

## October 2021

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### Brexit Update

Mid-October, the European Commission (EC) presented a [new package](#) of solutions aimed at tackling post-Brexit disruptions to trade between Great Britain (GB) and Northern Ireland (NI) but rejected UK demands to open the Northern Ireland Protocol for renegotiations.

The EC [confirmed](#) it would modify EU legislation to allow GB to continue acting as a hub for the supply of generic medicines to NI, which is not possible under the current protocol. The proposal would remove the need for drug manufacturers based in GB to relocate infrastructure to NI. The EU aims to conclude the legislative changes to enable this adjustment by the end of this year with a possibility of extending the grace period, due to end in December 2021, if more time is needed for the adoption of such legislation.

However, this is likely to fall short of Britain's demands as the UK has previously argued that EU proposals don't satisfactorily deal with certain medicines, such as new cancer drugs, which must be licensed by the European Medicines Agency (EMA) before they can be sold in NI. Consequently, the UK is demanding to remove all medicines from the scope of the protocol.

Regarding cancer drugs, the EC argues that the protocol already ensures full access to life-saving medicines and there is no evidence of any shortage of such medicines in NI. Innovative, new life-saving medicines (i.e. containing a new active substance) like those needed to treat cancer or other illnesses such as diabetes, neurodegenerative diseases, auto-immune or other immune dysfunctions, viral diseases (e.g. COVID-19), are centrally approved in the EU, via the EMA procedure. Generics of centrally approved medicines, or providing a significant innovation or advantage for patients, also need to undergo the EMA procedure. Medicines centrally approved in the EU, via the EMA procedure, can be placed on the NI market without any further formalities, and are therefore automatically available to NI as well.

If a new cancer drug is submitted for approval to both the EMA and the Medicines and Healthcare products Regulatory Agency (MHRA), and if the latter is quicker in issuing its approval, it will always be possible to bridge this short gap, and supply and administer the medicine concerned in NI. This can be done under the special procedure for exemptions for compassionate use that is available in EU legislation on human medicines. This involves the administration of a medicine that has not yet received the necessary regulatory approvals to individual patients under the direct personal responsibility of a doctor (this procedure was used to allow the immediate availability of the AstraZeneca vaccine to Northern Irish patients pending the EU's approval).

In addition, the EC's response leaves three major UK asks unanswered: a demand to remove the oversight of the Court of Justice of the EU (CJEU) when it comes to EU law in NI; a request to change state aid rules in the region; and allowing pets to move freely between GB and NI. Guide dogs are the only exception and the EU proposed earlier this year that they should continue to enter NI from the rest of the UK without the animal health certificate usually required by the EU for pets.

Recently, EC President Ursula von der Leyen once again rejected UK demands to change the role of the CJEU stating that *'there's one institution that is ruling on European law and it is the European Court of Justice.'*

In addition to the BMA letter sent to Lord Frost, as reported in [September European Brief](#), the BMA also sent a letter to EC Vice-President Maroš Šefčovič, supported by our European partners, including the Standing Committee of European Doctors (CPME), European Union of General Practitioners (UEMO), European Union of Medical Specialists (UEMS) and European Junior Doctors Association (EJD). The letter stated that there is an increasing level of concern within the European medical profession as any disruption to the medicines supply to NI is likely to significantly impact upon the provision of vital

healthcare in NI and the border area and called for pragmatic solutions to be agreed between the two parties to ensure there will be an uninterrupted supply of medicines to NI so that the medical profession can continue treating their patients to the highest possible safety levels.

Since the publication of the new measures, EU and UK officials continue their talks on how to reduce trade disruption across the Irish Sea.

On 14 October 2021, the Home Office released the monthly EU Settlement Scheme (EUSS) [statistics report](#) covering the period ending on 30 September 2021. According to the report, 6,223,100 applications were made with 5,823,300 statuses granted. The backlog of outstanding applications still remains at 399,800. To date, 3,027,300 citizens have been granted settled status and 2,441,200 pre-settled status. There have been 165,600 applications refused, 99,700 withdrawn or void and 89,200 invalid applications. Since the conclusion of the grace period, the number of EUSS applications stands at 172,200 with 63,260 made only in September. This demonstrates a steady application rate of about 60,000 per month. The Home Office has also recently confirmed that dependent relatives who are extended family members of EU citizens settled in the UK before Brexit are eligible for residence status. According to the Independent Monitoring Authority (IMA), this category of EU nationals will be allowed to apply for a family permit under the government's EUSS.

The IMA has launched its first legal action against the Home Office on the expiry of pre-settled status under the EUSS stating that the current UK position is in breach with the Withdrawal Agreement (WA). According to the EUSS if a pre-settled status holder fails to apply for settled status five years from the date of which they were granted pre-settled status they will lose their rights all together under the WA. The legal action mirrors the concerns raised by the EC at previous meetings of the Specialised Committee on Citizens' Rights.

