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## **NOTE**

From:	General Secretariat of the Council	
To:	Council	
Subject:	Employment, Social Policy, Health and Consumer Affairs Council session on 15 June 2021	
	Global Health initiatives	
	- Information from the Presidency	

Delegations will find an information note on Global Health initiatives prepared by the Presidency together with the Presidency Report on Strengthening the EU role on Global Health in the Annexes to this note.

This note is intended to be presented under "Any Other Business" at the meeting of the EPSCO (Health) Council on 15 June 2021

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# Global Health | EPSCO 15<sup>th</sup> June 2021 | Luxembourg

## Strengthening the EU role on Global Health

## I - Background

Since the Working Group on Global Health was launched under the Finnish Presidency as a multi-Presidency initiative, the political dimension of global health has increased substantially.

The EU and its Member States have worked to developed a strong coordinated response to the COVID-19 pandemic and, together, have played an active role in highlighting the potential to improve their role in the field of global health.

A stronger and more resilient EU, capable of acting in a coordinated manner and recovering from the crisis caused by COVID-19 remains a priority. This cross-sectorial approach requires a decisive and comprehensive multilateral action calling for an increased engagement involving Non-Governmental Organizations, academia, and other relevant partners.

Furthermore, COVID-19 has exposed the frailty of national and transnational health systems, placing additional pressure on the most vulnerable groups, while exacerbating inequalities and differences between communities, countries, and regions, including within the EU. Considering the economic impact of the pandemic, values which have, In the past, been considered as expenditures in health systems may be hereafter seen as investments in resources - at a human, Infrastructure and financial level.

The lessons learned highlighted the importance of EU preparedness and response capacity to face future global health crisis and how full cooperation between Member States' Health Authorities, the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) is crucial.

In this context, two important legal pillars will improve the EU's capacity to better respond to cross-border health threats and challenges: the EU4Health Program, with a significant increase of financial resources within the new Multiannual financial framework and the European Health Union package, reinforcing the mandates of ECDC and EMA, and improving health security and protection.

## II- The Report and the way forward: Strengthening the EU's role on Global Health

The Report considers the outcome of all the work related to the role of the EU on Global Health led by the Portuguese Presidency during the first semester of 2021.

Additionally, it includes the new legal proposals in the public health domain and the coordinated response to the pandemic, developed in close cooperation with the Commission, which will contribute to strengthening the role of the EU in global health in the future.

This consolidated work aims to provide some guidance and topics where further discussion shall be continued by the next Presidencies to define the way forward and to develop mechanisms, operational

procedures, and working arrangements aiming at improving coherence and strengthening the EU coordinated approach to address global health challenges.

Furthermore, the development and common use of the appropriate tools for data management is of major importance. A single EU tracking system to follow all the activities, both at a technical and at a political level, would be beneficial for decision-making, and access to key information available in a transparent, inclusive and accountable manner.

The development of an EU Global Health Strategy, based in a new global health governance model will improve public health with a solid cross sectorial perspective, including through the One Health approach and based on a stronger and more robust EU Health Union, counting on reinforced mandates for the ECDC and EMA.

The opportunity for the EU to improve its coordination, leadership and strengthening its role internationally has never been more timely. This pandemic is a true turning point for global health, at a time when investment in global health, as a driver of political commitment and development, is positively viewed by stakeholders.

Through constructive multilateralism and through the pursuit of strategic alliances, the EU is expected to strengthen its political influence and responsible leadership in global health.

Strengthening and reforming the World Health Organization, reviewing the International Health Regulations or future discussions related to the International Treaty on Pandemics are also important challenges that the EU will have to deal with a stronger voice in the short term.

Global health diplomacy is thus a common need. It is time to make the necessary efforts to build a permanent and common Agenda based on a Global Health Strategy in line with a stronger European Health Union.





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## Acknowledgements

This report considers the valuable contribution and reflections made by the members and observers of the Working Group on Global Health, of the TRIO of Presidencies, established during the Finnish Presidency, and the outcome of the informal discussions in this domain during the Council Working Party on Public Health at Senior Level in June 2021. It is a working document.



#### **ABBREVIATIONS**

ACT - Access to COVID-19 Tools

AMR - Antimicrobial Resistance

AU - African Union

Commission - European Commission

ECDC - European Centre for Disease Control

EDTCP - European and Developing Countries Clinical Trials Partnership

EFSA - European Food Safety Authority

EMA - European Medicines Agency

EU - European Union

EU4H - The European For Health Programme

FAO – Food and Agriculture Organization of the United Nations

FENSA - Framework of Engagement with Non-State Actors

HERA - Health Emergency Preparedness and Response Authority

IHR - International Health Regulation

LMIC - Low- and Medium-Income Countries

MS - Member State

NGO - Non-Governmental Organizations

OACPS - Organization of African, Caribbean and Pacific States

OECD - Organization for Economic Co-operation and Development

OIE - World Organisation for Animal Health

Portuguese Presidency – Portuguese Presidency of the Council of the European Union

R&D - Research and Development

R&I - Research and Innovation

SDG - Sustainable Development Goal

UHC - Universal Health Coverage

**UN** – United Nations

WHO – World Health Organization



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#### INTRODUCTION

The current report "Strengthening the EU role in Global Health" is a contribution to the ongoing reflection on the way forward, aiming at improving coherence and the EU coordinated approach to address global health challenges, making the best use of common resources internally and externally.

The report takes, as a starting point, the outcome of the Working Group on Global Health (WGGH) established in 2019 during the Finnish Presidency and led by the successive TRIO of presidencies, and the work related to global health performed during the Portuguese Presidency of the Council of the European Union (Portuguese Presidency).

It addresses the need to develop an EU Strategy in global Health, building mechanisms, operational procedures and working arrangements, consolidating information and highlighting topics for further discussion under the following Presidencies.

Furthermore, this report considers the current work at the Council on the new legislative and non-legislative health proposals and the ongoing efforts aiming at a coordinated EU response to the pandemic in cooperation with the Commission, considering that it contributes to the mandate to strengthen the EU role in global health. Additionally, it Is also in line with the valuable contributions made during the International High-Level Conference on Global Health, organized by the Portuguese Presidency on March 25, 2021. The Presidency is thus committed to continuing to contribute to the overall work of the double TRIO joint approach and objectives.

Despite all the challenges faced during the last year and the substantial progress in strengthening the coordinated approach at the technical and political levels between MS and the Commission, difficulties persist in ensuring a common EU response and in preventing unilateral measures taken on a national basis.

The Portuguese Presidency is committed to reinforcing the EU's resilience and citizen's confidence in the European social model, promoting a Union based on the common values of solidarity, convergence and cohesion, in a particularly challenging time for the EU and its MS in light of the COVID-19 pandemic.

## 1. OVERALL APPROACH AND OBJECTIVES

#### 1.1. EU OVERALL APPROACH

The multidisciplinary approach and the relation with other policies increase the need to strengthen the efforts towards a coordinated EU voice and to make the best use of the EU strategic vision and role in the international arena. The will of the Commission to strengthen the EU's united voice in the world, both at multilateral and bilateral levels, seeking new partnerships especially with Africa, is welcomed.



The ongoing pandemic, declared on March 11, 2020, by the World Health Organization (WHO), has caused an unprecedented global health crisis with serious socio-economic consequences and great human suffering.

A strong EU, capable of acting in a coordinated manner and recovering from the crisis caused by COVID-19 remains the priority.

The Council and the Commission have worked closely for a strong coordinated response and playing an active role in global health. This engagement has put, in a new way, the EU as a global health player on the world map. The involvement at the level of Heads of State and Government in the health domain has recognized the EU position and its capacity in global health, a role highlighted also by the WHO, requiring decisive action for a common response, with particular relevance to the follow-up of UN-wide decisions and actions with a multisectoral dimension.

This approach requires increased collaboration and engagement involving NGOs, academia and other relevant partners. Policy priorities, appropriate legal instruments, and the EU coordination processes in the public global health domain should be evaluated to improve the capacity, role and robust intervention of the EU and its MS in a coordinated way - internally and at the international level.

## 2. SCOPE OF EU PRIORITY ACTIVITIES UNDER GLOBAL HEALTH

Due to the wide scope and nature of global health, several working areas have been recognised as being of major importance internationally to focusing the attention of the EU with a high degree of priority. Common priority topics are the strengthening of health security and pandemic preparedness, health promotion and research, the implementation of the International Health Regulation (IHR), the fight against Antimicrobial Resistance (AMR), cancer, the access to affordable quality medicines and vaccines including disruptions in global production chains, ensuring sufficient and qualified health workforce and rising topics under the Digital Agenda (e-health, Artificial Intelligence and big data,) - as areas where the EU could take a more prominent role.

Furthermore, COVID-19 has exposed the fragility of national and transnational health systems, placing additional pressure on the most vulnerable societies and exacerbated inequalities and differences between communities, countries, and regions. In the EU, the urgency to better respond to the European and global challenges lead to the adoption of the EU4H Programme for 2021-2027 in March 2021, with a substantial increase of the financial envelope, a budget of €5.1 billion and including several priority areas relevant in global health.

