European brief



July 2022

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Brexit Update

Following the publication of the <u>Northern Ireland Protocol Bill</u>, which gives British ministers the power to override parts of the Northern Ireland (NI) Protocol, European Commission (EC) Vice-President Maroš Šefčovič issued a <u>statement</u> and advised:

'Let it be no doubt: there is no legal nor political justification whatsoever for unilaterally changing an international agreement. Opening the door to unilaterally changing an international agreement is a breach of international law as well. So let's call a spade a spade. This is illegal.'

Consequently, the EU has launched a number of <u>legal actions</u> against the UK in response to unwillingness to engage with the EU in a constructive dialogue and proceeding with the Bill. However, it is possible the disagreement between the UK and EU may be resolved without the EC taking the infringement procedure to its next stage. Commenting on the EU legal action, Maroš Šefčovič said that EU's 'door remains open to dialogue' and that it wanted to discuss solutions with the UK Government. The EU is currently in a listening mode, hoping to restart talks with the UK after the summer recess and with the new PM in place.

The Sub-Committee on the Protocol on Ireland/Northern Ireland recently published a <u>follow-up report</u> on the impact of the Protocol. The report finds that the Protocol is having a 'feast or famine' economic impact, whereby businesses able to take advantage of North-South trade benefit, while those reliant on East-West trade lose out. The Committee calls for a renewed commitment by the UK and EU, together with the Northern Ireland political parties and stakeholders, and the Irish Government, to rebuild trust and dialogue and to repair damaged relationships in order to address the problems Brexit and the Protocol have presented for Northern Ireland. A summary of conclusions and recommendations can be found on pages 71-76.

Another major stumbling block in the UK-EU relationship is the UK's Government decision to request all EU citizens to reapply for pre-settled -status (2.4 million people). Under the UK's EU Settlement Scheme (EUSS), EU citizens who settled in the UK before Brexit and lived in the country for less than five years can be granted pre-settled status, allowing them to preserve their rights to live, work and access UK public services. However, the EU has for many months fought the UK's decision to require this group to make a second application within five years of the granting of pre-settled status and stated that even though they had already been granted pre-settled status. This is seen by the EU as a breach of the Withdrawal Agreement (WA). The High Court has granted permission to the Independent Monitoring Authority (IMA) which has started a legal proceeding against the Home Office on this issue. It considers that the Home Office's position that citizens who fail to apply for settled status before the expiry of their pre-settled status automatically lose their rights, is unlawful. The case is expected to be heard in Autumn 2022. The BMA is engaging with colleagues in the Cavendish Coalition and finalising a letter to be sent to the Home Office addressing these issues.

Due to the ongoing dispute over the NI Protocol, the EU notes the lack of engagement in UK-EU cooperation in other areas, notably finalising the UK's association of Horizon Europe, health security and the <u>UK Turing Scheme</u>.

As part of a broader post-Brexit government strategy to make the country more globally competitive, the UK has launched a new <u>High Potential Individual (HPI)</u>. It offers visas to people who completed a degree from a qualifying university outside the UK within the past five years and is available to people of any nationality who are at least 18 years of age. More than half of



the 37 universities on the list are based in the US, including Harvard, Duke, Johns Hopkins and Chicago and just three from the EU - LMU Munich, Paris Sciences et Lettres University, and Sweden's Karolinska Institute. Universities are included in the UK's list if they appear in the top 50 in two out of three selected ranking tables – the UK-based QS and Times Higher Education rankings, and the Shanghai-based Academic Ranking of World Universities. The BMA is currently discussing lobbying opportunities to broaden the eligibility.

Up to 30 June 2022, <u>6.69 million applications</u> to the EUSS have been made with 50,500 submitted in June and 225,400 applications remaining pending. There have been 3.2m grants of settled and 2.6m grants of pre-settled status. As of now the Home Office will release the data on a quarterly basis only. The Home Office has <u>removed</u> the mandatory pause on processing certain applications where the applicant has a pending criminal prosecution which should speed up the processing of applications that would previously have been delayed. In addition, All Party Parliamentary Group on Migration has launched an inquiry into the "general problems that EU citizens continue to encounter".

