OUTPUT DOCUMENT

A NEW IMPETUS FOR EU HEALTH POLICIES: Which agenda in times of crisis?

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1. Introduction

Even before the COVID-19 epidemic exploded on the world, including in Europe, the EU healthcare systems were already facing several challenges such as an ageing population and chronic diseases, antimicrobial resistance, vaccination prejudice, together with the persistent digital divide. Chronic diseases have revealed to be the leading cause of mortality and morbidity in Europe and research suggests that complex conditions such as diabetes and depression will become an even heavier burden in the future. **Universal access to health services is threatened both by financial and non-financial barriers** and it is clear that all this has contributed to increasing the demand and availability of treatment and personalised lifelong care. This will create an even heavier stress on health systems that the current structure will no longer be able to sustain in the long term. **Today, the COVID-19 pandemic is placing health systems across Europe under enormous strain** since the **unprecedented surge in demand for intensive care has rapidly brought health systems to a breaking point**, **with health workers being stretched thin and medical resources becoming scarce**. However, not all European countries are impacted to the same extent, thus revealing **the different levels and capacity in being able to cope with this external shock**. While the first and **foremost priority is to deal with the immediate effects of the pandemic, the EU must learn from this crisis and reflect** on how its Member States, and the EU itself, can **become more resilient**. We should not forget that the resilience of a healthcare system is not only related to the capacity to activate extraordinary and extra measures but also to its pre-existent level of overall sustainability (equity, access, efficacy and efficiency).

For a long time, in order to build more sustainable healthcare systems, **the scientific community, patients and institutions all around Europe have been calling for a paradigm shift**. The latter involves integrating patient care across the continuum of life, bridging the gap between acute, treatment-driven demand and normal, healthy living. **Therefore, investments must be made in health promotion and prevention and, at the same time, in actions aimed at promoting equity that can significantly contribute to better health** (i.e. poverty reduction, social inclusion and security). Health outcomes and health inequalities are indeed mainly affected by the social, economic and environmental determinants of health, such as the conditions in which we are born,

grow, live, work and age. **This is the reason why policies adopted in all sectors can have a profound effect on population health and health equity**. The State of Health in the EU's 2019 Companion Report[1] recalls that after the financial crisis, the Commission drew up, through the European Pillar of Social Rights, a set of principles to support EU citizen rights and safeguard social standards in a fast-changing world. One of these principles declares that everyone has the right to timely access to good quality, affordable, preventive and curative health care, accessibility being a vital and multi-dimensional aspect of health system performance. **Despite a limited room for manoeuvre, the past European Commission mandate made some significant steps forward in terms of health policy**. However, more efforts are needed since Europe must **tackle unprecedented challenges affecting people's health**. Indeed, **although healthcare services fall under the responsibility of national authorities, their capacity to address their public's needs can be impacted by EU policies, or by the absence of them**.

2. Health in the EU: the agenda for the next five years?

The health policy priorities set by the European Commission when the COVID-19 pandemic was still far from taking its present toll, try to comply with the abovementioned need for a paradigm shift. The ongoing public health crisis, together with the economic impact it will have on EU Member States, **strengthen the need to intervene, once the immediate management of the crisis is over, for a collective reflection at both the European and national levels**.

Before going more deeply into this issue, the already defined EU health strategy for the next five years should be recalled. The first three priorities of the European Commission for 2019-2024 represent a **new strategic paradigm which relies on three pillars**, where the European social market economy and technological innovation are closely interconnected and are **strongly linked to health**. In the mission letter, the president of the new EC entrusted the new Commissioner for Health with the task to **constantly improve the quality and sustainability of Member States' health systems** over the next 5 years. To do this, actions should be included in two main chapters promoting and protecting public health and improving food safety and animal and plant health.

The main priorities to be addressed in the first chapter (promoting and protecting public health) are:

- ensuring the supply of affordable medicines;
- allowing for the effective implementation of the new regulatory framework on medical devices;

[1] Companion Report 2019, State of Health in the EU, ec.europa.eu/health/state

- making the most of the potential of e-health to provide high-quality healthcare and reduce inequalities by creating a European Health Data Space to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes;
- fully implementing the European One Health Action Plan against Antimicrobial Resistance;
- prioritising communication on vaccination;
- promoting Europe's Beating Cancer Plan to support Member States in improving cancer prevention and care.

