FOCUS-EU

HEALTH

April 2020

Overview of EU and global policy developments

'ERAvsCorona' actions
Launching European COVID-19 Data Platform

The European Commission has launched the European COVID-19 Data Platform that enables researchers to upload, access and analyse COVID-19 related reference data and specialist datasets. This is a joint effort with the European Bioinformatics Institute of the European Molecular Biology Laboratory (EMBL-EBI), the Elixir, the COMPARE project, the EU Member States and other partners.
The platform is one of the *ERAvsCorona actions* agreed by the Commission and the Member States containing 10 short-term priority actions to strengthen the coordination of research and innovation activities in the fight against the coronavirus. The plan includes among others the extension of EU-funded clinical trials of therapies, the interdisciplinary call for innovative solutions on medical and preparedness measures, and possible top-up funding of ongoing calls for innovative small and medium businesses via the European Innovation Council. The *ERAvsCorona actions* plan will be updated regularly.

Access the portal: https://www.covid19dataportal.org
Source: https://ec.europa.eu/IP_20_680

INTERPOL and Europe

The INTERPOL has issued a reminder to the public to be vigilant as organized crime groups continue to adapt their activities to benefit from the global health crisis. The warning comes after health authorities in Germany procured €15 million worth of face masks from a cloned website. The sophisticated fraud scheme using compromised emails, advance-payment fraud and money laundering has been uncovered by financial institutions and authorities across Germany, Ireland and the Netherlands, as part of a case coordinated by INTERPOL.

Source: https://www.interpol.int/COVID-19

European Parliament

Medical Devices Regulation postponed by a year

The European Parliament has voted to postpone the application of the Medical Devices Regulation until 26 May 2021 to prevent shortages or delays in getting key medical devices on the market and to allow authorities and manufacturers to prioritise medical devices needed to fight COVID-19 by continuing under current procedures.

Source: https://www.europarl.eu/postpone-MDR

European Commission

Guidance on managing CTs during the pandemic

A harmonised EU/EEA-level guidance on the management of clinical trials during the pandemic has been developed by the Good Clinical Practice Inspectors' Working Group. The guidance aims to mitigate the negative effects of the pandemic on the conduct of clinical trials and contains among other on informed consent; methodological guidance on statistical considerations; advice on Investigational Medicinal Products stocks, safety reporting, conduct of audits and temporary halts.

Guidance document: ec.guidanceclinicaltrials_covid19_en.pdf

Recommendations on lifting containment measures

A coordinated lifting of containment measures at EU level is planned integrating the twin green and digital transition with attention to the proportionality of the measures taken by Member States as the situation evolves. The European Commission may request the lifting of measures considered disproportionate, particularly those with an impact on the Single Market. The set of recommendations developed based on the scientific advice of the ECDC and the Advisory Panel on COVID-19 include among other:

- longer protection for most vulnerable groups;
- replacement of general states of emergencies and exceptional emergency powers for governments with more targeted interventions in line with their constitutional arrangements for democratic accountability and transparency of the measures taken and guarantee fundamental rights and respect for the rule of law;
- lifting of measures to start with those with a local impact (e.g. measures affecting people's lives more directly) with gradual extension to those with a broader geographic coverage, taking into account national specificities and regional differences of the COVID-19 spread;
- restoring the Schengen area through phased coordinated approach for the economy and the opening of internal and external borders once the epidemiological situation of the border regions converges sufficiently and social distancing rules are widely and responsibly applied: reintroduction of transport services should be adapted to the phasing out of travel restrictions and the phasing in of particular types of activities with lower-risk, individualised transport (e.g. private cars) followed by collective means of transport with necessary health-oriented measures;
- authorities and businesses should consider several models for resuming activities as jobs with low interpersonal contact, jobs suitable for teleworking, economic importance, shifts of workers, etc. with priority for cross-border and seasonal workers and with no discrimination against EU mobile workers;
- efforts to secure supply chains should be reinforced during the transition period;
- restrictions on travel should first be eased between areas with comparably low reported circulation of the virus with ECDC maintaining a list of such areas in cooperation with Member States with additional guidance to follow as the health situation allows it, also in view of planning summer holiday travel;
- external border reopening and access of non-EU residents to the EU should happen in a second stage, taking into account the spread of the virus outside the EU, and the risks of reintroduction;
- Gatherings of people to be progressively permitted focussing on the most appropriate sequencing and the specificities of different categories of activity, such as:
    a. schools and universities with measures such as enhanced cleaning, e-learning, etc.;
    b. commercial activity (retail) with possible gradation e.g. limit number of people allowed, etc.;
    c. gradation in social activities e.g. restricting opening hours/number of people in cafés, etc.;
    d. Mass gatherings e.g. festivals, concerts, etc.