COVID-19 Response

EU Health Commissioner Stella Kyriakides sent a letter to the EU's health ministers alerting to the renewed threat of the coronavirus and urged them to step up their preparations ahead of the winter. She added that the latest wave has coincided with a higher number of patients in hospitals and intensive care units, and that countries must prepare for a possible worsening of the epidemiological situation. The letter states that at the same time, health authorities need to prepare vaccination campaigns for the arrival of the so-called bivalent vaccines that also target the Omicron variant, and which the European Medicines Agency (EMA) may approve in September. It also recommends combining COVID-19 and influenza vaccinations campaigns ahead of the winter season. EU Health Commissioner also advised that ministers should have plans in place to reintroduce measures like masking and social distancing, but they should avoid school closures.

The European Centre for Disease Prevention and Control (ECDC) and the EMA recently issued a joint <u>statement</u> calling on countries to urgently offer a second COVID-19 booster dose to more people as cases of coronavirus surge and hospitalisations have doubled in recent weeks in the World Health Organization (WHO) Europe region, which has recorded close to 3,000 deaths per week, mainly driven by the BA.5 subvariant of Omicron. It adds that with severe cases rising, it was critical that all people aged between 60 and 79 and those with medical conditions be considered for a second booster.

Rates of vaccination vary widely across the bloc. The EU/EEA average vaccination rate for a first booster stands at 52.7 percent as of June 30, while just 3.2 percent have had a second booster, according to ECDC data. The ECDC and EMA in April advised a second booster for those over 80, stating at the time that this should be expanded to those from the age of 60 and vulnerable groups if cases rise, which is now the case. The EU health authorities are recommending a second booster four months after the first booster, prioritising those whose last dose was six months ago or more. Currently, there is no clear evidence to support giving a second booster to people under 60 who are not at higher risk of severe disease. Nor is there clear evidence to support giving early second boosters to health care or care home workers, unless they are at high risk. The ECDC and EMA note that all authorised vaccines continue to be highly effective in reducing COVID-19 hospitalisation, severe disease and death in the face of emerging variants. Nonetheless, vaccines adapted to the first Omicron variant, known as BA.1, are also being assessed by the EMA with a view to being approved in September. BioNTech/Pfizer and Moderna have submitted clinical trial data to regulators, showing better protection with these BA.1 bivalent vaccines against variants of concern, including Omicron, than another dose of their original shots. Both vaccines also demonstrated better protection against the BA.4/5 strains, but to a lesser extent than against BA.1. As further evidence emerges on vaccine effectiveness, the EMA and ECDC will update their advice.

Some experts are calling instead for public health measures such as masks, testing, contact tracing, isolation, venue capacity limits and more, to be harmonised across Europe advising that the ECDC could play a vital role in this process. EU health ministers also recently concluded that the ECDC could play a greater role in leading Europe's pandemic response. In response, the ECDC advised that a coordinated response based on recognised trigger points was just not realistic, given the differences between countries in health care capacity, vaccination coverage and social acceptance of measures to control COVID-19. The ECDC added that it is not feasible to define meaningful numerical thresholds for severity indicators that could be applied in all EU/EEA countries in a harmonised manner. Instead, the ECDC and WHO Europe jointly issued broad guidance on how to boost their monitoring and surveillance of respiratory viruses, including COVID-19, ahead of the Autumn.

The WHO program - ACT-Accelerator (ACT-A) - for the fast-tracking and distribution of COVID-19 vaccines, diagnostics and therapeutics is expected to be terminated as it stands now in the Autumn. The programme is a collaboration among the WHO, governments and global health organisations that works to ensure equitable access to COVID-19 tools. It faced significant obstacles to get vaccines to low-and middle-income countries, but it eventually succeeded in shipping over one



billion vaccines. As COVID-19 cases have declined from the height of the pandemic, ACT-A has struggled to secure funding. Over the last two years, the ACT-A consortium has raised more than \$23bn to fund its efforts. In February, representatives of the consortium asked the world to donate \$16.8bn in 2022 to help end the COVID-19 pandemic. So far, Germany, Sweden, Norway and Canada have promised to pay the amount requested of them. The most well-known ACT-A initiative is the vaccines pillar COVAX, which aims to ensure vaccines are distributed around the world, particularly in countries that can't afford them. An end to the current project raises questions about how the global health community, including the WHO, will continue to fund the fight against COVID-19. ACT-A is the largest global health consortium committed to ensuring equitable access to life-saving treatments and vaccines for people living in low-income countries. A spokesperson for the ACT-Accelerator advised:

'As the pandemic isn't over, ACT-A's work to enhance equitable access to COVID-19 tools will continue. As countries are moving from managing COVID-19 as an acute emergency to integration into longer-term disease control programs. The consortium's strategic plan was always supposed to end in September. In this context work is underway to develop a plan to manage this transition.'