The main priorities to be addressed in the second chapter (improving food safety and animal and plant health) are:

- promoting a new 'Farm to Fork' strategy for sustainable food from production to consumption;
- working on protecting plant health and reducing dependency on pesticides in order to deliver on the zero pollution goal;
- improving consumer information especially on the health and sustainability of food products;
- equipping Europe to prevent and fight against animal diseases that can be transmitted, and enforcing the animal welfare legislation and promoting European standards globally;
- focusing on the implementation and enforcement of the extensive legislation in the areas of food safety and animal and plant health;
- developing a strategy with concrete measures against food fraud.

At the top of the list of the health priorities is **access to affordable medicines** and the implementation of the new regulatory framework for medical devices, two key areas in both pharmaceutical and health technology policies which have now been firmly returned to the health portfolio. Indeed, responsibility for pharmaceuticals and medical devices will return to DG SANTE, five years after a decision of the Juncker Commission moved them to DG GROW (the Directorate for Industry, Enterprises and the Internal Market). In her answers to the European Parliament[2], the Commissioner designate for health, Stella Kyriakides, underlined that it is important to recognise the **role that science and new technologies play in developing new solutions** to the challenges society faces. For this reason, the EU needs to ensure that regulatory frameworks remain up-to-date, fit-for-purpose and with a citizen-centred approach. Open, transparent

[2] https://ec.europa.eu/commission/commissioners/sites/comm-cwt2019/files/commissioner_ep_hearings/answers-ep questionnaire-kyriakides_0.pdf

dialogue with stakeholders and citizens throughout the policy making process is essential to win their trust and support. The "State of Health in the EU Companion Report 2019" underlines that **gaps in the access to health care are still very much a reality in the EU** and the types of problems with accessibility and the extent to which EU citizens experience them vary enormously. However, standard data does not reveal how differences in covered services and medical goods relate to socio-economic aspects or clinical needs. Several -Member States tend to show similar exceptions to their benefit packages, and these often create gaps in being able to access expensive or experimental treatments. According to the report, this is the case for experimental or very expensive new pharmaceuticals that are not systematically covered, or delayed in terms of their inclusion in the benefit packages. It especially affects cancer patients in Austria, the Czech Republic, Estonia, Hungary, Latvia and Slovakia, and patients with rare diseases in Austria, Estonia, Croatia, Latvia, Poland, Malta and the Netherlands. To build an inclusive and fair system, epidemiology, severity of needs and **outcome-based data** must be factored in. The last requires a clear and mutually recognised definition of outcomes whereby a more holistic approach to measuring access could be implemented, taking into account both the system's cost-effectiveness and the patient's perspective.

According to the World Health Organisation, access to essential medicines is part of the right to health, however, access to health treatment is becoming increasingly dependent on the availability of affordable medicines. Findings reveal striking differences in the sales and availability of innovative medicines among different Member States and, according to the European Parliament, the problem has been exacerbated by the economic crisis. In 2016, the Council adopted conclusions on strengthening the balance in the EU's pharmaceutical systems[3] and, in 2017, the EU Parliament adopted a resolution on options for improving access to medicines[4] where it called for national and EU-wide "*measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies*" . Moreover, it called on the Commission and the Member States "*to foster R&D driven by patients' unmet needs, such as by researching new antimicrobials, coordinating public resources for healthcare research in an effective and efficient manner, and promoting the social responsibility of the pharmaceutical sector*". Given the increasing concerns regarding shortages of certain medicines, their supply side also requires attention. To this end, the EMA recently issued guidance on the detection and notification of shortages of medicinal products[5]. New legislation concerning **medical devices and**

[3] Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States (2016/C 269/06).

[4] Options for improving access to medicines, European Parliament resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(INI)).