# 2.1. PANDEMIC PREPAREDNESS AND RESPONSE IN THE CASE OF PUBLIC HEALTH EMERGENCY OF INTERNATIONAL CONCERNS

For the first time in the EU, crisis management has required strategic coordination of all health measures involved in crisis response and its communication: from diagnosis to research, from

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preventive health actions to protective equipment and medical devices, from the development, authorisation, purchase and distribution of vaccines - quality, safe and effective - to genome testing and sequencing or, finally, actual vaccination in the field. Pandemic preparedness and response have since last year become the priority, both at the EU and global levels. The EU has been managing a coordinated action with MS and the Commission in close cooperation with the relevant European agencies - the ECDC and EMA — for a harmonised COVID-19 response strategy, implemented in a coordinated manner, down to local level, throughout the territory.

The EU challenge is to improve the delivery of national health services, to equip and optimise their human and financial resources in preparedness and response, and to improve the EU's role on the external front, notably in international cooperation and assistance, in particular with the WHO, and with other partners at the multilateral level. The resilience of stronger health systems will continue to be a priority for the EU.

#### 2.2. ONE HEALTH APPROACH

One Health approach has been considered a common priority at all levels of international discussions. The EU has recognised the importance of **AMR** and health threats posed by climate change impact, notably **vector-borne zoonotic diseases (VBD)**.

The EU strongly supports the orientations of the tripartite One Health strategy of the WHO, the World Organisation for Animal Health (OIE) and the FAO, along with the strengthening of public health and veterinary services mechanisms to enable its implementation, contributing to animal and environmental health in the protection of public health.

In view of the threats posed by emerging and borderless diseases originating from animals and vectors in the environment, prevention and control measures respecting the One Health approach still need to be implemented on the ground.

Furthermore, the EU health systems, following the WHO-OIE-FAO tripartite approach, need to be more engaged in the fight against AMR and infection prevention. Global and accountable Governance Leadership on AMR is needed and should be put in place both at a national, regional and global level.

From a global perspective, it is necessary to adopt multi-disciplinary approaches and intersectoral collaboration between entities - whose missions are to guarantee human, animal, and environmental health - as a guiding pathway to sustainable development.

## 2.3. E-HEALTH - THE DIGITAL TRANSITION, A NEW ERA

Digital is at the top of the EU political agenda, at both horizontal and sectorial levels. It is fundamental to accelerate the digital transition as a driver of economic recovery in the context of the COVID-19 pandemic, whilst promoting European leadership in digital innovation.



Digital transition of national health systems and European cooperation is vital to strengthening the EU's resilience in response to cross-border public health challenges, as COVID-19, and therefore, to strengthen global health.

Capacity building in digital health has a multisectoral and global approach, focusing on people, technology, and processes. E-health has the potential to promote health literacy, cross-border cooperation, and interoperability of national data systems, as well as infrastructures that can boost digital transformation of the internal market.

Moreover, e-health is a crucial area and a useful instrument in health diplomacy used in development and cooperation policy, where the EU can contribute for the benefit of society and to the rest of the world.

#### 2.4. ACCESS TO MEDICINES AND VACCINES SOLIDARITY MECHANISM

Access, availability and affordability of safe and effective medicines and vaccines to everyone are a pillar of the EU health policy and in line with the Universal Health Coverage objective. The Access to COVID-19 Tools (ACT) - Accelerator, including its vaccine pillar COVAX, will need to reach the in-need priority countries. In addition, an established mechanism to facilitate structured EU support on personal protection equipment, diagnostic tests, medical oxygen/ventilators and other relevant materials should be in place and reinforced. The EU strategy for vaccines against COVID-19 aims to accelerate vaccines' development, production, and distribution, as well as to ensure equitable access to vaccines for all. The capacity to manufacture active substances is critical to prevent, manage and mitigate shortages and disruptions in its supply chain.

At the multilateral level, the EU aims to enhance regulatory cooperation and, where possible, within the International Pharmaceutical Regulators Programme and the International Coalition of Medicines Regulatory Authorities. The EU chairs the International Coalition of Medicines Regulatory Authorities (ICMRA), which has allowed, during the pandemic, to significantly expedite and streamline the development of COVID-19 vaccines and treatments. The global regulators also cooperate under the umbrella of ICMRA on common challenges. The need to facilitate the implementation of interoperable systems for tracking and tracing medicines around the world is one recent example to illustrate cooperation where the EU may have a stronger voice.

Research priorities must be geared to making the biggest impact on public health. Access and innovation need to be addressed simultaneously, to increase the access, availability and affordability to essential medicines, including vaccines. Generic competition1 and rational use of medicines is of major importance to ensure the sustainability of healthcare systems<sup>2</sup>.

<sup>1</sup> COM (2009) 351 of 08.07.2009

<sup>2</sup> COM (2008) 666 10.12.2008



## 2.5. EU BEATING CANCER PLAN AND TRANSNATIONAL RESEARCH COOPERATION

The fight against cancer requires bold action from all countries - particularly in the current context, in which the COVID-19 pandemic has seriously affected the response to cancer. The Portuguese Presidency promoted the continued implementation of Europe's beating Cancer Plan and organised a Cancer Research Summit in Porto, Portugal.

Transnational research bridges with preclinical, clinical and prevention research builds on innovation and requires international scientific cooperation to bridge, a priority key area under global heath perspective.

## 3. THE MULTILATERAL APPROACH: THE EU IN THE INTERNATIONAL FORA

Since the WGGH was launched as a multi-Presidency initiative, the political dimension of global health has increased substantially and attention is paid to the new interface, reshaping the geopolitical perspective of the EU actions at global level.

Through constructive multilateralism and pursuit of strategic alliances, the EU is expected to strengthen its political influence and responsible leadership in global health. Likewise, a stronger EU voice is required at International level.

The effective mobilisation of all EU solidarity mechanisms deserves our priority: strengthening national health systems around the world in line with international health standards, through the mobilisation of global funds, as well as in the pursuit of sustainability of continuous healthcare coverage in an accessible, affordable and universal manner.

#### 3.1. THE UN AGENDA 2030

The EU and its MS stand strongly behind the 2030 Agenda for Sustainable Development and its Sustainable Developments Goals (SDGs), which continue to guide the actions taken by the EU and its MS. The work developed under the 2030 Agenda for SDGs shall be considered as the effort for the MS call for a comprehensive EU strategy for the implementation of the 2030 Agenda.

Moreover, the EU puts upfront health as a Human right. It is of increasing importance that the EU speaks with one voice, not only for the way the EU is perceived as a community from the outside but also as a defender of the respect of the rule of law and Human rights.

COVID-19 exposed all countries' vulnerabilities to achieve the UN Agenda 2030. The EU should promote a leadership role to continue to avoid silos and rather bridge a regular dialogue that provides a clear and wide view on the concrete actions taken towards the SDGs, progress achieved and areas in which further improvement or action is necessary and to step up efforts to integrate the SDGs further in a consistent and coordinated manner across policies.



During the Portuguese Presidency, the EU reaffirmed and reshaped the EU's commitment to the UN Agenda 2030 and the efforts needed to achieve SDGs globally. This new approach already addresses the impact COVID-19 is having on societies and advances a global and ambitious response. The EU, by supporting its action on multilateralism and partnerships with international partners, such as the UN, is in a position of leading the way and accelerate the process towards the SDGs achievement worldwide by pushing forward the global health initiatives aiming SDG 3 reaching, namely the Universal Health Coverage (UHC) 2030.

#### 3.2. THE WORLD HEALTH ORGANIZATION

The mandate of WHO in global health is derived from its Constitution and is further detailed in its Thirteenth General Programme of Work, 2019–2023: "Broad and sustained efforts are needed to build a community to work for the shared future of humankind, empowering all people to improve their health, address health determinants and respond to health challenges". In short, strengthening and reforming the WHO, the review of International Health Regulations or future discussions related to the International Treaty on Pandemics will be the important challenges that the EU will have to deal with a stronger voice. At the multilateral front, the EU has reiterated its support to the WHO and the organisation's coordinating role in the global public health response.

The EU has contributed to significant health improvements and advocated for <a href="health-systems-strengthening">health-systems-strengthening</a>, providing funding to the WHO to support appropriate national policy developments, as well as bilateral support to countries. Many health challenges cannot be addressed solely at a national level. Only through joint efforts between states and international organisations, with the WHO at the centre, it is possible to ensure preparedness, coordination, and capacity to respond to global health challenges and to mitigate its social-economic consequences.

The Commission has engaged with several actors seeking to align efforts, as part of the ACT-Accelerator. This unique collaborative venture integrates countries, international organisations, civil society, industry and beyond to speed up the creation of COVID-19 tests, treatments and vaccines and ensure that all these are equitably and universally accessible. The access to ACT-Accelerator and the COVAX Facility (its vaccine pillar) are powerful examples of collaboration on what can be achieved when joint forces are mobilised.

Launched in April 2020 by the EU, the **Team Europe** aims to support partner countries in the fight against COVID-19. The focus is on the most vulnerable countries and those most at risk, in particular in the EU's neighbourhood and Africa. A key aspect of the Team Europe is its capacity to mobilise resources from the EU, its MS and financial institutions. Team Europe has been at the forefront acting as one of COVAX's leading donor with a contribution of €2.2 billion. COVID-19 brought new opportunities to build upon the strong existing basis and to enhance cooperation between the EU and the WHO for better health in Africa.



