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REPORT FROM THE COMMISSION TO THE COUNCIL

on the implementation of Regulation (EU) 2020/521 on activating emergency support to finance necessary expenditure to address the COVID-19 pandemic

CONTENTS

1. Introduction 2

2. Activation of the Emergency Support Instrument 2

2.1. An instrument made to respond to an ever-changing crisis 3

2.2. Governance and decision-making 3

2.3. Budget and implementation 4

2.4. Communication and coordination 7

3. Outputs and results 7

3.1. Actions financed under the ESI 7

3.1.1. Mobility Package 7

3.1.2. Facility for essential health-related products 8

3.1.3. Treatment of COVID-19 patients with convalescent plasma 9

3.1.4. Clinical testing of repurposed medicines to treat SARS-COV-2 patients 9

3.1.6. Support in reception facilities in Greece 10

3.1.7. Break-through systems to effectively cope with the spread of the virus 10

3.1.8. The benchmark of the EU response to the pandemic: the EU DCC 10

3.1.9. Common digital passenger locator form exchange platform 11

3.2. Implementation and Performance 11

3.2.1. Financing vaccines in the EU and beyond 11

4. Added value of the activation of the ESI regulation in the context of the COVID 19 pandemic 12

5. Way forward 14

1. INTRODUCTION

COVID- 19 was declared a pandemic by the World Health Organization (WHO) on 11 March 2020. The pandemic led to a heavy loss of life in the European Union and worldwide and Member States adopted exceptional measures to limit the spread of the virus with severe social and economic consequences. National healthcare systems have been, and in some cases still are, under severe strain: Member States were faced with urgent and high needs for medical devices, personal protective equipment, and medicinal products including COVID-19 treatments and vaccines, additional hospital beds and the reinforcement of the workforce. Whilst all EU Member States have been easing the restrictions caused by the pandemic and the severity of the illness caused by the Omicron variant of the virus -coupled with an enhanced vaccine-induce immunity- has been decreasing over the last few months, the virus still remains a persistent threat and the extra pressures on health services could continue with new waves of COVID-19 infections.

The quick spread of the virus in Spring 2020 and the critical situation called for a comprehensive EU response to address the crisis in a spirit of solidarity. It quickly became clear that the early actions taken by the Member States independently would fall short of citizens' needs and risked broader damage to the single market.

EU consensus was swiftly reached to provide needs-based emergency support to prevent and alleviate human suffering, and to maintain human dignity. This support would complement Member States' efforts. In April 2020, the Council agreed to activate the Emergency Support Instrument (ESI). The ESI enabled a direct support to the Member States through targeted measures deployed strategically and in a coordinated manner.

The ESI equipped the Member States' healthcare sectors with a broad toolbox to support and complement the national healthcare systems in their efforts to address the pandemic. It provided a fast, flexible and efficient instrument to mitigate the immediate acute consequences of the pandemic.

This report aims to provide an overview of the key impact of the ESI since its activation in the context of the COVID-19 pandemic, an analysis of the main challenges encountered, and an outline of planned future activities.

2. ACTIVATION OF THE EMERGENCY SUPPORT INSTRUMENT

The ESI was established in 2016 (Council Regulation (EU) 2016/369 of 15 March 2016[1]) and first activated for a period of three years in response to the influx of refugees and migrants into the Union.

On 2 April 2020, the Commission proposed[2] to activate the ESI in the context of the COVID-19 pandemic for the period from 1 February 2020 to 31 January 2022. This was informed by a first survey on crisis-related needs (needs assessment) by the Commission departments, providing the non-exhaustive list of possible areas of ESI action contained in its activation proposal. In parallel, the Commission proposed and negotiated with the Budgetary Authority the related Draft Amending Budget 2/2020 to provide EUR 3 000 000 000 in commitment appropriations and EUR 1 530 000 000 in payment appropriations, out of which EUR 2 700 000 000 in commitment appropriations and EUR

1 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0369&from=EN

2 https://ec.europa.eu/info/sites/info/files/about_the_european_commission/eu_budget/com175final_-_en_-_proposal_council_regulation_activating_esi.pdf

1 380 000 000 in payment appropriations under heading 3 Security and Citizenship to finance the provision of emergency support within the Union through the Emergency Support Instrument.

On 14 April 2020, the Council adopted the Council Regulation (EU) 2020/521 activating emergency support under Council Regulation (EU) 2016/369 and amending its provisions to finance expenditure necessary to address the COVID- 19 pandemic. The amending budget 2/2020 was adopted on 17 April 2020.

2.1. An instrument made to respond to an ever-changing crisis

The activation of the ESI was designed to allow for a comprehensive and flexible response to the urgent, evolving and diverse Member States' needs emerging during the pandemic.