[5] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-detection-notification-shortages-medicinal-products-marketing-authorisation-holders-mahs_en.pdf

in vitro diagnostic devices has also been adopted recently. Regulation (EU) 2017/745 and Regulation (EU) 2017/746 set the rules on placing medical and in vitro diagnostic devices on the market and on related clinical investigations. Devices are grouped according to their risk category, each of which has a specific set of rules. These regulations were a significant step towards strengthening patient safety as they introduced more stringent procedures for conformity assessment and post-marketing surveillance, requiring manufacturers to produce clinical safety data, establish a unique device identification system for the traceability of devices, and provide for the setting up of a European database on medical devices. Their effective implementation should improve patient safety and consolidate the EU's role as a global leader in this field.

Among the priorities for promoting and protecting public health, there is the effective implementation of the **One Health Action Plan against Antimicrobial Resistance (AMR)**. Antimicrobial agents are substances that kill or inhibit microorganisms, including bacteria, viruses, fungi and parasites. The use (and misuse) of antimicrobial agents is linked to an increasing prevalence of microorganisms that have developed resistance to such agents, thereby posing a threat to public health. EU-level actions to tackle antimicrobial resistance dates back to the late 1990s, while the European One Health Action Plan against Antimicrobial Resistance (AMR)[6] is the latest policy initiative. Adopted in 2017, its main goal is to maintain the possibility of effective treatment of infections by reducing the emergence and spread of AMR and increasing the development and availability of new, effective antimicrobials. Moreover, the action plan highlights the need to set up incentives to boost early research, as well as the development of novel antimicrobials and innovative alternative medicinal products (e.g. vaccines, antibacterial, antifungal, antiviral agents) and diagnostics. It also underlines the need to develop new Health Technology Assessment methodologies and reimbursement reforms, to better capture the added value of new antimicrobials, alternatives and diagnostics. The EU Parliament responded to this action plan in a recent resolution[7] and in 2019 the Council adopted conclusions[8] on the next steps for making the EU a best practice region in combatting AMR. In its resolution, Parliament emphasised its conviction that "*diseases have to be tackled in both people and animals, while also taking into special consideration the food chain and the environment, which can be another source of resistant microorganisms*" and underlined the important role of the Commission in coordinating

[6] https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/amr_2017_action-plan.pdf
[7] European Parliament resolution of 13 September 2018 on a European One Health Action Plan against Antimicrobial Resistance (AMR) (2017/2254(INI)).
[8] Council conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance (2019/C 214/01).

and monitoring national action plans implemented by Member States and the importance of cross-administrative cooperation.

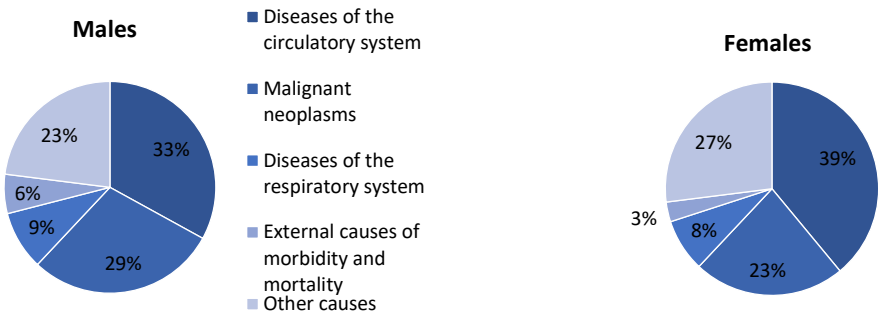
Health priorities for the Commission, moreover, include the need to prioritise communication on vaccination. **Vaccination is indeed among the main tools for primary prevention and it is recognised as one of the most cost-effective public health measures available**. However, several EU and neighbouring countries are currently facing unprecedented outbreaks of vaccine-preventable diseases due to insufficient vaccination coverage rates. The waning of public confidence in vaccinations, geographical differences in accessibility and the **rise of disinformation on vaccinations are a cause of concern and a major challenge for public health experts**. Vaccine confidence, the trust in the effectiveness and safety of vaccines and trust in the healthcare system that delivers them, refers to the belief that vaccination serves the best health interests of the public and its constituents. The EU has one of the lowest confidence levels in the safety and effectiveness of vaccines worldwide, as reported by the latest European Commission report "State of vaccine confidence in the EU 2018". For this reason, ensuring equitable access to vaccines for all EU citizens, fighting disinformation, and improving vaccine confidence are objectives shared by the European Commission and EU Member States. In December 2018, the Council adopted a Recommendation to strengthen EU cooperation on vaccine-preventable diseases, an initiative that aims to tackle vaccine hesitancy, improve coordination on vaccine procurement, support research and innovation, and strengthen EU cooperation on vaccine-preventable diseases. The European Commission is reinforcing its support on national vaccination efforts to increase coverage, including through the European Joint Action on Vaccination co-funded by the EU Health Programme9 with € 3.55 million. The action seeks to increase vaccination coverage in the EU and it is coordinated by INSERM (France) involving 20 partners (among them 17 EU countries and 3 non-EU countries). A "Coalition for Vaccination" that involves the European Association of Healthcare Workers and the Students' Association was also convened in spring 2019 to support delivering accurate information to the public and combating myths.

