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CORRIGENDUM
This document corrects COM(2021)355 final of 6.5.2021.
Correction of a footnote.
Concerns the English version only.

The text shall read as folllows:

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

EU STRATEGY ON COVID-19 THERAPEUTICS

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

EU STRATEGY ON COVID-19 THERAPEUTICS

STRONGER TOGETHER: AN 'END TO END' APPROACH ON COVID-19 THERAPEUTICS

The COVID-19 pandemic has inflicted unprecendented human, social and economic costs in the European Union and around the world. The skills and dedication of scientists, coupled with sustained research and innovation efforts at both European and international level, have led to the development of several effective vaccines. However, the vaccines will not eliminate the disease overnight and therapeutics will still be needed for patients in hospitals and at home, including people suffering from 'long COVID' (the long-term effects of COVID-19 infection). For these reasons, **therapeutics** will continue to play a significant role in **the response to COVID-19**, complementing the successful EU strategy for COVID-19 vaccines[1].

While it took less than a year after the outbreak of the pandemic to start the vaccination campaign, the availability of therapeutics for affected patients is still limited. So far, remdesivir is the only therapeutic authorised at EU level for treating COVID-19. Efforts remain fragmented and there is no common framework for the development and deployment of targeted therapeutics in the EU. To complement the EU strategy for COVID-19 vaccines, **a reinforced and strategic approach to developing, manufacturing and procuring safe and effective COVID-19 therapeutics at EU level** will limit the need for hospitalisation, speed up recovery times and ultimately save lives.

This approach will cover a wide range of areas, including research, development, authorisation, production and the procurement of safe and effective novel or repurposed therapeutics, tailored to the different disease phases (including recovery) and degrees of severity – caused both by the original strain of SARS-CoV2 and its variants. Joint EU efforts on therapeutics will also pay particular attention to research on, and the treatment of, 'long COVID', which is characterised by symptoms persisting after the normal recovery period and requires a different therapeutic approach. While implementing the strategy actions, particular attention will be taken to ensure access and availability of medicines for children and the most vulnerable patients like for example elderly patients and persons with disabilities.

Since the outbreak of the pandemic, the Commission, the Member States and the industry have taken action on various fronts, in particular on antivirals and neutralising antibodies against SARS-CoV2. The Commission mobilised research funds from the start, the European Medicines Agency (EMA) engaged with national medicines agencies and industry to support the authorisation of promising therapeutics, and large-scale joint procurement contracts on behalf of Member States supported timely access to treatments such as remdesivir and intensive care unit (ICU) medicines.

However, more coordinated efforts are needed to boost ongoing initiatives and develop new ones, in order ultimately to improve the prospects of recovery for all COVID-19

[1] COM(2020) 245 final.

patients. This EU strategy on COVID-19 therapeutics draws on an 'end to end' approach to building a broad portfolio of COVID-19 therapeutics. It covers the full lifecycle of medicines from research, development, selection of promising candidates, fast regulatory approval, manufacturing and deployment to final use.

The strategy will build on existing efforts to ensure a coordinated EU approach to achieve this ambitious but realistic objective. Building on experience from the EU vaccines strategy, the Commission is ready to mobilise all available tools and resources to ensure a genuine gear-change in the development and delivery of safe and effective therapeutics for COVID-19 patients, with the **aim of having three new therapeutics available by October 2021 and possibly two more by the end of the year**. This could make a significant difference in the treatment of COVID-19 patients in a real-world setting.

This EU strategy will be scalable for the benefit of COVID-19 patients globally, supporting a worldwide inclusive approach via bilateral and regional partnerships and established multilateral structures in the fight against the pandemic, and equitable access to treatment.

1. RESEARCH, DEVELOPMENT AND INNOVATION

Research, development and innovation is the first step to ensuring safe and effective therapeutics. Research on therapeutics focuses either on discovering completely novel candidate therapeutics or on repurposing existing therapeutics. Very early on (30 January 2020), the Commission launched a first call for research and innovation on COVID-19[2]. To date, it has supported 45 research projects on COVID-19 therapeutics and treatment options, for a total value of €119 million. Projects in the field of repurposed therapeutics have identified already existing medicines that have potential to be used as therapeutics for COVID-19, and could be produced at scale and made available quickly[3,4]. Other projects employing innovative technologies such as antibody-based therapies[5,6] are already delivering substantial results.