The EMA recently published the "Good practice quidance for patient and healthcare professional organisations on the prevention of shortages of medicines for human use" which provides patient and healthcare professional organisations with key principles for prevention and management of shortages of medicines, which has been amplified by the COVID-19 pandemic.

Updates on the BMA's extensive work and guidance on this area can be found <u>here</u> with updates on the EU's response <u>here</u>, from the ECDC <u>here</u>, from EMA <u>here</u> and from WHO Europe <u>here</u>.

Horizon Europe Update

As the UK's association of Horizon Europe has not yet been officially formalised by the EU, the UK Government has <u>published details</u> of how the UK will transition to a new R&D programme and outlined the longer-term alternatives in the case of non-association. The proposed package of transitional measures will keep funding flowing to researchers and industry based in the UK while longer-term measures are established. It includes the <u>UK Guarantee Fund</u> which is already in operation. It would also include funding for successful current applicants, uplifts to existing prestigious UK talent and innovation schemes and funding to invest in talent and research programmes for higher education institutions to ensure funding continuity.

Currently, UK organisations can already apply to Horizon Europe and are treated as an Associated Country at the application stage as stated in the <u>European Commission's Q&A on the UK's Participation in Horizon Europe</u>. Therefore, UK organisations should continue to apply to Horizon Europe and request the EC funding in the proposal.

These transitional measures will come into force if the UK is not able to associate to Horizon Europe which includes: an extension to the UK Guarantee Fund; a commitment to assess any 'in-flight' applications; and a commitment to fund all eligible UK entities participating as part of consortia in calls open to 'third countries' where the Grant Agreement is signed before 31 March 2025. The UK Government will consider the approach to funding for third country participation beyond this date and make an announcement by October 2024. The UK will make funding available so that UK applicants will still be eligible to apply to most collaborative Horizon Europe calls, as part of consortia with partners from EU member states or associated countries. Further details on longer term plans will be published in the Autumn.

The BMA European Office recently attended a meeting, organised by the UK Mission to the EU, which resulted in the following outcome:

- The UK Government's preference remains association and it continues with its efforts towards association but given the delays the UK must be prepared for all scenarios,
- The UK-EU cooperation at the administrative level remain close and strong, the opposite situation is at political level,
- The EU research community strongly supports the UK's association of Horizon Europe, and the EU Czech Presidency (held between 1 July and 31 December 2022) wrote an official letter supporting UK's association,
- In the event of a UK's decision to opt for 'Plan B' an alternative to Horizon Europe a possibility to associate would still be possible.

The BMA continues engaging with EU officials reiterating the importance of UK's association of Horizon Europe to continue with profound and long-lasting EU-UK research partnerships and live-saving medical research which are of high value to Europe as a whole.



Monkeypox Update

EU Health Commissioner Stella Kyriakides recently met with members of the ECDC, EMA and the Health Emergency Preparedness and Response Authority (HERA) to discuss the spread of the viral disease, including bringing back COVID-19 contact tracing apps and re-engineer them specifically for monkeypox. EU Health Commissioner is planning to send a letter to the EU member states with concrete measures to be taken in terms of surveillance, case reporting and follow up, contact tracing and vaccination, as well as public communication for monkeypox.

Bavarian Nordic recently <u>announced</u> that its vaccine Imvanex, originally approved for smallpox, has had its marketing authorisation extended to include monkeypox. The rubber stamp from the EC now formally greenlights the vaccine at European level.

The Joint United Nations Programme on HIV and AIDS (UNAIDS) is calling on governments to make sure that their response to the monkeypox outbreak is both equitable and non-discriminatory stating:

The current monkeypox outbreak has revealed new symptoms that could signal the disease. The UK Health Security Agency (UKHSA) has <u>updated</u> its list to include a single lesion or lesions on the genitals, anus and surrounding area, lesions in the mouth, as well as anal or rectal pain or bleeding.