Since cancer is the second leading cause of mortality in EU countries (after cardiovascular diseases), accounting for 29% of all deaths among males and 23% among females in 2016, improving prevention and care cannot be ignored. 40% of cancer cases in the EU would be preventable, however, only 3% of health budgets is spent on health promotion and disease

[9] The Health Programme is a funding instrument to support cooperation among EU countries and underpin and develop EU health activities. The legal basis for the Health Programme is agreed on with the European Parliament and the Council for a period of several years.

prevention[10]. Moreover, a number of non-communicable diseases share common risk factors and their prevention and control would result in benefits for the majority of citizens.

Fig. 1: Main causes of mortality among women and men in EU (2016)



Source: Eurostat, 2019

Europe's Beating Cancer Plan was launched on World Cancer Day on 4 February 2020 in the European Parliament in Brussels, supported by the MEP Against Cancer Interest Group. The mission letter to the Health Commissioner, Stella Kyriakides, defines **the four pillars of Europe's Beating Cancer Plan as prevention, early diagnosis, treatment and follow-up care**. The plan will be linked to other priorities of the new Commission and has the support of Members of the European Parliament, Member States and stakeholders who work together with the Commission to improve cancer prevention and care in Europe. Speaking in the European Parliament, the Commissioner gave an early indication of what the plan might focus on, specifying a horizontal approach which addresses key determinants, such as tobacco consumption, alcohol abuse, physical exercise and healthy diets, as part of a prevention-focused strategy. Figure 4 reports the actions included in the plan in reference to prevention, diagnosis, treatment and quality of patient and survivors. On February 4, the European Commission opened a public consultation on the plan (running for 12 weeks) inviting all interested individuals or organisations to share their views and experiences to feed into a European cancer plan putting European citizens at the centre. The roadmap foresees the adoption and presentation of the Commission Communication and Action Plan by the end of 2020.

[10] Europe's Beating Cancer Plan - Let's strive for more.

Fig. 2: Europe's Beating Cancer Plan proposes actions for all stages of the disease

PREVENTION	DIAGNOSIS	TREATMENT	QUALITY OF LIFE OF PATIENTS & SURVIVORS
Taxation's role of alcohol and tobacco	Address gap in knowledge	Improved treatment times	Improving quality of life for patients and survivors
Reducing exposure on carcinogens in the workplace and in the environment	Digitalisation reduces detection time	Incentives for innovation	Avoiding discrimination
'Farm to fork' strategy to promote healthy diets	Technical support for member states	Pharmaceutical strategy for affordable therapies	Psychological support
	Regulatory support reduces inequality	European Health Data Space promotes exchange and research	Back to work support

Source: European Commission, 2020

As reported in Figure 2, the plan includes a 'farm to fork' strategy to promote healthy diets, thus indirectly supporting the priorities included in the second chapter of the mission letter. These measures should be considered as cross – cutting issues essential to supporting and being in line with measures for health prevention and promotion in the EU. The abovementioned actions should be closely linked with the research mission on cancer in the future Horizon Europe Programme. The European research and innovation missions aim to deliver solutions to some of the greatest challenges facing our world and they are an integral part of the Horizon Europe Framework Programme beginning in 2021. Cancer research is one of the five mission areas

identified during the negotiations of Horizon Europe with the aim to act jointly in order to reverse the frightening trends in cancer[11].

