European Committee of the Regions

CoR INTERREGIONAL GROUP ON HEALTH & WELL-BEING

"Discussing the future opinions of the CoR on strengthening the mandate of the ECDC and on the Pharmaceutical Strategy"

Tuesday, 2 March, 10h00-12h00

Online meeting

Minutes

10.00 Welcome and introduction by the Chair, Birgitta Sacrédeus

The chair of the Interregional Group, **Ms. Sacrédeus**, welcomed all the participants and explained that the meeting was organized to discuss the European Commission's proposals on strengthening the mandate of the ECDC and EMA, and the Pharmaceutical Strategy in view of the Committee of the Region's plenary session scheduled for early May.

10.05 Discussion on the 'Regulation for tackling cross-border health threats and legislative proposal for changing the mandate of the European Centre for Disease Control (ECDC)'

1. *Exchange with Ms. Agnes Molnar, Deputy Head of 'Health security and Vaccination' Unit, DG SANTE*

Ms Molnar opened her contribution with an overview of the European Commission's proposal to build a European Health Union, which is defined by the following documents: the EC's communication 'Building a European Health Union', the proposal for a 'Regulation on serious cross-border threats to health, the proposal to extend the mandate of the European Centre for Disease Prevention and Control (ECDC), and the proposal to extend the mandate of the European Medicines Agency (EMA). These proposals aim to strengthen the EU's health security framework and to reinforce the crisis preparedness and response role of key EU agencies. COVID-19 pandemic highlighted the need to build strong capacities for surveillance, preparedness, early warning, risk assessment, and response. As regards the proposal for a Regulation on serious cross-border threats to health, Ms. Molnar explained that the EU health crisis and pandemic preparedness plan includes interregional elements and the coordination for the adoption of plans at national levels, a comprehensive and transparent framework for reporting and auditing on preparedness, regular public health and cross-sector stress tests and exercises carried out with the Member States, targeted training and knowledge exchange activities

for healthcare and public health staff, and a reinforced joint procurement agreement beyond the EU. According to this proposal, the epidemiological surveillance will be structured on a new system at the EU level, which will use artificial intelligence, harmonised datasets and digital tools, risk assessment and response for novel pathogens based on common EU case definition. ECDC will have strengthened access to health data for research and epidemiological aspects in the context of the European Health Data Space. Another important point will be the creation of an EU reference laboratories network that would allow alignment on diagnostics, serological testing and testing methods, and the creation of a network including Member States services for transfusion, transplantation, and medically assisted reproduction. Ms. Molnar pointed out that a coordinated response at the EU level will be guaranteed through recommendations by ECDC as part of rapid risk assessment, the adoption of opinions and guidance by the Health Security Committee and Commission Recommendation on response measures, and the support of an independent Advisory Committee in recognizing emergencies. The proposal will extend the mandate of the ECDC by giving it more responsibilities and power about recommendations, epidemiological surveillance, early warning, and response mechanism (in terms of alertness, information exchange, and preparedness planning).

2. *Exchange with Mr Sándor Rónai (S&D, HU), MEP from ENVI Committee and Shadow Rapporteur for "Public health: European Centre for disease prevention and control".*

Mr. Rónai opened his contribution by stressing the importance to take into consideration the lessons we have learnt from the COVID-19 pandemic, especially in terms of opportunities for collaboration between the Member States in the field of health. In November 2020, the European Commission adopted two legislative proposals which are among the first steps towards building the European Health Union and put forward the aim to strengthen the EU's health security framework, and to reinforce the crisis preparedness and response role of key EU agencies. Mr. Rónai informed that, as a member of the ENVI Committee, he is working as a shadow rapporteur for the procedure file "Public health: European Centre for disease prevention and control".

Mr. Rónai is convinced that the ECDC must have more powers to act in emergencies and in view of future health challenges. Currently, ECDC is unable to collect data autonomously and relies heavily on the willingness of Member States to provide requested data. Moreover, it has no authority to enforce standards in the collection and reporting of data. He underlined that reliability and comparability of data is a key point, especially during health emergencies. The proposal aims to reinforce the capacities of the ECDC to assess and support the preparedness of countries, so they can appropriately face future cross-border health threats. According to Mr. Rónai, the key points to control epidemics and outbreaks

are better integrated digital systems, automated contact tracing, the monitoring of health systems capacity, better coordination and trust among networks (including EU reference laboratories). Moreover, the ECDC will have the capacity to mobilize and deploy the task force to assist local responses to the outbreak in the Member States.