As announced on 17 February 2021, the Commission has mobilised an additional €90 million under Horizon Europe[7]. The funding will support vaccine and therapeutic trials to boost prevention and treatment. It will also support the development of large-scale, COVID-19-related population studies on particular groups, and foster the spread of networks outside Europe. Such studies and networks aim to establish links between risk factors and health

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2 https://ec.europa.eu/info/sites/info/files/research_and_innovation/research_by_area/documents/ec_rtd_cv-projects.pdf

3 For example, the Exscalate4CoV project in relation to raloxifene. Raloxifene is mainly used to prevent and treat osteoporosis in postmenopausal women. The Italian Medicines Agency has authorised a clinical trial for its use in COVID-19 patients with mild symptoms. The trial marks the completion of the first phase of the Exscalate4CoV project, which (through the use of a supercomputer platform) has screened 400 000 compounds (approved drugs and natural products that are safe in humans) for their potential as therapeutics for COVID-19.

4 CARE (funded by the Innovative Medicines Initiative) brings together 37 partners from industry and academia to screen for clinically approved drugs in a SARS-CoV2 cell-based assay. It has screened large libraries of chemical compounds and identified antibodies that could be candidates for therapeutic development.

5 The ATAC project has developed a promising second-generation antibody that is effective in neutralising the SARS-CoV2 and its variants, and could be used in both prevention and treatment of COVID-19.

6 The BRIGHT project (supported by the European Innovation Council) is responsible for XAV-19, an antibody-based treatment that is now in clinical development.

7 A specific 'emergency' work programme for health and infrastructures was adopted on 31 March 2021, with a call for expressions of interest published on 7 April 2021.

outcomesto further inform public health policy and clinical management, including for long COVID patients[8].

The Commission will also set up a COVID-19 **'therapeutics innovation booster'** to take stock and develop a clear overview of the COVID-19 therapeutics projects under development in order to better support the most promising ones from preclinical research to market authorisation. This platform will bring together all relevant actors, including EMA, national authorities, and the private sector, to identify promising research projects and technologies, their stages of development and provide guidance on where to best focus investments, in order to accelerate innovation. It will build on current initiatives and investments in therapeutic development, working in a close cooperation with the European Health Emergency Preparedness and Response Authority **(HERA) preparatory action on mapping therapeutics**. Based on this overview, it will support the development of new and repurposed therapeutics and help promising candidates progress to their next stages of development, mobilising the appropriate financial instruments (including Horizon Europe, InvestEU and EU4Health). It will therefore ensure the coordination of all research projects on COVID-19 therapeutics, allowing to stimulate innovation and boost therapeutic development.

ACTIONS

- Establish a 'therapeutics innovation booster' platform – by July 2021.
- Monitor and further support research and development, including on long COVID based on the results of ongoing and upcoming initiatives under Horizon Europe.

2. ENSURING ACCESS TO AND SWIFT APPROVAL OF LARGE-SCALE CLINICAL TRIALS IN THE EU

The main source of evidence for the authorisation of innovative medicines are robust clinical trials. Large-scale, well-designed randomised trials enrolling a sufficient number of participants and using harmonised protocols are the basis for producing robust results in a timely manner. Trials should include representative participation of population groups, such as gender and age groups, people with disabilities and those with a minority ethnic or racial background, so as to ensure appropriate safety and efficacy.

This is why **large EU-wide clinical trials** for the clinical management of COVID-19 patients have been developed in close cooperation with Member States and with funding from Horizon 2020[9]. The EU-wide network for COVID-19 therapeutic trials enables the rapid integration of new compounds to test. These trials have already yielded results[10].

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[8] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2021-corona-01-01
https://ec.europa.eu/commission/presscorner/detail/en/IP_21_1548

[9] With around €30 million Horizon 2020 funding, an EU-wide network for COVID-19 therapeutic trials was set up early on in the pandemic. It is based on two large-scale adaptive platform trials: DisCoVeRy and REMAP-CAP.

