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HEALTH EMERGENCIES AND LEGAL PREPAREDNESS IN THE EU: TAKING STOCK OF THE POST-PANDEMIC REFORMS

Monday, June 24th 2024 - Room 1, Piazza Scaravilli, Bologna

09:15-09:30 Welcome
Prof. Federico Casolari - Director of the Department of Legal Studies, University of Bologna
Prof. Giacomo Di Federico - Professor of European Union Law, University of Bologna

09:30-10:30 Session I - The Institutional Perspective
The reinforced role of EMA
Dr. Chiara Bortoluzzi, Head of General Affairs and Anti-Fraud, European Medicines Agency

The new mandate of the ECDC
Dr. Adriana Romani, Expert Emergency Preparedness and Response Support, European Centre for Disease Prevention and Control

The creation of HERA
Dr. Bartłomiej Kurcz, Head of Unit, European Commission

10:30-11:00 Coffee Break

11:00-12:00 Session II - The Academic Perspective
Strengthening legal preparedness in the European Union after the pandemic
Prof. Tamara Hervey, Jean Monnet Professor of EU Law, City, University of London

The expansion of EU power in Public Health
Prof. Anniek De Ruijter, Professor of Health Law and Policy, University of Amsterdam

Digital health and future regulatory challenges for the European Union
Prof. Vincenzo Salvatore, Professor of EU Law, Università degli Studi dell'Insubria

12:00-12:30 Debate

The meeting can be followed online through the following Teams link: https://teams.microsoft.com/l/meetup-join/19%3ameeting_MTZkOWJkZWEtYjhkZi00ZWQ2LWI4NjItZTRkYzk0MDg2ZGJi%40thread.v2/0?context=%7b%22Tid%22%3a%22e99647dc-1b08-454a-bf8c-699181b389ab%22%2c%22Oid%22%3a%220f0856c9-4f37-404e-9e1b-50e5fefea7fa%22%7d
Meeting ID: 369 770 571 257 - Passcode: EEUqH5

EVENT REPORT

HEALTH EMERGENCIES AND LEGAL PREPAREDNESS IN THE EU: TAKING STOCK OF THE POST-PANDEMIC REFORMS

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09:15-09:30 Welcome

Prof. Federico Casolari - Director of the Department of Legal Studies, University of Bologna

Prof. Casolari explained that this is an event organised within the realm of the project HELP 'Health Emergencies and Legal Preparedness'. The project is a Research Project of Relevant National Interest (*Progetto di ricerca di Rilevante Interesse Nazionale – PRIN*) and is co-funded by the European Union (EU). It involves the University of Bologna (Department of Legal Studies) and Scuola Superiore Sant'Anna (Institute of Law, Politics and Development – DIRPOLIS). The idea behind the HELP project is to elaborate a reflection on how we prepare for health emergencies from a legal point of view at the national, regional and international levels. Health emergencies happen and institutions must be prepared for them. There should be a regulatory framework in place, and this framework should also respect human rights. Institutional actors should be able to reply to emergencies by design.

Prof. Giacomo Di Federico - Professor of European Union Law, University of Bologna

Prof. Di Federico mentioned that this event is also connected to the Jean Monnet module HEAL (The protection of Health in Europe: Actors and Legal Instruments). HEAL investigates the legal aspects related to the creation of a European Health Union, EU health governance and legal preparedness (LP) at the EU level. HEAL includes the implementation of a course on 'European Health Law' in Italian. The aim is to promote studies in this branch of EU law both among Italian and international students.

09:30-10:30 Session I - The Institutional Perspective

The reinforced role of EMA

Dr. Chiara Bortoluzzi, Head of General Legal Affairs and Anti-Fraud, European Medicines Agency

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Dr. Bortoluzzi's presentation concerned the reinforced role of the European Medicines Agency (EMA). She focused on two main fields: a) the reinforced role of the EMA in crisis preparedness and crisis management, and b) the reinforced role of the EMA in the management of shortages of medicinal products and medical devices. EMA is an EU agency, whose competence is laid down in Reg. 726/04. In particular, the EMA is responsible for coordinating the existing scientific resources put at its disposal by Member States (MS) for the evaluation, supervision and pharmacovigilance of medicinal products. In addition, the EMA provides the MS and the EU institutions with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products.

