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COVER NOTE

From:	European Economic and Social Committee
date of receipt:	29 April 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
Subject:	Reinforcing the EU's resilience for cross-border health threats 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 Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU *- Opinion of the European Economic and Social Committee*

Delegations will find attached the opinion adopted by the European Economic and Social Committee on the above.

Other language versions, if needed, will soon be available on the following website:

https://dmsearch.eesc.europa.eu/search/opinion

European Economic and Social Committee

SOC/665
Building a European Health Union

OPINION

European Economic and Social Committee

Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions
Building a European Health Union:
Reinforcing the EU's resilience for cross-border health threats
[COM(2020) 724 final]

Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices
[COM(2020) 725 final – 2020/321(COD)]

Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control
[COM(2020) 726 final – 2020/320 (COD)]

Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU
[COM(2020) 727 final – 2020/322 (COD)]

Rapporteur: **Ioannis VARDAKASTANIS (EL-III)**

Referral	Council, 14/12/2020 European Parliament, 14/12/2020 Commission, 12/11/2020
Legal basis	Article 168(5) and Article 304 of the Treaty on the Functioning of the European Union
Section responsible	Employment, Social Affairs and Citizenship
Adopted in section	16/04/2021
Adopted at plenary	27/04/2021
Plenary session No	560
Outcome of vote (for/against/abstentions)	231/3/7

1. Conclusions and recommendations

1.1 Through this package for an "EU Health Union", the European Union (EU) and the Member States (MS) must respond to the desire of people living in the EU to play a more active role in protecting their health and promoting the right to health. According to a recent EU survey, 66% of EU citizens would like to see the EU given more say over health-related matters. 54% of people surveyed say that public health should be a spending priority for the EU budget[1]. There needs to be particular improvement in the EU's capacity to effectively prevent, detect, prepare for and manage cross-border health threats. As such, a discussion and potential review of subsidiarity, the sharing of competences and the references to cross-border health threats and preparedness in the EU Treaties needs to take place once there has been time to fully evaluate this pandemic and the EU and national response. In the meantime, ambitious actions within the current framework of the Treaties should continue.

1.2 It has been observed and felt by the people living in Europe during the pandemic just how ill-prepared the EU was to keep people safe, with its fragmented healthcare architecture and prevention strategy, as well as decades of austerity and under-investment in health and social care services. This had an impact on loss of life, increasing inequality and poverty rates. It also revealed that many people are still not protected against discrimination in the EU or do not have access to public health information or healthcare. The EESC permanently calls for an upwards convergence of health and social systems and general common EU principles[2]. Health protection measures always have to respect all fundamental rights and should be based on solidarity-based health systems. The EU Semester procedure should check the performance and conditions of MS crisis management and health systems.

1.3 The COVID-19 pandemic has demonstrated how vital health and care services are and that health is a public good. To that end, the EU and Member States should ensure that everyone has equal access to quality, well staffed, well equipped health and social services.

1.4 During the pandemic, health workers, social workers, health mediators, civil society actors and essential service providers (food, transport) have been at the forefront of the pandemic and demonstrated an outstanding degree of solidarity during the most difficult times. Special attention should be given to healthcare workers and the need to improve working conditions, including pay, recruitment and retention, as well as their health and safety. The pressure of the pandemic has caused many to consider leaving the profession. This package needs to take note of this and of the role all the actors mentioned above can play in the area of health. Likewise, local authorities, service providers and the healthcare workforce should be consulted more thoroughly. Better coordination between EU, MS, regional and local levels including civil society will increase efficiency to benefit people in the EU.

1.5 While the European Economic and Social Committee (EESC) commends the EU for the solidarity shown in the vaccination strategy, we are seeing severe delays in the vaccine reaching

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1 Public opinion in the EU in time of coronavirus crisis 3 (europa.eu)

2 OJ C 13, 15.1.2016, p. 40, OJ C 14, 15.1.2020, p. 1

people. The EESC asks the European Commission (EC) to ensure that access to the vaccination remains, as was originally stated by the EC, a public good, free for all people. The availability of future vaccines should not be impaired by intellectual property rights and EU legislation on data and market exclusivity. Furthermore, there should be legal obligations for beneficiaries of EU-funds to share COVID-19 health technology-related knowledge.

