# TOWARDS
# A EUROPEAN HEALTH UNION
## PREVENTION, CRISIS MANAGEMENT AND MULTILATERALISM

■ Report by the Health Working Group
chaired by XAVIER PRATS-MONNE

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# MEMBERS OF THE HEALTH WORKING GROUP .

Our President, Enrico Letta, wanted to seize the opportunity of the global shockwave caused by the COVID-19 pandemic to initiate a reflection on European health within our Institute at a time when the work of the Conference on the Future of Europe was being carried out. Under the chairmanship of Xavier Prats-Monné, Councillor of the UOC (Universitat Oberta de Catalunya) and former Director General of Health and Food Safety of the European Commission, this working group focused on defining recommendations for a true Europe of Health.

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Thanks to **BENJAMIN COUTEAU**, research assistant at the Jacques Delors Institute, for his help and careful proofreading. ▪

This document has been unanimously approved by the members of the dedicated Jacques Delors Institute working group. While diverging opinions were expressed during discussions, the report is a reflection of their common stance.

# INTRODUCTION .
# THE HEALTH SYSTEMS OF THE EUROPEAN UNION, LESSONS LEARNED FROM THE PANDEMIC

COVID-19 has reminded us of an undeniable truth when it comes to shaping future European Union (EU) initiatives: **Robust and resilient health systems do not represent a cost to society. On the contrary, they are a long-term investment and a requirement for solidarity and prosperity.** Through centuries of forest fires, we have learned that emergency preparedness is neither a waste of time nor money. Every European city has a permanent fire service with readily available fire engines and aircraft. Within Europe, we now find that there is also a need to better prepare for pathogens which are easily transmitted across our borders and societies.

The Covid-19 pandemic highlighted the shortcomings of health systems across the globe. These include a lack of foresight, inadequate research and cross-border healthcare, insufficiently resilient national systems and an overall dearth of human, financial and material resources. Very few systems or institutions were prepared with respect to personnel, strategic planning, infrastructure and technology.

European countries implemented lockdown measures which were essentially similar, albeit to varying degrees of speed and performance. Many countries have been unable to use transparent health data for effective decision-making and monitoring. Most public administrations and government departments did not have functioning or practical systems to coordinate between regional, national and European authorities nor between their public healthcare and social welfare establishments.

Nothing could more starkly expose the Achilles heel of the European project than Covid-19. Over the years, the EU has acquired life-transforming powers with regard to trade, competition and macroeconomic stability. Nevertheless, citizens specifically expect political leaders –be they European, national or regional– to deliver

results in the EU's areas of lesser direct competence, such as health, employment, social welfare and education. Perhaps the clearest example of the gap between EU powers and citizen concerns is healthcare.

To address the cross-border risks that had already highlighted the importance of cooperation within the single market prior to Covid-19, the EU's only legal instrument to date was a 2013 Council decision on cross-border health threats[1]. This text was adopted in the wake of the H1N1 influenza epidemic, a decade after the first SARS coronavirus outbreak. It establishes "epidemiological surveillance rules for serious cross-border threats to health". Yet, as could be expected, such an administrative decision agreed between health ministries did not sufficiently guarantee a transparent flow of information between EU Member States. The decision also failed to ensure the coordination of mobility and trade restrictions, or the distribution of protective equipment aimed at combatting the worst pandemic since the "Spanish flu" of 1918-1919.

To some extent, all of this was inevitable. A common European demos lacks the robustness to give EU institutions the legitimacy to make difficult societal decisions. At the same time, though, these public policies have a strong national cultural and historical component, and any attempt to harmonise this would be unrealistic and most likely counterproductive. That said, in response to health threats, **the benefits of solidarity between countries united by a shared border and values should be clear for everyone to see.** How can we convince citizens that the EU matters for them, if we cannot ensure their health and well-being?

After a difficult start, the EU proved its added value by cementing its global leadership position in Covid-19 vaccination, even if the pandemic is not yet under control either in Europe, with several countries lagging behind, or the rest of the world, where vaccine access is still far from guaranteed.

Since spring 2020, the initiatives proposed by the European Commission (hereafter "the Commission") chaired by Ursula von der Leyen are by far **the boldest in the history of EU health policy.** They include: a multi-annual "EU4Health" healthcare programme[2] with more substantial resources than in previous years; a "Pharmaceutical Strategy for Europe"[3]; a new Europe's Beating Cancer Plan[4]; a

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**1.** Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health.

**2.** European Commission (website), "EU4Health 2021-2027 – a vision for a healthier European Union".

**3.** European Commission (website), "A pharmaceutical strategy for Europe".

**4.** European Commission (website), "A cancer plan for Europe".

European Health Data Space; and a set of measures to strengthen health crisis preparedness and response capabilities which includes an all-new European Health Emergency preparedness and Response Authority (HERA).

**Against this backdrop, a fully operational European Health Union is within reach;** the pandemic response has raised hopes of effecting real change.

At a time when the Union is considering its own future, our working group does not claim to provide a conclusive and comprehensive response to the far-reaching and complex challenges that Member States and the European Union institutions are facing. Nonetheless, we hope that our recommendations will provide guidelines and food for thought in the development of a more ambitious health policy.

**Based on an analysis of the proposals put forward by European institutions, this report is consistent with calls for more integration made by the "European Citizens' Panels"[5]** organised as part of the Conference on the Future of Europe. Initial findings are expected in spring 2022, led by the French Presidency of the Council of the European Union. The panels make health a top priority for citizens who single out the importance of mental health and the connection between health and the environment. In particular, citizens express a need for:

- Strengthened EU health systems, ensuring healthcare access for everyone;
- More EU-coordinated investment in health research, particularly in relation to the EU's ageing demographic profile;
- Measures to promote health literacy, healthy lifestyles and diets as well as a more preventative public health approach.■

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# 1.