The COVID-19 pandemic was an unprecedented moment for the EMA and the public interest in the activities of the Agency increased. Arrangements under EMA Health Threats Plan became crucial for response to the pandemic – in particular, the operations of EMA Pandemic Task Force (ETF) and of the EU Executive Steering Group on Shortages Caused by Major Events. In addition, the EMA coordinated EU-wide actions to address medicines shortages. The success of these initiatives created during the pandemic led to the adoption of the new Reg. 2022/123 which extended the EMA's mandate.

Reg. 2022/123 makes permanent some of the structures and processes established by EMA during the COVID-19 pandemic, for example, the ETF. It creates new structures within the EMA to ensure a response to manage issues related to shortages of medicines and medical devices: Medicine Shortages Steering Group (MSSG) and Medical Device Shortages Steering Group (MDSSG). It entrusts several new tasks to EMA, such as the monitoring of medicines shortages. These new tasks are performed in close collaboration with the European Commission (EC), the Health Emergency Preparedness and Response Authority (DG HERA) and the European Centre for Disease Prevention and Control (ECDC).

The ETF is an advisory and support body on medicines for public health emergencies and preparedness to be convened in preparation for and during public health emergencies. Among others tasks, the ETF provides scientific advice on the development of products intended for use in public health emergencies. It reviews scientific data and provides recommendations on the use of unauthorized medicines. Thus, ETF's tasks concern preparedness activities for future emergencies, such as monitoring outbreaks and epidemics; providing scientific advice on medicines with potential to address future emergencies and coordinating activities with DG HERA, ECDC and the World Health Organization (WHO).

Under Reg. 2022/123, EMA has strengthened and new roles in data collection. There are two main projects in this regard: DARWIN EU (Data Analysis and Real World Interrogation Network) and the EMA/ECDC Vaccines Monitoring Platform. EMA has also a reinforced role in the management of shortages of medicinal products and medical devices. Reg. 2022/123 provides a framework to monitor and mitigate potential and actual shortages of medicines and sets tools for shortages reporting and coordinating responses; establishes the MSSG and the MDSSG; foresees the development of the European Shortages Monitoring Platform (ESMP), which should be ready in February 2025.

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The new mandate of the ECDC

Dr. Adriana Romani, Expert Emergency Preparedness and Response, European Centre for Disease Prevention and Control

Dr. Romani focused on the new mandate of the ECDC. The ECDC was established in 2005 by Reg. 851/2004. It is an independent European Agency for disease prevention and control aiming at strengthening Europe's defences against infectious diseases. The main areas of work of the ECDC include surveillance; emergency preparedness and capacity strengthening; epidemic intelligence, risk assessment and outbreak response; public health training, and scientific advice and guidance.

COVID-19 highlighted gaps in the effectiveness of the ECDC's response to the pandemic. This led to Reg. 2022/2370, which amends Reg. 851/2004 establishing the agency by expanding the mission and tasks of the ECDC. The expansion aims to enhance ECDC's capacity to provide robust and independent scientific expertise and to enhance actions which are relevant to the prevention, preparedness and response planning for the combatting of serious cross-border threats to health.

In addition, Reg. 2022/2371 of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU was published on 6 December 2022. This new regulation aims at creating a more robust mandate for coordination at EU-level, updating reporting requirements as regards health system indicators and streamlining cooperation between EU countries, the EC and EU agencies.

According to Art. 5b of Reg. 2022/2370, the ECDC must contribute to the development, regular review and updating of frameworks for national preparedness plans and to the development, regular review and updating of the Union prevention, preparedness and response plan; facilitate self-assessments by MS of their prevention, preparedness and response planning and external evaluation of such planning; ensure assessment of preparedness gaps and the provision of targeted support to MS; support and complement additional targeted activities addressing at-risk groups and community preparedness.

The ECDC supports the MS reporting on emergency preparedness and response planning. In parallel, the centre coordinates the assessment of the MS's state of implementation of their prevention, preparedness and response plans every three years. The ECDC collaborates with countries to identify challenges, gaps or areas for improvement, and supports countries through targeted assistance upon request.

