



# FOCUS-EU

HEALTH

June 2020

Overview of EU and global policy developments

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## WHO: COVID-19 and impact on care delivery

A survey by WHO across 155 countries has confirmed that prevention and treatment services for noncommunicable diseases (NCDs) have been severely disrupted since the COVID-19 pandemic began with low-income countries being most affected. The WHO calls for countries to find innovative ways to ensure that essential services for NCDs continue, as people living with NCDs are at higher risk of severe COVID-19-related illness and death.

Source: [https://www.who.int/covid-19\\_NCDs](https://www.who.int/covid-19_NCDs)

## Authorising Remdesivir in EU

The European Medicines Agency (EMA) has recommended a conditional marketing authorisation to Veklury (remdesivir) for the treatment of COVID-19 for patients from 12 years of age with pneumonia who require supplemental oxygen. The recommendation is mainly based on data from study NIAID-ACTT-11 of the US National Institute of Allergy and Infectious Diseases. Data assessment was carried out through a rolling review procedure set up for public health emergencies.

Source: <https://www.ema.europa.eu/first-covid-19-treatment>

## Re-open EU: A website for safe EU travelling

'Re-open EU', a web platform, has been launched by the European Commission to support safe travelling and tourism across Europe. It provides among others: real-time information on borders; information provided by Member States on travel restrictions, public health and safety measures e.g. use of face masks, etc.

Source: <https://reopen.europa.eu/en>

## European Parliament

### Next Generation EU recovery plan to the European Parliament

The European Parliament discussed the recovery measures and the *Next Generation EU*, the new financing tool worth of €750 billion which presented for debate to the European Parliament. *Next Generation EU* will be temporary and it will be made possible by the Own Resources Decision and it will allow the Commission to exceptionally borrow up to €750 billion on behalf of the Union, through the issuance of bonds, for measures over the period 2021- 2024.

*Own Resources Decision lays down the basic provisions for financing the EU budget.*

Source: <https://ec.europa.eu/NextGenEU>

### European Strategy on COVID Vaccine

The Environment, Public Health and Food Safety (ENVI) Committee has debated how to support the [European strategy](#) on COVID-19 vaccines. The initiative includes:

- deployment of advance purchase agreements for up to six COVID-19 vaccine candidates using the EU €2.3 billion emergency measure;
- an accelerated procedure for authorisation;
- flexibility in relation to labelling and packaging;
- relaxation of certain provisions of the GMO legislation to speed up clinical trials of COVID-19 vaccines and medicines containing genetically modified organisms.

A number of MEPs have called for greater transparency and guarantees for safety and accessibility for all in the EU Strategy

on COVID. The greatest concern was the removal of the need to carry out environmental assessments in advance of clinical trials for vaccines that use genetically engineered viruses. MEPS also called for access to full clinical trial data before any EU funding is released on COVID-19 vaccines to prevent a repetition of the Tamiflu case where investment may have been wasted as indicated later by the [Cochrane Review on NIs](#).

*Since 2002 governments around the world have spent billions of dollars stockpiling neuraminidase inhibitors (NIs) such as Tamiflu® (oseltamivir) and Relenza® (zanamivir) in anticipation of an influenza pandemic. In 2014 a Cochrane review found little evidence regarding the effectiveness of the products.*

Sources: <https://www.europarl.eu/strategy-covid-vaccines>  
[https://ec.europa.eu/IP\\_20\\_1103](https://ec.europa.eu/IP_20_1103)

## European Commission

### EU4Health: New Health Programme with €9,4 billion

The European Commission has published a proposal for a new health programme - 'EU4Health to run until 2027'. The stand-alone funding Programme of €9,4 billion will see an over 2000% budget increase compared to current resources for health. Key objectives are crisis preparedness and crisis management that includes:

- strategic stockpiles of necessary affordable protective equipment, medicines and medical devices;
  - provision of a reserve of healthcare staff - including flying doctors for times of crisis.
  - capacity building across EU to support overburdened hospitals in one Member State by releasing resources available elsewhere.
  - reinforcing the European Medicines Agency;
  - assigning a stronger coordinating role to the European Centre for Disease Control for medical responses in crises.
- The programme will address gaps revealed by the COVID-19 crisis. The main goal is to build more resilient health systems and strengthen a common crisis preparedness and response with specific objectives:
- to support actions to reduce inequalities in cancer screening and treatment across Europe;
  - to reduce the number of antimicrobial-resistant infections and improving vaccination;
  - to accelerate digital health capacity, cross-border health care and increase investment in disease prevention and health promotion.
  - to upscale existing tools such as the European Reference networks to other diseases.