[10] The REMAP-CAP trial has shown that the monoclonal antibodies tocilizumab and sarilumab (normally used to treat rheumatoid arthritis) were found to cut the relative risk of death of severely-ill COVID-19 patients by 24%. Results from the DisCoVeRy trial (launched in March 2020 by INSERM, in the framework of the WHO Solidarity trial) suggest that the treatments hydroxychloroquine, lopinavir and interferon have no effect on the clinical improvement of patients. Such results are important, since they can halt treatments that previously seemed promising but actually have no benefit.

A common **Trial Coordination Board** has been set up with participants from the new network for COVID-19 therapeutics, representing all population groups, together with policy-makers, regulatory bodies (the EMA) and scientific experts. It promotes complementarities between, and supports cooperation with, other EU and international bodies[11], helping to avoid overlaps in their work. With research progressing, promising novel candidate therapeutics, using different therapeutic action mechanisms and potentially impacting on our ability to treat future variants of SARS-CoV2, are now reaching the stage where they can be tested in later-stage clinical trials.

Under this Strategy, the Commission proposes that €5 million are earmarked for a new action under the 2021 annual work plan (under preparation) of the EU4Health programme[12] to support **cooperation in safety assessment**, and improve the generation of high-quality **safety data in clinical trials**.

Clinical trials in the EU need an authorisation by Member States before they can start. In the case of multi-country trials, this involves several regulatory bodies (competent authorities and ethics committees) in several Member States, often giving rise to different national regulatory requirements and significant delays. Member States have established a voluntary harmonisation process for coordination; this is free of charge to sponsors, but the assessments are often long and burdensome. Financial support to cover costs associated with expedited and coordinated assessment by means of such a procedure would allow fast approval of harmonised clinical trial protocols in the EU, making it more attractive as a location for large, multi-country trials using master protocols.

The way clinical trials are conducted in the EU will undergo a major change with the full implementation of the **Clinical Trial Regulation**[13] in January 2022. This will introduce a framework for a robust and agile approval process and regulatory oversight for clinical trials. It will facilitate close coordination between Member States for multi-country trials and thus promote harmonisation and the conduct of larger, multi-country trials with broader geographical scope, including also Member States with fewer applications at present.

ACTIONS

- Support cooperation in safety assessment and improve the generation of high-quality safety data in clinical trials – €5 million to be earmarked under EU4Health programme.
- Provide national competent authorities with financial support of €2 million under the EU4Health 2021 work programme for expedited and coordinated assessments to authorise clinical trials for COVID-19 treatments.
- Explore how to support developers of therapeutics in building capacity for material in line with 'good manufacturing practice' (GMP) for clinical trials and start providing GMP-grade materials.

[11] The VACCELERATE EU-wide network for vaccine trials was recently launched as part of the HERA Incubator Communication; it builds on experience from the therapeutic trials network.

[12] Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (OJ L 107, 26.3.2021, p. 1).

[13] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

3. SCANNING FOR CANDIDATE THERAPEUTICS

The COVID-19 crisis has demonstrated the need to reinforce the timely availability of scientific advice mechanisms and intelligence to identify effective medicines. To this end, the EMA established an ad hoc EMA **Emergency Task Force**[14] to identify and support the development of promising medicinal products in the fight against COVID-19. The EMA has issued scientific advice on as many as 57 COVID-19 therapeutics in development, including small molecules and monoclonal antibodies, antivirals and immunomodulators[15], and three are under rolling review. This will enable the establishment of a broader portfolio of ten potential COVID-19 therapeutics.

In addition, under the upcoming HERA proposal, the Commission will propose capacities for mapping future developments (emerging technologies for medical countermeasures, such as artificial intelligence and high performance computing) and market intelligence and foresight (anticipatory action against a possible threat and capability assessments/modelling). This will generate information for other tools described in this strategy, including research and development, and joint procurement.

In the meantime and to complement the current EMA mapping, an additional **HERA preparatory action** under EU4Health will mobilise €5 million for **mapping promising therapeutics.** It will analyse their development phases, production capacities and supply chains, including possible bottlenecks. This will result in an interactive mapping platform available for all Member States by mid-2022 at the latest.

ACTIONS

- Establish a broader portfolio of ten potential COVID-19 therapeutics and identify five of the most promising ones – by June 2021.
- Set up an interactive mapping platform for promising therapeutics, to analyse their development phases, production capacities and supply chains – second quarter 2022.