1.6 The pandemic has revealed the toxic relationship between communicable and non-communicable diseases. The vast majority of COVID-19 deaths were linked to underlying and pre-existing health conditions. Another observed effect of the pandemic was the impact on patients with chronic diseases whose access to treatment was negatively affected by the pandemic. Therefore, the crisis response mechanism and the European Health Union should also include a focus on non-communicable diseases. It should also contain a strong focus on the mental health crisis which was already present before the pandemic but is arguably exploding due to the strain under which many people now find themselves.

1.7 Regarding the EU regulation on serious cross-border threats to health, the EESC stresses the need: to stockpile and develop medicines that are useable and affordable for the entire population; for preparedness in protecting high-risk groups to begin immediately, particularly with regard to those in closed settings and institutions; for data collection to be better disaggregated to provide a clear understanding of the people most at risk; and for medical innovations and responses to be accessible to all, regardless of their income, MS or region of residence.

1.8 In light of the renewed mandate of the European Centre for Disease Prevention and Control, the EESC underlines the importance of making the reduction of health inequalities in the EU central to the Centre's work, as well as of including non-communicable diseases; being fully equipped to collect fully disaggregated and anonymised data, and generate recommendations on the social and commercial determinants of health[3]; and of having a mandate to monitor investments and generate recommendations on the financing of health surveillance, risk assessment, preparedness and response, both for the EU and the national level.

1.9 When it comes to the reinforced role for the European Medicines Agency (EMA), the EESC urges that: the Medicines and Medical Devices Steering Groups include and meaningfully consult civil society and social partners; the supply of medicines and medical devices across the EU be not only consistent and sufficient, but that the EMA also work with all health stakeholders to establish a European model for pricing medicines in a fair, accountable and transparent way.

1.10 The new EU health package should be combined with the roll-out of the European Pillar of Social Rights (EPSR), particularly its principles 12, 16, 17 and 18 and the Action Plan on the EPSR which proposes, among other things, an EU Health Data Space. It should also be part of achieving Sustainable Development Goal (SDG) 3.

3 https://www.who.int/bulletin/volumes/97/4/18-220087/en/

1.11 The overlap between the objectives of the different regulations needs to be addressed and the mandates of the different agencies clarified, to increase efficiency and avoid confusion about who is responsible for different actions. Furthermore, the formal comments recently issued by the European Data Protection Supervisor (EDPS) on the proposed European Health Union package should be followed up.

1.12 It is the opinion of the EESC that some elements of this package of regulations perhaps come too early, since we are still in the midst of the COVID-19 pandemic and are still learning about its impacts. At the same time, we appreciate that urgent action is required in certain areas of EU health coordination. We invite the EC to present a report by June 2021 on the lessons learned so far from the pandemic.

2. General comments

2.1 The EESC welcomes the EC's proposed package for building a strong European Health Union. The proposed package includes: a) the communication on *Building a European Health Union*, strengthening the EU's resilience to cross-border health threats; b) the adoption of a new regulation on serious cross-border threats for strengthening preparedness, reinforcing surveillance and improving data reporting; c) improved capacity of the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) to better protect people living in the EU and address cross-border health threats; d) the setting-up of an EU Health Emergency Response Authority (HERA) to efficiently support the EU level response to cross-border health threats; and e) the establishment of the new Health and Digital Executive Agency (HaDEA) which will be tasked with the roll-out and management of the annual work programmes of the EU4Health Programme.

2.2 The EESC calls on the EU and the MS to respond to the demand of European citizens to make health a priority. As pointed out by the EC in its communication, "European citizens increasingly express their desire for the EU to play a more active role in protecting their health, in particular against health threats that transcend national borders".

2.3 The EC's proposed package is the point of departure for the realisation of the right to quality health, and for strengthening inclusive health and healthcare systems for all people in the EU, neighbouring and EU accession countries. It also strengthens the platform for the EU's contribution to global public health. Furthermore, social protection in health must be prioritised in the EC's international partnerships.

2.4 While the "European Health Union" package goes in the right direction, there is a need to expand beyond coordination alone. New measures should be combined with a possible revision of the EU Treaties, particularly the second subparagraph of Article 168(1) TFEU, to broaden EU competences in the field of health emergencies and cross-border threats to health and outline health protection as a public good. Article 35 of the Charter of Fundamental Rights of the European Union states that: "Everyone has the right of access to preventive healthcare and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities". To that end it must be ensured that

Member States invest adequately in public health and social care. The right balance between democratically approved national health and care systems and common needs for Europe should also be taken in account. All relevant scientific sources should contribute to accountable political decisions and a mandatory health impact assessment of all EU policy initiatives should be implemented. Finally, health protection measures must respect all fundamental rights. Limitations of such rights should be proportionate, controlled by the courts and follow the principles of democracy and of the rule of law.