Then, he highlighted the strict relationship between public health issues and environmental issues, and for this reason, the European Union needs a holistic approach that should take into consideration not only humans but also the environment. In Mr. Rónai's opinion, the EU needs a more active role of ECDC in the prevention and the Member States should have more legally binding obligations. Another big area in this expansion of the scope of the ECDC should be more inclusiveness in terms of diseases (not only communicable diseases). Finally, Mr. Rónai stressed that he is aware that the EU needs a significant increase in budget and needs to include regional authorities, civil society, international organisations, agencies, Member States, and other stakeholders in the dialogue.

10.30 Questions and Answers

Ms. Sacrédeus agreed with Mr. Rónai on the importance to take into consideration the local and regional authorities. She stressed that in 19 out of the 27 Member States local and regional authorities share health competencies and are involved in funding healthcare. She asked the speakers how we can involve the local and regional level in the framework proposed by the European Commission.

Ms. Deirdre Forde, a member of the Interregional Group on Health and Well-being, expressed her confidence in the role of the European Union in protecting the health of European citizens and stressed the need to work together in a more integrated way. In Ms. Forde's experience, during the COVID-19 outbreak, local agencies had a very important role and their action was successful. She added that data is a crucial issue and regional authorities can be and should be responsible for the gathering of data. According to Ms. Forde, strengthening EU agencies is the only way to build up a stronger European Health Union, and cross-border cooperation is a fundamental element in achieving this objective.

Mr. Jacques Scheres, former European Parliament representative on the Management Board of the European Centre for Disease Prevention and Control from 2004 to 2016, agreed with Mr. Rónai on the weak use of ECDC potential to fight the pandemic and address other issues. He asked the speakers how to exploit the ECDC potential and how to reinforce the effectiveness of ECDC.

Mr. Rónai recalled one of the slogans used for the European Parliament elections of 2019, which was the construction of the United States of Europe. This slogan reflects the awareness that only a united Europe can have the strength to face global challenges. Members States have to communicate and collaborate to find common solutions. Referring to his experience as a politician in local authorities in Hungary, he stated that it is very important to have global solutions and be aware of how to connect these solutions with local politicians and citizens.

Ms. Molnar took the floor pointing out that the extension of the ECDC mandate and the cross-border regulation provides a framework that respects article 168 of the TFEU, which gives the EU only supporting competence in the health policy domain. Concerning the extension of ECDC's responsibilities to chronic and non-communicable diseases, she stressed that previous external evaluations (2019) on ECDC addressed the question of extending the mandate to chemicals, environmental threats, and non-communicable diseases, which should be carefully assessed considering resources and potential overlap with other mechanisms and bodies at EU level. As regards the role of regions and local authorities, she emphasised the added value of the regional and local authorities during the COVID-19 outbreak, especially in terms of cross-border cooperation. The Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare include elements from the new health security framework proposed by the European Commission, such as the intensification in exchange of services, the capacities of intensive care, emergency transports, and so on. This system was developed to include a functionary framework for the Member States, and there is the possibility to exchange information with regions. The European Commission hopes that regional and local authorities will be involved in this new EU preparedness and response system. The discussion on the challenges, objectives, and instruments should be discussed between the European Union, Member States, CoR, and other stakeholders.

11.00 Discussion on the 'Europe's pharmaceutical strategy and legislative proposal for changing the mandate of the European Medical Agency (EMA)'

1. *Exchange with Mr. Sylvain Giraud, Head of 'Medical products: quality, safety, innovation' Unit, DG SANTE.*

Mr. Giraud dedicated the first part of his contribution to the proposal of extending the EMA mandate. This is a specific proposal that tries to address how to reinforce the crisis preparedness and response role of the European Medicines Agency for future health emergencies. He analysed that the pandemic

has highlighted some of the challenges that already existed in terms of ensuring the security of supply, the security of imports from a certain country, better coordination of the different levels of governance of medicines policy across Europe, and in terms of reinforcing the capacity of the public authority to monitor the supply chain and have an understanding of possible difficulties in getting products into the market. The EMA mandate should be enforced to ensure and facilitate this coordination concerning shortages of medicines and medical devices, but also to monitor and to address and prevent risks, and to ensure that therapies and new vaccines can be compatible as fast as possible. The proposal aims to develop a certain number of necessary tools and mechanisms to identify the medicinal products that are considered predictable during crises, to collect data and more regularity on demand and supply for this particular product by establishing a network of national contacts in collaboration with industry organisation and the relevant marketing authorization orders. During the first wave of the pandemic, the European Union gave EMA the capacity to coordinate and the possibility to recommend measures that could be taken by the Commission and the Member States.