## TOWARDS A EUROPEAN HEALTH UNION

## 1.1 . Shifting the paradigm

At present, the EU's health systems must meet a threefold challenge. First, a demographic challenge in light of an ageing and increasingly vulnerable population, particularly with migrants who can carry atypical diseases. Second, an epidemiological challenge, linked to the effects of climate change and extended social risk through disease, retirement, unemployment and exclusion. Third, a scientific challenge with advances in leading-edge technologies and digital applications (remote consultations and surgical interventions, etc.).

Faced with these developments and societies' common goal to increase life expectancy and extend good health, we must **transition from a "right of access to healthcare for all" to a "right of access to good health for all".** To this end, health systems must evolve from downstream management of disease risk to overall health management. This starts from an early age and continues throughout life by adopting primary (diet) and secondary (screening) preventative measures. The new European health models must take action on all health determinants whether medical (health systems) or non-medical (individual behaviour, environment, socio-economic data). Together, such factors impact the system's financial sustainability.

The pandemic should encourage Member States to address an age-old problem which is now assuming new importance: the insufficient levels of investment (in absolute and relative terms) in health promotion and disease prevention (2.8% of total average health expenditure, representing €82 per year per capita)[6]. **Strengthening primary healthcare and preventative measures in Member States** is essential, not only as a key driver of performance and public health resilience but also in ensuring continuity of care. This also requires investment in the recruitment and training of healthcare workers and in health system capabilities, as well as an effort to upgrade the status of healthcare work and to address gender inequalities in health systems and policy development.

**Moreover, the EU has always been an advocate of multilateralism and global governance;** whilst the rise of populist ideology in recent years makes the task at hand difficult, the Covid-19 crisis clearly demonstrates the relevance of this European ambition. Indeed, no political science treatise could make a more convincing case for strong European solidarity and improved global governance than the

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[6]. European Commission, Eurostat, "3% of healthcare expenditure spent on preventive care", 18 January 2021.

Covid-19 pandemic. Do we still need to prove the merits of cross-border cooperation in the aftermath of the wildfire spread of coronavirus and on the back of the extraordinary success of global scientific cooperation in developing several vaccines in record time?

## 1.2 . Setting a high level of ambitions

In the context of this paradigm shift, **a number of arguments plead for broader initiatives at the European level.** The EU is in a position to support the transition to health systems that focus not only on healthcare but also on prevention, research and innovation. The priority now lies in managing new systemic pandemic and ecological risks which cannot be tackled exclusively at national level. Instead, Member States must build on a shared vision with a fully integrated approach and more robust shared tools and instruments. Lastly, sustainable health systems require the development of a European strategic plan which includes inventories, diversified supply chains and innovation.

The EU and its Member States must show ambition in their efforts to increase their self-reliance, contribute to inclusive growth and develop a multi-sector plan that incorporates human health, animal health and overall environmental status, with a focus on two main cross-sector approaches: "*One Health*" and "*Health in All Policies*". The Union and its Members must also play a strategic role in global governance, which involves strengthening and improving the position and resources of the World Health Organization (WHO).

**This does not mean that health system organisation or healthcare delivery, which are both national tasks, should be decided at the European level.** Member States should still be primarily responsible for setting prices and reimbursing medicines, for instance. However, despite the diversity between countries, there is a threshold effect at EU level regarding public health organisation which meets relatively consistent standards. **Plans to tackle major health threats** or to focus on environmental health must be discussed and researched with the development of joint plans and shared tools.

At the time of writing this report, a number of European Commission proposals remain under negotiation with the European Parliament and the Council of Ministers. The final outcome is still uncertain. **There is a genuine risk that the inertia of the past combined with some Member States' reluctance will reduce**

**the level of ambition and limit the impact of the proposed new instruments and measures.**

The purpose of this report is to call on European and national decision-makers to press ahead and develop a "European Health Union" as part of the Conference on the Future of Europe, since health is a strategic factor in delivering economic growth, sustainable development and social equality.

## 1.3 . Stepping up political commitments

Health policy gained importance in the Treaty on the Functioning of the European Union (TFEU). In the Treaty's Article 168.1, it is stated that "*A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities*".

Furthermore, the performance, affordability and adaptability of national health systems are analysed in each cycle of the "European Semester", the framework used since 2014 to coordinate economic policy in the EU. This framework presents considerable opportunities to encourage and support structural health reform with regard to Member States' various economic, social and fiscal policies.

Based on the Commission's recent proposals, this report shows that **the Union's legal instruments and financial tools provide ample flexibility and unprecedented opportunities for reform.** A case in point is *NextGenerationEU*[7], the largest ever financed recovery package aiming to rebuild Europe in the post-Covid world.

Admittedly, one of the lessons learned from the pandemic could suggest the need to strengthen the constitutional powers of the EU in the field of healthcare. **What we really need, though, is to strengthen the political will of Member States, European institutions and the key healthcare stakeholders, in order to deepen their cooperation and strengthen their solidarity through concrete actions.** What really matters is not so much legal jurisdiction but rather relevance and outcomes: the prime concern is not determining who has the right to act but rather who provides added value for citizens.

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[7]. European Union, NextGenerationEU (website).

Taking into account the provisions of the Treaties, the balance of power, the constraints and the uncertainties surrounding any change in this area, our group takes a realistic approach and focusses on the remit of the existing EU treaties. Therefore, we outline ways of making the best use of the wide range of instruments already available to the EU. We provide recommendations for progress in sectors considered a priority by the Union and we urge European leaders not to set aside their promises once the crisis abates.

The proposals put forward in recent months are ambitious, and those to come must be equally bold. For Member States and European institutions, the cornerstone issue now lies in implementing a fully-fledged European Health Union and in contributing to better multilateral governance. ▪

# 2.

## HEALTH AS AN INVESTMENT IN THE FUTURE OF EUROPE

## 2.1 ▪ The challenges

Healthcare can and should be a sector that drives growth, inclusion and jobs. Health spending is a long-term investment that seeks to develop robust and resilient health systems both in terms of prevention and innovation, in areas such as e-health and new therapeutic approaches. The digital transition and artificial intelligence (AI) must drive the transformation of healthcare assessment and research as well as epidemiological surveillance, clinical optimisation and the development of more patient-centred models. The G20 held in Rome on 31 October 2021 rightly insisted on the urgent need to develop inclusive and resilient health systems and ramp up investment in health[8].