All the actions relating to crisis resilience will be heavily front-loaded in the first years of the programme.

Source: <https://ec.europa.eu/EU4Health>

### Pharmaceutical Strategy: Roadmap

The European Commission has published the Pharmaceutical Strategy Roadmap. The Strategy aims to ensure a supply of safe and affordable medicines to meet patients' needs while supporting the competitiveness of the European pharmaceutical industry. A series of consultations and stakeholder engagement events are to feed into the Pharmaceutical Strategy which is expected to be adopted by the end of the year.

(see [Consultations & Events at p.3](#) for details on the online public consultation on the Pharmaceutical Strategy).

Source: [https://ec.europa.eu/Pharma\\_strategy](https://ec.europa.eu/Pharma_strategy)

### International initiative in healthcare products trading

The EU has joined the discussions of the 'Ottawa Group', a group of thirteen Trade Ministers and partners of the World Trade Organisation (WTO). The group explores how to facilitate access to affordable pharmaceutical and medical goods and avoid trade disruptions at times of crisis including plurilateral negotiations on e-commerce. It is hoped that an international agreement open to all WTO members will facilitate trade in healthcare products and contribute to stronger global preparedness for future crises by:

- abolishing tariffs on pharmaceutical and medical goods;
- establishing a scheme of global cooperation in times of health crisis, covering import and export restrictions, customs and transit, public procurement and transparency;
- improving the current WTO rules applicable to trade in essential goods.

Source: <https://trade.ec.europa.eu/>

### Report on the Impact of Demographic Change

The European Commission has adopted its first-ever Report on the Impact of Demographic Change. The report shows long-term demographic trends in Europe's regions - from longer life expectancy, to lower birth rates, ageing societies, smaller households and increasing urbanisation. It also shows Europe's declining share of global population - expected to account for less than 4% of the world's population by 2070. The report illustrates the considerable differences in demographic change across regions, as well as the need to address its impact on growth and sustainability, employment, health and long-term care in different parts of Europe.

The report will provide the foundation for the upcoming Green Paper on Ageing and Long-term Vision for Rural Areas and it is complemented with country fact sheets and a full statistical breakdown.

Webpage on demography: <https://ec.europa.eu/demography>

Source: [https://ec.europa.eu/report\\_demographic-change](https://ec.europa.eu/report_demographic-change)

## EXPH: health and social care post COVID-19

The new mandate of the Expert Panel on Effective Ways for Investing in Health (EXPH) focusses on the health and social care organisation. The EXPH will provide recommendations to improve resilience of health systems and address the following common challenges across health systems that were highlighted during the pandemic:

- Primary care providers reportedly struggled to ensure care continuity and found it difficult to switch swiftly to new methods of service delivery (e.g. telemedicine, tele-monitoring and other e-health solutions);
- Hospitals had to face a lot of strain due to insufficient capacity, unavailability of adequately trained health workers as well as lack of experience in managing an unprecedented emergency situation;
- Social care facilities, unaware of the implications and unprepared for protecting residents, recorded a surge in infections and mortality;
- Weak integration between primary care, outpatient specialist and hospital care and social care resulted in overburdened hospitals in some Member States and many elderly homes became hotspots of the pandemic;
- Clinical activities organised across different care settings, like transplant programmes, have come almost to a standstill due to resource and logistical problems;
- Increased risk to patients with rare or low prevalence and complex diseases or conditions, not only affecting the access to their usual doctors or medicines but – in case of COVID-19 related complications – also the access to ICU services, ventilators etc. due to their underlying diseases;
- Underdeveloped crisis preparedness resulted in resource and coordination problems at national and at EU level, which took time to resolve (e.g. low availability of personal protective equipment, limited laboratory and testing capacity etc.);
- The pandemic and the confinement measures created a psychosocial burden for the population and affected heavily the wellbeing of the health workforce.

The public hearing on the post-pandemic care organisation is expected to be scheduled in October. The final opinion will be finalised and published in November.

*The EXPH supports the European Commission in identifying specific aspects to be considered as well as tangible results that should be achieved in reforming health systems and investments at the EU level. The EXPH hearings gather views from experts on public health and stakeholders in health care services and health-related areas (industry, research, economy).*

Source: [https://ec.europa.eu/EXPH\\_careorganisation](https://ec.europa.eu/EXPH_careorganisation)

## Free EMA scientific advice for academia

The EMA will waive all fees for scientific advice for academic researchers developing orphan medicines, to further encourage the development of treatments for rare diseases. Eligible applicants will include public or private higher education establishments awarding academic degrees, public or private non-profit research organisations whose primary mission is to

pursue research, and international European interest organisations. These entities should not be financed or managed by private for-profit organisations in the pharmaceutical sector or have concluded any agreement with pharmaceutical companies concerning their sponsorship or participation to a specific research project for which a fee exemption is sought.