Another relevant article of Reg. 2022/2370 is Art. 8a, which concerns public health risk assessments. According to this article, the ECDC provides risk assessments in the case of a serious cross-border threat to health, including where it relates to substances of human origin that can potentially be impacted by communicable diseases and in case of threats of unknown origin. Risk assessments can include general and targeted science-based recommendations. Where the risk assessment falls outside the mandate of the ECDC, and at the request of the agency or body carrying out the risk assessment within its mandate, the ECDC must provide the

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agency or body with relevant information and data that are at its disposal. It must be noted that several agencies might be involved in the risk assessment. The aim is to be able to efficiently produce a risk assessment for complex scenarios with multi-factorial risks by promoting cross-agency collaboration, harmonizing procedures and developing effective risk assessment methodology.

The ECDC has also established an EU Health Task Force (EUHTF, under Art. 11a of Reg. 2022/2370). According to this article, the ECDC must ensure that there is a permanent capacity and an enhanced emergency capacity to mobilise and use the EUHTF. The EUHTF provides assistance with regard to operational response and crisis preparedness, including responses to outbreaks of communicable diseases or support for after-action reviews implementation in MS and in third countries, in cooperation with other relevant organizations such as the WHO or Commission Services. Through the EUHTF, the ECDC should provide EU field response experts in international response teams mobilised by the WHO Health Emergencies Programme mechanism and the Global Outbreak Alert and Response Network (GOARN). In other words, the EUHTF is a mechanism to address requests with a systematic approach and encourages direct country support following a country request. The EUHTF operates in the EU but also outside the EU. Collaboration with other institutional actors is key to avoiding duplication.

Lastly, according to Art. 6 of Reg. 2022/2370, the ECDC must provide independent science-based recommendations for actions to prevent and control communicable diseases and other serious cross-border threats to health. The recommendations are not binding but allow the ECDC to make its views known and to suggest a line of action.

To conclude, the new mandate strengthens direct and country-driven support. It increases the options for operational work. It increases the cross-sectorial and cross-agency collaboration. It includes a systematic approach to different aspects of ECDC work. It increases the engagement of MS in the EU-level preparedness and response activities.

The creation of HERA

Dr. Bartłomiej Kurcz, Head of Unit, European Commission (HERA)

Dr. Kurcz's presentation concerned the creation of HERA. Several reasons led to the creation of HERA, including the fragmentation of preparedness and crisis response in the EU; weak anticipatory threats and risk assessments; and market failures in specific contexts. HERA was established through the EC Decision 2021/929. Another key document is the Communication (COM/2021/576 final). The Communication makes clear that there is a preparedness phase (intelligence gathering, threat assessment) and an emergency phase (activation of emergency research and manufacturing). According to the Communication HERA was set up to strengthen Europe's ability to prevent, detect, and rapidly respond to cross-border health emergencies, by ensuring the development, manufacturing, procurement, and equitable distribution of key medical countermeasures.

HERA tasks during the preparedness phase include threat assessment and intelligence gathering; promoting advanced research and development (R&D) of medical countermeasures

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and related technologies; addressing market challenges and failures and boosting the Union's open strategic autonomy; ensuring the provision of medical countermeasures; strengthening knowledge and skills.

The core mission of HERA is to strengthen health security coordination within the EU during preparedness and crisis response times in the area of medical countermeasures. This will bring together the MS, the industry and the relevant stakeholders in a common effort; to address vulnerabilities and strategic dependencies within the EU related to the development, production, procurement, stockpiling and distribution of medical countermeasures; to contribute to reinforcing the global health emergency preparedness and response architecture. It is interesting to note that among the mission of HERA, there is a reference to the industry ('bringing together […] the industry'). The cooperation between HERA and other institutional actors is essential. As a new DG, HERA is finding its place.

MS play a role within HERA. In particular, the HERA Board brings together senior representatives from the MS. The HERA Advisory Forum is a group of experts from the MS that assists the HERA Board. They represent technically competent bodies in the field of health security and are designated by the Member States. The European Parliament (EP) was also invited as an observer to the HERA Boar. However, the EP would like to have a more prominent role.

HERA's main actions include managing COVID-19 contracts management; dealing with emergencies (such as Mpox); there is the ATHINA platform; there is the EU FAB, which reserves manufacturing capacities for the EU to produce vaccines in case of public health emergencies; HERA Invest, an initiative of HERA to promote private investment in R&D in Europe, reduce market failures and leverage public funding to incentivise investment. In 2023, a Communication (COM(2023) 672 final) on medicine shortages in the EU was adopted. The EU project DURABLE is another success story. DURABLE aims to provide high-quality scientific information in record time to support HERA's decision-making in preparing for and responding to cross-border health threats and assessing the impact of countermeasures.