The EU can mobilise various drivers to harness its potential. These include: academic and applied research, innovation, development cooperation and industry –comprising international corporations and many innovative laboratories and startups. Where there is promising progress in research, these organisations are called upon to join forces with multinational companies as evidenced in the BioNTech-Pfizer partnership. That being said, there is a need for closer collaboration between research and production.

Industry is reluctant to invest in sectors or treatments considered either too risky or commercially unprofitable, such as older medicines which still have high added value for patients but are now off-patent. In this regard, the EU must urgently reduce its dependence by developing fully secure supply chains.

Though admittedly its resources are limited, the EU has the capabilities to reduce inconsistencies between Member State health systems. For example, the EU could share best practices, provide access to innovative methods and ensure consistent healthcare information systems. Another top priority is the development of an approach that integrates human health, social policy and environmental quality. This would make it possible to tackle social inequalities, which in turn, cause health inequalities. Such inequalities are substantial between countries and population groups, as highlighted in the latest report of the European Institute for Gender Equality (EIGE) published in October 2021[9].

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**8.** G20 Rome Leaders' Declaration, 2021.
**9.** EIGE, Gender Equality Index 2021: Health, 28 october 2021.

## 2.2 ▪ The response of the EU institutions

The proposals unveiled by the Commission in recent months are ambitious and will provide the Union with large-scale healthcare instruments and resources.

With investment of €5.3 billion earmarked for 2021-2027, the new European healthcare programme, "*EU4Health*" has set several objectives: ensure fair and affordable availability of medicines; consolidate health systems through better cooperation; share high value-added initiatives and tools across Europe; and strengthen the "***One Health***" concept in an endeavour to boost the resilience of national health systems with a focus extended beyond pandemic preparedness. Announced in February 2021, **Europe's Beating Cancer Plan,** with funding of some €4 billion, defines a new EU approach to prevention, treatment and care. In June 2021, the Commission launched the Knowledge Centre on Cancer which is the Plan's first flagship initiative.

The *EU4Health* programme also allows for the introduction of European initiatives based on the ***European Reference Networks* (ERNs) model for rare diseases**[10]. The latter allows for cooperation between EU healthcare professionals and hospitals in research and patient treatment. Initiated in 2017, the first twenty-four European networks have achieved some noteworthy successes: supportive networking, discussions, medical and scientific collaborations, development of shared practices. Yet the ERN also suffer from weaknesses which reflect broader challenges, namely varying levels of healthcare access, digital health and highly specialised medical and paramedical personnel coupled with regulatory differences and how data circulates and is shared.

In November 2020, the Commission adopted a **"Pharmaceutical Strategy for Europe"** to provide patients with access to innovative and affordable medicines, to support competitiveness and innovation in the EU's pharmaceutical industry and to ensure a secure supply of medicines and medical devices. The strategy is designed for the entire pharmaceutical product ecosystem and also focuses on specific medical device aspects. A review of existing basic pharmaceutical legislation to bolster the pharmaceutical industry's appeal and fight against shortages is scheduled for end-2022.

The **creation of a European Health Data Space (EHDS)**, also expected in 2022, will help to improve data exchange and access to different types of data to facilitate

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**10.** European Commission (website), *European Reference Networks*, "Networks".

healthcare provision and expedite research and policy development. A new joint initiative will facilitate the sharing of health data –whilst complying with data protection measures– for public health, treatment, research and innovation. There are significant disparities between countries as regards health data governance, interoperability and standardisation.

In June 2021, an agreement-in-principle was reached between the European Parliament and the European Council on the new **Health Technology Assessment (HTA) Regulation**[11]. This agreement is a major step forward in improving the availability of health policies and technologies including patient-centric, innovative medicines and medical devices which aim to provide the best value for money.

The European Institute of Innovation and Technology (EIT) is a pan-European organisation, founded in 2008 to strengthen EU innovation in several strategic sectors including health. The EIT acts as a platform for collaboration between partner institutions from academia, business, research and healthcare provision. With this in mind, the **European Institute of Innovation and Technology-Health (*EIT-Health*)**[12] can help Member States overcome the difficulty of transforming the EU's higher education, cutting-edge research and high-performing industrial sectors into new products and services.

## 2.3 ▪ Recommendations

**1/ Strengthen the European research ecosystem and the incentives to innovate in response to significant health challenges:** cancer, rare diseases, development of new antibiotics, mental health, paediatric medicines, the fight against obesity, chronic diseases, etc.

Research consortia already exist with a shared ambition to take action, but the EU can do more: **facilitate financing via public-private partnerships; develop biotechnology companies by selecting higher risk projects; create or consolidate connections between academic research, hospitals, the healthcare industry and patients; and enhance capabilities and coordination between innovation drivers.**

Several measures would help to promote innovation, translating basic research results into clinically applicable solutions: **supporting joint initiatives** (university

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**11.** European Commission, Proposal for a regulation of the European Parliament and of the Council on health technology assessment, COM(2018) 51 final, 31 January 2018.
**12.** EIT-Health (website).

hospitals, biotechnology and pharmaceutical sectors, patient advocacy groups, government funding agencies); **systematising wide-scale statistical clinical trials at the European level** (research institutes, laboratories, hospitals and Member State patients); and **creating cross-border clusters in sectors of the future** (bioengineering, immunotherapy, messenger RNA, etc.) to bring together public and private institutions and entities developing, producing and distributing biotechnological health products.

The **role and impact of the _EIT-Health_ should also be strengthened**, particularly through its involvement in the HERA Strategic Research Action Plan (StRAP) alongside the European Innovation Council (EIC) and the European Research Council (ERC), and in the future "Important Project of Common European Interest (IPCEI)" on health.