As regards the Pharmaceutical Strategy for Europe, Mr. Giraud explained that it is a different kind of document: it is not a legislative proposal, but it is a policy paper and has a broader focus. On the basis, there is the revision of the basic pharmaceutical legislation. The European Commission has the ambition to generate and push further cooperation between Member States authorities and was working on this policy document before the COVID-19 outbreak to address challenges identified in terms of availability, accessibility, affordability, and innovation. Mr. Giraud stated that the European Commission needs to ensure that the industrial sector can continue to provide and produce the type of products that reflect the needs of patients and health systems. This new system is adapted to scientific developments and new types of products, which have to be absorbed appropriately by the system. Then, Mr. Giraud stressed that there are two types of instruments the EC can use: the first type is legislation, which regulates the authorization and other aspects of pharmaceutical products at the EU level; the second type the use of cooperative instruments at the EU level between the Member States supported by the Commission, which provides the framework to work together on common priorities.

11.20 Questions and Answers

As rapporteur of the CoR's opinion on EMA mandate and Pharmaceutical Strategy, **Ms. Sacrédeus** informed that CoR's NAT Commission will discuss the document and the whole package on the 22nd of March. Then, she opened the Q&A session asking Mr. Giraud if there is a risk that the proposal on

extending EMA's mandate and Pharmaceutical Strategy would require the Member States to share sensitive information about national preparedness.

Mr Giraud said that during the COVID-19 outbreak public authorities realised that sharing information - on medicines, masks, beds, medical devices, healthcare workforce, vaccines - is crucial. The focus of the authorities is not on the manufacturing aspects but safety, and this is why the European Union needs to put in place instruments to ensure safety and efficacy, for example concerning pharmacovigilance, the understanding of scientific risks, and the availability of products. He underlined that having a detailed overview of the situation allows public authorities to take rights public health decisions: to optimize these decisions we have to consider these aspects as international organisational issues. As regards the responsibilities of the EU and other agencies in the health field, he pointed out that it is not about the transfer of competencies, powers, or responsibilities from the national level to the EU level. At the European level, there is now a broad consensus that there are challenges that countries cannot face alone. Sharing information and having common tools and mechanisms can be an opportunity to be stronger in national policymaking.

Mr. Jean-Luc Vanraes took part in the debate by stressing the inefficiencies in the delivery of vaccines in European countries in terms of supply and vaccination campaigns. In this regard, he asked if the contracts signed in the EU have some clause similar to US contracts, in which there is a clause that guarantees that vaccines first go to the country where they are produced. Another problem stressed by Mr. Vanreas was the lack of cooperation between countries for some exceptional and specific medicines in terms of affordability and access.

Mr Giraud pointed out the EU Member States decided to buy vaccines together and ask the Commission to provide a framework in which they could coordinate. He expressed his disappointment in blaming the European Commission for the inefficiencies that are due to pharmaceutical industries and the vaccination campaigns in the Member States. At the moment, the European Commission is trying to work very carefully and closely with the companies to support and help them as much as possible, so these companies can develop contractual arrangements with other companies to increase the production. The countries are receiving doses according to their population, but not all countries are efficiently implementing vaccine distribution. As regards the contracts for vaccines, there are also clauses in the EU contracts about the obligation to provide products that come from countries inside the EU. On the 29th of January, the European Commission took a measure to give more transparency and visibility to the exports of vaccines and products that are produced in Europe. The European

Commission put in place a measure by which we impose on them to let the EC know how much, where and how companies are exporting to have more transparency about the supply chain.
As regards the high cost of some medicine, Mr. Giraud assured that this is an aspect on which the European Commission is working and recalled that they relaunched a group of national authorities responsible for pricing and reimbursement to address this issue collectively. This aspect falls within national competence.

Mr. Yve Verboven (MedTech Europe) focused his question on the opportunity to exploit potential digital advances in the Pharmaceutical Strategy framework and the need to accelerate the processes of approval in crises.

As regards the first aspect, **Mr. Giraud** affirmed that some elements in the Pharmaceutical Strategy deal with the promotion of health technology assessment, scientific developments and technological transformation. As regards the acceleration of approval processes, Mr. Giraud stressed that the way to accelerate and promote better integration is by ensuring that those processes – assessing the efficacy and safety, assessing the cost-effectiveness, assessing the value for money, and the capacity of reimbursement – are considered simultaneously in the development of the product.

Ms. Sacrédeus thanked those presents and the speakers for participating and the EUREGHA Secretariat for the organisation of the meeting. She reminded those presents that these proposals will be discussed in the CoR's NAT commission on the 22nd of March and she informed that the final opinions on these proposals should be adopted by the CoR at the plenary session scheduled in May.

12.00 End of the meeting