4. SECURING SUPPLY CHAINS AND THE DELIVERY OF MEDICINES

The Communication on Updating the 2020 new industrial strategy[16] acknowledged that giving patients access to COVID-19 therapeutics and ensuring that ICUs do not run short of medicines requires adequate manufacturing capacities and effective, predictable supply chains. It is essential to develop and maintain a comprehensive overview at EU level of various supply chains and their potential strategic dependencies (e.g on active pharmaceutical ingredients imports[17]) in order to secure a constant flow of all lifesaving therapeutics. Currently, public authorities do not systematically have such an overview. The interactive mapping platform for COVID-19 therapeutics will help improve the understanding of these supply chains.

As outlined in the February 2021 Communication on Preparing Europe for COVID-19 variants: HERA Incubator[18], investment in innovation and manufacturing capacities for

[14] i.e. the body to be established under the proposal to reinforce the EMA's mandate. It will replace the 'COVID-19 EMA pandemic task force' (the current operational structure).

[15] https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/treatments-covid-19/covid-19-treatments-research-development

[16] COM(2021) 350.

[17] SWD(2021) 352.

[18] https://ec.europa.eu/commission/presscorner/detail/en/fs_21_650

vaccines is one of the cornerstones of any future pandemic preparedness and response, and part of the EU's open strategic autonomy. The Commission will fund a €40 million preparatory action to support flexible manufacturing and access for COVID-19 therapeutics under the **EU Fab project**, which will set up a network of 'ever-warm' production capacities for vaccine and therapeutics manufacturing at EU level. This project will become over time an asset for the future HERA.

Furthermore, building on the experience of the EU Task Force for Industrial Scale-up of COVID-19 vaccines, the Commission will facilitate cooperation between actors in the supply chain to ensure that available therapeutics are produced in sufficient quantity as soon as possible. In the context of a surge in demand, it remains crucial to ensure the speedy production of current and new therapeutics against COVID-19. To support the industry, the Commission will organise **matchmaking events** for all supply chain actors, so that they can find solutions for the bottlenecks encountered.

The Commission supports cooperation between undertakings where necessary to scale up research and development, production or supply, and where the companies acting alone would not be in a position to do so. Where necessary, it provides competition law guidance, e.g. in light of the criteria set out in the Antitrust Temporary Framework Communication[19]. To date, it has provided guidance in relation to the production of vaccines[20] and essential medicines for COVID-19 treatment[21]. EU State aid rules in the Temporary Framework[22] enable Member States to take swift and effective action to help companies, in particular small and medium-sized enterprises, to increase capacities to produce and supply COVID-19 medicines and active substances.

ACTIONS

- Pan-European matchmaking events for therapeutics industrial production – starting in third quarter 2021.
- Support flexible EU manufacturing and access to COVID-19 therapeutics under the EU Fab project, with €40 million in EU funding to be earmarked in 2021.

5. ENSURING A RAPID AND FLEXIBLE REGULATORY PROCESS

The EU's regulatory system allows for significant flexibility when it comes to authorisation procedures in the context of public health emergencies, while making sure that medicinal products are safe. In particular, the Commission, together with the EMA, is:

i) stepping up engagement with developers;

ii) offering scientific support to accelerate review procedures[23];

iii) making full use of conditional marketing authorisations;

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19 C(2020) 3200.

20 See comfort letter on vaccines upscale production: https://ec.europa.eu/competition/antitrust/comfort_letter_coronavirus_matchmaking_event_25032021.pdf For additional information on the matchmaking event, see: https://matchmaking-event-towards-vaccines-upscale.b2match.io/

21 See comfort letter on improving the supply of urgently needed critical hospital medicines to treat COVID-19 patients: https://ec.europa.eu/competition/antitrust/medicines_for_europe_comfort_letter.pdf

22 See practical guidance for Member States and list of COVID-19-related State aid decisions approved to date, including for research and development:https://ec.europa.eu/competition/state_aid/what_is_new/covid_19.html

23 https://www.ema.europa.eu/en/human-regulatory/overview/supporting-smes

iv) providing flexibility in relation to labelling and packaging requirements; and

v) providing flexibility in relation to manufacturing, import distribution and pharmacovigilance activities.