2.5 The EESC has already adopted opinions in the field of health[4]. In June 2020, the EESC's plenary also adopted a Resolution on EESC proposals for post-COVID-19 crisis reconstruction and recovery[5].

2.6 The move to improve the EU's capacity to effectively prevent, prepare and manage cross-border health threats in a holistic way should be combined with the roll-out of the EPSR, particularly principles 12, 16, 17 and 18 and the Action Plan on the EPSR, which proposes among other things an EU Health Data Space. The space should be regulated as a public good. This initiative should also be part of achieving the SDGs and be linked to reforms funded by the Recovery and Resilience Facility (RRF), which could pave the way for advances in accessible e-health and telemedicine. The EESC looks forward to the RRF scoreboard, which will highlight what investments have been taken via the RRF in the health sector.

2.7 Despite European cooperation programmes between cross-border regions, with more than twenty years of investment from EU funds to promote health mobility in these areas, we have not yet achieved a more integrated model of cross-border care. A new impetus and long-term vision are needed to make cross-border territories the drivers of solidarity and cooperation in health. Where Member States share a land border, "Prevention, Preparedness and Response Planning" should include familiarity with public health structures and staff in the adjoining State and should involve conducting joint cross-border exercises.

2.8 The pandemic has dramatically increased poverty rates and exacerbated pre-existing inequalities, especially in MS that have been badly hit by the economic crisis over the previous decade. The health crisis has strongly affected the economy, the labour market and social cohesion. Noticeable impacts on the labour market are the rise in unemployment, the freeze on hiring, a lack of new jobs being created and the reduction of working hours. Eurostat figures show a clear impact on unemployment rates in the EU because of the pandemic, with things likely to continue worsening in the years to come. The EU unemployment rate was 7.6% in October 2020, up from 6.6% in November 2019. For young people the situation is even worse, with unemployment having shot up from 14.9% to 17.7% between November 2019 and November 2020[6]. It should be noted that Article 31(1) of the Charter of Fundamental Rights of the European Union states that "Every worker has the right to working conditions which respect

4 OJ C 429, 11.12.2020, p. 251; OJ C 440, 6.12.2018, p. 150; OJ C 242, 23.7.2015, p. 48; OJ C 181, 21.6.2012, p. 160; OJ C 14, 15.1.2020, p. 1; OJ C 13, 15.1.2016, p. 40

5 EESC resolution

6 https://ec.europa.eu/eurostat/en/web/products-euro-indicators/-/3-08012021-ap

his or her health, safety and dignity". Article 3(3) TEU also expresses the aim of full employment.

2.9 Existing healthcare systems throughout the EU – not least those in MS that have been affected by austerity-driven policies, ongoing underinvestment and extreme cuts to public spending in the previous decade – were unable to respond effectively to the immense pressure that the COVID-19 pandemic caused. This pandemic has highlighted the deficiencies in health systems across Europe and the need to shift how we think about healthcare. Healthcare cannot be treated as a commodity. Equal access to treatment, increased staffing in the health sector and improved conditions for health workers must become a priority.

2.10 The EU's coordinated vaccination strategy and joint vaccine procurement has proven to be insufficient. The EU is also still struggling with production capacity, which is resulting in an unnecessary loss of life. The EESC calls for a thorough review of the EU's central purchasing system for COVID-19 vaccines. Once the pandemic is over, it would be useful to see how this central purchasing took place, what worked and what could have been done better. It is vital that we learn all possible lessons from this current situation and take such lessons forward into our future planning.

2.11 During the pandemic, civil society and social partners have played a crucial role in protecting and promoting rights. In all future actions directed at improving the health of the Europeans most affected by COVID-19 – older persons, especially those living in residential care, homeless persons, persons living in poverty, persons with disabilities, persons with chronic diseases, migrants, refugees, ethnic minorities and the LGBTIQ+ community – civil society organisations and social partners must be at the core of the design and execution of such actions.

2.12 The pandemic has revealed that many people are still not protected against discrimination in the EU or do not have access to public health information or essential healthcare. Furthermore, we have observed the growth of so-called medical deserts[7]. According to the EU Treaties, people should also be free from discrimination. Currently, protection against discrimination at EU level in the field of healthcare does not cover all areas. The failure of the Council to adopt the Equal Treatment Directive published in 2008 means that protection against discrimination in healthcare is still not ensured on the grounds of age, disability, gender or sexual orientation, for example. This became clear during the pandemic. The gaps in services, access and protection against discrimination in the EU must be addressed.