#### 3.3. G20 GLOBAL HEALTH SUMMIT

The Summit was co-organised by the Italian Presidency and the Commission, aiming at collectively taking stock and agreeing on common principles and joint actions to strengthen health systems and improve preparedness and response capabilities — in the current and future health crisis.

The "Rome Declaration" includes 16 principles for future actions in promotion of global health and in fighting health crisis, reinforcing the global health architecture, the increase of vaccines production, the training and education of health professionals, and the use of new financial tools and mechanisms to ensure the resilience of health systems.

## 4. TOWARDS AN EU STRATEGIC APPROACH IN GLOBAL HEALTH

The multilateralism on health systems across the world has faced enormous challenges due to threats, underlying how urgent it is to agree on an EU position. The parallel work performed at the EU, WHO and UN levels on the topics of the global agenda, is continuing to receive high-level attention (and at G7 and G20). A common EU approach will need to be ensured to secure One Voice leadership in Brussels, Geneva or New York, strengthening the EU as a stronger strategic player.

The development of a new EU Global Health Strategy – Improving public health with a solid cross-sectorial perspective and a larger scope of involvement needs to consider building internal EU mechanisms for better coordination and the development of an EU Global Health Communication.

The European Union's influence in global health must be understood in a more proactive and broadened view, beyond processes to strengthen the WHO and crisis management of COVID-19.

Challenges persist related to the way the strong agreement reached technically in many areas is reflected and endorsed at a political level feasibly and consistently. To reach a stronger proactive and leading role, this is to be reflected in a robust EU framework in the public health domain. It is therefore widely agreed that the EU needs to find agreement on common policy positions, without prejudice of the coordinating role on the WHO reform process, by defining its policy and strategic lines and elaborating concrete road maps concerning the implementing measures jointly agreed and defined.

A future European Global Health Strategy should cover four main goals:

- In the short term, 1) to make vaccines available in the field and 2) to ensure vaccination;
- In the medium-term, to set a regulatory framework to declare vaccines as a public good and leverage the financing needed;
- In the long-term, to come out with an EU contribution to the IHR review process and international treaty on global health crisis and supporting WHO health systems strengthening mechanisms;
- A foresight perspective, to develop a forward-looking focused vision on equity for global health, both within the EU and beyond its borders, axed on the European values and capabilities.



The EU should be right in front at the technical level of the identified priority areas (Crisis preparedness and response, One Health approach: AMR and zoonotic-vector diseases, access to medicines, Digital, cancer and research) in all global health efforts worldwide.

A comprehensive approach around the building blocks of the health systems are needed, including the need to have more qualified health workers, more affordable medicines and make sure the health sector gets the financing mechanism it needs. The EU needs to contribute to longer-term capacity building, to foster resilience and sustainability of countries' health systems.

The EU remains strongly committed to the SDGs and pursuit a Universal approach to health, in line with the values of the EU. Advancing UHC through primary healthcare to meet the needs of the most vulnerable is critical in the defence of health as a global public good.

It is necessary to improve mechanisms for cooperation and coordination to be better prepared for future health crises and health systems strengthening. The implementation of the European Health Union will contribute, notably, to increase protection, prevention, preparedness and response to global health threats.

The priorities of the Portuguese Presidency regarding global health are focused on the following dimensions:

- Strengthening the EU's response capacity to public health crises, starting with the response against the COVID-19 pandemic, and progress on discussions related to the European Health Union and resilience of health systems based on the One Health approach;
- Promoting universal and sustainable access to affordable medicines and medical devices;
- Prioritising Digital Health in the framework of the digital transformation of the EU;
- Strengthening the EU role in Global Health and Health Diplomacy.

A strengthened EU role will go hand in hand with the WHO reform process, building on the lessons learned from this global crisis and the opportunities created by new digital technologies and global research.

## 5. THE EU GOVERNANCE MODEL

The opportunity for the EU to improve its coordination, leadership and strengthening its role internationally has never been better. The pandemic is a global health turning point, in a time to invest in global health, as a driver of political commitment and development.

The vision and strategy of the EU's role in global health in the coming years consider that:

- (1) the geopolitical situation and health governance systems have changed dramatically;
- (2) the EU role and capacities in internal health policy (i.e. within the EU) as well as in global health have progressed, as MS coordination capacity changed;
- (3) some challenges for the EU to live up to its potential/responsibilities in global health have persisted.



The MS are working towards a consensus, on how such an EU strategy should be built, refining the EU's role in global health considering the experience acquired with the global crisis. At the same time, strengthening the EU role in GH in the international arena also implies that the EU speaks with one voice. A wider global health architecture will be considered to adjust an EU Global Health governance model providing the needed flexibility and making the best use of the existing networks and new mechanisms.

Global health governance has an increasing recognition, including the need for intergovernmental cooperation to address health problems, the growing importance of the private sector, civil society organisations and philanthropies, and the emerging need for collective actions to create large-scale solutions to urgent health problems through shared resources. The rising undisputed power of NGOs, the power of vertical funds and new geopolitical drive impacts at a global financial decision-making level.

Together, the EU and its MSs constitutes one of the biggest financial contributors to global health. Improving EU coordination is key to both setting priorities for Global Health actions and maximising the impact of EU funding in line with EU priorities.

The EU Global Health Governance model needs to operate beyond the WHO - including all international organisations where the EU has a seat and those where only some MS are represented. This will help to strengthen the EU's influence and enable it to play a more active role at one voice in international negotiations, resulting from better articulation and shared from and between the various players.

From the experience of the pandemic crisis, the EU will be able to withdraw lessons and best practices on how to improve coordination mechanisms at different levels to strengthen the EU's positions.

A common approach and well-defined mechanisms need to be established timely to allow the EU to "speak with one voice" on international fora. The following should be considered 3:

- The development of an EU Global Health Intelligence mechanism:
- The EU Institutions and MS should have permanent access to the updated information and be regularly informed about the agenda of international organisations and global initiatives in time for them to be able to influence said agenda;
- ii) To improve the information flow among services from the EU Commission, the European Parliament, the EU council and MS to let the different actors know in a timely manner when activities are discussed and launched;
- iii) To enhance a more efficient and regular dialogue and concerted approaches between Brussels, Geneva and New York EU's voice.

3 Additional information on the wider global health architecture was prepared by the German Presidency expressing views in this context

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- Privileging soft power approaches to deal with all the **global health architecture actors** and position the EU as a *key player rather than a bigger payer*.
- i) Complementing the EU's political leadership with a "knowledge leadership" will allow the EU or when it is the case its MS:
- ii) A more active and leading role in the setting of global priorities and international negotiation;
- iii) Developing the "EU knowledge leadership" approach in global Health: Enhance the EU's capacity of accessing more information on third countries, their priorities and positions on matters that relate to the EU's global health priorities;
- iv) Increasing cooperation and coordination with MS when they are best placed to gather information, build bridges with third-country authorities and facilitate negotiations and/or are present in political fora where the EU has no seat. Relevance of the country-level information networks.
- Negotiating mandates via the implementation of a common long-term EU Strategy for Global Health approved by the Council<sup>4</sup>.

A strategy expressing the values and objectives of the EU, axed on multilateralism and providing the main guidelines to be taken into account by the EU and its MS when in international negotiations will allow the EU to "speak with one voice" often and proactively shape the global agenda.

• Revision of the **level of interaction, scope of action and mandate of intervention** of the EU  $vis-\dot{a}-vis$  its MS at international organisations and fora, with the WHO and the UN. Strengthening the role of the Commission at the WHO to an enhanced observer status like in the UN.

To improve the quality and consistency of the coordinated voice at the different EU and international *fora*, previous discussions highlighted the relevance to establish a clear guidance on the appropriate forum where preparation and discussions should take place, making best use of existing resources.

A well-structured Smart-Network-System may be re-shaped and operate considering:

## European Union / Brussels:

- Increasing the "global health share" in the EU Council WP on Public Health at Senior Level.
- Ensuring that global aspects in EU legislation and Council Conclusions across policy areas that
   are relevant to health are flagged, acknowledged, and potentially used on a global level.

## World Health Organization - Executive Board (EB):

 Representation in the EB: Change the sub-regional grouping in the European Region from a geographic grouping to a geopolitical grouping to improve the representation of EUMS in the WHO

<sup>4</sup> WPPHSL 12823/19



EB. This could enable four seats for the EU in the Executive Board and six seats for the EU in the Standing Committee. Otherwise, the EU might lose one seat in each body.

- Candidates from countries: There should be a definition of clear criteria when EU members are putting forward their candidates for EB. Or at least, the EU members could streamline the selection.
- Speaking on behalf of the EU: Within the EU group, it should be reconsidered that only the EU-Presidency or the member of the TRIO closest to EU-Presidency speaks on behalf of the EU. It might be supportive of the coherent continuity of topics and it would also help to engage the other EB members.

Finally, the development and common use of the appropriate tools for data management is of major importance. A single EU tracking system to follow all the activities, both at a technical and political level, would be beneficial to facilitate decision-making, and access to key information available in a transparent, inclusive, and accountable manner.