**2/ Build a European industrial base for medicines and other health products**, to reduce the EU's dependence on raw materials and active ingredients. This requires the establishment of **diversified supply chains and investment in products and sectors of the future within the EU, as well as the production of essential medicines.**

Both health products and the healthcare industry are very much globalised. As a result, the focus should shift from full autonomy to promotion of investment and innovation, identification of medicines with significant therapeutic benefits and building stocks. The Commission's "_Structured dialogue on security of medicines supply_ " _initiative_[13] can help Member States, national regulators, laboratories and research institutes to increase the resilience of pharmaceutical supply chains and to safeguard a secure medicine supply for patients in Europe.

**3/ Strengthen the EU's role in the regulation and distribution of pharmaceutical products.** This would ensure that such products are readily available to all Member States, as with Covid-19 vaccines.

Some European countries have serious difficulties in obtaining certain medicines, either for material reasons linked to the location of production outside Europe, or financial reasons, owing to the very high price of the most innovative therapies.

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**13.** European Commission (website), "Structured dialogue on security of medicines supply".

In addition to the measures provided in the legislative package on cross-border health threats (see below), there are several possible scenarios: **entrusting the European Medicines Agency (EMA)** with the **medical assessment** for the marketing authorisation of medicinal products using clinical criteria (therapeutic value) and safety criteria (benefits/risks); **developing European clinical trials** and providing for European standardisation, which to date is mostly limited to ethical aspects; and **entrusting the EMA with the potential task of overseeing emergency clinical trials.**

**European University Hospitals must be given the resources to contribute to developing new therapies as well as impact indicators on clinical practice research. Promoting agreements with the pharmaceutical industry** is an option worth considering to counter price hikes for specific innovative treatments which threaten access to healthcare across Europe (*e.g.* immunotherapies).

#### 4/ Improve digital health data.

While digital technologies are essential to improving and modernising the healthcare pathway (e-health, access, portability, indicators, telemedicine), the exchange of health data for healthcare and research purposes is still inadequate. To protect patient data and guarantee citizen confidence in the system, the future European Health Data Space must **develop a "federated data" infrastructure to enable localised storage of data which can be accessed** in various locations via a fail-safe security environment.

The EU can adopt a series of measures: **increase interdisciplinary collaboration** to showcase the value of health data through large-scale analyses and open source solutions based on the *Observational Health Data Sciences and Informatics* (OHDSI) open science community[14] model; provide leadership in **facilitating the adoption of international standards such as ORPHAcode**, the Orphanet nomenclature for rare diseases, supported by the creation of common definitions and standardised norms for data extraction; **improve the use and interoperability of health data** from various national sources (health records, medical devices, research); **ensure ethical use of data** in line with European values of inclusiveness and accessibility. The creation of a **European health cloud** could mark a key milestone, provided that the problems of data hosting, processing and use are resolved.

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**14.** Observational Health Data Sciences and Informatics (website).

**5/ Ramp up the European Reference Network for Rare Diseases (ERNs) and extend their model to other complex diseases.**

According to the principle of European solidarity for rare diseases, the maturing of ERNs –or even the expansion of this model into other complex diseases– must be firmly embedded into health systems. **In addition, reference network centres at the national level must be set up and closely connected to the European level, with contributions from patient organisations.** The system, which started up in 2017 must transition to a robust and sustainable European structure for rare diseases, following the trailblazing example of the French model. **With improved pan-European reimbursement for innovative therapies and fuller integration into national health systems,** specialists and patients can treat and be treated respectively in these reference centres under the authority of ERN-coordinated networks. The EU should ensure financial sustainability in steering these initiatives, specifically the integration of healthcare aspects, the financing of training and research on a European scale.

**6/ Enhance and build a European dimension to training for health professionals,** to tackle health crises and counter the vulnerability of public healthcare services (hospitals and residential care homes for the elderly).
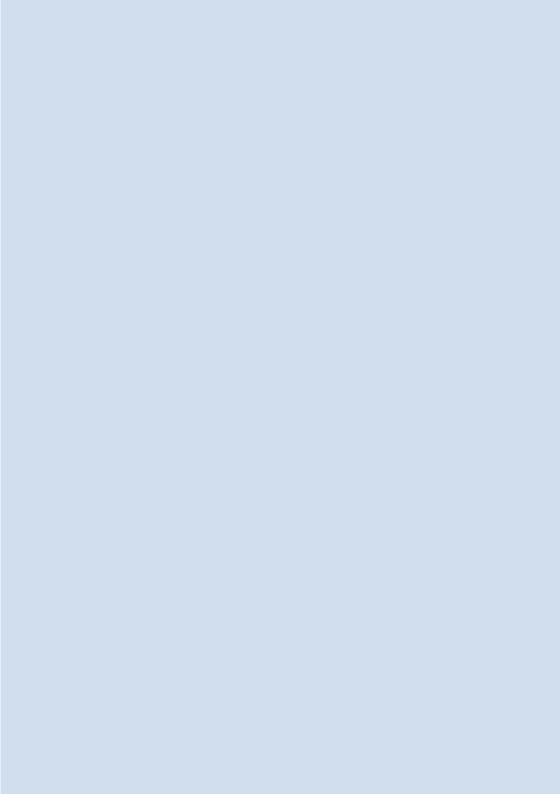
Several Member States suffer from shortages of healthcare professionals. Although, the EU's ambition is not to harmonise higher educational studies nor working conditions between its Member States, it should nevertheless **foster greater support for lifelong professional training, the development of curricula and shared skill sets for public health professionals, and mobility of postgraduate junior doctors** (via notably a "skills portfolio")**, researchers and PhD students, as well as the creation of European University networks to promote public health training** in all health care segments. It would also be important to strengthen the teaching of immunology in order to combat the lack of information or misinformation about vaccination among citizens and to increase awareness of this issue among the health professionals. The creation of a **"European Hospital" label** could simplify European funding procedures.

**7/ Support Member States' prevention policies and the comparative analysis of national health systems.**

This could be achieved by leveraging **European tools to analyse, simulate and assess the impact of policies and the return on health investments**, such as ongoing cooperation between the Commission and the Organisation for Economic

Co-operation and Development (OECD) in the fields of antimicrobial resistance and chronic disease prevention.