Another important cross – cutting issue, which is the responsibility of the Health Commissioner, is the **creation of a European Health Data Space** as part of an agenda to expand the use of eHealth and to address three key public health challenges - antimicrobial resistance, vaccine scepticism and the fight against cancer. In the recently published[12] EC Communication, **"A European Strategy for Data"**, to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, the Commission has taken it upon itself to develop sector-specific legislative or non-legislative measures for the European health data space, complementing the horizontal framework of the common data space, and to deploy the data infrastructures, tools and computing capacity for the European health data space. In its November 2019 report "Strengthening Strategic Value Chains for a Future-ready EU Industry"[13], the EC singles out "smart health" as a strategic value chain in itself and as an enabler for Europe to reach its aspired position as a global player vis-a-vis the US and China. The objective is: "By 2030 there will be a **federated European common health data space** across all Member States for use in research, medical science and healthcare services, driving the development towards patient-centred and outcome-focused healthcare systems". The latter can be attained by enabling a "European ecosystem between users, payers, authorities and industry in compliance with the relevant data protection legislation and ethical standards for the development and uptake of Smart Healthcare products and applications, including digital therapeutics". The digital healthcare transformation and realising the potential of health data can be major tools in enhancing the efficiency, sustainability and integration of healthcare systems by **enabling the shift towards value-based healthcare models and systems**, ensuring that Europe plays an important role in clinical research, with more patients being able to participate in targeted treatment trials, and by advancing the use of outcomes-based payment models . In order to implement a long-term strategy, as described by the Expert Panel on Effective Ways of Investing in Health (EXPH) for value-based healthcare data integration and interoperability[14], the research and development of methodologies for value assessment is needed. Information should be relevant, timely available, comparable and reliable, and efforts should be constantly made to improve data collection without adding new administrative burdens, by using, for instance, universal patient identification numbers and linkages between datasets and eHealth solutions. An important step is seen in the EC's recently

[11] https://ec.europa.eu/info/horizon-europe-next-research-and-innovation-framework-programme/mission-area-cancer_en#what-are-missions-and-mission-areas
[12] Brussels, 19.2.2020 COM(2020) 66 final
[13] https://ec.europa.eu/docsroom/documents/37824
[14] https://ec.europa.eu/health/expert_panel/sites/expertpanel/files/docsdir/024_defining-value-vbhc_en.pdf

adopted "Recommendation on a European Electronic Health Record Exchange Format", to further develop eHR exchanges. The Recommendation sets out a framework for the development of a European electronic health record exchange format in order to achieve secure cross-border access to electronic health data in the EU. Therefore, the new EU institutions should reasonably consider further policy actions to facilitate the creation of health registries and increased interoperability of existing datasets to overcome fragmentation of outcome measurements and guarantee European healthcare system efficiency. The new Commissioner has recognised that "one of the drawbacks of what we see in today's digital age, is how easy it is to spread misinformation through so much media". For this reason, one of the priorities should be to act through education in order to fight and challenge the misinformation "that is now out there and that is directly impacting on human health", and equipping citizens with the necessary digital skills. Moreover, the Commissioner underlined the need to be careful regarding patient data protection. Concerning data protection legislation, it is worth mentioning that the Commission is planning to examine the application and functioning of Chapter V of the EU General Data Protection Regulation 2016/679 (GDPR) on the transfer of personal data to third countries or international organisations with particular regard to decisions adopted pursuant to Article 45(3) of this Regulation and decisions adopted on the basis of Article 25(6) of Directive 95/46/EC by 25 May 2020. The package of responsibilities received by the new Commissioner for Health and Food Safety is validated by the "*need to support the health sector and the professionals working within it, to invest in new technologies, to promote healthy lifestyles and to cooperate better within the EU*." Action is thus needed to achieve universal health coverage, reduce the burden of non-communicable diseases, promote mental health, ensure access to safe and quality healthcare services for all, and so on. Although it is undeniable that a strong mandate is a good starting point for a successful European term, we should be aware that significant steps still need to be taken to ensure a more comprehensive and effective approach to health.