These flexible approaches are already being used to speed up the assessment of promising COVID-19 vaccines and therapeutics. First, in emergency situations, it is possible to use a **rolling review**, allowing the EMA to check data from ongoing studies as they become available, before a formal application for the (conditional) marketing authorisation is submitted. Currently, the EMA is conducting rolling reviews of three COVID-19 therapeutics building on monoclonal antibodies and **seven rolling reviews** for promising COVID-19 therapeutics are expected to start by the end of 2021.

The Commission can also grant **conditional marketing authorisations**, as it did for remdesivir[24]. These are based on a less comprehensive dataset than would normally be the case, subject to a **positive benefit-risk balance**. The work is then completed at a later date on the basis of the incoming data. Together with the EMA, the Commission will work towards granting conditional marketing authorisation for three new COVID-19 therapeutics by October 2021.

Member States can provide access to medicines in advance of their authorisation, including through **compassionate-use**[25] or **emergency-use authorisation** mechanisms. The EMA provides harmonised advice on which Member States can base their decisions authorising the use of these therapeutics at national level before formal (conditional) marketing authorisations are issued. This has been done for remdesivir before the conditional marketing authorisation was granted, dexamethasone and medicines consisting of monoclonal antibodies against SARS-CoV2[26].

The Commission is considering a legislative proposal[27] for an **EU emergency-use authorisation of medicinal products** that would ensure an even faster access to medicinal products in the context of public health emergencies.

The pandemic has shown that, **in times of crisis, every day counts in the effort to save lives**[28]. The proposal would therefore complement the current regulatory toolbox with an emergency-use authorisation at EU level. This crisis response mechanism, which today exists only at national level, would allow for a simplified while still safe procedure compared to the conditional marketing authorisation, by which Member States would jointly agree to market medicinal products with shorter deadlines, under specific liability and monitoring rules and ensuring the safety of the product.

Timely access to real-world data and real-world evidence for research and development is also key for therapeutics development and their quicker scientific assessment. The Commission will launch a pilot project before its future proposal for a **European Health Data Space**, which is aimed at facilitating access to, and the exchange of, health data collected in the course of healthcare provision, for research, policy-making and regulatory

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[24] https://www.ema.europa.eu/en/documents/other/summary-compassionate-use-remdesivir-gilead_en.pdf

[25] https://www.ema.europa.eu/en/human-regulatory/research-development/compassionate-use

[26] https://www.ema.europa.eu/en/human-regulatory/post-authorisation/referral-procedures/article-53-opinions

[27] As referred to in the Communication on "HERA Incubator: Anticipating together the threat of COVID-19 variants", COM(2021) 78 final of 17 February 2021.

[28] As of week 2021-15, 662 622 deaths had been reported in the EU/EEA. The 14-day COVID-19 death rate for the EU/EEA, based on data collected by the European Centre for Disease Prevention and Control from official national sources for 30 countries, was 77.6 (country range: 0.0-353.4) per million population. The rate has been stable for seven weeks.

purposes. This pilot will facilitate the EMA's and national medicine agencies' access to real-world data in order to check the safety and efficacy of therapeutics.

ACTIONS

- Work towards granting an authorisation for three new COVID-19 therapeutics – by October 2021.
- Subject to research and development outcomes, start seven rolling reviews for promising COVID-19 therapeutics (EMA) – by end 2021.
- Launch pilot project ahead of upcoming European Health Data Space proposal, financed by EU4Health to facilitate the EMA's and national medicine agencies' access to real-world data to check the safety and efficacy of therapeutics – third quarter 2021.

6. FLEXIBLE, FIT-FOR-PURPOSE AND WELL-RESOURCED FINANCING AND PROCUREMENT CAPACITIES

The **Joint Procurement Agreement for medical countermeasures**[29] provides for a voluntary mechanism enabling participating countries and EU institutions to jointly purchase medical countermeasures for different categories of cross-border health threat, including vaccines, antivirals and other therapeutics. It aims to improve preparedness to mitigate serious cross-border threats to health and secure more equitable access to specific medical countermeasures, greater security of supply and more balanced prices for the participating countries.