The EU is expected to launch a call for a tender for the joint purchase of monkeypox treatment Tecovirimat. The antiviral drug, developed by US pharmaceutical company SIGA Technologies, is approved in the EU as a treatment for monkeypox, as well as related diseases smallpox and cowpox. SIGA Technologies <u>disclosed</u> back in May that it was in talks with the EU on stockpiling Tecovirimat. The joint purchase of more doses of the monkeypox vaccine developed by Bavarian Nordic is also being planned. The latter recently <u>announced</u> that its vaccine Imvanex, originally approved for smallpox, has had its marketing authorisation extended to include monkeypox. The EC has already bought more than 160,000 doses of the monkeypox vaccine directly, using EU funds. The new purchase would allow countries to put in individual orders under an EU-negotiated contract. While a first tranche of 30,000 doses have already been sent to nine member countries, a second batch of 70,000 doses is delayed, and the EC expecting the majority to be delivered by the end of August but there is no timetable for the remaining doses.

The WHO recently <u>declared</u> the ongoing monkeypox outbreak a public health emergency of international concern, the health body's highest level of alert. WHO <u>data</u> shows the number of cases worldwide approaching 17,000. Nearly 10,000 confirmed cases, more than half of the total, are in the EU regions. So far no deaths have been recorded outside of central and western Africa, where the disease is already endemic. But the concerns remain that the virus risks escaping its current normal area of circulation to become established globally.

The UK has stopped with its isolation requirement for close contacts of people with monkeypox as it records over 2,000 cases in the country. The UKHSA advised that close contacts no longer need to stay at home for 21 days if they don't have any symptoms. The agency has bought another 100,000 doses of Bavarian Nordic's smallpox vaccine, which is authorised for monkeypox in the US and under review for this indication in Europe.

WHO Report on Refugee and Migrant Health

The war in Ukraine has pushed the number of people around the world being displaced by crises to record levels, according to the first WHO global <u>report</u> on refugee and migrant health.

Presenting the report, WHO Director General Tedros Adhanom Ghebreyesus stated that the war in Ukraine had pushed the number of displaced people above 100 million for the first time ever. The total number of people on the move globally stands at one billion or about one in eight people. The report finds that refugees and migrants in vulnerable situations have worse health outcomes than their host communities facing multiple barriers, including out-of-pocket costs, discrimination, and fear of detention and deportation. It argues that many countries do have health policies that include health services for refugees and migrants. But too many are either ineffective or are yet to be implemented effectively.



When it comes to the WHO's European region, data from mid-2020 shows international migrants made up 13.5 percent of the total population, with a median age of 44 years old. In 2020, the top three host countries for international migrants were Germany, the UK, and Russia, making up 18.8 percent of Germany's total population, 13.8 percent of that of the UK, and 8 percent in Russia.

The report examines the health status of this population, including non-communicable diseases like cancer, mental health and maternal health. It also looks at determinants of health and barriers to accessing health services, finding that refugees and migrants in the WHO's European region are disproportionately affected by a number of diseases, including cardiovascular diseases, for instance.

And when it comes to cancer, the report cites studies in Italy and Norway suggesting it tends to be diagnosed at an advanced stage in refugee and migrant populations, leading to worse outcomes. Migrant women report lower uptake of cervical cancer screening, for example, compared with non-migrant women, the authors write, citing multiple studies in the WHO European region.

The report finds that all migrant groups were more likely to have diabetes compared to host populations in the WHO European region.

And although the coronavirus pandemic also disproportionately affected some refugee and migrant groups' health, the authors note their role in the health care systems of many countries. Seven of the 20 countries with the largest number of COVID-19 cases globally — as of March 2021 — relied heavily on migrant workers in the health care sector. This includes the Czech Republic, France, Germany, Italy, Spain, the UK and the US

The WHO also highlights the need for better data on refugee and migrant health, saying the current fragmentation makes it difficult to draw comparisons between countries and over time.

MEPs Vote for Abortion Rights

Members of the European Parliament (EP) voted in favour of a <u>resolution</u> calling for the right to abortion to be included in the <u>EU Charter of Fundamental Rights</u>. The resolution, which also condemns the US Supreme Court decision to overturn federal abortion rights in the US, was adopted with 324 MEPs in favour, 155 against and 38 abstentions.

Abortion rights within the EU vary from country to country, with Malta having the strictest laws, making abortion illegal under any circumstances. The resolution calls on EU member states to decriminalise abortion and remove barriers affecting access to abortions. In addition to the situation in Malta, it also cites a ban in Poland; that medical abortion in early pregnancy is not legal in Slovakia or available in Hungary; and that access to abortion is being eroded in Italy and denied in other EU member states, like in Croatia.

The MEPs expect the European Council to convene to discuss a revision of the EU Treaties - a complex process requiring unanimity - which would allow an amendment to the Charter to include that everyone has the right to safe and legal abortion.

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