Another necessary measure would involve the development of **better health inequality indicators** particularly regarding vulnerable population groups, ethnic minorities and displaced populations including migrants and refugees and **on health system performance** by comparing the assessment of patients' perceived healthcare quality and outcomes. ▪

# 3.

## RISING TO THE CHALLENGE OF CROSS-BORDER HEALTH THREATS

## 3.1 . The challenges

The Covid-19 pandemic revealed that European institutions were lacking prepared-ness and response capabilities. There was no overall EU plan and no coordination of national emergency plans. Risk communication was disorganised and cri-sis-specific institutional tools were lacking, with no large-scale pan-European clinical trials adapted to the emergency. What's more, existing organisations, inclu-ding the European Centre for Disease Prevention and Control (ECDC) and European solidarity instruments such as the Civil Protection Mechanism, were under-utilised.

The Union and its Member States did not have sufficient inventories of certain medicines and medical devices. This was because of an insufficiently coordinated approach to support their development, production and procurement, combined with a lack of real-time data on demand for essential raw materials, components and products.

The experience has also emphasised the need for better communication on health and science at European level but especially on a national basis, in order to reassure citizens, combat vaccine hesitancy and to cut short the misinformation on social networks and conspiracy theories.

## 3.2 . The response of the EU institutions

In recent months, the Commission has made a number of wide-ranging proposals to lay the foundations of a European Health Union through health crisis prepared-ness and response measures.

**The proposal for a regulation on serious cross-border health threats**[15] aims to strengthen the framework for health crisis preparedness and response at the EU level. In particular, this is achieved through the development of a European health crisis and pandemic preparedness plan and the definition of requirements for national plans. It is also achieved through the following measures: rules for a strengthened and integrated EU epidemiological surveillance system; rules for health system data transmission (hospital beds, intensive care capacity, medical personnel); provisions for the appointment and financing of reference laborato-ries; and rules on the recognition of emergency situations and the activation of

**15.** European Commission, Proposal for a regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU, COM(2020) 727 final, 11 November 2020.

EU emergency mechanisms. This proposed regulation, which will spearhead new arrangements for combatting cross-border threats, must be adopted as soon as possible.

**The proposal to strengthen the European Centre for Disease Prevention and Control (ECDC)**[16] should enable the ECDC to support the Commission and Member States in various areas. These include: real-time epidemiological surveillance; strengthened planning and forecasting capabilities; development of prevention and response plans for future epidemics; capacity to mobilise and deploy an EU health operations team; strengthened surveillance and capacity assessment of national health systems with regard to communicable diseases as well as patient safety; creation of a network of EU reference laboratories for public health.

**The proposal for a regulation aimed at strengthening the role of the European Medicines Agency (EMA)**[17] in crisis preparedness and management will sustain and consolidate the measures taken during the Covid-19 crisis. On 28 October 2021, the European Parliament and the Council reached a political agreement on a revised mandate which will enable the Agency to closely monitor and mitigate shortages of critical medicines and medical devices at the time of significant events and public health emergencies. Through this agreement, the Agency will also be in a position to accelerate the development and approval of high-quality, safe and effective medicines that can treat or prevent a disease causing a public health crisis. Two steering groups will be formed to monitor the situation and inventories of certain essential products: one for medicines and the other for medical devices. A task force will facilitate the launch of clinical trials in the event of an emergency. A database to collect information on shortages should be created from an existing EMA database on health products.

Lastly, on 16 September 2021, the Commission established **a European Health Emergency preparedness and Response Authority (HERA)**[18]. Its purpose: address a range of health risks (chemical, biological, radiological and nuclear threats,

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**16.** European Commission, Proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control, COM(2020) 726 final, 11 November 2020.
**17.** European Commission, Proposal for a regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, COM(2020) 725 final, 11 November 2020.
**18.** European Commission, Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union, COM(2021) 576 final, 16 September 2021.

epidemics, emerging diseases and antimicrobial resistance). This new structure, which is a significant step forward for the European system, will be tasked with the following main responsibilities: deepening health security cooperation within the EU before and during crises (identification of threats, intelligence gathering, development of forecasting models) by uniting Member States, industry and stakeholders around a common strategy; addressing strategic vulnerabilities and dependencies in the EU regarding the development, production, procurement, inventory replenishment and distribution of impactful medical treatments, devices and equipment (e.g., supporting research through EU-wide clinical trial networks and rapid data sharing platforms); and contributing to strengthening the global architecture for health emergency preparedness and response actions. HERA should be supported by collaboration with similar national agencies, third countries, the WHO and other partners. **The Council Regulation on medical countermeasures in the event of a public health emergency at Union level**[19] will set out the critical measures that HERA can adopt under such circumstances (procurement, purchasing and manufacture of medical countermeasures, emergency funding).

## 3.3 ▪ Recommendations

The raft of measures proposed since the beginning of the pandemic will allow for better preparation and management of future crises, **provided that the final outcome of the negotiations is in line with the bold ambition** that governed the Commission's proposals, and **that HERA, as the central component in this new system, has sufficient resources to carry out its mission. Against this background, our report provides a set of recommendations.**

**8/ Bolster the role of the ECDC.** There has been inadequate implementation of the lessons learned since the 2009 H1N1 influenza pandemic at the national and European levels. There are many illustrative examples. Pandemic preparedness plans, facilitated by the WHO and the ECDC, have not been deployed at the operational level; the required structures and skills sets are either lacking or, once acquired, are not regularly put into practice and therefore not maintained. **We must bolster the role of the ECDC in several areas** if we are to deliver a more effective European response to new health threats and crises.

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**19.** European Commission, Proposal for a Council regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, COM/2021/577 final, 16 September 2021.

As regards **crisis preparedness**, based on ECDC's expertise, Member States should agree on an adequate level of preparedness as well as **on criteria/indicators which will enable ECDC to transparently assess conditions for the overall communicable disease prevention and control system** in Member States.