#### 6. GLOBAL HEALTH DIPLOMACY

Global Health is about the worldwide improvement of health due to the lack of conditions to implement effective public health policies. Global Health Diplomacy is a cornerstone for the EU's foreign policy. The EU vision for its role is axed in a strong belief in multilateralism, active engagement in coalition building and restless pursuit for global solutions. Therefore, in a volatile geopolitical context, (re)new Strategic Alliances, partnerships and ways of cooperation are envisaged to strengthen the EU position and influence in the international *fora*. Global health diplomacy is thus a common need. It is time to make the necessary efforts to build a permanent Agenda based on a Global Health Strategy in line with a stronger EU role under a new European Health Union.

The challenge to strengthen the EU role in global health, set out in the EU Strategic Agenda 2019-2024, has been greatly accelerated by the first pandemic of our time, which laid bare the fragility of national systems around the world. This political commitment made by the EU has been reiterated by Health Diplomacy, with one voice, in Brussels, Geneva or New York and the TRIO of Presidencies will keep working in this direction to ensure a robust coordinated response, keeping solidarity at the top of our principles.

The EU contribution to the WHO's reform and its leadership positioning in Global Health initiatives as ACT-Accelerator are examples of the EU's Global Health Diplomacy. However, the EU role and influence in Global Health Diplomacy and in international *fora* should be understood beyond EU-WHO relationships and the EU's leading role in the pandemic crisis management. It should be extended to:

Broadening the vision of the EU's role in global health and health diplomacy: To reinforce
the EU's commitment to the UN Agenda 2030, the Sustainable Development Goals (SDGs)
achievements and a more synergetic EU approach of Health in all Policies.



- Fortifying Diplomatic Approaches: Expand the Alliances with third countries to reinforce
  common positions in international organisations and *fora*, with special attention to Africa,
  WHO Europe Region neighbouring countries and Global South. If the EU and its MS are visible,
  strong, and unified international interlocutor, axed in solidarity principles, countries sharing
  the same grounds may defend EU positions to join efforts in the same direction.
- Forging funding Alliances: Explore funding alliances within and among EU Institutions, MS, national institutions as well as regional and international organizations (e.g. World Bank, International Monetary Fund, African Development Bank) to secure the funding to global health priorities beyond the pledging calls. Such alliances will reshape the way how global health funding is used and how the EU will be represented in some actors' governance bodies.
- Building partnerships global initiatives, civil society and international agencies and organisations: To foster the EU Global Health policy goals and benefit from their support.
- Enhancing EU-Africa Alliance: A strategic partnership, including:
  - i) Cooperation at both political and diplomatic level both bilaterally and multilaterally;
  - ii) Contribution for the alignment of goals and priorities of both EU and African Union (AU) economic and development agendas;
  - iii) Reinforce technical cooperation with Africa Centres for Disease Control and Prevention (Africa CDC) and support to the implementation of African Medicines Agency.

With the EU ambition to become more influential globally, there is an opportunity to raise the profile of global health as a strategic priority, especially in partnership with our neighbours and allies. Existing good practices demonstrate that a stronger coordinated political commitment results in a stronger position for the EU and a better allocation of funds to health across the relevant EU research, development and innovation, emergency response and humanitarian aid programmes.

Diseases have no borders and the EU needs to strengthen its role internally and internationally, Global Health Diplomacy is not an option for countries, but rather a common need.



#### 7. THE WAY FORWARD

Health is a fundamental Human right. It is a foundation for development and a sustainable development goal (SDG). From society's perspective, health is a political choice.

For the EU, the integration of the health dimension in all policies is key and is reflected in the European pillar of social rights. Furthermore, Article 168 TFEU states that a high level of human health protection must be ensured in the definition and implementation of all Union policies and activities.

The policy areas cross notably health to foreign policy, civil protection, education and social protection, food security, food safety and nutrition. This will contribute to "ensure healthy lives and promote well-being for all at all ages", i.e. in achieving the Objective Sustainable Goal 3, a shared responsibility between the Commission and the EU MS.

The current EU global health policy is more than 10 years old and the world has significantly changed since then. As the pandemic represents and imposes a turning point dealing with global health threats, the opportunity of the EU to improve its coordination, leadership and strengthening its role in global health internationally has never been better.

Considering the health impact and lessons learned from the COVID-19, it is therefore clear the need to reinforce the fragile EU legislation in the health domain to face cross-border threats. It is now the time to invest in health, as a motor of political commitment and development. Internal coordination and coherence to enable the EU to speak with one voice in different settings may be significantly reinforced based on a stronger common denominator in the health domain.

The two TRIO of Presidencies call for a more strategic approach for the EU, in line with the Agenda 2030 — with shared values and seen as a good basis for common strategic lines. Holistic, more inclusive, comprehensive, and coordinated strategies are needed to address global challenges.

The EU has the potential to take a more proactive and leading role in global health. Europe is regarded as a powerful actor, both financially and politically, in all relevant international health *fora*: it has a significant external influence and the potential to develop best practices, globally. The Union is thus expected to strengthen its influence and responsible leadership in global health through constructive multilateralism.

Achieving global health security requires a sustained, coordinated and intersectoral approach linking human health, animal health and environmental health, under the "One Health" approach. The assurance of appropriate provisions, in line with public health as a public good and under the One Health approach, are still not yet prioritised, deserving further attention. In addition, when strengthening national health systems, cross-sectoral implications, digital tools or policy areas concerning determinants of health that have been deprioritised with the pandemic and will need special attention.

The dimensions of Global Health and Health Diplomacy for the EU and its relationship with the world, are focused on the role of health leaderships in achieving UHC and progressively under the



"One Health" approach, as a response to the global challenges of climate change and its impact on zoonotic diseases, pandemic and AMR.

A stronger EU voice in global health also means the allocation of funds to health, across the relevant policy areas of One Health, research and innovation, development, emergency, and humanitarian programmes. Therefore, the development of a new EU Global Health Strategy – Improving public health with a solid cross-sectorial perspective and a larger scope of involvement, needs to consider building internal EU mechanisms for better coordination and the development of a Smart-Networking-System, making the best use of placed resources, together with a common structured EU Global Health Communication policy. The strategy needs to ensure consistency, synergism and making the best use of complementarity of global one health priority scope of activities, foreseeing consistent and resilient financing mechanisms.

Our common values related to the public health protection of EU citizens are not yet reflected in the EU public health legal framework. A stronger common Union's health policy and the progress in legal harmonisation will contribute to a coherent stronger voice at the external dimension.

A robust European Health Union will be the pillar. At this first stage, the new Commission proposals to the Council and European Parliament aim to further strengthen the EU's health security framework and to reinforce the crisis preparedness and response role of key EU agencies. This approach will contribute to a stronger science-based EU voice in global health. The adoption of this legislative package, the EU preparedness, response capacity and management of cross-border health threats, with reinforced mandates of ECDC and EMA, will be important steps in that direction.

The EU needs to make the necessary efforts to put in place a permanent, stronger and renewed European Agenda for Global Health, including a well-structured EU Global Health Strategy, reflecting its strengthen EU role in global health externally under a future robust European Health Union.

The Conference on the Future of Europe process, to look at the medium to long term future of the EU, may identify what reforms should be made to current policies, including how to develop EU policies addressing the challenges facing Europe and the changes needed.



## **ANNEXES**

#### 1. TOWARDS A EUROPEAN HEALTH UNION: LEGAL FRAMEWORK AND THE GLOBAL CONTEXT

A more robust public health legal framework will contribute to strengthen the EU policy and strategy in the health sector, and a stronger EU voice in the external context.

#### 1.1 - LESSONS LEARNED FROM COVID-19

The lessons learned from the COVID-19 pandemic have an impact on the EU preparedness and response capacity to other diseases and guiding the work towards the improvement of global preparedness for the future health crisis. Full cooperation between MS and with ECDC, EMA, and the European Commission has proved to be pivotal. Risk communication has also been crucial in the management of the crisis.

There are two new and important instruments that will contribute to improving the EU capacity to better respond to the global threats and health challenges:

- The Financial Programme of the EU4Health, aiming at building more resilient health systems in Europe.
- The European Health Union package, which will ensure better protection of citizens in normal and crisis time.

A stronger ECDC and EMA are needed to foster a higher EU role in Global Health. Furthermore, appropriate tools need to be developed and put in place to better respond to global threats and health challenges.

#### 1.2 - THE EUROPEAN HEALTH PROGRAMME (EU4Health)

The EU4Health Programme<sup>5</sup> is the new Union's Programme in the field of Health for the period 2021-2027. As a result of the pandemic context, Global Health has become part of the Union's political and technical agenda more than ever.

The Programme, as a part of the Next Generation EU recovery instrument, with a budget of 5.1 billion, complements MS policies in order to improve human health across the Union, to ensure a high level of protection of human health in all Union policies and actions and in line with the "One Health" approach, where applicable. The Programme includes the protection of people from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination between MS to address serious cross-border threats to health. At the same time, foresees the availability, access and affordability of medicines, medical devices and relevant products in crisis situations, and support for innovation related to these products.

The priority, in the future, will be the strengthening of health systems, including the health programs as the pillars to structure a sustainable implementation of health policies at field level. It implies the provision of appropriate human, infrastructures, and financial resources to face the ambitious and needs. The new strengthened European Health Programme for the period 2021-2027 will reinforce MS's capacity to improve preparedness, prevention and control of the spread of serious human infections and diseases across borders. The EU4Health implementation will have a significant Impact in the future EU role in global health.