On 8 October 2020, the Commission signed a joint procurement framework contract with the pharmaceutical company Gilead for the supply of up to 500 000 treatment courses of remdesivir. All participating countries were able to place their orders to procure remdesivir directly. It also directly purchased doses under the Emergency Support Instrument, for a total of €70 million, and distributed these to Member States. Since late October 2020, it has signed over 70 joint procurement contracts for 19 medicines (analgesics, antibiotics, muscle relaxers, anaesthetics, resuscitation, including dexamethasone, etc.) to treat more severe COVID-19 cases in ICUs.

The Commission is ready to conclude further **joint procurement contracts** to facilitate the equitable availability of, and access to, new COVID-19 therapeutics across the EU. Currently, discussions are ongoing on **three new joint procurements** for COVID-19 therapeutics awaiting marketing authorisations from the Commission on the EMA's recommendation.

However, while joint procurement agreements have proved successful in securing equitable access to medicines for all interested Member States, the instrument has also shown its limitations. The Commission will consider **streamlined solutions** in this context to maximise the strategic role of joint procurement in achieving key preparedness goals – emphasising fair access, choice, quality, sustainability and value for public spending, while enabling adaptation to national conditions.

[29] As of April 2020, the Joint Procurement Agreement had been signed by 37 signatories, including all EU and EEA countries, the UK, Albania, Montenegro, North Macedonia, Serbia, and Bosnia and Herzegovina, as well as Kosovo* (* This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence).

Further account needs to be taken of the special requirements of procuring in emergency contexts. To achieve greater speed and flexibility in the current legal framework, participating Member States and other joint procurement agreement signatories would need to:

i) adhere to shorter administrative deadlines;

ii) use a distribution key where the resources being procured prove to be scarce;

iii) place a certain percentage of orders in the first few months of the contract; and

iv) refrain from engaging in parallel procurement processes for the same products or services.

Finally, the Commission is also ready to make use of **other EU mechanisms** and mobilise all necessary funding to procure COVID-19 therapeutics, including where appropriate by means of **advance purchase agreements** or the 'innovation partnership' procurement procedure[30], allowing the development and purchase of therapeutics that are not yet available on the market, or direct purchasing and donation. This may also include the emergency stockpiling of therapeutics under **rescEU**, as part of the **Union Civil Protection Mechanism**, bearing in mind the need to ensure complementarity with other EU programmes.

By engaging EU funds while pooling negotiating power at EU level, advance purchase agreements put the EU and its Member States in a position to leverage scale in discussions with the industry and ensure equity of access, in a way that cannot be achieved with multiple and sometimes competing national and European channels.

ACTIONS

- Launch new joint procurements of COVID-19 authorised therapeutics in the EU on behalf of Member States – by end 2021.
- Explore the possibility of engaging with Member States in advance purchase agreements or innovation partnerships with producers of promising new therapeutics.
- Review options for a fast-track pathway for joint procurement of medical countermeasures.
- Stockpiling of therapeutics under rescEU/Union Civil Protection Mechanism.

7. INTERNATIONAL COOPERATION

Collaboration on therapeutics is also crucial at global level. The Commission is committed to working together with international partners on COVID-19 therapeutics. The EU will intensify its cooperation with lower- and middle-income countries to strengthen their health systems and healthcare workforce, so as to ensure equitable and timely access to high-quality and affordable medicines. In the spirit of European solidarity, the Union Civil Protection Mechanism allows the Commission to support (financially and/or logistically) Member States willing to donate therapeutics to countries impacted by the crisis and in need of assistance as

[30] Innovation partnership is a relatively new type of public procurement procedure provided for in Directive 2014/24/EU. It can be used only in cases where no solution for a public buyer's needs is available on the market. The main feature of the innovation partnership is that the innovation occurs during the performance of the contract. In most other procedures, the public buyer knows what type of solution it is buying: innovation occurs in the pre-contracting phase and usually ends with the conclusion of the contract, when the solutions' exact features are agreed.

demonstrated most recently in responding to the request for assistance from India[31]. Furthermore, the Commission is exploring how to support the enabling environment for manufacturing health products, while strengthening research capacity and public health institutes in partner countries around the globe (including their capacity to generate evidence), through the EU's external relations instruments and the international cooperation component of Horizon Europe.