Especially in the early phase of the crisis, a lack of information about needs at both Union and national/sub-national level slowed down the common response. To mitigate this, the work of the COVID-19 Clearing House for medical equipment[3], and in particular the results of its Member States' needs surveys and projections, were leveraged to lay down an action programme for the instrument. The needs reported by Member States were cross-referenced against the epidemiological methodology of the European Centre for Disease Prevention and Control (ECDC) in order to ensure the equitable distribution of equipment and products for donation to Member States.

In line with the legal basis, the Commission cooperated closely with the Member States in the implementation of the instrument. Discussions in the Permanent Representatives Committee (Coreper) and the Integrated Political Crisis Response (IPCR) meetings were of particular importance to provide input on possible areas of action, in addition to the dedicated meetings with Member States' contact points.

2.2. Governance and decision-making

The Emergency Support Instrument is based on Article 122(1) TFEU, which allows the Council, on a proposal from the Commission, to decide, in a spirit of solidarity between Member States, upon the measures appropriate to the economic situation, in particular if severe difficulties arise in the supply of certain products.

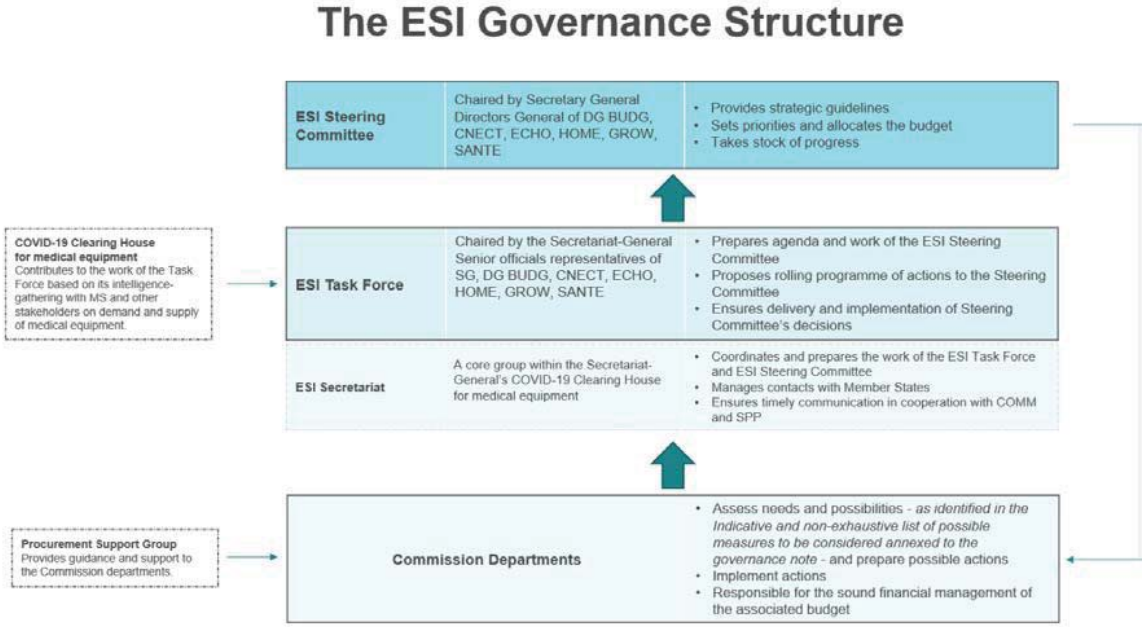
Other Union's instruments already existed to respond to different types of internal challenges, e.g. the measures provided for under the Union Civil Protection Mechanism (UCPM) established by Decision No 1313/2013/EU, rescEU or the Joint Procurement Agreement for medicines and medical equipment. Nonetheless, while the EU already benefited from them, these instruments were limited in scale and the response they could provide was insufficient to address the exceptional and wide-ranging needs resulting from the pandemic. Within its scope and only in exceptional circumstances, when no other instrument available to Member States and Union would prove to be sufficient, the ESI complemented the efforts of Member States while maintaining close cooperation and consultation with them.

In order to provide strategic coordination of the instrument, in particular as concerned priority setting and allocation of funding, a specific internal governance arrangement was created. This included a Steering Committee ("ESI Steering Committee"), whose main

[3] https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/emergency-support-instrument/covid-19-clearing-house-medical-equipment_en

tasks included providing guidelines to ensure strategic actions under the ESI framework, setting priorities and allocating the relevant budget, and eventually taking stock of the progress. Chaired by the Secretariat General (SG) – and as from 15 July 2021 by the Directorate General for Health and Food Safety (DG SANTE) –, it was composed of the Directors General for Budget (BUDG), Internal Market Industry, Entrepreneurship and SMEs (GROW), Health and Food Safety (SANTE), European Civil Protection and Humanitarian Aid Operations (ECHO), Migration and Home Affairs (HOME) and Communication Networks, Content and Technology (CNECT).