2.13 The EESC is willing to be the central focal point for the participation of civil society organisations in the European Health Union processes, bringing together the representatives from EU institutions, MS and civil society organisations both at EU and national level.

2.14 The "European Health Union" is an important new development. It must contribute to improving access to healthcare, and the safety and wellbeing of people living in the EU; it will reinforce an appreciation of the Union's commitment to serving its people, and will also protect the MS against the threats of rising nationalism and populism. It should therefore be a topic to

7 https://www.aim-mutual.org/mediaroom/tackling-medical-deserts-across-the-eu/

be included in the Conference on the Future of Europe. To that end, the EESC draws attention to the recommendations in the WHO - High Level Commission on Health Employment and Economic Growth report "Working for health and growth: investing in the health workforce" and to the Five-Year Action Plan for Health Employment and Inclusive Economic Growth (2017–2021) which should be implemented as part of improving the EU's preparedness for future health emergencies.

2.15 A genuine, inclusive European Health Union cannot be achieved with the proposed measures alone. It must go beyond pure crisis management and ultimately aim for a Europe where everyone enjoys the highest achievable health standard with equal access to high quality treatment. It should initiate systemic change to be better prepared not only for the next pandemic but also for other cross-border health challenges such as antimicrobial resistance, and the obesity and non-communicable disease epidemics affecting all European countries. It should also adopt the "one health" approach, working on the link between human, animal and environmental wellbeing to preserve our health.

2.16 Given that in many MS it is the local or regional level that is responsible for prevention and delivering healthcare services, it is of paramount importance that the EU's health package foresees multi-level governance that fully includes local and regional authorities, emergency organisations and service providers. It needs to be clear that, in the event of a major health incident, the local authorities will have a vital role to play in relaying information and data and in communicating the availability of hospital beds, nurses and life-saving devices and medicines in their locality. This information needs to be collected centrally at the EU level and, in the case of border regions, solidarity should be shown between the MS in supporting neighbouring regions and EU accession countries who have exceeded capacity in the provision of emergency healthcare. In some MS, health services are provided by social economy enterprises as non-profits, such as mutual health insurance companies. In all MS there should be adequate legal and financial frameworks for these services to ensure direct participation in EU measures, fair competition and upwards convergence in quality and accessibility, while ensuring that the principle of health as a public good is maintained. Besides, taking into account its opinion "Towards an appropriate European legal framework for social economy enterprises", the EESC proposes introducing into EU law a legal framework suited to better recognition of Social Economy Enterprises (SEE). All relevant stakeholders within the MS should be addressed directly, digitally and quickly by the central data-collection team, to maximise the accuracy of the data collected and que quality of the EU's coordinated response.

2.17 The EU should also look more closely at the recruitment, retention and working conditions of health and social care workers. Safety of health and social care workers should also be made a priority, given the number of fatalities seen during the pandemic. Additionally, the EU should collect relevant and transparent data on the impact of COVID-19 on health and social care workers. This will allow the EU and Member States to assess the long-term consequences of COVID-19 more accurately and to develop measures to ensure that healthcare systems are better prepared for future health emergencies.

2.18 There appears to be an overlap between the objectives of the different Regulations. It is unclear how the division of responsibilities will work in practice. There is a lack of clarity around which

agency or body will lead on the overlapping actions, which could lead to confusion and inefficiency in the EU's coordination efforts. This needs to be clarified. Where repetition remains in the different Regulations, care must be taken to ensure a common set of definitions for all the terms used, such as what constitutes a "public health crisis".

2.19 COVID-19 drew attention to the fragmentation of the EU's health architecture and the need to strengthen the role of all relevant European agencies. Despite EU funding, there is still insufficient investment in view of the scale of the challenges, including prevention. The EESC also regrets that the Recovery and Resilience Facility investment in health was reduced compared to the EC's proposal. This in our view is a major mistake.

2.20 The EESC urges caution when acting on proposals within the package. Whilst we generally support the package of regulations, the EESC expects an assessment to be made of the situation and the adequacy of the package of regulations once the pandemic is over and a more clear picture of the impact emerges.

3. EU Regulation on serious cross-border threats to health

3.1 The EESC welcomes this Regulation that will lead to the creation of a stronger and more comprehensive legal framework allowing the Union to better prepare for and react rapidly to cross-border health threats.