#### 1.2.1 - Cooperation and response to health crisis

The current COVID-19 crisis has demonstrated the need for further action at Union level to support cooperation and coordination between MS. It is appropriate to establish a new and strengthened Union action program in the field of health, to improve the interoperability of MS' health systems through cooperation and the exchange of good practices. The EU4Health Program's response in matters of Global Health and Cooperation can be detailed in the following areas:

 $<sup>\</sup>frac{5}{2} \ \text{Regulation (EU) 2021/522 of the European Parliament (EP) and the Council of the European Union of 24 March 2021}{2} \\$ 

<sup>&</sup>lt;sup>6</sup> More concrete examples in: Regulation (EU) 2021/522



- 1. Cross-border threats to health: supporting coordinated publichealth measures at EU level, namely:
- Strengthen the capacity to prepare, respond and manage possible future health crises in the Union, including actions to strengthen preparedness planning and response capacity at national level.
- Strengthen the role of the ECDC.
- Strengthen the role of the EMA; and
- Create a health emergency preparedness and response authority.
- 2. Prevention, response and management of health crises: Strengthening of an effective capacity to respond to health crises, taking in consideration preventive measures to vaccination and immunization, reinforced surveillance programs, provision of health information, platforms for sharing good practices including and preparation of contingency plans and preparation exercises, in line with the "One Health" and "Health in All Policies" approaches. The Programme should contribute to the establishment of a reserve of relevant essential products in a crisis.

#### 1.2.2 - Medicines and health technologies

It is essential that patients and health systems have access to sustainable, effective, equitable medicines, affordable prices, including in a cross-border context, and that they can fully benefit of a transparent, consistent and patient-oriented medical information. The Programme should support the development of a Union system for monitoring, communicating information and notifying shortages of health technologies, in order to avoid fragmentation of the internal market and ensuring availability and affordability of these health technologies. The Programme encourages the manufacturing of medicines and medical devices in the EU, paying special attention to antimicrobials and vaccines, to fight, respectively, resistance to antimicrobial agents and diseases that can be prevented by vaccination.

#### 1.2.3.- United Nations - Agenda 2030

The Commission is committed to support MS achieving the sustainable development goals set out in the United Nations (UN) resolution of 25 September 2015 entitled "Transforming our world: the 2030 Agenda for Sustainable Development" ("UN 2030 Agenda"), in particular the Sustainable Development Goal 3 - "Ensuring a healthy life and promoting well-being for all, at all ages". Therefore, the Programme contributes to the actions taken to achieve these goals. In order to maximize the effectiveness and efficiency of actions at UN and international level, for the implementation of the Programme it is necessary to develop cooperation with relevant international organizations, such as the UN, the World Bank, as well as with the Organization for Economic Co-operation and Development (OECD). In order to increase the impact, synergies should also be sought with national organizations in the MS that are active in the field of global health.

## 1.2.4 - Budget and governance

The Regulation should enter into force as a matter of urgency and be applicable retroactively from 1 January 2021, to ensure continuity of support provided in the health field and to allow implementation from the beginning of the multiannual financial framework 2021-2027. The financial framework for the execution of the Program for the period 2021-2027 is EUR 5.1 billion (2018 prices). It increases progressively: EUR 316 million in 2021, rising to over EUR 900 million in 2027. Furthermore, it foresees the parameters for overall spending during the upcoming 7-year period: Minimum of 20% for health promotion and disease prevention, a maximum of 12.5% for procurement to complement national stockpiling of essential crisis relevant products, a maximum of 12.5% for supporting global commitments and international health initiatives and a maximum of 8% for administrative expenses.

For the first time in its history, the EU has a budget for its own health programme - EU4Health - together with a legislative agenda, to which the Portuguese Presidency is very committed, that aims to implement a European Health Union with the view to strengthening EU actions on health. The EU plays an important role ensuring cohesion among MS, but its role is even more important at the global stage fostering cooperation with other regions and organisations. Promote sustainability and social cohesion is paramount to strengthen global health both within the EU and globally.



The new EU4Health Programme will strengthen the Union's support of international and global initiatives in the field of health, including initiatives by the WHO, with a view to improving health, combating health inequalities and strengthening protection against global health threats. The initiatives will be funded by the new EU4Health programme which is a clear sign of EU's ambition on the role it aims to play in global health.

#### 1.3 - THE EUROPEAN HEALTH UNION PACKAGE

At European level, the COVID-19 pandemic has undeniable political consequences. It has demonstrated, weaknesses in the European legal and institutional framework and highlighted that the EU was not well prepared to manage public health crises of such magnitude. In the face of the COVID-19 crisis, there is a new opportunity to call for increased EU competencies in the field of health, and a growing appreciation of how many other areas of EU policy impact health and pandemic preparedness and response.

In addition, closer integration of the EU's internal health policies is also needed. Therefore, it should not only be focus on deal with pandemics. It should have a much broader scope of action and cover a wider range of global health challenges and the universal health coverage. Vaccine equity has become the key global health challenge of 2021.

Europe needs also to fine tune to health geopolitics. The call for a European Health Union by the European Commission brings an important political opportunity as its internal legal and political capacity for health immediately interacts with the EU's capacity to strengthen global health.

#### 1.3.1 - Proposal on cross-border threats to health7

Cross-border cooperation to provide access of healthcare to patients moving between MS and collaboration in the assessment of health technologies, are examples of areas where integrated work between MS has shown to have strong added value and great potential for increase the efficiency of health systems. The proposal consists of specific legislation aimed at increasing the EU's capacity combating major cross-border health threats, especially through monitoring and early warning. Combatting cross-border health threats requires good preparedness and coordinated action.

#### 1.3.2 - Proposal revising the mandate of European Centre for Disease control (ECDC)

This proposal and the one on serious cross-border threats to health are closely linked. The Regulation on serious cross-border health threats will create a more robust mandate for coordination at EU-level and the proposed EU Health Task Force, which will be set up within the ECDC in its expanded mandate, should help the agency to be better informed about the situation in countries, inside and outside the EU, giving it the additional competences for better preparedness and response to global threats.

## 1.3.3- Proposal revising the European Medicines Agency (EMA)

The European Health Union Initiative, includes an extension of the EMA mandate to prepare and coordinate responses of MS to public health crisis, also of a global dimension - a Regulation for a reinforced role for the EMA<sup>8</sup> in crisis preparedness and management for medicinal products and medical devices.

EMA's expanded mandate is aligned with international efforts to foster interoperability of regulatory solutions for public health and it provides EMA with the legal basis as well as the resources to put in place systems, which will contribute to strengthen the EU to play a more relevant role in global health. It is also clear that international collaboration is essential

<sup>&</sup>lt;sup>7</sup> 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

<sup>8</sup> 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 - 2020/0321 (COD)



to tackle cross-border health threats, such as COVID-19, and to address long-standing challenges, such as AMR, availability and access to medicines and effectively tackle the structural vulnerabilities of global supply chains.

EMA has been building capacity, promoting the EU network model and its use of mutual reliance, trust and collaboration. As a result, the European model is being adopted by other regional or continental initiatives such as the African Medicines Agency or the Eurasian Community - an expression of the EU health diplomacy.

#### 1.3.4 - Future proposal: Health Emergency Preparedness and Response Authority

The European Health Union Package will include a new agency for biomedical advanced research and development. The establishment of the HERA authority, to monitor and anticipate next health threats, will complete the new Pharma Strategy – envisaging better supply chains and ensuring the EU is able to fulfil unmet medical needs.

The new EU health initiatives – the Pharmaceutical Strategy, the European Health Union, including the expanded mandates of the EMA and ECDC, the future HERA and the European Beating Cancer Plan - will highly contribute to strengthening the EU, with a more robust role at the international level.

The revision of the current health legislative package is an essential move towards the implementation of a true European Health Union. The European Health Union must go further in coordination and, above all, in leadership to be able to better address future global public health emergencies. The European Health Union is thus essential to the EU accomplished its ambition in global health.

#### 1.4 - THE EUROPEAN DIGITAL COVID-19 CERTIFICATE

The current pandemic has made it clear that not only our health systems are vulnerable, but also that we need a strong global multilateral and multi-sectoral cooperation to prevent, prepare for and respond to a global health crisis. It is important to work on standardisation of vaccination registries for the purposes of monitoring the vaccination status of the population.

To limit the spread of the virus, countries have adopted various measures, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine/self-isolation or a test for SARS-CoV-2 infection. In this context, on 17 March 2021, the Commission presented a proposal to create a European Digital Covid-19 Certificate to facilitate the safe free movement of citizens within the EU during the COVID-19 pandemic. The proposal takes into account ongoing efforts at the international level, such as under the auspices of specialized agencies of the United Nations including the WHO, on the basis of the International Health Regulations, to establish specifications and guidance for using digital technologies for documenting vaccination status. The EU encourages third countries to recognise the "Digital Green Certificate" when waiving restrictions on non-essential travel.

The Digital Covid-19 Certificate trust framework shall seek to ensure interoperability with technological systems established at international level.