The ESI Steering Committee was supported by the ESI Task Force, responsible for drafting the agenda and coordinating the activities of the Steering Committee, ensuring timely delivery of its decisions and effective implementation of its actions. Together, the Steering Committee and the ESI Task Force selected the beneficiary activities, according to the emerging needs at each moment of the pandemic, after ensuring that no possibility existed to finance those activities through other EU mechanisms and funds.



As a result of the selection of actions prioritised for funding, there were additional services implementing part of the budget, through co-delegations or cross sub-delegations (DGs Informatics (DIGIT), Mobility and Transport (MOVE), Environment (ENV), The Joint Research Centre (JRC), Health Emergency Preparedness and Response Authority (HERA), and International Partnerships (INTPA)). There were no actions implemented in the field of Internal Market, Industry, Entrepreneurship and SMEs.

The ESI was centrally managed by the Commission and implemented very largely through direct management (grants (9%) and procurement (89%)), with around 2% of the funding being implemented through indirect management via the International Federation of the Red Cross (IFRC), the European Union Aviation Safety Agency (EASA) and the International Organization for Migration (IOM).

2.3. Budget and implementation

Upon the activation of the ESI on 14 April 2020, the Budgetary Authority authorised EUR 2 700 000 000 for the implementation of the Emergency Support actions. By its

Decision C(2020)2794[4], the Commission authorised financing of emergency support actions under the ESI Regulation.

In June 2020, the Commission approved[5] the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and decided[6] to use part of the funding available under ESI finance the purchase of COVID-19 vaccines (so called "Vaccine Instrument" initiative) and already in July 2020 an urgent decision was taken[7] to increase the funding allocated to this action.

In December 2020, new actions were added to the ESI by its Decision C(2020)8800[8], reflecting emerging needs related to the crisis. The latter Decision also adapted the budget of the "Vaccine Instrument" following contributions from Member States under Article 4(2) of the ESI, which provides for the possibility for Member States and other public or private donors to make contributions to the ESI as external assigned revenue in accordance with Article 21(5) of Regulation (EU, Euratom) 2018/1046. Additional resources were necessary because all existing flexibilities under the 2020 budget had already been exhausted.

By the end of December 2020, the Member States contributed to the Instrument with a total amount of EUR 750 million of external assigned revenue in the context of the vaccines initiative. Thus, by the end of 2020, the "Vaccine Instrument" totalled at EUR 2.9 billion.

Given the emerging needs linked to the emergence of new variants, it was decided to reinforce the ESI budget and mobilise it for additional measures. The Commission proposed to reinforce the ESI with an additional EUR 231.7 million in commitment appropriations (EUR 75.5 million through a Budgetary Authority transfer DEC 5/2021 from the Solidarity and Emergency Aid Reserve (SEAR) and EUR 156.2 million through the Draft Amending Budget 2/2021) to cover new actions. It created a reserve of EUR 100 million for emerging needs. Following intense negotiations on the regulation between the European Parliament, the Council and the Commission, this reserve was later allocated to grants to Member States to support accessibility of diagnostic test that qualify for the issuance of the EU Digital Covid Certificate[9].

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4 Commission Decision C(2020)2794 of 24 April 2020 on the financing of Emergency Support under Council Regulation (EU) 2016/369.

5 Commission Decision C(2020)4192 of 18 June 2020 amending Decision C(2020)2794 as regards approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures.

6 Commission Decision C(2020)4193 of 18 June 2020 amending Decision C(2020)2794 as regards the financing of the Vaccine Instrument.

7 Commission Decision C(2020)5162 of 23 July 2020 amending Decision C(2020)2794 as regards the financing of additional actions under the Emergency Support Instrument and the increase of the budget of the Vaccine Instrument.

8 Commission Decision C(2020)8800 of 4 December 2020 amending Decision C(2020)2794 as regards the financing of additional actions under the Emergency Support Instrument and the increase of the budget of the Vaccine Instrument regarding donations from Member States.

9 Commission Decision C(2021)4791 of 24 June 2021 amending Decision C(2020)2794 as regards the financing of additional actions under the Emergency Support Instrument and the increase of the budget of the Vaccine Instrument regarding donations from Member States.

Decision C(2021)2347[10] of 29 March 2021 provided that the amendment for the global budgetary envelope reserved for each line of the general budget of the Union and each implementing method would be made via subsequent Steering Committee decisions in line with the flexibility provided for in Article 4 of Decision C(2020)2794. It also extended the period of validity of the Financing Decision to the end of the ESI activation period, given the need to reinforce the emergency support with further actions and associated budget in 2021.