3.2 It is the view of the EESC that the current coordination mechanisms were vastly insufficient to contain the COVID-19 pandemic and protect people living in the EU, in as much as:

3.2.1 Current health security arrangements, based on the Early Warning and Response System (EWRS) and the exchange of information and cooperation within the Health Security Committee, could do little to trigger a timely common EU-level response, coordinate the crucial aspects of risk communication, or ensure solidarity among MS.

3.2.2 There was a fragmented approach to containing the virus which undermined Europe's ability to prevent its spread. In too many MS the measures introduced were not done according to scientific advice. We have seen this reflected in the infection rate of countries that were slow to adopt preventative measures, did not impose lockdowns or opted for a "herd immunity" approach. Specific geographical circumstances of MS, such as the borders they share with other countries with high infection rates or those experiencing a significant flow of migrants and refugees, were not taken sufficiently into consideration.

3.2.3 Persons in institutional care were particularly prone to infection and accounted for a disproportionate number of fatalities. For example, data available indicate that people in institutional settings were facing, and continue to face, the highest rates of infection and mortality from COVID-19. In Slovenia, for instance, 81% of COVID-19 deaths were among care-home residents[8]. The virus has had a devastating impact in these settings and future EU action on health security should fully address this gap.

8 A. Comas-Herrera et al., *Mortality associated with COVID-19 outbreaks in care homes: early international evidence*, (May 2020)

3.2.4 When primary and emergency care units reached saturation, those most at risk of infection and severe health implications were the first to be denied treatment under systems of *triage*. Older people and persons with disabilities were particularly at risk of being denied emergency treatment.

3.2.5 The start of the pandemic saw severe shortages in personal protective equipment (PPE) and medical equipment. The pandemic exposed cracks in EU solidarity, with some MS preventing the export of PPE or ventilators to other MS that were in dire need of them. The lack of central EU Health Technology Assessment (HTA) for pharmaceuticals and medical devices also came to light as a considerable issue. These are issues the EU should never be faced with again.

3.2.6 There was a lack of disaggregated data on the groups most affected by COVID-19, which hampered attempts to identify and protect those most at risk.

3.2.7 Inconsistent communication with the public and stakeholders such as healthcare professionals across the EU, as well as between MS, had a negative impact on the effectiveness of the public health perspective response. There is also a lack of effective implementation of EU e-health tools and new artificial intelligence technologies.

3.3 It is the view of the EESC that the EU Regulation on serious cross-border threats to health could help alleviate such problems during future EU-wide health crises by:

3.3.1 Establishing a joint EU procurement procedure and providing for strategic stockpiling via the rescEU reserve to help mitigate similar shortages during future EU-wide health crises. It will be especially important to provide for medicines that are useable by the entire population and, in cases where certain groups will require adapted or alternative forms of treatment owing to their age, sex and gender, condition or disability, that this is taken fully into account.

3.3.2 Creating a comprehensive legislative framework to govern and effectively implement action at Union level on preparedness, surveillance, risk assessment, and early warning and responses. Preparedness for protecting high-risk groups should begin immediately, particularly with regard to those in grouped living conditions and institutions where it has been shown to be very difficult to sufficiently protect residents and respect their rights, as well as to ensure health and safety in terms of working conditions and an adequate level of personnel both in the health and care sectors. This Regulation should also foresee improved monitoring of the shortages of health and care workers in order to assist Member States, the European Commission and the national and European social partners to consider solutions to make work in the sector more attractive and so improve recruitment and retention.

3.3.3 Mobilising scientific expertise and interdisciplinary dialogue in a coordinated manner. It is the opinion of the EESC that this should be done hand in hand with the expertise of civil society, particularly organisations representing groups that are at high risk during pandemics such as older people, homeless people, people from ethnic minorities and persons with disabilities. It should also include the healthcare sector, researchers and other relevant actors, including social economy enterprises.

3.3.4 Enabling the EU's Health Security Committee (HSC) to deliver guidance in the adoption of common measures at EU level to face a future cross-border health threat. The European social partners in the health sector (such as in the European Social Dialogue Committee for the Health Sector) should be consulted and included in the governance of the committee.