Source: <https://www.ema.europa.eu/free-ema-scientific-advice>

## Across the World

### Study on impact of FDA policy on cornea donation

A Healio article on the analysis the impact of an FDA policy that automatically disqualifies men who have had sex with men in the preceding 5 years from donating corneas..

Source: <https://www.healio.com/fda-cornea-donations>

## Other

### COVID vaccine: Vaccine Alliance

France, Germany, Italy and the Netherlands have formed the 'Inclusive Vaccine Alliance' to negotiate with potential developers and manufacturers of a coronavirus vaccine. The alliance is in discussions with a number of pharmaceutical companies and they intend to have the vaccines manufactured in Europe if possible. The alliance also wants pharmaceutical companies to agree that any vaccine developed must be accessible, available and affordable everywhere in the EU and they are working to make a portion of vaccines available to low-income countries, including in Africa. Given the statement of the EU health commissioner Stella Kyriakides that no parallel trading will take place, in order for the EU to have much stronger negotiation power with vaccine developers, the expectation is that the EU initiative on vaccines (details p1) and the Alliance may merge in the future.

Sources: <https://www.government.nl/Alliance>  
[https://www.europarl.europa.eu/eu-strategy\\_covid-19-vaccines](https://www.europarl.europa.eu/eu-strategy_covid-19-vaccines)

### European Medical Research Infrastructures

Three international Medical Research Infrastructures, which manage large scale research collaborations, have published their recommendations regarding research in diagnostics, treatments and vaccines against coronavirus. EATRIS-ERIC (European Infrastructure for Translational Medicine), ECRIN-ERIC

(European Clinical Research Infrastructure Network) and BBMRI-ERIC (European Research Infrastructure for Biobanking) called for cross-border, multi-sector and multi-disciplinary research based on existing networks. In addition the organisations called for a comprehensive quality management programme with exchange of information, protocols, guidelines and reference materials.

Source: <https://eatris.eu/Joint-statement-COVID>

## Register your pharmacoepidemiological studies

Register your study in the [EU PAS Register](#) to enable the sharing of information and increase research efficiency. The EU PAS Register is the European Union electronic register of Post-Authorisation Studies run by the EMA and the [European Network of Centres for Pharmacoepidemiology and Pharmacovigilance \(ENCePP\)](#)

More information and registration details: <http://www.encepp.eu>

### A note to our readers

Click on **Call, Consultation** or **Event title** for information on how to apply, participate or attend

## Calls

### ERC Open Calls

[ERC Advanced Grants 2020](#)

**Deadline: 26 August 2020**

For established researchers and for ground-breaking, high-risk projects; €2.5 million over 5 years.

[Proof of Concept 2020](#)

**Deadline: 17 September 2020**

For ERC grant holders looking to establish proof of concept of an idea generated during their ERC project.

[Co-funding of regional, national & international programmes](#)

**Deadline: 29 September 2020**

For early-stage researchers' training, mobility and career development for doctoral and fellowship programmes.

[Call for proposals on new infrastructures \(ESFRI\)](#)

**Deadline EXTENDED: 9 September 2020**

ESFRI Guide: <https://ESFRI-Roadmap2021-Public-Guide.pdf>

Health Research Infrastructures: <http://esfri>

## Consultations & Events

[Pharmaceutical Strategy for Europe: Online survey](#)

The consultation focus on key themes: strategic autonomy and manufacturing of medicines, access to affordable medicines, innovation, and environmental sustainability and health challenges.

**Deadline: 15 September 2020**

**Free online course on AI**

Finland offers European citizens a free online course, the Elements of artificial intelligence in all the official EU languages.

Access the course: <https://www.elementsofai.com>

Source: <https://ec.europa.eu/finland-skills-basicsAI->

### Webinars on clinical management of diseases during COVID-19

[COVID-19 and Intensive Care Medicine](#)

[Impact of COVID 19 for people living with a Rare Disease](#)

[COVID-19 and Transplantation in Children](#)

[COVID-19 and the Kidney](#)

[COVID-19 and Rare Connective Tissue and Musculoskeletal diseases and conditions](#)

[Second Wave of COVID-19: Preparatory actions - Consultation with Clinicians](#)

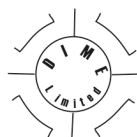
**The EU EYE continues to be a partner of the European Innovation Partnership on Active and Healthy Ageing (EIP-AHA) with a commitment to the B3 Action Group on Integrated care accessible at: <https://ec.europa.eu/eip/b3/>**

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