The ESI expired on 31 January 2022 and hence no commitment appropriations were requested for 2022.

During the State of the Union address on 15 September 2021, President von der Leyen announced a donation of another 200 million vaccine doses to low-income countries. The unused appropriations under the exceptional Member States' contribution of 2020 (upon the agreement of the respective Member State) were redirected towards this new action. The ESI financing[11] complemented the financing of this action through the Neighbourhood, Development and International Cooperation Instrument (NDICI).

Subsequently, on 12 May 2022, during the Second Global COVID-19 Summit, the President announced the intention to accelerate the roll-out and uptake of vaccines and other COVID-19 tools in low income countries.

This intention was formulated taking into account the considerable change to the supply and demand situation of COVID-19 vaccines which took place over the past months. However, the challenge to match the supply with the absorption capacity of countries of the doses donated remains partly unmet, due to often structurally weak health systems and low access to health care in third countries. Therefore, it was decided to reorient the action to better support low and lower-middle income countries to rollout COVID-19 vaccination and also cover other needs linked to their COVID-19 response, namely auxiliary material, diagnostics, therapeutics and related health systems strengthening. The initial objective to boost global vaccination to contribute to global immunisation that would also protect the EU from the emergence of other variants elsewhere remained unchanged.

Finally, from the EUR 750 million in external assigned revenue from Member States' contributions, EUR 27 million were not spent following negative answers from Member States indicating that they refused the use of their contribution for proposed actions differing from the original vaccines APAs.

Donation of vaccines doses and resale at paid price to third countries

Eight Advanced Purchase Agreements (APAs) were signed under the ESI between the Commission and the contractors. They contain provisions for resale of vaccine doses by the Member States -in all but one APA, where resale is possible also by the Commission- and for donations to third countries in all but one APA, where donation is only possible to Member States.

The APAs included up-front EU financing to de-risk essential investments to increase the speed and scale of manufacturing successful vaccines. In return, the APAs would provide the right – or under specific circumstances the obligation – to participating Member

[10] Commission Decision C(2021)2347 of 29 March 2021 amending Decision C(2020)2794 as regards the financing of additional actions under the Emergency Support Instrument.

[11] Commission Decision C(2021)10001 of 20 December 2021 as regards the financing of additional actions under the Emergency Support Instrument.

States to buy a specific number of vaccine doses in a given timeframe and at a given price. The last APA (2021), however, did not receive funding through the ESI but was entirely financed by the Member States.

In light of the 'spirit of solidarity *between Member States*' laid out in Article 122(1) TFEU, the direction of ESI funds towards third countries could be demonstrated as '*measures appropriate to the economic situation*' within the meaning of that Article. In that respect, the approach on the absence of reimbursable amounts in case of donations or resales without economic advantage was presented by the Commission to the Vaccines Steering Board (Member States) in December 2021. Consequently, in February 2022, the Commission adopted the decision[12] on the absence of receivable amounts under the ESI in case of donations or resales without an economic advantage of COVID-19 vaccine doses by Member States to third countries. This decision concludes that there should not be any amounts receivable in the sense of Article 98 of the Financial Regulation in case of donations and sales at paid price by Member States.

Resale of vaccines doses with economic advantage

As regards the resales done by Member States at a price including the ESI contribution, Member States were also informed that the Commission would recover the ESI funds in cases of resales of vaccine doses to third countries at full price. Hence, the Commission requested Member States to inform on these resales. By 12 May 2022, an amount of EUR 22 million has been reimbursed by the Member States however the process is ongoing.

2.4. Communication and coordination

Since the activation of the ESI, the Commission has strived to report all important developments linked to the approval and implementation of the measures created by the instrument. For this purpose, a dedicated website was created. The official website has been regularly updated through the application of the instrument.[13]

In addition, the Commission has maintained regular communication with Member States on their needs and how these were being taken into account in programming, while keeping them informed on the state of play of the actions to be financed by the instrument. This was done via written information, through Coreper and the Integrated Political Crisis Response (IPCR) meetings, as well as through dedicated meetings with Member States' contact points. The Health Security Committee, the eHealth Network and the Civil Protection Committee were also regularly engaged. The European Parliament was also informed on the top up funds from Member States, the resales of vaccines and the allocation of grants to Member States to support the implementation of the EU DCC

This cooperation and exchange of views allowed for a prioritisation of the actions to be taken, in the absence of specific objectives in the legal basis.

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12 Commission Decision C(2022) 698

13 https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/emergency-support-instrument_en#general

3. OUTPUTS AND RESULTS

3.1. Actions financed under the ESI

In line with the broad scope of possible interventions provided for by the legal basis and its need-based rationale, the ESI financed a strategically chosen range of actions. These reflected the needs expressed by Member States during consultations and focused on response and increased preparedness, while bringing fast, targeted and tangible impact with maximum EU added value.