3.3.5 Facilitating the reporting of health system data and other relevant data for the management of cross-border threats. This data collection needs to be disaggregated to provide a clearer, Union-wide understanding of which groups are most at risk and most affected by health threats. The data should take into account gender, age, ethnicity, migration background, disability and chronic diseases. It should also cover data on the supply of health and social care professionals, stock of medicines, medical devices and personal protection equipment, intensive care and acute care bed capacity and beds in use, ventilators and ventilators in use, testing capacity and tests performed, and data on the resourcing of public health departments to ensure adequate, needs-oriented staffing levels, in particular per capita staffing levels for community medicine. It is also important to gather information on the inclusiveness of the national healthcare systems to ensure more equal access. This data should be used to adopt recommendations including on ratios for resources per population unit, including the number of healthcare and social services personnel, developed on the basis of good practice and policy assessments.

3.3.6 Establishing new EU networks of laboratories. Attention should be paid to how to ensure that medical innovations and responses are accessible to all, regardless of their MS or region of residence, and how to make them affordable to everyone.

3.3.7 Training programmes for specialists, which should also take into account the specific needs of different profiles of patients, health and care workers and the move towards e-health and telemedicine. We have seen during the COVID-19 pandemic that age and the existence of various conditions and disabilities has had an enormous impact on the risk of serious symptoms and fatalities. Regarding persons with disabilities and chronic diseases in particular, it is crucial that specialists understand how to properly consult patients, respect the free will of all and ensure nobody is coerced into treatment. Training should be consistent with the one-health approach. Moreover, at border regions, joint cross-border exercises should be promoted and familiarity with public health systems encouraged.

4. European Centre for Disease Prevention and Control

4.1 The EESC welcomes the reinforcement of the mandate of the European Centre for Disease Prevention and Control ("the Centre") addressing surveillance, preparedness, early warning and response under a strengthened EU health security framework.

4.2 This extension and expansion of the Centre's mandate comes at an opportune time and, if it is successful, will be a building block to enable the Union to better deal with the COVID-19 pandemic. It also has the potential to address the weaknesses the pandemic has highlighted in public health and health crisis response at EU and national level.

4.3 It is the view of the EESC that the Centre did not have the mandate, the mechanisms or the resources needed to respond to the COVID-19 pandemic in a consistent and effective way.

4.4 The principle of subsidiarity applies to national public health matters. However, in our Union, which involves significant movement of people and goods across borders, all communicable diseases are, potentially, cross-border health threats which deserve EU-level surveillance, preparedness, risk assessment, early warning and response.

4.5 The pandemic has revealed the toxic relationship between communicable and non-communicable diseases. The vast majority of COVID-19 deaths have been linked to underlying and pre-existing health conditions and chronic disease patients' access to treatment was negatively affected by the pandemic. Therefore, the crisis response mechanism and the European Health Union should also include non-communicable diseases.

4.6 The external evaluation of the Centre published in September 2019 highlighted important ways in which the Centre should be strengthened. It highlighted the need to strengthen relevance to MS, and to focus on addressing structural gaps and deficiencies in MS' public health systems that affect their ability to effectively contribute and optimally benefit from the ECDC's activities. The evaluation pointed to the need to review and expand the mandate of the Centre, and to amend the existing regulation.

4.7 The EESC notes that health protection is fundamental to the protection of human rights. Failure to adequately survey, prepare for, warn about and respond to health threats, as we continue to observe during the pandemic, undermines human rights, notably the right to health, and drives inequalities.

4.8 The proposal includes important improvements in the Centre's capacities:

- Improved ability to monitor the health situation will be strengthened based on digitalised surveillance systems.
- Better preparedness in the MS, through development of national prevention and response plans and stronger capacities for integrated rapid health responses.
- Reinforced measures to control epidemics and outbreaks through binding recommendations for risk management.
- Expanding the capacity to mobilise and deploy the EU health task force.
- Monitoring and assessment of health systems' capacity for diagnosis, prevention and treatment of specific communicable and non-communicable diseases.
- Reinforced capacity to identify the sections of the population most at risk and in need of targeted response measures.
- Strengthened links between research, preparedness and response, and policy liaising between public health and research communities.
- Building up competencies for health protection through the coordination of a new network of Union reference laboratories and a new network of national services supporting transfusion, transplantation and medically assisted reproduction.
- Expanding work on communicable diseases.
- Contributing to the EU's commitment to global health security and preparedness.

4.9 The EESC has repeatedly called for the strengthening of public health investment in the EU. In doing so, through the reinforcement of the Centre's mandate, it will be important to keep in mind the following:

4.9.1 The Centre should have the mandate and resources to address health inequalities and ensure EU health responses are targeted to those classed as being most at risk by multi-disciplinary scientific experts. Identification of those most at risk should be based on quality disaggregated data that includes these populations. This should meaningfully involve civil society, social partners, service providers and members of the most affected communities. Coordination between public health systems, the medical profession and civil society, including the social partners and SEEs working in the field of health, is key to sharing information.