To gain an accurate and timely overview of the situation **in times of crisis, the ECDC should be able to provide standards for surveillance**, and to conduct **emergency public health studies** on request. The ECDC should also work closely with the Commission (including HERA) and international organisations such as the new WHO Hub for Pandemic Intelligence in Berlin. Additionally, a more stable ECDC presence in key third countries would boost the development of crisis prevention capabilities.

**9/ Mobilise additional financial resources to level up the performance of HERA**, going one step further in the arrangements agreed within the EU's budget and the Commission's administrative resources, in order to create sufficient leverage and achieve the research and development objectives.
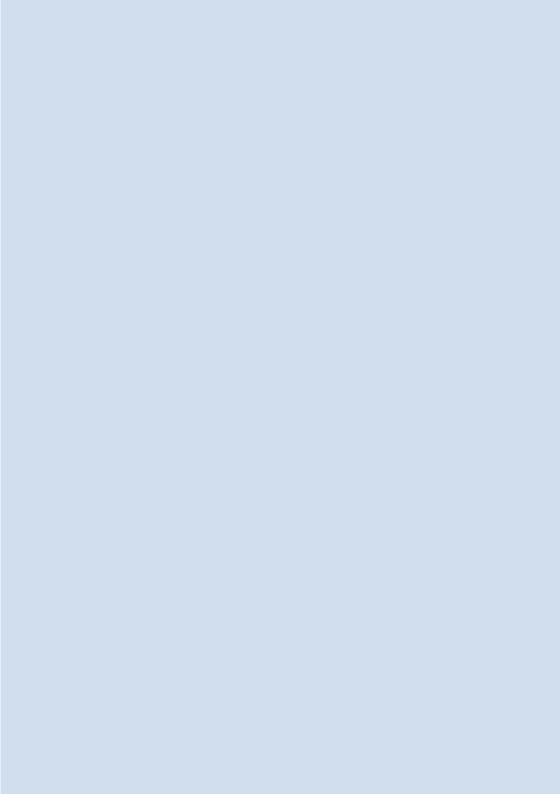
**Various instruments and mechanisms could be mobilised:** public-private partnerships, which would partner academic researchers with industry; the European Investment Bank (EIB), which has long supported research projects on infectious diseases; and the contribution of the IMI (Innovative Medicines Initiative), a public-private partnership between the Commission and the pharmaceutical industry. Leverage could also be generated through innovative national funding. The fast launch of the Important Project of Common European Interest (IPCEI) in health, which is intended to support the development of healthcare innovation, could also help.

**10/ Increase coherence and coordination at European and national levels in health crisis scenarios**, to extend efforts beyond sharing national medical product inventories. This involves two main types of measures.

First, **to identify priority strategic health products in the event of a pandemic, and to establish strategic inventories** and/or guaranteed special access to the creation of the required health countermeasures. Reliable information on shortages and inventories and agreement on what constitutes strategic materials will be critical.

Second, **to establish a national health crisis monitoring and management committee in each Member State.** The committee would comprises a group of

experts to carry out some of HERA's assignments in each EU country, alongside the governance structures provided by this new Authority (Board of Directors, network of national and regional authorities, stakeholder advisory forum, health crisis management council). ▪

# 4.

## STRENGTHENING GLOBAL GOVERNANCE

## 4.1 . The challenges

As a health working group, we seek to underline the importance of better global health governance and to make some suggestions on the potential role for Europe on the international stage. Nonetheless, this report does not claim to present a full diagnosis in this area. Other organisations have reviewed the situation in recent months and our goal is not to duplicate their work.

The May 2021 report on pandemic preparedness and response, prepared by the WHO-commissioned Independent Panel *"Covid-19: Make it the Last Pandemic"*[20], proposes several undisputable approaches going forward. These include: simplification of procedures; reinforcement of the WHO's financial independence through dedicated resources and a single seven-year term for the Director-General; and the establishment of a security council to deal with global health threats, which would be backed by the United Nations Security Council.

Other institutions have also drawnlessons from various countries' health system response to the Covid-19 pandemic, providing recommendations for investment and reform. In particular: the G20 High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response ("*A Global Deal for Our Pandemic Age*"), in June 2021 [21]; and the Pan-European Commission on Health and Sustainable Development, established by the WHO Office for Europe, in September 2021[22].

Factoring in the work carried out by the above organisations and consistent with the efforts of European institutions, our report only puts forward a limitednumber of recommendations.

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**20.** WHO, The Independent Panel for Pandemic Preparedness and Response, Main Report & accompanying work, May 2021.
**21.** Report of the G20 High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response, « A Global Deal for Our Pandemic Age », June 2021.
**22.** WHO Regional Office for Europe, Report of the Pan-European Commission on Health & Sustainable Development, "Drawing light from the pandemic: A new strategy for health and sustainable development", September 2021.

## 4.2 ▪ The response of the EU institutions

The EU is one of the largest donors in global health, both on a bilateral basis (to low and middle-income countries) and multilaterally. Between 2014 and 2021, the EU invested €1.3 billion in 17 bilateral health programmes with an additional €1.3 billion earmarked for global initiatives including the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Global Alliance for Vaccines and Immunisation (Gavi), the Global Financing Facility for Women, Children and Adolescents (GFF) and the United Nations Population Fund (UNFPA).

**Collaboration between the Commission and the WHO** is focused on a number of areas: communicable diseases; environment and health; health research and public health policy. More recently, a range of topics have been discussed such as universal health coverage, vaccination, antimicrobial resistance and air quality. The EU also works closely with other international organisations such as the OECD.

**With respect to the pandemic, the EU played a pivotal role on the international stage**, with the launching, in spring 2020, of the Access to COVID-19 Tools Accelerator (ACT-A) and its vaccines pillar, COVAX. ACT-A brings together governments, scientists, businesses, civil society, and philanthropists and global health organisations[23], qui ont décidé d'appuyer la mise au point et la production de tests de diagnostic, de traitements et de vaccins contre le Covid-19.