3. Coronavirus outbreak: rethinking the future of public healthcare.

Given the rising COVID-19 case numbers, the WHO declared a public health emergency of international concern at the end of January 2020, then turning it into **a pandemic at the beginning of March**. The epicentre of the disease, which was in China at the time of the outbreak, shifted first to the European region and then to the Americas. **Uncoordinated containment measures were initially adopted in different EU Member States**, **slowing down the EU's capacity to respond as a single system** to the crisis, as managing healthcare systems remains entirely in the hands of each Member State. Each state decides on what preparedness and response measures they take, whether and when they introduce containment measures and how stringent those are, when they lift or ease them, and how they proceed with testing and contact tracking. **The Union has the**

possibility to support and complement the actions taken at national level and, despite a slow beginning, **it is playing a proactive role by issuing guidance and recommendations and acting to bring Member States together** under the European solidarity principle. **Decision No 1082/2013/EU** on cross-border threats to health lays down rules on epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health. Under the Decision, **a Health Security Committee (HSC) made up of MS representatives, and chaired by the Commission, was set up, together with an Early Warning and Response System (EWRS)** for direct and permanent communication between the Commission and the national authorities. In March, **the Commission launched a panel of 7 independent epidemiologists and virologists, who provide guidelines on science-based and coordinated risk management measures and play an advisory role** on response measures for all Member States, gaps in clinical management, prioritisation of health care, civil protection and other resources and policy measures for the long-term consequences of coronavirus. **The epidemic caused shortages in medicines and medical disposals** in the EU Members States, requiring them **to increase capacity in order to cope with the sudden exponential surge in demand for both COVID and non-COVID treatments**, and this was possible **thanks to the constant efforts of life science companies across Europe, focused on the vital need to secure continuity of supply**. The European Commission issued **guidance on optimisation of supply of medicines for COVID-19**, urging Member States to **remove export bans and avoid stockpiling** which could lead to shortages elsewhere in the EU. The guidelines focus on the rational supply, allocation and use of vital medicines to treat coronavirus patients and of medicines which may be at risk of shortage. Finally, **the Commission set up a "Clearing house for medical equipment" that helps identify available supplies, including testing kits, and accelerates their matching with demand** by Member States. In this context the **EMA**, together with the pharmaceutical industry, **set up the i-SPOC (industry single point of contact) system**, through which pharmaceutical companies can report directly to the Agency any issues related to the availability of crucial medicines being used in the context of COVID-19, whilst also continuing to report to the Member States concerned. Moreover, the European Commission, the EMA and the Heads of Medicines Agencies (HMA), **drew up a paper to provide detailed guidance to stakeholders[15] on adaptations to the regulatory framework for medicinal products to address COVID-19 challenges**. Last but not least, **mobilising research for public health is essential in order to advance the knowledge for the clinical and public health response to the new coronavirus epidemic**. With the aim to address epidemiology, preparedness and response to outbreaks, the development of diagnostics, treatments and vaccines, as well as the infrastructures and resources that enable this research, the **EU released € 48.5 million in emergency research funding**, made

[15] https://ec.europa.eu/health/sites/health/files/human-use/docs/guidance_regulatory_covid19_en.pdf

available **from the Horizon 2020 Research Framework Programme** and its annual work programme on health research. A **further € 90 million in public and private funds were made available for therapeutics and diagnostics via the Innovative Medicines Initiative** (IMI).
On April 15, the Commission recognised that the necessary extraordinary measures taken by Member States and the EU have slowed down the spread of the virus containing the epidemic. However, the cost related to these measures and the corresponding uncertainty for society and the economy is dramatic, so **the time is ripe to carefully develop an exit strategy**. **The Commissioner for Health and Food Safety, Stella Kyriakides, underlined that returning to normality after the corona lockdowns will require a carefully coordinated and European approach among Member States**, based on the awareness that such a public health crisis is global, meaning that **local, European and global phenomena are strongly interdependent**. The **European roadmap towards lifting COVID-19 containment measures** presented by the President of the European Commission and the President of the European Council, responds to the European Council Members' call for an exit strategy and **will prepare the ground for a comprehensive recovery plan and unprecedented investments**. According to the roadmap[16], **three sets of criteria are important to assess whether the time has come to begin relaxing the confinement** measures, but, at the same time, defining the level of compliance with the criteria above will be the decision of each Member State. The criteria are:

