporary protection allowing a stay in the EU for at least one year with residency rights and access to the labour market, housing, welfare assistance, and medical or other assistance. Unaccompanied children and teenagers are entitled to legal guardianship and access to education. The also EU committed distributing nearly 300,000 diptheria and tetanus vaccines, donated by French pharmaceutical company Sanofi, to Ukrainians.

Consequently, the EU has published a set of information for people fleeing the war and a dedicated webpage providing information for Ukrainian nationals relocating to the EU. The EC also published its recommendations on the recognition of academic and professional qualifications for people fleeing. It provides member states with guidance and practical advice to ensure a quick, fair and flexible recognition process. Regarding healthcare professionals, the EC encourages EU countries to explore how people granted temporary protection can, where appropriate, be employed in healthcare services. It involves assessing Ukrainian training curricula for medical professions and, where feasible, developing up-skilling programmes to meet the minimum training standards required. EU member states might allow people with temporary protection to perform certain activities, with a different status than that of a full member of the profession.

The EC and the Government of Canada announced the launch of a global campaign – Stand Up for Ukraine - to raise funding in support of people fleeing the invasion of Ukraine, in partnership with international advocacy organisation Global Citizen. The Stand Up for Ukraine global pledging event and campaign has raised €9.1bn for people fleeing the Russian invasion, inside Ukraine and abroad, including €1bn from the EC and an additional €1bn in loans from the European Bank for Reconstruction and Development to cover their needs.

The EC has also launched the European Research Area for Ukraine portal, a one-stop-shop for information and support services to Ukraine-based researchers and researchers fleeing Ukraine; meanwhile it has suspended cooperation with Russian entities in research, science and innovation, rejecting any new contracts/agreements with Russian organisations under Horizon Europe.

The BMA has updated its webpages with the latest immigration concessions granted by the Home Office to support Ukrainian nationals, this includes the Ukraine Family Scheme and Humanitarian Sponsorship Visa. The BMA also refers members directly impacted by the crisis to its dedicated Immigration Advice Service, where they can get free legal advice on their initial enquiry.

For refugee doctors, the BMA provides the Refugee Doctors Initiative (RDI) where doctors can use BMA membership benefits free of charge up until they get GMC registration. The BMA is also working with outreach organisations across the UK (such as
REACHE and Building Bridges) who, in addition to raising awareness of the RDI, support refugee doctors on the ground with passing the Professional and Linguistic Assessments Board test (PLAB) and the English language test.

Given the scale of the unfolding humanitarian crisis as a result of the war and huge displacement of people, the BMA has committed £25,000 to support the British Red Cross Ukraine Crisis Appeal. Currently, the BMA is looking at ways to publicise the Fund set up by the World Medical Association (WMA), European Forum of Medical Associations (EFMA) and Standing Committee Of European Doctors (CPME) to coordinate the support from the medical community. This initiative aims at raising funds and establishing routes to send medical supplies through Poland and Slovakia and providing relevant contacts.

In addition, The GMC has a package of support in place and works with refugee doctors who may have difficulty providing evidence for registration purposes, as well as help with registration fees. The GMC has published a statement signposting its registration support for refugee doctors and the BMA’s services.

The BMA is closely monitoring developments on the situation in Ukraine and will continue with its efforts to mitigate the repercussions of the ongoing humanitarian crisis following the war.

BMA Report on the Global Human-Rights Landscape

The BMA recently published a report on the emerging threats to human rights around the world - including those brought into focus by the COVID-19 pandemic and ongoing war in Ukraine - and the potentially devastating implications they pose for the health of the global population.

Building on the BMA’s decades-long commitment to human rights and healthcare, the report looks at the shifting landscape in which new technologies, environmental change, geopolitical shifts, global conflict and the mass movement of people are all placing increased pressure on human rights in medicine and healthcare. The report focuses and makes a series of recommendations on:

- neoliberalism, inequality and health,
- migration, ethnicity and health,
- climate change and environmental degradation,
- new media and the assault on health expertise,
- conflict, human rights and health.

More than two years in the making, the report’s preparation coincided with the outbreak of the Covid-19 pandemic, which itself brought keenly into focus a number of issues highlighted in the report – not least in the chapter on misinformation and the threat that ‘fake news’ poses to public health. And in its final stages of drafting, ahead of its publication on World Health Day, Russia invaded Ukraine, sparking new humanitarian concerns, not least around attacks on civilian targets including healthcare facilities and personnel, making the final chapter on conflict tragically relevant.

For further information on any of these news items, please contact:
Robert Delis: rdelis@bma.org.uk