Source: https://ec.europa.eu/roadmap_liftingmeasures_Covid.pdf

Remote audits for medical devices during Covid-19

The Medical Device Coordination Group (MDCG) of the European Commission has allowed notified bodies to perform remote audits during the coronavirus outbreak, according to a new guidance.
Guidance Document https://ec.europa.eu/documents/40705

European Council

Emergency Support Instrument for healthcare sector

The European Council has approved the Emergency Support Instrument (ESI), a flexible crisis instrument to complement those that already exist in Member States and within the Commission. It will be centrally managed and deployed during the current acute stage of the outbreak, during the exit strategy and also during the recovery phase. It will have a budget of €2.7 billion with a further €300 million foreseen for the medical stockpiling of rescEU. Additional contributions will be possible from Member States and also individuals, foundations and crowd funding.
In this way, the Commission will be able to:

- directly purchase or procure emergency support on behalf of Member States and distribute medical supplies such as masks and respirators;
- financially support and co-ordinate pressing needs such as cross-border transportation of patients and medical equipment;
- support the construction of mobile field hospitals.

rescEU is integrated into the Union Civil Protection Mechanism and it has entered into force in 2019. It aims to protect citizens in need and to strengthen European preparedness for emerging risks and disasters.

Sources:

https://ec.europa.eu/qanda_20_577

https://ec.europa.eu/preparedness_response/20200415.pdf

Across the World

COVID-19: FDA, EMA and 16 drugmakers take part in development effort

A RAPS article by Michael Mezher on the *Accelerating COVID-19 Therapeutic Interventions and Vaccines* (ACTIV) partnership, an initiative of the National Institutes of Health with the US Food and Drug Administration and other US health agencies, the European Medicines Agency and pharma industry to develop a coordinated approach for clinical trials and regulatory processes for Covid-19.

Source: https://www.raps.org/covid-19-fda-ema-drugmakers

Other

Safe use of medicines

The European Medicines Agency is issuing advice on the safe use of medicines during the COVID-19 pandemic and is continuously reviewing all available clinical evidence.
Advice is available at:
https://ema.hypertension-heart-kidney-disease-during-covid-19
https://ema.europa.eu/non-steroidal-anti-inflammatories-covid-19

Register your pharmacoepidemiological studies

If you or your research group have started or are planning observational studies related to the utilisation and effects of drugs in relation to the Covid-19 pandemic, consider registering your study in the EU PAS Register in order to support the sharing of information on performed or planned studies and increase the efficiency of research. 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

Medicinal products during Covid-19 pandemic

A document outlining regulatory expectations during the pandemic has been developed in cooperation between the European Commission, the Coordination group for Mutual recognition and Decentralised procedures – human, the Inspectors Working Group and the European Medicines Agency. It addresses a variety of issues such as those related to marketing authorisations and procedures (renewal applications, triggering the 'sunset clause', etc); changes in manufacturing/ supply chain to ensure continuity of supplies to the EU; quality variations, pharmacovigilance and adverse reactions.

Full details: https://ec.europa.eu/medicines/guidance_covid19.pdf

Kromeya

Withdrawal of the marketing authorisation in the European Union.

Source: https://www.ema.europa.eu/kromeya-EU.pdf

Mobile apps in the lifting of confinement measures

EU Member States have adopted an EU toolbox for the deployment of mobile applications which record contacts that a person may not notice or remember. The toolbox was developed by the e-Health Network with the support of the European Commission. The apps will enable at-risk individuals to be contacted and, if necessarily, to be tested as quickly as possible, regardless of where they are and the app they are using. The essential requirements for national apps to serve such purpose are:

* voluntary;
* approved by the national health authority;
* privacy-preserving - personal data is securely encrypted; and
* dismantled as soon as no longer needed.