MS, in close collaboration with the Commission, are implementing common tools and developing national issuing and verification solutions to be rendered interoperable at EU and, where possible, with technological systems established at international level.

#### 2. EU PRIORITY ACTIVITIES UNDER GLOBAL HEALTH

## 2.1 - ZOONOTIC-VECTOR DISEASES - PREVENTION OF PRIORITY DISEASES

Climate change is causing one of the most relevant health threats to the world, driving an expansion in the distribution of VBD, including in Europe, with a more prominent impact in Southern Europe. There is a positive correlation between climate change, the increase of temperatures and the proliferation of diseases, including vector-borne diseases,



globally. VBDs are projected to rise at the higher temperatures. Warmer temperatures enable vectors to spread to new locations, surviving the colder seasons.

Ensuring better surveillance and control of vector-borne zoonotic diseases is a safety imperative. Vector-borne diseases are a global threat, but they are also preventable diseases. Nevertheless, they account for 17% of all infectious diseases and each they are responsible for 1 billion cases of sickness and 1 million deaths.

Vectorial capacity of the dengue mosquito has significantly rise in Europe over the past decades. All factors supporting the increasing of vectorial capacity for disease transmission are influenced by temperature. Research and monitoring on the climatic suitability of the dengue mosquito in urban areas clearly shows that Italy, France, Spain, Portugal, Slovenia, the Balkan countries, Netherlands and Belgian are among the EU countries at higher risk.

Integrated surveillance both of the distribution of cases of vector-borne diseases in humans and in nature is crucial for effective prevention and control. Integrated climate monitoring, disease surveillance and vector surveillance can support better forecast and planning both at MS level and the EU level. It is important to joint efforts at global level, because early action and awareness raising can reduce the human and economic costs of vector-borne diseases.

To address vector-borne diseases threats it is critical Health and Veterinary services to be agile to react well equipped and proper financed. It is important to improve and put in place One Health Surveillance Systems, both at MS, at EU level and with third countries and Organizations and a matter of urgency that all countries, particularly those more expose to the risk of originating vector-borne diseases are able to ensure they have the necessary technically and scientific support.

The close link between climate change and zoonotic diseases offers a set challenges to the future such as: sustainability of surveillance, integrated systems, national authorities' engagement, high-level commitment and support, research and assessment of community knowledge. Well designed and integrated surveillance systems with common indicators, sharing disease intelligence in a timely and transparent manner to support Health Authorities in their risk management process combined with comprehensive surveillance Monitoring & Evaluation frameworks to improve health risk management strategies will enable and reinforce intersectoral as well as cross-countries collaboration.

Promoting integrative approaches in line with the One Healthapproach must be a coordinated and improved exercise within countries and cross-regions. It is a matter of urgency that all countries, particularly those more expose to the risk of originating vector-borne diseases, can ensure they have the necessary technically and scientific support. This is an area where EU can strengthen its role in global health.

## 2.2 - ANTIMICROBIAL RESISTANCE

AMR is already considered the silent pandemic of our times. The One Health approach is the way to tackle and act towards the enormous challenge ahead on AMR. The EU strategy for AMR has 3 goals: to make the EU the best practice region in AMR, to boost AMR research and development and to continue the EU international involvement in global initiatives.

Regarding surveillance, the ECDC, EMA and European Food Safety Authority (EFSA) jointly agree on a comprehensive set of indicators on AMR, medicines consumption or animals and humans to better tackle the evolutions of the policies in place. AMR consumption data collection systems as well as AMR surveillance and monitoring programmes are in place in the EU and its MS.

The EU Plan on One Health is one of the key priorities of the European Commission regarding health as part of EU's commitment on preparing for serious cross-borders health threats. EU is fully commitment to strengthen and enlarge its partnerships with international organisations, private sector and other key actors through global and holistic approach to tackle AMR.



#### 2.3 - E-HEALTH - THE DIGITAL TRANSFORMATION, A NEW ERA

Digital is in the top of the EU political Council and Commission's agenda, both at horizontal and sectorial levels. It is fundamental to accelerate the digital transition as a driver of economic recovery in the context of COVID-19 pandemic, whilst promoting European leadership in digital innovation. A robust digital transformation contributes to a fairer and more competitive economy and to strengthen the fight against disinformation, critical to successfully implement public health measures.

E-Health technology is thus a fundamental and integral part of national and transnational health information systems, recognizing the need to guarantee the availability of timely and of quality-data and including monitoring of health inequality.

The COVID-19 pandemic has proved that Europe must act jointly in the digital transition by working towards improving common instruments, upscaling a European data infrastructure and exploring the technological potential in the health sector. Digital transition of national health systems and European cooperation are vital to strengthen the EU's resilience in response to cross-border public health challenges, as COVID-19, and therefore, to strengthen global health.

The world health crisis highlighted the need to reinforce EU resiliency and capacity to ensure public health sustainability, namely regarding global interdependence. This is the opportunity to reinvent health care policies towards a citizencentered approach, while enabling the timely application of digital tools, hence resulting in a stronger e-health ecosystem enhanced by technological autonomy and value-based health care.

Capacity building in digital health has a multisectoral and global approach, focusing on people, technology, and processes. E-health has the potential to promote health literacy, cross-border cooperation, and interoperability of national data systems, as well as infrastructures that can boost digital transformation of the internal market for the benefit of society and to the rest of the world.

#### 2.3.1 - The role of e-learning in international cooperation

International and cross-border cooperation using digital health technologies, namely by e-learning, is one of the most relevant instruments to strengthen the capacity to respond promptly, effectively and in a coordinated way to global challenges. It is recognized that appropriate e-training may contribute improve the implementation of common or simultaneous new procedures, actions or practices under the coordinated response to global challenges.

The positive experiences and success stories at national, regional or global levels recognize e-learning processes as an efficient way, being easily replicated, making efficient management of resources. At the same time, this option may avoid heavy constraints in technical assistance related to travelling and infrastructures needed for the particular type of support activities, that may be, thus, replaced by e-training standardized packages.

## Strengthening the diagnostic capacity at national level:

Technical assistance and training to improve the testing capacity is a crucial in strengthening fragile national systems. This capacity contributes to the operation of well-designed and integrated surveillance systems with common indicators, sharing disease intelligence in a timely and transparent manner to support Health Authorities in their risk management process. Combined with comprehensive surveillance Monitoring and Evaluation frameworks to improve health risk management strategies will enable and reinforce intersectoral as well as cross-countries collaboration in the pre-defined areas, where zoonosis are of key importance.

## Surveillance of vector-diseases schemes, certification of laboratory results, quality control external exercises):

The Africa CDC, created after the lessons leamt with Ebola outbreak in 2014, is having a big impact in management the current pandemics. It has also benefit from the collaboration and cooperation with ECDC. R&D is an area where the EU and Africa have a broad scope for collaboration, the EDCTP is illustrating this potential. The impact of this collaboration

<sup>&</sup>lt;sup>9</sup> Data including disaggregated data by sex, health, race, ethnicity gender, age, education and place of residence.



needs to be expanded and leverage to other areas, as well as the exchanges between EU and African researchers, encouraged. The EU-Africa partnerships can - and should - explore the power of triangular and south-south cooperation.

#### 2.3.2 - Movement of citizens: The Passenger Locator Form Platforms

In parallel to the workrelated to the European Digital Covid-19 Certificate, the EU is working in the draft implementation decision on a digital Passenger Locator Form (dPLF) to facilitate the exchange of travel data and contribute to minimize barriers for effective cross border contact tracing for travelers within the EU and MS that participate. The purpose of the EU dPLF is to create a single-entry point and database for the collection of dPLFs. The platform is available in several languages. At this stage, benefits mentioned with the experience, were related to multi-language, functionalities, harmonised data collection, rapid retrieval and exchange of data between public health authorities in EU MS, common point of entry for all travelers in the EU. The voluntary countries may collect personal information, contact details, information about visited countries, information about the need of sick leave, laboratory test results, acquaintance with the rules of isolation and decision of the chief epidemiologist.

The authorities are coordinating with national stakeholders. The dPLF, in addition to other health measures for reducing the risk of transmission, is a relevant tool when using any means of transport: how the cross border contact tracing applications are related, sharing of information to enable contact tracing and possibility to add additional epidemiological information on the infected passenger.

The proposal includes the minimum data set for the dPLF, the responsibilities of the voluntary participating MS and the ECDC responsibility as data processor.

The dPLF exchange platform is set up to enable the secure, timely and effective exchange of data between the Early Warning Response System competent authorities. This work may provide a positive EU contribution in the development of these tools at international level.

#### 2.4 - ACCESS TO MEDICINES AND VACCINES SOLIDARITY MECHANISM

## Medicines, vaccines, medical devices and tests

There is a need to ensure that safe and effective medicines and vaccines are available and affordable to everyone. The ACT- Accelerator, including its vaccine pillar COVAX, will need to reach the in-need priority countries. In addition, an established mechanism to facilitate the EU support on personal protection equipment, diagnostic tests, medical oxygen/ventilators and other relevant materials should be in place and reinforced. The EU strategy for vaccines against COVID-19 aims to accelerate vaccines' development, production, and distribution, as well to ensure equitable access to vaccines for all.