1. **Epidemiological,** showing that the spread of the disease has significantly decreased and stabilised for a sustained period of time;

2. **Sufficient health system capacity,** fundamental since healthcare systems are increasingly likely to face a backlog of elective interventions that had been temporarily postponed during the pandemic's peak. Health systems should have recovered sufficient capacity in general, and not only related to the management of COVID-19;

3. **Appropriate monitoring capacity**, including large-scale testing capacity to detect and monitor the spread of the virus combined with contact tracing and possibilities to isolate people in case of reappearance and further spread of infections.

One of the primary challenges, at the time of this crisis, is to **integrate and streamline digital infrastructures at various stages of the public health response**, particularly in the context of epidemic **forecasting and decision-making**. Among the accompanying measures outlined in the

[16] https://ec.europa.eu/info/sites/info/files/communication_a_european_roadmap_to_lifting_coronavirus_containment_measures_0.pdf

roadmap recognised to be relevant for all Member States in order to successfully manage the gradual lifting of the existing confinement measures, **two points directly concern this issue**. On the one hand, the Commission recommends **gathering data on the spread of the virus and developing a robust and harmonised system of reporting**. Social media and mobile network operators can offer a wealth of data on mobility, social interactions, as well as voluntary reports of mild disease cases and/or indirect early signals of disease spread. Such data, if pooled and used in an anonymised, aggregated format in compliance with EU data protection and privacy rules, could contribute to improving the quality of modelling and forecasting for the pandemic at an EU level. For this reason, the Commission **has proposed the Joint Research Centre (JRC) and ECDC to centralise this data collection and modelling work**. On the other hand, **the roadmap urges for the creation of a framework for contact tracing and warning with the use of mobile apps**, which respects data privacy since, as experienced by other countries dealing with the COVID-19 pandemic, these applications can **help interrupt infection chains and reduce the risk of further virus transmission.** They, of course, should be deactivated as soon as the COVID-19 crisis is over and any remaining data erased. All the above will be complemented by Commission guidance that will specify **relevant privacy and data protection principles**.

A considerable number of interventions put in place both at a European and at national levels has speeded up important pre-existing processes through the activation of **collaboration and synergies that in "time of peace" seemed to be far from being able to be implemented.**
Current events remind us that **investing in segments of the public sector that are directly and indirectly connected with health is crucial.** Therefore, we should not lose the opportunity to follow the steps already adopted in responding to this crisis in order to reform our healthcare systems and, above all, **to act in light of the interconnecting results of the different policy interventions**.
This is the way towards what the Commissioner for Health had already defined as the strategy for the next five years, in order to increase the quality and sustainability of European healthcare systems. **A large part of this strategy involves**: the **support to life science industrial investments (both productive and in research and development)**; the **development of value-based healthcare models;** and the completion of a **European health data space**. Today, it is undeniable **that efforts should be jointly made in this direction in order to create resilient systems**. Both the EU and Member States should learn from this crisis to act looking forward, also rethinking the approach to calculating public budgets and to defining constraints. **Investments that are clearly targeted to modernise, equip and strengthen vital parts of the public sector, especially the health system should not be considered as mere costs to the systems**. Eventual reforms, should be accompanied by strong investments in innovation, which in turn can contribute to enhancing the effectiveness,

accessibility and affordability of European health systems. **Delivering on this objective will require an ambitious economic recovery plan together with resilience-building interventions**. The huge challenge is to implement solutions in order to lower inequalities among EU Member States by lifting their healthcare systems up to a common capacity and resilience level.

4. VideoTalk Main Highlights

A holistic approach to EU health policies

The Covid-19 emergency is making the EU institutions and Member States take note of a lesson-learned exercise, which involves constantly exploring new solutions for emerging problems. Overall, the crisis has highlighted that not all European countries have been impacted to the same extent, thus revealing the different levels and capacity in being able to cope with this external shock. The crisis has showed the inherent weaknesses of some national health systems and the lack of integration and coordination at a EU level, while, on the other hand, it has somehow strengthened the solidarity and cooperation among Member States.