The Advanced Purchase Agreement, the EU Digital Covid Certificate, the creation of a mobility package to facilitate transport of medical products, personnel or patients and the acquisition of essential sanitary products are some of the most important actions established by the ESI. The full list of actions implemented under ESI and their relative allocated budgets are detailed in the Annex to this report.

3.1.1. Mobility Package

Under the Mobility Package (ESI-MP), coordinated by DG ECHO, the following actions were launched via a first invitation to submit applications to Member States in June 2020:

- Cargo transport (e.g. personal protection equipment, medical and vaccination-related equipment, and therapeutics) to the EU from third countries and within the EU.
- Transfer of patients within the EU and from the EU to third countries (from a Member State to either a Member State or a third country welcoming patients); and
- Transport of medical personnel and teams, within the EU and into the EU from third countries, as well as operational support for mobile medical response capacities.

Since April 2020, more than 2 000 operations via air, land or sea for transport of medical equipment and the transport of approximately 515 health workers and 135 patients have been supported via 78 projects (60 related to cargo operations and 18 to transfer of patients and medical teams) with 73 grant agreements signed. Overall, cargo operations have been financed with more than EUR 164 million and EUR 9 million have been awarded so far to Member States for the transport of medical teams and transfer of patients.

3.1.2. Facility for essential health-related products

The ESI allowed all Member States to have access to the therapeutic Remdesivir, (some 34 000 courses of treatment) the first EU-authorised medicine to treat COVID-19 and the best available scientific evidence at the time, although this was subsequently challenged, and at a time when national contracts with the sole producer were not on offer.

Also under this facility, the instrument allowed the Union to procure and donate to the interested Member States over 23 million rapid antigen tests and 10 million masks.

The action to provide training in intensive care skills has proved very successful to increase the available capacity to support the regular Intensive Care Unit staff to take care of COVID-19 patients. With the collaboration of the European Society of Intensive

Care Medicine (ESICM), more than 17 000 professionals were trained in 24 EU Member States plus UK, in 717 hospitals between August 2020 and May 2021. A total of 5 696 medical doctors and 6 400 registered nurses were certified.

Following the success of the initiative, the Commission received requests from third countries and international organisations to benefit from the established system and access the training platform. Therefore, an assignment agreement which settles the transfer of rights from the EC to ESICM was signed. As a result, ESICM opened the C19_SPACE for training to all health professionals interested and by March 2022 already 700 additional users had completed the programme. In March 2022 ESICM signed a contract with WHO to deliver the C19_SPACE training programme in the 6 languages of the WHO and it will be opened in the second trimester of 2022.

3.1.3. Treatment of COVID-19 patients with convalescent plasma

As regards the treatment of COVID-19 patients with convalescent plasma, the instrument financed 20 projects across 13 Member States and the UK. It aimed at increasing the capacity of the public and NGO blood services to collect plasma from donors that had recovered from COVID-19, involving 150 collection centres.

About EUR 22.5 million of the EUR 35 million allocated were spent: to purchase or lease 299 plasmapheresis machines, to expand plasma storage capacity through the purchase of 145 low temperature freezers, and to buy equipment/furniture and more than 70.000 collection kits. In addition, 35 new collection centres were opened while the other beneficiaries were able to expand their collection capacity. According to the final reports provided, beneficiaries have collected 165 444 units of convalescent plasma. The increase in plasmapheresis capacity will have a secondary long-term benefit of helping to address a significant dependence of the EU on the US for an adequate supply of plasma donations for the manufacture of essential medicinal products.

3.1.4. Clinical testing of repurposed medicines to treat SARS-COV-2 patients

With regards to clinical trials for testing repurposed medicines, a call was launched to five beneficiaries of Horizon 2020 funding to apply. The intention was to develop the generation of clinical data to support the application for a marketing authorisation for existing medicines to be repurposed to treat COVID-19 patients. The ultimate objective was to increase the capacity of Member States to deal with the demand for medicines and therapies, to assess the safety and efficacy of investigational medicinal products in human subjects for the treatment of COVID-19; and to ensure that all Member States have fair access to essential medical products for treating COVID-19, including new and repurposed treatments. Unfortunately, there were no adequate results.
One applicant received a grant of EUR 1 million to carry out a clinical trial with the substance Raloxifene so as to study its use for preventing the evolution of COVID-19 towards severe and critical disease. Concerning the clinical trial itself, the company faced several operational problems and as a result, the action was (slightly) prolonged in order to recruit the foreseen number of participants. The results of the trial act as a proof of concept on the use of raloxifene. Three other submissions were rejected as they did not fall within the scope of the call and one did not apply.