4.9.2 Health is not a stand-alone issue. It is closely linked with a decent standard of living, decent work, adequate housing and nutrition and a full range of services and support. The EU has already committed to advance a Social Europe through the EPSR. The Centre must also be equipped to measure and to generate recommendations to the relevant EU structures such as those overseeing the European Semester process and the renewed Social Scoreboard of the EU Pillar of Social Rights. In coordination with these structures, it should be able to guide MS on the social determinants of health and on how to enhance health by addressing social determinants.

4.9.3 The Centre should be mandated to monitor investments and generate recommendations on the financing of health surveillance, risk assessment, preparedness and response, both for the EU and the national level.

4.9.4 Collaboration in systematic monitoring should take place between the ECDC and national centres for disease control. Together they should monitor who is most affected by health threats, detect cases and hotspot, spot trends and give recommendations.

5. EU Regulation on a reinforced role for the European Medicines Agency

5.1 The EESC welcomes the renewed role of the European Medicines Agency (EMA) and its increased capacity to mitigate shortages of medicines and medical devices across the EU.

5.2 It is the view of the EESC that the current role of the EMA was insufficient to deal with the challenges posed by the COVID-19 pandemic, particularly given that at the start of the pandemic in particular the EU saw severe shortages in life-saving medical equipment such as ventilators. Shortages were particularly noticeable in some MS and there was insufficient coordination in distributing devices and PPE fairly throughout the Union.

5.3 The renewed role and increased capacity of the EMA, to be activated in the event of another health crisis at EU level, will help alleviate the problems witnessed during the COVID-19 pandemic by:

5.3.1 Establishing a Medicines Steering Group and a Medical Devices Steering Group that would report back to the EC and MS on shortages or risks of future shortages. The Steering Groups, made up of experts from across the EU to offer a coordinated approach, should include professionals specialised in adapted medical treatment for those more at risk of health complications during pandemics such as the one we have just experienced. This will of course depend on the type of health crisis the EU is going through, but will typically necessitate knowledge of adapted treatment according to sex and gender for older people, persons with disabilities and persons with serious health conditions. Civil society organisations should also be included and consulted in a meaningful way.

5.3.2 Reacting before there are shortages of medicines and spotting potential shortages. This needs to be the case not only for the most commonly-used medicines on the market in the EU, but also to ensure the continued availability of medicines and medical devices for rarer conditions, to ensure they are available in all MS and in all localities when needed.

5.3.3 Coordinating studies alongside the European Centre for Disease Prevention and Control (ECDC) to monitor the effectiveness and safety of vaccines, and facilitating a "rolling review" in which a taskforce will look at data and evidence coming out of clinical trials in real time in order to speed up the process. This taskforce will also give scientific advice on draft clinical trials for medicines and vaccines. In exercising this competence, the taskforce should encourage the setting of the clinically most relevant performance targets for medicinal products to be measured in clinical trials. The agency already gives scientific advice, but this will now be done in a fast-tracked way within 20 days and free of charge.

5.4 There are several challenges for the EMA in its future activities. The agency needs to ensure that the supply of medicines and medical devices across the EU is not only consistent and sufficient, but that there is availability of stock that is affordable for citizens.

5.5 At this time the biggest challenge is rolling out the COVID-19 vaccinations It is to be regretted that the EU's strategy for vaccination overlooks certain high-risk groups as being eligible for fast-track vaccination, such as persons with disabilities and persons with chronic diseases. The order of treatment should be defined by multi-disciplinary scientific analysis that takes into account discrimination and the exposure of groups of people to the virus. The vaccine should be treated as a public good, and as such it is crucial to ensure that the timely administering of vaccines to the population is not overly hindered by restraints linked to things such as intellectual property rights. The saving of lives must always be the top priority for the EU. It is therefore vital that the EC ensure that Europe remains the leading continent when it comes to vaccine development.

5.6 During the COVID-19 pandemic the EMA has proactively shared data on approved vaccines and medicines and information on the conduct of the Agency's activities. The EMA has also explained the regulatory processes to the public. This level of transparency is considered highly

beneficial and should be also ensured in the future. For this purpose, the Regulation should include a provision that all clinical trial data on the basis of which the Agency authorises medicines or vaccines should be published, as should clinical trial protocols on which the Agency advises, in line with the Clinical Trial Regulation.