Covid-19 has also highlighted the need to develop solutions to protect the health of EU citizens as a whole, particularly for the more fragile sub-groups of the population, i.e. patients with mental illnesses, isolated elderly people, home violence victims, etc. The highest impact of the health emergency was experienced by patients already affected by chronic diseases. Hence, the need to support pharmaceutical innovations to facilitate the access to medicines for this group of patients is fundamental to avoid shortages, budget restrictions and organizational limitations.

It is now clear that there is a need to develop a holistic approach to address health issues in the future, e.g. by integrating health aspects into all the other EU policy areas and taking into account risk assessments and economic costs of health emergencies. The concept of citizen wellbeing should underlie the EU's strategy, by taking into consideration other important aspects to ensure a healthy lifestyle, such as prevention, safeguarding the environment and the sustainability of the food system.

The EU crisis management and the need for enhanced coordination among Member States

The coordinated response to the pandemic at EU level has been one of the key issues since the beginning of the Covid-19 crisis. The pandemic has placed health systems across Europe under enormous strain since the unprecedented surge in demand for intensive care has rapidly brought health systems to a breaking point, with health workers being stretched thin and medical resources becoming scarce.

Initially, Member States understandably opted for immediate measures aimed at first protecting their own population, without taking into consideration a European-wide solidarity and

cooperation. The pandemic has showed the urgency to develop a system which can allow for a smoother coordination among MSs in several sectors, whereby health systems can directly cooperate without the need to develop and adopt new harmonization policies. The emergency showed that concrete cooperation, (e.g. transfer of patients, exchange of medical staff) emerged where the systems where already connected, e.g. cross-border hospitals.

This is important not only within EU borders, but also at a global level. The ECDC, in close collaboration with the EU Health Security Committee has played a fundamental role here in the crisis management. For instance, the ECDC has been key in sharing information with international institutions and following the guidelines suggested by the WHO. For this reason, the European Parliament is calling for an initiative, also supported by some Member States, that aims at permanently strengthening the role of the ECDC and transforming it into a permanent crisis management mechanism. The objective is to define a framework so that during a health emergency, policy measures, definition of cases, data transfer, testing strategies, etc. could be harmonized and coordinated at the EU level.

EMA is also playing a key role in terms of coordination, especially by monitoring shortages of medicines and intervening as a mediator between industries and Member States. This role of coordination could become a long-term instrument to address the chronic shortage of medicines on the internal market, an issue that will be surely addressed in the new EU pharmaceutical strategy.

More investments for health systems at EU level

Strong investments in R&D&I are key to contributing to improved effectiveness, accessibility and affordability of European health systems. COVID-19 has highlighted the importance of supporting with more R&D investments those research-intensive sectors that are also deeply integrated in the health system. Therefore, the pharmaceutical strategy will focus more strongly on the need to increase future investments in the life science sector, e.g. EU public-private partnerships could be supported even more in the future. This issue will also be essential in the revision and reassessment of EU industrial strategy.

Structural funds could play a key role in reinforcing and modernizing national health systems. A series of initiatives to extend the flexibility in their allocation have been recently introduced to contribute to facing the crisis. In the long-term, Member State health systems will need to be able to access structural funds more easily, with the aim to gradually reinforce all the different components of healthcare, from hospitals to the availability of medicines and medical devices, to the development of new skills.

Looking ahead - Access to vaccines

The consequences of a lack of coordination among Member States is also evident in other areas. The current pandemic has caused the shortage of relevant medical products and highlighted that countries can also have a limited capacity in implementing testing strategies. The interdependence among countries is high also when it comes to the access to vaccines.

The EU is exploring regulatory flexibility in order to facilitate the access of vaccines to the market and the concrete delivery of the future vaccine for COVID-19, without opting for an emergency authorisation. Hence, the Commission has already started discussions with the major vaccine producing companies. However, this issue, in the future, needs to be more coordinated and take into account the global perspective.