The European agenda regarding access to medicines is based on sustainable, equitable and universal access to medicines and medical devices. The availability of medicines and the capacity to manufacture active substances are critical to prevent, manage and mitigate shortages and disruptions in the context of European Pharmaceutical Strategy.

This strategy, adopted on 25 November 2020, aims at creating a future proof regulatory framework and at supporting industry in promoting research and technologies that reach patients to fulfil their therapeutic needs while addressing market failures.

Ensuring access to affordable medicines for patients, and addressing unmet medical needs, in the areas tackling AMR and rare diseases, for example, is key to reinforce EU position at global level. Development of novel antimicrobias or of the tapeutic alternatives is an example of unmet medical need, given the lack of options to address AMR. It is fundamental to bear in mind that AMR is a multifactorial problem of global concern, with serious health and economic implications in the world.

The EU is committed to continue an open dialogue with other regions and countries, including with low and middle income countries, to explore how to make the procedure for issuing opinions on medicines intended exclusively for



markets outside the EU, often more appealing, as a mean of cooperating with other countries and facilitating the access to medicines outside the EU. At the multilateral level, the EU aims to enhance regulatory cooperation and, where possible, within the International Pharmaceutical Regulators Programme and the International Coalition of Medicines Regulatory Authorities.

Through a solid European Pharmaceutical Strategy, the EU will support the WHO work strengthening the regulatory capacity through encouraging reliance mechanisms and establishing a framework for designating regulators as WHO Listed Authorities.

Furthermore, while supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry and the development of high quality, safe, effective, and greener medicines, the EU will further encourage, through international cooperation, actions to address the environmental risks in other countries where pharmaceutical emissions from manufacturing and other sources may contribute to the spread of AMR. In this regard, the EU will cooperate with the WHO, the OIE and other key international organizations, to raise awareness of environmental risks, including by sharing best practices and developing international guidelines.

EMA's network strategy to 2025 will strengthen the EU's regulatory capacity to support further internal coordination and will be complementary to the EU's Pharmaceutical Strategy. This strategy details how the network can continue to enable the supply of safe and effective medicines that meet public and animal health needs given the fast-paced challenges in science, medicine, digital technologies, globalisation as well as emerging health threats that Europe has and will have to deal with.

The EU chairs the International Coalition of Medicines Regulatory Authorities (ICMRA), which has allowed, during the pandemic, to significantly expedite and streamline the development of COVID-19 vaccines and treatments. The global regulators also cooperate under the umbrella of ICMRA on common challenges.

The need to facilitate the implementation of interoperable systems for tracking and tracing medicines around the world is one recent example to illustrate cooperation where the EU may have a strongervoice.

It is essential that research priorities are geared to making the biggest impact on public health. Access and innovation need to be addressed simultaneously, to increase the access, availability and affordability and access to essential medicines, including vaccines. Generic competition and rational use of medicines are of major importance to ensure the sustainability of healthcare systems.

## 2.5 - EU BEATING CANCER PLAN AND TRANSNATIONAL RESEARCH COOPERATION

Cancer is one of the main priorities of the European Commission in the health domain. The Europe's beating Cancer Plan is based on a Health in all Policies approach, pooling all strings together under a common goal, beating cancer. It is about health but beyond health policy, a whole-of-society effort. In a strong European Health Union, cancer becomes a shared political, operational and scientific priority.

A strong European Health Union foresees the citizens protection of avoidable cancers, access to early screening, diagnosis and to high quality care, at every step of the way.

The fight against cancer requires bold action from all European countries - particularly in the current context, in which the COVID-19 pandemic has seriously affected the response to cancer. The Portuguese Presidency will highlight the continued implementation of the Europe's beating Cancer Plan.

Transnational research bridges with preclinical, clinical and prevention research, builds on innovation and requires international scientific cooperation to bridge, a priority key area underglobal heath perspective.



#### 2.6 - THE INTERNATIONAL PANDEMICTREATY

Recognizing the need to act proactively and better predict and prevent future health crises, EU is committed in move from ad-hoc solutions towards a sustainable system.

COVID-19 has exposed the world's unpreparedness to adequately and promptly deal with such a global pandemic. As lessons learned for the future, it must retain that:

- Cross-border health threats require cross-border cooperation. Local health threats need to be managed rapidly
  and in solidarity, before they turn in global crises.
- Health has to be placed at the centre of all public policies. Investments in health promotion and preparedness shall be adequately and strategic, involving all government departments as well as civil society and the private sector in a collectively effort.

It is broadly agreed on the importance of cooperation with non-state actors and promoting their engagement in this area, especially considering their fields of expertise and activities in the international arena. At this regard exchange of views with the NGOs and non-state actors is envisaged within the context of WHO Framework of Engagement with Non-State Actors (FENSA).

The need of a more structured framework—such as a Treaty - to address future global health threats, complementary to the International Health Regulation, became more relevant.

#### 2.7 - THE EU-AFRICA STRATEGY AND NEIGHBOURHOOD POLICY

Health vulnerability in African countries is widespread and includes not only communicable diseases, such as COVID-19, but also non-communicable diseases. The Region has experienced remarkable economic growth, UHC and primary health care have generally improved as well, but progress needs to be accelerated to reach the SDG targets.

Strategic alliances between EU-Africa must go further than access to vaccines, go beyond health crises and focus on more resilient national health systems, improving their monitoring and surveillance systems, promote the capacity of their medical personal, and UHC through primary care. On a post-pandemic, it is imperative that EU and AU improve the work based on bilateral and multilateral relations.

There is a common interest in promoting investments in basic health and development infrastructure and capacity to cope with diseases outbreaks, contributing to the IHR full implementation, strengthening the ongoing collaboration between ECDC-Africa and CDC Agencies on harmonized surveillance and monitoring systems, accelerating the implementation of Africa Medicines Agency.

The recognition that Africa is Europe's closest neighbour is the way for a successful partnership relation as these two regions experiment: proximity, common interests and shared health threats. At a global dimension, strengthening the EU's role in global health can be leveraged ensuring the needs of African countries are taken into account.

The EU's commitment to the Sustainable Development Agenda calls for a dedicated approach to support the achievement of SDG 3, thus including support for a global health cooperation with Africa to achieve UHC and achieve the right standards of health, remaining the principle of "leaving no one behind". <sup>1011</sup>

The coordinated response of EU and WHO on health threats is impactful in Africa. Global pandemic requires a global solution, the basis for the EU commitment to support the universal access to COVID-19 vaccine including in Low- and Medium-Income Countries (LMIC). COVAX—Team Europe is one of the leading and larger donors of COVAX. The main constraints for a faster roll out is the difficulty of scaling production capacity. To overcome this, pharmaceutical companies are transferring their knowhow to regional partners, a practice that needs to be strongly encouraged.

<sup>10 \*</sup>SWD(2021)37/F1 - EN (europa.eu)

<sup>&</sup>lt;sup>11</sup> Strategic Plan on Health Cooperation, 2018-2021 from Community of Portuguese-speaking Countries



The new partnership, the EU-Africa global health partnership under Horizon Europe, the new EU research framework program, builds on the first and second European & Developing Countries Clinical Trials Partnership (EDCTP) and aims to advance the clinical development of suitable, effective, safe, accessible and affordable health technologies (e.g. diagnostics, treatments and vaccines) to help reduce the burden of infectious diseases in sub-Saharan Africa and strengthen capacities to improve research and innovation response to emerging infectious diseases <sup>12,13</sup>.

Due to the needs exposed by the pandemic, is important to take to consider the scope of the EU cooperation in Health with Africa to be extended to  $^{14}$ :

- Training and Development of the Health Workforce: i) From pre-graduate to post-graduate training and using new training facilities in digital format.
- National Health Systems: i) Always with the principle of strengthening national health systems, structurally and guided by universality, comprehensiveness, equity and quality, with reinforced governance through leveraging the creation of strategic partnerships in the field of health, leading to the creation of and investment in robust and fruitful EU-Africa diplomaticalliances.
- Health Information and Communication: i) Expanding access to technical and scientific information in the health field to health workers and researchers in general and expanding the dissemination of policies, strategies and activities of national health systems.
- Monitoring and Analysis of the health situation and compliance with the SDGs: i) Contribute to the fulfilment of the 2030 Agenda goals, and particularly strengthening the capacity to carry out the SDG 3; ii) Implement Health Indicator Monitoring Systems in All Policies to assess the SDGs.
- Public Health Emergency Surveillance and Response: i) Expansion of the coordination of actions and the speed of joint solidarity responses to emergency situations; ii) Cooperate bi and / or multilaterally in Capacity Building in Surveillance and Emergency Response in Public Health.

The effective response to COVID-19, including vaccination, is not a race between countries but a race against time. Beyond the technical and financial support provided by Team Europe to COVAX Facility, the EU launched in April 2021<sup>15</sup> a humanitarian initiative to support COVID-19 vaccination rollout in Africa of €100 million. This initiative aims to increase the cooperation with the Africa CDC and helping to scale up preparedness in Africa for health emergencies, the African Union support program (AUSP) on disease surveillance and the deployment of health care workers.

The EU-Africa Partnership and the priority given to the most fragile systems deserves the EU best and increased attention.