Recently, the Home Office updated its [guidance](#) for UK education providers who are licensed by the Home Office and must carry out immigration checks on EU students seeking to enrol at their institutions. Prior to Brexit, institutions would only have needed to check the nationality of EU citizens to enrol them for studies. From 1 July 2021, EU students must show either that they have applied to the EUSS, been granted EUSS status or possess a student visa (or other type of immigration permission that allows them to study), to enrol for studies. There were numerous reports of EU students with pending applications to the EUSS being refused enrolment by universities as they were insisting that they could only enrol after EUSS status was granted. The revised Home Office guidance makes it clear that universities can accept certificates of application as evidence that the student has the immigration permission to study in the UK. There is no reference in the guidance to in time applications or late applications. To complement the change in guidance for sponsors, the Home Office also published an open [letter](#) about certificates of application which states:

*Applicants who have a digital Certificate of Application can log into the online View and Prove service using their UKVI account and generate a share code to prove their rights. This includes share codes for the right to work, study or rent and other purposes.*

Mid-October, the Home Office [announced](#) a further £3m to help vulnerable and at-risk EU citizens apply to the EU SS. The Welsh Government also [announced](#) its intention to continue its similar funding programme in Wales. Scotland will also continue to fund EU citizens' support organisation until at least March 2022. The funding will be available to the existing [grant-funded network](#) of 72 organisations until the end of March 2022. However, there is no information on whether the Home Office will provide any funding beyond this date to assist citizens making late applications, or applications to convert pre-settled to settled status.

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## COVID-19 Response

The EC announced that as of 28 October the British NHS COVID pass will be accepted as full proof of vaccination and equivalent to the EU's current certificates. This will allow NHS COVID pass-holders to prove their vaccination status when traveling, visiting bars or restaurants, and entering any other places, such as museums, across the EU.

The EC [established](#) a list of ten of the most promising COVID-19 treatment candidates that are likely to be authorised and become available in the EU. The list of treatments is divided into three categories including Antiviral monoclonal antibodies that are most efficacious in the earliest stages of infection; Oral antivirals for use as quickly as possible after the infection; and Immunomodulators to treat hospitalised patients. The EC intends to organise a pan-European event for the therapeutics industrial production to accelerate the development of new and repurposed medicines for COVID-19 therapeutics and mobilise the EU's pharmaceutical manufacturing capacity.

Recently, the World Health Organisation (WHO) and its partner organisations [called](#) upon EU member states and stakeholders to strengthen the monitoring and reporting of COVID-19 infections, ill-health and deaths among health and care workers. A [new WHO working paper](#) estimates that between 80,000 and 180,000 health and care workers could have died from COVID-19 in the period between January 2020 to May 2021. On vaccination, the available data from 119 countries suggests that by September 2021, 2 in 5 health and care workers were fully vaccinated.

The EMA [advised](#) that booster shots of the Moderna coronavirus vaccine may be considered for those 18 years and above citing data showing that boosters given to people six to eight months after their second dose, when their antibody levels were going down, showed their immune system protection to raise. The EMA's decision doesn't amount to an official recommendation for boosters, which the agency said can be given by national regulators. Early October the agency issued [similar advice](#) for booster shots of the BioNTech/Pfizer vaccine. In addition, the EMA is currently assessing data received from AstraZeneca in support of using the company's COVID-19 vaccine as a booster. It comes after the WHO announced that the Europe region was once again the epicentre of the global pandemic, accounting for 59% of new cases in the world in the last week.

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](#).

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## Horizon Europe update

Maria Leptin, the new president of the European Research Council (ERC), which is part of Horizon Europe, stated:

*'scientists agree Britain and Switzerland should take part in EU-funded research and politicians must figure out how to get the non-EU countries involved. Science is collaborative, we don't care about borders, we want to cooperate, and we want our colleagues from these countries to be in the program and they themselves want to be in. It would be terrible if science becomes a bargaining chip.'*

The UK has accused the EC of delaying to sign Britain's association agreement with Horizon Europe and suggested the EU may be withholding because of the wider political row over Brexit. David Frost warned the UK has *'waited quite a long time and further delays could amount to a breach of the agreement.'* Switzerland is facing exclusion from Horizon Europe because of a dispute over its contribution to the EU's cohesion policy.

Both countries are among the most successful in [winning ERC funding](#). Between 2014 and 2020, UK-based researchers received nearly €2.3bn from the council, which supported 1,395 projects in 87 host institutions. Switzerland won €993m for 529 projects in 27 host institutions over the same period. However, the two countries have been pushed to the back of the queue, while other non-EU countries like Iceland, Norway, Ukraine and Turkey have completed the association process and gained full access to Horizon Europe.

UK Science Minister George Freeman recently announced that Britain has a solution, in the event of being blocked from the scheme, by setting up an ERC rival to award individual grants to UK scientists doing cutting-edge research and to invite other leading non-European nations, such as South Korea or Israel, to participate.