3.1.5. Increased testing capacity

Working with the national branches of the International Federation of the Red Cross, the instrument ensured the stepping up of testing capacity across seven Member States which expressed an interest. Between July 2020 and September 2021, a total of 9 222 volunteers and professionals were trained in testing techniques, 1 795 mobile testing teams were established and 1 263 309 tests conducted.

3.1.6. Support in reception facilities in Greece

The action to provide medical capacities for the reception facilities and their host communities in Greece was complementary and built upon the lessons learnt by providing structural investment to increase the capacity of local hospitals and within reception centres, geared towards the particular challenges related to the COVID-19 pandemic. The focus on structural investments increased the sustainability of the action, in line with the evaluation recommendations. Needs were assessed jointly, consulting in a bottom-up approach with the local hospitals and Greek health partners, and the selection of partners for the grant ensures a combination of local involvement and relevant expertise. The action was implemented by the International Organisation for Migration and will be running until 30 June 2022, where all the relevant procurement processes are expected to be completed and delivered to the Greek Authorities. Finally, the action was designed to be complementary to the funding for healthcare in the Greek migration reception system under the Asylum, Migration and Integration Fund.

3.1.7. Break-through systems to effectively cope with the spread of the virus

The instrument funded the supply of 305 UV disinfecting robots to hospitals in all 27 Member States, providing innovative, efficient and effective solutions to ensure the safety of healthcare environments and their staff.

EU wastewater monitoring system or the urgent characterisation of the SARS/CoV2 Omicron variant were also additional actions financed with this instrument and that could not have been implemented otherwise.

The instrument also financed the biological, immunological and epidemiological characterization of the SARS-CoV-2 Omicron variant. The Omicron characterization brought a lot of added value to implementing effective public health measures as it contributed to understanding the virulence, pathogenicity, and the immunological features of the variant

Through the instrument, the Union was able to provide solutions to other common challenges, such as the development of interoperability between national contact tracing apps. The system went live in October 2020.

3.1.8. The benchmark of the EU response to the pandemic: the EU DCC

The establishment of a framework for the common issuance, verification and acceptance of interoperable Covid vaccination, test and recovery certificates was one of the big successes of the EU to allow mobility of the citizens and contribute to the reopening of services and travelling.

The instrument financed grants to 24 interested Member States for developing systems for the issuance and verification of EU Digital COVID Certificates (EU DCC) as a proof of vaccination, recovery or negative test, between 29 March and 31 December 2021. The cornerstone of the EU DCC system is the EU DCC gateway developed and maintained

by the European Commission. The gateway is crucial for the trust framework of EU DCC, as it is used for sharing information on digital signatures, business rules, value sets, and revocation lists. The development of the EU DCC gateway was also financed through the instrument. Additionally, grants to 18 interested Member States supported accessibility of tests for the delivery of the Digital Covid Certificate, for the period 1 June-31 October 2021.

3.1.9. Common digital passenger locator form exchange platform

The common digital passenger locator form exchange platform (including Pilot project), namely the ePLF exchange platform, was also financed by the Instrument. This platform offered the possibility to strengthen Member States' contact tracing capabilities for cross-border travel through a dedicated platform for the exchange and processing of selective passenger data between Member States.

To enable the functioning of the platform, the implementing acts of May and July 2021 established this platform, specified the operators and indicated a number of minimum data to be collected through national PLFs to ensure that all potentially exposed passengers are identified and outlined the necessity for a dedicated exchange platform effective in cross border contact tracing. The acts specify that the exchange of data shall cease to exist after the 31st May 2022 or until the World Health organization has declared, in accordance with the International Health Regulations, that the public health emergency of international concern caused by SARS-CoV-2 has ended.

Following the emergence of the Omicron variant in autumn 2021, the Commission put forward draft measures to make the collection of passenger locator forms (PLFs) and the connection to the PLF exchange platform mandatory for all Member States. Yet the initiative met with strong resistance by several Member States and was not pursued further.

As of April 2022, there were five countries connected to the ePLF exchange platform, namely France, Italy, Malta, Slovenia, and Spain. Following the expiry of the relevant implementing decisions on 31 May 2022, no exchange of data is currently possible. Exchange of messages using this PLF exchange platform has been limited. The Commission and the ECDC have been working since spring 2022 on a project integrating the PLF exchange platform and Early Warning and Response System (EWRS), in view of possible future needs.

3.2. Implementation and Performance

The ESI has proven its effectiveness in terms of quickly mobilising resources towards the needs identified in the context of the COVID-19 pandemic. Therefore, it managed to effectively respond to the urgent, evolving and diverse needs of Member States in responding to the crisis. The flexibility enshrined in the legal basis and the mandate given to the Commission to centrally manage the funding, in cooperation with Member States, allowed the prioritisation of those collective actions that could generate more timely interventions and outcomes that could not have been achieved by Member States acting individually.