As the current chair of the **International Coalition of Medicines Regulatory Authorities**, the EMA (together with the Commission) is working with international partners to expedite and streamline the development, assessment and availability of COVID-19 therapeutics worldwide. In particular, in December 2020, it started piloting a new **'OPEN' initiative**[32] to increase international collaboration with the **Committee for Medicinal Products for Human Use** on its evaluation of COVID-19 vaccines and therapeutics. Through the confidentiality arrangements that they have concluded with third parties (including the EMA's ad hoc COVID-19 confidentiality arrangements) and through the EU's mutual recognition agreements, the Commission and the EMA are able to use information produced by international regulators, **avoid duplication and focus efforts on at-risk areas**. The EMA collaborates and actively exchanges information with other non-EU national medicines agencies and the World Health Organization (WHO) to speed up the development of therapeutics and vaccines, including for virus variants.

The Commission is actively engaged in the **Access to COVID-19 Tools Accelerator**, a global collaborative project to accelerate the development and production of, and equitable access to, COVID-19 tests, therapeutics and vaccines. Set up in response to a call from G20 leaders in March 2020 and launched by the WHO, the Commission, France and the Bill & Melinda Gates Foundation in April 2020[33], it brings together governments, scientists, civil society, foundations, charities and global health organisations.

Equitable access to therapeutics means equitable supply by governments and companies. The Commission is promoting cooperation between the EU-funded European platform trials and the Access to COVID-19 Tools Accelerator partnerships, in particular to ensure the rapid sharing of clinical evidence for the assessment of therapeutics and candidate vaccines, and to facilitate the global roll-out and uptake of therapeutics that successfully exit research and development. It will also continue to promote a 'trade and health' initiative in the World Trade Organization with a view to facilitating trade in essential goods in the context of health emergencies.

At the **Global Health Summit** in Rome, co-hosted by Italy and the EU on 21 May 2021, G20 leaders, international and regional organisation heads and representatives of global health bodies will share lessons learned from the pandemic and, following consultation of the scientific community and civil society organisations, agree on principles for further cooperation and joint action to prevent future global health crises, in a spirit of global solidarity.

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[31] Responding to India's request for assistance under the Union Civil Protection Mechanism, submitted on 23 April 2021, many Member States offered needed medical supplies (including oxygen and remdesivir). For more details see: https://ec.europa.eu/echo/news/india-eu-civil-protection-mechanism-continues-coordinate-emergency-supplies_en

[32] https://www.ema.europa.eu/en/news/ema-covid-19-assessments-open-non-eu-regulators

[33] https://www.who.int/news/item/10-09-2020-coronavirus-global-response-access-to-covid-19-tools-accelerator-facilitation-council-holds-inaugural-meeting

ACTIONS

- Engage with international partners to develop COVID-19 therapeutics and ensure their fair distribution.
- Reinforce, together with Member States, engagement in the therapeutics pillar of the Access to COVID-19 Tools Accelerator.
- Step up EU support for affected countries through the Union Civil Protection Mechanism.

CONCLUSIONS AND NEXT STEPS

While safe and effective vaccines against COVID-19 are increasingly available, the development and deployment of therapeutics and diagnostics also remain a priority when it comes to saving lives. Joint EU action, within a common strategic framework on therapeutics is urgently needed to enhance and accelerate significantly the return to normality for economic and social life in the EU and across the world. The Commission will implement this EU strategy for COVID-19 therapeutics together with the Member States and the European Parliament, thus contributing to equitable and affordable access to the most appropriate and effective therapeutics in the shortest possible timeframe.

These actions are part of the strong European Health Union, in which all EU countries prepare and respond together to health crises and ensure the availability of affordable and innovative medical supplies – including the therapeutics needed to treat COVID-19.

This framework will be further strengthened by the establishment of the HERA, due to be proposed by the European Commission in 2021, which will ensure that the EU can anticipate and respond effectively to serious cross-border health threats, and builds on the pharmaceutical strategy for Europe[34], which will create a future-proof regulatory framework, supporting research and technologies resulting in safe and effective therapeutics that reach patients.

[34] COM(2020) 761 final.