In response, Leptin advised that such a move would not challenge the ERC. She acknowledged a new British funding body might attract researchers who would otherwise apply to the ERC, but she warned: *'there are many EU expats in Britain trying to get back to the Continent.'*

In addition, lobby groups for over 1,000 universities sent a [letter](#) to EC President Ursula von der Leyen urging the EC to finalise the UK's association to the EU's research and innovation program.

Early October the EC launched the 2022 Health Cluster topics with a budget of over €900m. The 2022 calls include both single and two-stage application processes, with deadlines depending on the call topic:

- the deadline for single stage call topics is 21 April 2022
- the two-stage call topics have a first stage deadline on 1 February 2022. For those who pass the first stage, the second stage deadline is 6 September 2022

The 2022 call topics are listed below, each with a direct link to the call webpage for further info on the project type, budget, scope and expected impact. All call topics can also be found in the [2021-2022 Horizon Europe Health Work Programme](#).

**Destination 1 - Staying healthy in a rapidly changing society**

- [HORIZON-HLTH-2022-STAYHLTH-01-01-two-stage: Boosting mental health in Europe in times of change](#)
- [HORIZON-HLTH-2022-STAYHLTH-01-04-two-stage: Trustworthy artificial intelligence \(AI\) tools to predict the risk of chronic non-communicable diseases and/or their progression](#)
- [HORIZON-HLTH-2022-STAYHLTH-01-05-two-stage: Prevention of obesity through the life course](#)
- [HORIZON-HLTH-2022-STAYHLTH-02-01 - Personalised blueprint of chronic inflammation in health-to-disease transition](#)

**Destination 2 - Living and working in a health-promoting environment**

- [HORIZON-HLTH-2022-ENVHLTH-04-01: Methods for assessing health-related costs of environmental stressors](#)

**Destination 3 - Tackling diseases and reducing disease burden**

- [HORIZON-HLTH-2022-DISEASE-06-02-two-stage: Pre-clinical development of the next generation of immunotherapies for diseases or disorders with unmet medical needs](#)
- [HORIZON-HLTH-2022-DISEASE-06-03-two-stage: Vaccines 2.0 - developing the next generation of vaccines](#)
- [HORIZON-HLTH-2022-DISEASE-06-04-two-stage: Development of new effective therapies for rare diseases](#)
- [HORIZON-HLTH-2022-DISEASE-07-02: Pandemic preparedness](#)
- [HORIZON-HLTH-2022-DISEASE-07-03: Non-communicable diseases risk reduction in adolescence and youth \(Global Alliance for Chronic Diseases - GACD\)](#)

**Destination 4 - Ensuring access to innovative, sustainable and high-quality health care**

- [HORIZON-HLTH-2022-CARE-08-02: Pre-commercial research and innovation procurement \(PCP\) for building the resilience of health care systems in the context of recovery](#)
- [HORIZON-HLTH-2022-CARE-08-03: Public procurement of innovative solutions \(PPI\) for building the resilience of health care systems in the context of recovery](#)
- [HORIZON-HLTH-2022-CARE-08-04: Better financing models for health systems](#)

**Destination 5 - Unlocking the full potential of new tools, technologies & digital solutions for a healthy society**

- [HORIZON-HLTH-2022-TOOL-11-01: Optimising effectiveness in patients of existing prescription drugs for major diseases \(except cancer\) with the use of biomarkers](#)
- [HORIZON-HLTH-2022-TOOL-11-02: New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment](#)
- [HORIZON-HLTH-2022-TOOL-12-01-two-stage - Computational models for new patient stratification strategies](#)

**Destination 6 - Maintaining an innovative, sustainable and globally competitive health industry**

- [HORIZON-HLTH-2022-IND-13-01: Enhancing cybersecurity of connected medical devices](#)
- [HORIZON-HLTH-2022-IND-13-02: Scaling up multi-party computation, data anonymisation techniques, and synthetic data generation](#)
- [HORIZON-HLTH-2022-IND-13-03: New pricing and payment models for cost-effective and affordable health innovations](#)
- [HORIZON-HLTH-2022-IND-13-04 - Setting up a European Smart Health Innovation Hub](#)
- [HORIZON-HLTH-2022-IND-13-05: Setting up a European Electronic Health Record Exchange Format \(EEHRxF\) Ecosystem](#)

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**New EU legislation on professional migration**

The EU adopted new [legislation](#) establishing the entry and residence conditions for highly-qualified non-EU nationals coming to live and work in the EU which aims to attract and retain highly-qualified workers, particularly in sectors facing skills shortages. The new Directive provides more inclusive admission criteria, facilitates intra-EU mobility and family reunification including for non-EU family members of EU citizens and beneficiaries of international protection and grant easier access to the labour market. This new EU framework can be complemented by national laws on migration. The Directive states that ethical recruitment policies and principles that apply to public and private sector employers should be developed in key sectors, including the health sector. This measure is consistent with the EU's commitment to the 2010 World Health Organisation's Global Code on the International Recruitment of Health Personnel, as well as with the conclusions of the Council and the member states of 14 May 2007 on the European Programme for Action to tackle the critical shortage of health workers in developing countries (2007-2013).

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