5.7 The EESC encourages the EMA to work with all health stakeholders to establish a European model for the fair, accountable and transparent pricing of medicines and for accessible pharmaceutical innovations.

6. Health emergency response authority

6.1 The EU is planning the creation of a European Health Emergency Response Authority (HERA). The legislative proposal to set up the agency is set to be released in the fourth quarter of 2021, but the outline of HERA has already appeared in the recently released Pharmaceutical Strategy for Europe.

6.2 The plan is for HERA to fill a major structural gap in the EU's crisis preparedness and response infrastructure. It will strengthen coordination between MS by developing strategic investments for research, development, manufacturing, deployment, distribution and use of medical countermeasures. In order to achieve this, HERA will help the EU better respond to arising health needs by:

- Anticipating "specific threats and enabling technologies through horizon scanning and foresight". This will require a considerable level of outreach to civil society groups representing people who are typically more at risk during health emergencies, in order to gauge the ways in which potential threats might have a disproportionate effect on them.
- Identifying and addressing investment gaps in key countermeasures including the development of innovative antimicrobials.
- Monitoring and pooling production capacity, raw material requirements and availability, thus addressing supply chain vulnerabilities.
- Supporting the development of cross-cutting technological solutions such as vaccine platform technologies, which sustain preparedness and response planning for future public health threats.
- Developing specific countermeasures, including through research, clinical trials and data infrastructure.

6.3 The EESC questions the overlap between objectives foreseen under the HERA and those under the ECDC, the EMA and the Regulation on serious cross-border threats to health. Issues of crisis preparedness, research, data and coordinated distribution of medicines and medical devices seem to be covered in the aforementioned Regulations. The added value of the HERA therefore seems unclear, and even perhaps risks blurring the lines between which body is responsible for which area of healthcare coordination. For example, it is unclear if the recommendations coming from the HERA would have precedence over those coming from the EMA in the case of the declaration of an epidemic affecting the EU.

6.4 The HERA should be a purely public organisation with a clear public health mission, not to be conflated with areas of industrial policy, and willing to exercise judgment that is independent of the pharmaceutical industry, and design solutions that are public health driven (for example, in the field of tackling antimicrobial resistance). It should have a sizable budget which will provide for independent long-term planning. A reasonable pricing clause should be envisaged in the legal texts governing how the HERA functions.

6.5 What can be seen, however, as HERA's added value is the coordination role for the manufacturing of medical and protective equipment, as well as medication. The monitoring and pooling of production capacity, raw material requirements and availability is also an area in which the HERA will stand out compared to the work of the EMA and the ECDC. A successful HERA is a strong, independent and transparent public agency. The public interest should be at its core, translated into its priorities, governance and actions. Ensuring better disaggregated data in vulnerable groups would be a prerequisite for fighting health inequalities.

6.6 The EESC considers there are unaddressed issues that the HERA could logically be given the authority to oversee, and which have not yet been alluded to in any previous communications. The HERA is a great opportunity to build on the excellence of European science, to learn the lessons from the ongoing crisis and ensure that the public sector acts as a wise investor which steers meaningful, public health needs-driven innovation. In light of the overlaps with the work of other authorities, it could be advantageous to adapt HERA's scope and responsibilities to include:

6.6.1 Coordinating an EU task force focusing specifically on the impact that health emergencies have on high-risk social groups, as well as on health and care workers. This working group could focus on, although not exclusively, older people, persons with health conditions and persons with disabilities.

6.6.2 Focusing on non-discrimination in the EU's response to future pandemics, ensuring that preventative measures, emergency medical care and treatments are available to everyone, including homeless people, travelling communities and undocumented people residing in the EU, all of whom are at risk of falling through the cracks during a public response to health crises.

6.6.3 Communication campaigns during health emergencies to ensure people have a better level of understanding on how to protect themselves, what adaptations they need to make to their daily activities to remain safe and, if and when treatments are available, how to have access to them. This communication needs to be directly addressed and accessible to all people and take into account the particular needs of high-risk groups such as older people, persons with health conditions and persons with disabilities. During the ongoing COVID-19 pandemic, this communication has depended to a large extent on the work of civil society organisations. They should therefore be consulted in this activity.

6.6.4 The governance structure of the HERA should be transparent and balanced, including patient and public health organisations, civil society and the social partners, and representatives of the research community. Whilst the industries will be important partners, they should not be part of any governance structure of this new public organisation. The definition of global unmet needs will be done by the public health sector only and the goal will be to engage in the development of new products to bring them to the market.

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