Source: https://ec.europa.eu/covid-19_apps_en.pdf

Temporary Reintroduction of Border Control

For a list of temporary border control per country as an immediate action against Covid-19:
https://ec.europa.eu/schengen/border-control

Calls

A note to our readers
click on the Call title to access more information on topic conditions, documents and submission service.

Co-funding of regional, national & international programmes
Deadline: 29 September 2020
CO-FUND supports researchers' training, mobility and career development for doctoral programmes addressing the development and broadening of research competencies of early-stage researchers; and fellowship programmes for individual research training and career development for experienced researchers.

MSCA Research and innovation Staff Exchanges
Deadline 12 May 2020
MSCA Research and Innovation Staff Exchange (RISE) is a short-term research and innovation staff exchange scheme between academic and non-academic sectors (in particular SMEs), based in Europe (EU Member States and Horizon 2020 Associated Countries) and outside Europe (third countries). Proposals must include at least three partners from three different countries. At least two of these should be from the EU or associated countries.
Support is provided for developing partnerships in the form of a joint research and innovation project for knowledge sharing via international and/or intersectoral mobility, with an in-built return mechanism. Exchanges can be for both early-stage and experienced researchers and can also include administrative, managerial and technical staff directly involved in the research and innovation activities of the proposal.

DHE 2020 Call for Twinnings Scheme
Deadline EXTENDED 22 May 2020
DigitalHealthEurope (DHE) is aiming to scale up digital health and care innovation across European regions. The Call for Twinnings will fund 28 projects in three priorities: citizens' secure access to and sharing of health data across borders, better data to advance

research, disease prevention and personalised health and care, and digital tools for citizen empowerment and person-centred care. All health and care organisations across Europe are eligible. Funding per scheme ranges from €5,000 to €43,000.

Open Call SC1-HCO-19-2020: Reliable and Accessible Information on Cell and Gene-Based Therapies
Deadline EXTENDED: 4 June 2020

Call for proposals on new infrastructures (ESFRI)
Deadline EXTENDED: 9 September 2020
Additional information:
ESFRI Guide: https://ESFRI-Roadmap2021-Public-Guide.pdf
Health Research Infrastructures: http://esfri

Open Call SC1-HCO-18-2020: Developing methodological approaches for improved clinical investigation and evaluation of High-Risk Medical Devices
Deadline EXTENDED: 4 June 2020

IMI 20th Call
Deadline EXTENDED: 12 May 2020
Draft texts of topics for inclusion in IMI's next Calls for proposals, **IMI2 – Calls 22 and 23** are published at
https://www.imi.europa.eu/future-call-topics-published-online

Open Call DT-ICT-12-2020: AI for the smart hospital of the future
Deadline EXTENDED: 17 June 2020

Open Call SC1-HCC-10-2020: Towards a Health Research and Innovation Cloud: Capitalising on Data Sharing Initiatives in Health Research
Deadline EXTENDED: 4 June 2020

Open Call SC1-BHC-06-2020:Digital Diagnostics - Developing Tools for Supporting Clinical Decisions by Integrating Various Diagnostic Data
Deadline EXTENDED: 4 June 2020

Open Call SC1-DTH-12-2020: Use of Real-World Data to Advance Research on the Management of Complex Chronic Conditions
Deadline EXTENDED: 4 June 2020

Open Call SC1-DTH-06-2020: Accelerating the uptake of computer simulations for testing medicines and medical devices
Deadline EXTENDED: 18 June 2020

Consultations & Events

White Paper on AI
Deadline: 31 May 2020

The White Paper on Artificial Intelligence is published by the European Commission. It sets out principles for a legislative framework for trustworthy AI and it is open for comments.

Source: https://ec.europa.eu/info/consultations_en

JRC 2nd Call for Expressions of Interest for the Collaborative Doctoral Partnerships
Deadline EXTENDED: 15 May 2020
The Joint Research Centre (JRC) has opened a call in many fields, including Health promotion and prevention of non-communicable diseases (NCDs). The call is open to higher education institutions/universities from EU Member States and countries associated to the EU Research Programme Horizon 2020.

Call for proposals of EU Health Programme - Support to reforms in health workforce - initiative on task shifting
Deadline: 10 June 2020

Free online course on AI
Finland offers European citizens with free access to an online course, the Elements of artificial intelligence available in all the official EU languages.
Access the course: https://www.elementsofai.com
Source: https://ec.europa.eu/finland-skills-basicsAI-

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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