Against the backdrop of the pandemic, the EU confirmed its status as a continent that produces (the first regarding messenger RNA) and exports vaccines to the rest of the world. The Union also featured prominently at the G20, particularly at the Global Health Summit which took place in Rome in May 2021. As things stand, the EU has exported more than half of the approximately 1.2 billion vaccine doses produced in Europe to other countries around the world. This figure is equal to the amount delivered to its citizens. The EU with its Member States is one of the leading contributors to COVAX having pledged over €3 billion. The facility is designed to help secure access to donor-funded vaccine doses for 92 low-income economies. The Commission is also working with industrial partners who produce vaccines in Europe with a view to making doses available to low and middle-income countries. At the Global Health Summit held in Rome on 21 May 2021, these industrial partners

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**23.** The participating global organisations are: the World Health Organization (WHO); the Coalition for Epidemic Preparedness Innovations (CEPI); Gavi; the Global Fund to Fight AIDS, Tuberculosis and Malaria; Unitaid (the global medicine health agency); the Foundation for Innovative New Diagnostics (FIND); the Wellcome Trust (a global charitable foundation active in healthcare); the World Bank; the Bill & Melinda Gates Foundation (BMGF).

committed to providing 1.5 billion vaccine doses by end-2021 for non-profit to low-income countries and at lower costs for middle-income countries. They also pledged 1.5 billion doses for 2022, a figure which still falls extremely short of the required levels.

Furthermore, discussions are underway to develop **a long-term project for an International Treaty on Pandemics**. The initiative was kick-started by European Council President, Charles Michel, at the G20 summit held in November 2020. The purpose of the Treaty is to ensure universal and equitable access to vaccines, medicines and diagnostics for pandemics and to make vaccination "a global public good"[24].

## 4.3 . Recommendations

**11/ Develop a strategy to strengthen the EU's role in global health governance.** Meaningful engagement on the world stage is justified through the consideration of global health as an internal security issue and a driver of inclusive growth. The EU requires a fully developed global health strategy if it is to exert its influence on decisions made at the international level. The Union must not only provide financial resources to global organisations, it must go one step further and invest in such organisations' governance to be the voice of European citizens.

The EU will need to increase the understanding and visibility of European health cooperation initiatives. This could include the adoption of **a strategic approach towards multilateral institutions** such as the G20 and third-country health agencies as well as the consolidation of the EU's positioning in relation to the Global Health Security Agenda (GHSA). It will also require a more proactive communications stance on third-country initiatives.

Institutional avenues could be explored. These include the development of **European mechanisms for analysing global trends** in collaboration with other international organisations such as the OECD and the WHO. More consideration must also be given to the monitoring and warning activities conducted by citizen networks on global health issues and trends.

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**24.** European Council, Press release, " 'COVID-19 shows why united action is needed for more robust international health architecture' – Op-ed article by President Charles Michel, WHO Director General Dr Tedros Adhanom Ghebreyesus and more than 20 world leaders", 30 March 2021.

The EU must take centre stage in the ongoing discussions within global organisations in an effort to strengthen preparedness and response to health emergencies. Global health discussions for all Member States must be further informed. We also need to learn from the lessons of the pandemic to accelerate and facilitate governance and decision-making within the WHO. A global health strategy must extend its focus beyond health support for low-income countries. This means that Europe needs to adapt its strategy to forge new types of partnerships, notably with regional organisations such as the African Union.

**12/ Link healthcare performance to Sustainable Development Goals (SDGs) and strengthen the EU's role in fighting climate change as a health factor.** This particularly applies to SDGs which are directly related to health (good health and well-being, clean drinking water and sanitation and reducing inequalities) and help to reach these goals[25]. The EU should step up its commitment to ensuring universal and equitable access to safe drinking water and access for all to adequate and equitable sanitation and hygiene services as well as improving water and air quality by reducing pollution and chemical discharges, and increasing child healthcare access.

The EU should also **highlight and advocate the importance of the *One Health* approach** to health security and pandemic preparedness, as evidenced by the international initiative, PreZode, which aims to prevent the emergence of zoonotic infectious diseases[26].

**Promoting universal health coverage worldwide by building on existing EU mechanisms** would improve well-being for all but also reduce health threats and migration crises which have an impact on European health and health systems.

**The EU must ensure that international cooperation mechanisms are developed to facilitate universal access to innovative health products**, including those developed under the new HERA.

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**25.** United Nations, Sustainable Development Goals (website), "17 Goals to Transform Our World".
**26.** Launched at the *One Planet Summit* for Biodiversity organised on 11 January 2021 and spearheaded by Emmanuel Macron, the international initiative PreZode (Preventing Zoonotic Disease Emergence) aims to prevent the risks of emergence of zoonotic infectious diseases and pandemics. It will support the integration and strengthening of human, animal and environmental health networks, in line with the "One Health" concept, in order to better assess and detect the risk of emergence of zoonotic infectious diseases and to develop preventive actions with all stakeholders to protect humans, the planet and socio-ecosystems, thereby reducing the risks of pandemics.

Furthermore, the EU should support the global transition towards sustainable agri-food systems through its trade policies and international cooperation instruments. **The Farm to Fork** initiative, which was unveiled by the Commission in May 2020[27], may form the basis of a global strategy. Its purpose: ensure food security, nutrition and public health, making sure that everyone has access to sufficient, safe, nutritious, sustainable food. To this end, implementation needs to be supported by a legislative **framework for sustainable food systems** to foster the development of a sustainable food policy as well as a contingency plan for ensuring food supply and food security.

**With regard to climate change, European health systems could lead by example** by reducing their carbon footprint and developing more eco-friendly practices. In this context, the EU could work hand in hand with other organisations such as the OECD and the WHO to measure progress. ▪

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**27.** European Commission (website), "Farm to Fork strategy for a fair, healthy and environmentally-friendly food system".

# CONCLUSION .

THE main responsibility for health policies –and indeed education and employ-ment– will continue to be borne by Member States; the diversity of situations within and between countries will require a differentiated approach.

Nonetheless, the European dimension of health can be strengthened. Member States and EU institutions are in a position to take meaningful action, even in the EU's limited areas of expertise. The worst way to address Europe's challenges –ranging from climate change to pandemic threats– would be for countries within the EU and the rest of the world to take uncoordinated action.