The EU can also improve its role working with WHO in Africa, and this EU cooperation can be improved in several ways:

- Joint advocacy to turn COVID-19 experience into increased financing for health at the continental and country level
- Influence policy decisions towards the most effective actions like preventive interventions and strengthen systems for monitoring, evaluation and accountability.
- Assist countries to build capacities and adopt innovations and new health technologies.
- Facilitation of multisectoral approaches to address issues that threaten many countries at once.
- Encourage the private sector, civil society, innovators, researchers, and investors mobilization through alliances able to link up across sectors and continents.
- Foster collaboration at the continental and regional levels, such as working with the AU and its institutions like the Africa CDC on the EU-Africa Strategy.

<sup>12 \*</sup>SWD(2021)37/F1 - EN (europa.eu)

<sup>13</sup> The next EU-Africa Global Health research Partnership: Building on the success of EDCTP)

<sup>14</sup> Strategic Plan on Health Cooperation, 2018-2021 from Community of Portuguese-speaking Countries

<sup>15</sup> EU humanitarian initiative to support COVID-19 vaccination rollout in Africa



#### 2.8 - THE AFRICA REGIONAL PROTOCOL

The world has greatly changed since the Cotonou Agreement was adopted and so have the EU and its partners. This meant redefining objectives, while setting new ambitions to respond to the emerging needs and challenges. The negotiated Agreement text initialed by the EU and Organisation of African, Caribbean and Pacific States on 15th April 2021, can be a guidance for the EU Strategic Partnerships. The new partnership agreement will constitute the new legal framework for the EU's relations with the African, Caribbean and Pacific (ACP) countries, reinforcing commitment in areas such as human rights, democracy and governance, peace and security, human development, which encompasses health (Article 32), education and gender equality, as well as environmental sustainability, climate change, sustainable development and growth and migration and mobility. The text will emphasis on cooperating in international fora and on building alliances on the global scene. This is especially important given that together the EU, its MS and the Members of the OACPS represent over half of the seats at the United Nations. The ratification of the text is expected to be happen during the second semester of 2021.

This agreement represents a new rethink of the strategic partnerships of the European Union, in the face of the current context, with the concept of global health being implicit in it.

It also includes three regional protocols (Africa, Caribbean and Pacific), tailored to each region's needs and dynamics, which will allow for an unprecedented regional focus.

#### 3. GLOBAL HEALTH CALENDAR - INITIATIVES DURING THE FIRST SEMESTER 2021

Date	Event	Venue
March, 25	High Level Conference on Global Health	Lisbon
April, 28	Working Group on Global Health Meeting	Lisbon
April, 29	High Level Conference – Access to Medicines	Lisbon
May, 3	RTD Cancer Summit	Porto
May, 21	G20 – IT Pres – Rome Declaration	Rome
May, 27	rking Party on Public Health at Senior Level (GH)	Lisbon
June, 15	EPSCO (GH)	Lisbon



## 4. ROADMAP OF THE WORKING GROUP ON GLOBAL DURING THE TRIO OF PRESIDENCIES

EU Global Health Initiatives	EU PRESIDENCY
17 November 2017- WPPHSL – Health priorities at EU and international level	PRES EE
13 Set 2019 – WPPHSL – Strengthening the role of the EU in Global Health Cooperation	PRES FI
21st October 2020 – 1st Meeting of the WGGH	PRES FI
9 December 2019 - EPSCO Ministers´ Lunch Debate on Global Health	PRES FI
10 February 2020 – 2 <sup>nd</sup> Meeting of the WGGH	PRES HR
11 February 2020 - WPPHSL - Strengthening the EU role in global health cooperation	PRES HR
28 October 2020 – 3 <sup>rd</sup> Meeting of the WGGH	PRES DE
25 March 2021 - High Level Conference: "Strengthening the EU role in global Health"	PRES PT
28 April 2021 – 4 <sup>th</sup> Meeting of the WGGH	PRES PT
7 June 2021 – WPPHSL – Strengthening the EU role in global Health:  Work Progress and addressing current challenges in the EU coordination mechanisms	PRES PT
15 June 2021 - EPSCO – Global He alth Initiatives, presentations of the Presidency Report	PRES PT



# 5. HIGH-LEVEL CONFERENCE "STRENGTHENING THE EU ROLE IN GLOBAL HEALTH Lisbon, 25 March 2021

#### Draft Executive summary - topics for reflection

- Health is a **Human Right** and a key dimension of the **UN 2030 Agenda**. A broader view of the European Union's role in global Health must be in line with **SDG**'s achievement.
- No one is safe until all are safe. Countries do not live-in isolation so only global, inclusive and multidisciplinary solutions apply as health knows no boarders since the world has never been so interconnected.
- Global health begins at home. **Global Solidarity** is vital to address global and shared public health threats. Together with other democracies, the EU has the obligation to strive for international solidarity and be able to provide globally equitable access to vaccines and other **public health goods**.
- To the **EU health diplomacy** is a cornerstone of its foreign policy. It is not an option for the EU and its Member States, rather is a shared need. EU's vision for its role in global health and health diplomacy is supported by a strong belief in cooperation and, an active engagement on coalition building and a determined pursuit for solutions that will stand the test of time. Global health is a political choice in geopolitics matrix
- **Health** has to be placed at the centre of **all public policies**. Investments in health promotion and preparedness shall be adequately and strategic. They should involve all government departments as well as civil society and the private sector in a collectively effort.
- For the EU, COVID-19 had undeniable political consequences. It exposed, from the outset, weaknesses in the European legal and institutional framework, and that the EU was not prepared to manage public health crises of such magnitude. The current health legislative package is an essential move towards the implementation of a true European Health Union.
- EU sees COVID-19 as an opportunity to renew its relationship with its partners and to build stronger global health systems based on collaboration, multilateralism, equality and human rights which will lead to more equal, more resilient and more sustainable societies globally.
- Coordination and collaboration are key as if countries are not able to collaborate, joint forces, resources and information and coordinate actions is more difficult to globally fix health threats. Therefore, more collaboration and coordination are needed within the EU Member States and between the EU with the rest of the world.
- Vaccines can only be achieved through partnerships. Vaccines have the potential to have a powerful impact on the pandemic than any fiscal or monetary stimulus. The best economic policy today is vaccine policy, this is the way to economies start rising again. Ensure equity on vvaccine's access has become the key global health challenge of 2021
- European Health Union package: the reinforces and revises mandate of the ECDC and EMA, the cross-boarders preparedness and response mechanisms, coupled with the Pharma Strategy, the HERA and the EU beating Cancer Plan provide the EU a robust toolkit to strengthen its role in global health worldwide
- The **EU4Health Programme** is a strong sign of EU's ambition on the role it aims to play in global Health arena



- COVID-19 demonstrated the need for closer integration of Member States regarding health policies and activities and the need for the EU to reinforce collaboration with WHO and other regions of the world on health-related topics.
- The **WHO** needs to be reinforced likewise the **International Health Regulations** (IHR) needs serious updating and reinforcement. Each country commitment to the effective implementation of the IHR must be encouraged.
- For the EU strengthening global health is a collective effort, based on global commitment, effective multilateralism and robust multilateral institutions, where a strong WHO is a vital part of that equation as a global coordinator in health emergencies.
- Strengthening the EU's role in Global Health can be leveraged ensuring the needs of African countries are taken into account. To that, the recognition that Africa is Europe's closest neighbour is the way forward to build and nurture successful partnerships and strategic alliances under an **EU-Africa** reinforced Partnership
- **EU-Africa strategic alliances** and close cooperation make a foundation upon which one can built in order to tackle this pandemic and, future ones. EDCTP collaboration, the support to the creation of Africa-CDC and African Medicines Agency or the COVAX Facility and the scale up of manufacturing solutions to provide access to vaccines are just examples.
- Universal Health Coverage is a pillar to guarantee primary health care to all and a building block of global health security. It is also the best way forward towards more resilient healthcare services that leave no one behind.
- One Health Approach is the best framework to address the health threats posed by climate change, vector-borne diseases and AMR. Therefore, a more comprehensive One Health Global Action Plan must be envisaged and adopted.
- Climate change is one of the major health threats and is driving an expansion in the distribution of vector-borne diseases in Europe. The close link between climate change and zoonotic diseases offers a set challenges to the future. Member States, the EU and International Organizations must be aware of and proactively act upon. The EU Green Deal package of strategies should be used to ensure a more significant focus on health consequences of climate change.
- To address **vector-borne diseases** threats it is critical that Health and Veterinary services be agile to react, be well equipped and proper financed. It is important to improve and put in place One Health Surveillance Systems, both at Member States, at EU level and with third countries and Organizations and a matter of urgency that all countries, particularly those more expose to the risk of originating vector-borne diseases are able to ensure they have the necessary technically and scientific support.
- AMR is the silent pandemic of our times. It does not know boarders and its roots are multifactorial. EU health systems need to be more engaged on the fight against AMR and infection prevention.







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Public Health Is a public good

One World, One Health

Diseases have no frontiers

Global threats require a global response

One Health Approach: human, animal and environment health

None is safe until everyone is safe

Prevention Is better than cure

Access to affordable medicines and vaccines

Health in all policies

European Health Union

Universal Health Coverage

Social Solidarity in global reduction of Inequalities

No one is left behind

Stronger and united one voice in the world

Time to deliver: a fair, green and digital recovery