Financial execution for the instrument – both in terms of commitments and payments – is on track. The implementation rate for commitment appropriations in 2020 and 2021 was 100% as concerns the EUR 2.9 billion available budget credits. Out of the EUR 750 million in external assigned revenue from Member States' contributions, EUR 27 million

were not spent following negative answers from Member States, which would otherwise have allowed these funds to be used in the vaccine sharing initiative for low income countries.

The instrument is unique under several points of view. It was deployed in a rapidly-evolving environment marked by uncertainties about the nature of the virus, the appropriate medical response, and both supply and demand. At the same time, however, it resulted effective in responding swiftly when needed, for example, by providing medical countermeasures (Remdesivir, rapid antigen tests, etc.) in support to Member State needs. Finally, the breadth of scope and possible interventions also required specialised policy-making in the context of an ever-changing epidemiological situation. This is particularly commendable especially considering the supporting competences of the EU in the health domain.

3.2.1. An unprecedented endeavour: financing vaccines in the EU and beyond

The major focus of the programme (around 70% of funding) has been on the vaccines initiative. This allowed the conclusion at an early stage of advanced purchase agreements with pharmaceutical companies developing COVID-19 vaccine candidates, to provide the necessary investment to accelerate the scientific development of those vaccines and, in parallel, the development of the production capacities needed to produce them at the scale needed.

As a result, 2.2 billion doses of COVID-19 vaccines for Member States were secured through arrangements financed with ESI funding[14]. The instrument provided the financial grounds to encourage Member States' to take a joint approach in this area. As a result, it provided Member States with access to a wider portfolio of vaccine candidates. Indeed, many individual Member States would have had little leverage to engage with developers of vaccines to secure supplies. Joint action increased the chances for Member States to have access to whichever of the candidate vaccines eventually proved successful.

The ESI funding also created greater support for vaccine candidates than would have been the case under individual arrangement. In other words, the approach facilitated by the ESI ensured that the successful vaccines were ready earlier than would otherwise have been the case, and at greater scale -and were available to all Member States on an equal basis. This joint approach also it leveraged the purchasing power offered by Union investment to reduce prices and obtain contractual conditions on issues such as liability and capacity increase which will mitigate Member States' risks going forward.

At the same time, the APAs funded by the instrument were always known to be risky investments by their nature. Whilst the Commission designed a portfolio of contracts with the most promising candidates across a wide range of technologies, there was no guarantee that individual vaccines would be successful and authorised in the EU. The Vaccines Strategy was based on the assumption that it was likely enough that at least one of the vaccine candidates would succeed. Risk was further mitigated by provisions in the APAs requiring the reimbursement of part of the unused EU investment in any such case.

The ESI instrument contributed with EUR 461 million to support the COVID-19 response and global vaccination efforts in low and lower-middle income countries –

[14] In total, contracts for 4.6 billion doses were signed; however this included both Advance Purchase Agreements and Purchase Agreements. Moreover, not all vaccine manufacturers succeeded in obtaining a conditional marketing authorisation for vaccines.

actions that will be implemented in 2022. This support to the rollout of COVID-19 vaccination targets the initial objective of boosting global vaccination to contribute to global immunisation that would also protect the EU from the emergence of other variants

4. ADDED VALUE OF THE ACTIVATION OF THE ESI REGULATION IN THE CONTEXT OF THE COVID 19 PANDEMIC

The ESI was designed to respond to severe humanitarian consequences resulting from acute crises. In 2016-2018, it enabled the Union to provide appropriate and timely support for refugees and migrants present in Greece, and in 2020, it enabled EU to directly support the healthcare systems of EU Member States in their efforts to address the COVID-19 pandemic. Given the specific context and focus of the objectives of the first activation, the findings of the evaluation are of limited relevance to the present programme.

In the period from February 2020 and January 2022, the ESI provided a fast, flexible and efficient instrument to deploy targeted actions preventing and mitigating the immediate acute consequences in one or more Member States and to support in a coordinated manner the needs related to the COVID-19 pandemic.

Complementarity and synergies with other mechanisms were a key test in the selection of actions. For example, there was no other EU instrument available to finance Advanced Purchase Agreements with vaccine developers: without the ESI funding and the legal basis of the ESI, a joint approach would have been far more difficult to construct, with the very likely outcome that Member States would have had great differences in access to safe and effective COVID-19 vaccines. Moreover, as concerns support to the medical facilities in Greece, no other instrument had the legal scope to provide funding to enhance the overall capacity of the local infrastructure to address the needs of hosting communities as well as those in reception centres. Actions such as the direct donations of UV disinfecting robots were delivered in partnership with the beneficiary local actors, at the level of individual hospitals. The action to increase testing capacity was implemented through the International Committee of the Red Cross, which is working through its national and regional branches to deliver localised increased testing.