It is today, and not in some distant future, that a "European Health Union" needs to become a reality[28]. It would be a tragedy if the Union and its Member States lacked the strength to learn from the lessons at the start of the Covid-19 pandemic because of insufficient coordination. Equally, it would be a shame if we did not build on the vaccine strategy, which is one of the clearest demonstrations of European added value and solidarity.

Time will tell, as the social and economic impact of Covid-19 takes its toll, whether Member States and EU institutions will be able to develop and implement effective common policies in areas of limited EU competence such as health. Member States' initial reluctant reaction to the Commission's bold proposals on a European Health Union already signals the challenging roadmap ahead.

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**28.** European Commission (website), "European Health Union. Protecting the health of Europeans and collectively responding to cross-border health crises".

The Conference on the Future of Europe is the perfect opportunity for European citizens to debate Europe's priorities and the challenges that lie ahead. Health is one of the main discussion items as part of a panel which also focuses on the environment and climate change. This event could prove to be an opportunity to fulfil citizens' expectations and to strengthen the EU's expertise, or even to amend the Treaties with enough political agreement to introduce a new legal basis enabling the EU to take swifter and more effective action on public health policy.

The EU's credibility will depend on its political commitment to shaping and practising narrative on sustainable development that addresses inequalities and ensures the well-being of its citizens. The task at hand is difficult, but not impossible and it will be all the more necessary in the post-Covid world. It is a social contract in which quality of life and distributive goals will have a greater influence on the European project and its overall impact.

The only way to meet these challenges is by establishing more extensive interdisciplinary and cross-border cooperation with a considerably increased role for knowledge, science and the social sciences. Whilst healthcare, science and technology are making huge strides forward, there is also growing scepticism towards health and science, which includes vaccination.

If we seek reassurance that a better and more inclusive future for Europe is possible, we need only consider that the post-war economic reconstruction of Western Europe was not based on natural resources but rather on intangible assets –namely people, their talent and their positive attitude towards personal development. ▪

## ■ RECOMMENDATIONS

1. Strengthen the European research ecosystem and the incentives to innovate in response to significant health challenges.

2. Build a European industrial base for medicines and other health products.

3. Strengthen the EU's role in the regulation and distribution of pharmaceutical products to ensure that such products are readily available to all Member States.

4. Improve digital health data.

5. Ramp up the European Reference Networks for Rare Diseases (ERN) and extend their model to other complex diseases.

6. Enhance and build a European dimension to training for health professionals.

7. Support Member States' prevention policies and the comparative analysis of national health systems.

8. Bolster the role of the European Centre for Disease Prevention and Control (ECDC).

9. Mobilise additional financial resources to level up the performance of the European Health Emergency preparedness and Response Authority (HERA).

10. Increase coherence and coordination at European and national levels in health crisis scenarios.

11. Develop a strategy to strengthen the EU's role in global health governance.

12. Link healthcare performance to Sustainable Development Goals (SDGs) and strengthen the EU's role in fighting climate change as a health factor. ■

# ANNEX .

The Jacques Delors Institute is a think tank created to further European integration. Founded by **Jacques Delors** in 1996 under the name Notre Europe, its work draws inspiration from Delors' unifying voice for the continent. Its Paris-based team works closely with the Jacques Delors Centre (Hertie School) in Berlin, founded in 2014, and since 2020 with Europe Jacques Delors in Brussels, with the shared motto of thinking Europe.

The **twofold vocation** of the Jacques Delors Institute is to stimulate, build up and disseminate ideas to unify Europe, based on analysis and insights, and to inspire and foster citizen dialogue on European construction. To do so, our think tank is placed at the crossroads of the academic, political and media worlds, with which it dialogues and interacts, as does the Jacques Delors Energy Centre which develops our expertise in this booming field.

The Jacques Delors Institute disseminates a range of **publications** covering the major issues of European integration. Our reports are benchmark studies on major themes and aim to clarify their challenges and propose strategic guidelines. Our policy papers analyse European issues to put forward realistic recommendations and new avenues. Our briefs present the keys to understanding European issues, as do our monthly infographics. Our blog posts give a specific review of a topical subject.

The Jacques Delors Institute organises many citizen dialogue **events** aimed at the general public, conferences and webinars on current themes (Euroquestions) and expert seminars. Members of our team and our various bodies are regular speakers at events and in the media, in France and other countries. Since 2017, the Académie Notre Europe has been providing citizen training on the EU to young people from all walks of life.

**Enrico Letta**, Secretary of the Italian Democratic Party and former Italian Prime Minister, has been President of the Jacques Delors Institute since 2016, following on from **António Vitorino**, **Tommaso Padoa-Schioppa**, **Pascal Lamy** and **Jacques Delors**. Our Director, **Sébastien Maillard**, leads a European team of around fifteen members.

The governing bodies of the Jacques Delors Institute comprise high-profile European figures. Our **Board of Trustees** takes care of our moral and financial interests. Our **Board of Directors** is responsible for the management and direction of our works, monitored by our Bureau.

Our activities can be accessed free of charge, in French and English on our **website** and are promoted on **social networks** and through our newsletters. The Jacques Delors Institute is wholly independent of any political influence or economic interests. ∎

The Covid-19 pandemic reminds us of the indisputable reality that must guide the European Union's future action: strong and resilient health systems are not a cost to society, but a long-term investment and an imperative for solidarity and prosperity. A true Europe of health can be achieved, provided that all actors show sufficient ambition: it is to seize this opportunity and to feed the reflections in this field that the Jacques Delors Institute has set up, in spring 2021, a working group on the future of the European health policy. Based on an analysis of the proposals presented by the European Commission and the positions taken by the main international bodies, the group is working within the framework of the existing European treaties and is putting forward twelve recommendations for making the best use of the vast range of instruments available to the Union, based on three main pillars: prevention, crisis management and multilateralism.

# TOWARDS A EUROPEAN HEALTH UNION
## PREVENTION, CRISIS MANAGMENT, MULTILATERALISM

Report the Health Working Group
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