The ESI contributed directly and in its entirety (EUR 3.7 billion) to Sustainable Development Goal 3: good health and well-being. The United Nations (UN) has acknowledged that COVID-19 is spreading human suffering, destabilising the global economy and upending the lives of billions of people around the globe, and that the pandemic provides a watershed moment for health emergency preparedness. The ESI, deployed in response to the health crisis, supports the whole-of-government and whole-of-society response needed, matching the resolve of frontline health workers.

The ESI provided medical equipment for health workers in the early days of the crisis, and therapeutics to treat nearly 35 000 patients later. It has provided rapid antigen tests and also supported Member States to perform more tests. It has provided increased testing capacities and promoted the availability of treatments such as convalescent plasma. It has provided solutions to support the interoperability of tracing and warning apps across border, helping to break the chain of coronavirus infections and helping to save lives. Most importantly, it has accelerated the development of vaccines and secured access to several billion doses of vaccines for EU Member States and – through COVAX – the wider world.

The ESI supported EU Member States in creating and leveraging the EU Digital COVID Certificate system (EU DCC). With 60 countries connected worldwide, the EU DCC was

the largest global system of interoperable digital COVID-19 certificates, allowing interoperability among all countries connected, not only with and within the EU. As reported by a Bruegel study[15], the EU Digital COVID Certificate[16] has helped increased uptake for vaccines, avoiding thousands of deaths and improving public health and economic performance, preventing losses in the billions of euros.

The digital Passenger Locator Forms, has been instrumental to enable the effective exchange passenger data among Member States and should be preserved and encourage further simplification and improvements. This would allow the platform to exist on standby and be more easily activated in case needed not only for the COVID-19 pandemic, but also for other potential cross-border diseases.

In summary, the ESI has been key to respond and fight the pandemic and no other EU mechanism on their own or even in combination with others could have been able to do it. It has been instrumental for supporting all EU Member States and guarantee that all of them had access to the same products and medicines at the same time and that cooperated and responded as a real Health Union in practical terms, even in the absence of specific legislation.

5. WAY FORWARD

The nature and consequences of the COVID-19 outbreak in 2020 were on a large-scale and transnational and therefore it required a comprehensive response. The measures foreseen under the Union Civil Protection Mechanism/rescEU, the Coronavirus Response Investment Initiative to deploy European Structural and Investment Funds and other Union instruments were partly contributing to address the current public health emergency. However, the scale and scope of the challenge required a stronger response, directed in particular to the EU healthcare sector. That is why the Commission proposed to mobilise the ESI to equip the EU with a broader toolbox commensurate to the large scale of the current COVID-19 pandemic. A coordinated action at EU level made it possible to both address the current crisis and ensure a proper response in its aftermath. For EU citizens, the ESI has been a clear demonstration of solidarity, proving that the EU can address pressing humanitarian challenges in a collective effort.

The instrument's activation expired on 31 January 2022 and the Commission is finalising the activities related to it.

There is currently no intention to continue, expand or deploy it again for the current pandemic.

The 24 months of implementation have allowed for the deployment of other legal instruments, under the European Health Union, in order to reinforce the EU competence on cross border health threats and reinforce the competences and scope of the European Centre for Disease Prevention and Control and the European Medicines Agency.

Building on the added value of the ESI interventions, HERA was established in October 2021 as a Commission service to lead the way forward to anticipating and addressing risks jointly. HERA has been mandated to assess health threats, gather intelligence and promote R&D of medical countermeasures and related technologies, address market challenges, boost the Union's strategic autonomy in medical countermeasure production,

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15 The effect of COVID certificates on vaccine uptake, public health, and the economy | Bruegel

16 The EU Digital COVID Certificate Regulation applied initially until 30 June 2022 and is extended by one year, until 30 June 2023.

and strengthen knowledge and skills in the area across the EU. The Commission's HERA will have at its disposal funding from various sources including the increased budget for the EU4health Programme, Horizon Europe and RescEU, including the activation of emergency funding in case of a health crisis.

The implementation of the ESI has allowed to shape the way forward towards better preparedness and response in the future.

The Commission is currently working on a proposal for a Single Market Emergency Instrument to ensure a well-functioning Single Market, the free movement of goods, services and people, with greater transparency and coordination in times of crises. The new instrument will be aligned with relevant policy initiatives, such as the setting up of the Commission's Health Emergency Preparedness and Response Authority (HERA), and the adopted contingency plan for transport and mobility. The proposal is planned for adoption in Q3 2022.