Joint procurement at the EU level has shown its potential during COVID-19 by enabling access to therapeutics and Personal Protective Equipment and will also continue contributing to the preparedness of the countries by ensuring long-term contractual relationships with medical countermeasures producers. With the launch of the Critical Medicines Alliance in April 2024, HERA is engaging with a wide variety of stakeholders to discuss mid and long-term industrial actions to reduce the risk of shortage for critical medicines in the EU, strengthening the EU manufacturing supply chain through bolstering Europe's capacity for production and innovation in manufacturing technologies in the EU.

Among the challenges HERA has to face, there is the reduction of EUR 1 billion from EU4Health's budget, which has an impact on the overall budget allocated to HERA for 2025. HERA will nevertheless continue to deliver on its core tasks, not only by supporting new projects but also by continuing and expanding ongoing activities that have proven to be pivotal in advancing the EU pandemic preparedness and response.

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In the end, there is going to be a review of HERA functions and operations. The main objective of the study, underpinning the review process, is to provide the EC with an analysis of the extent to which HERA has been delivering effectively and efficiently on its mission and task. Another interesting discussion concerns whether HERA should be or not an independent agency. Being an agency presents both pros and cons in comparison to being a service of the EC. In any event, being a part of the EC brings more political drive and coordination.

11:00-12:00 Session II - The Academic Perspective

Strengthening legal preparedness in the European Union after the pandemic

Prof. Tamara Hervey, Jean Monnet Professor of EU Law, City, University of London

Prof. Hervey addressed the topic of LP at the EU level, after the pandemic. Public health LP was defined in the 1980s as attainment by a public health system of legal benchmarks essential to the preparedness of the public health system. LP is not just about a state of being prepared – an attainment. As stated by the Global Health Security Legal Preparedness Action Package 2021, LP 'is the capability to map, develop, refine, and utilize legal instruments across sectors that enable the implementation of capacities to prevent, detect, and respond to infectious disease threats'.

LP is a legal concept that refers to both an outcome and a process ('an ongoing process that entails regularly reviewing and updating law and ensure that they are fully implemented', IFRC, 2023). LP includes paying attention to inequalities. Legal frameworks have the potential 'to create an enabling environment for effective and timely prevention, preparedness for, response to, and recovery from public health emergencies that ensures that no one is left behind' (Sachs et al., 2022).

Strengthening LP in the EU after the pandemic should involve a process of review and strengthening of legal instruments so that the EU has in place a set of well-designed, well-understood and well-implemented laws in advance of any public health emergency that arises. During emergencies, one risk is that the law becomes de facto non-transparent because it is poorly drafted or because it changes too frequently. The law should pay attention to common legal problems that arise during a public health emergency. The law has to be inclusive, in the sense of taken into account the unequal effects that public health emergencies have on the most vulnerable, both in the EU and globally. A common legal problem is that there is not sufficient attention to human rights, to issues of inequality and discrimination.

It must be noted that the EU operates under certain constitutional, or quasi-constitutional, constraints. The EU's competencies in health must be taken into account. Other parameters that surround the EU's LP processes are the range of types and forms of legal instruments available to the EU institutions. There is a 'hard law' harmonizing or mandating information sharing or coordinating or providing funding. There is 'soft law' supporting hard law. There are joint contracting opportunities. There should be a balance between the flexibility of soft law and the more mandatory power of hard law. There are also treaties, primary legislation, and administrative decisions. In terms of the institutional dimensions, many EU institutions will

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need to be engaged in LP, if it is to be effective. The obligation to ensure the EU is legally prepared does not sit just with the legal departments of DG SANTE, or HERA, or ECDC, but is dispersed across almost everything the EU does.

The other important constitutional dimension of post-pandemic preparedness is the 'transversal' nature of EU health law. EU health law is not just the law that flows from Art. 168 TFEU, or that involves DG SANTE, HERA and ECDC. EU health law cuts across internal market law, EU competition law; EU law on free movement of people, etc. LP requires to take into account the constitutional obligations of EU institutions and MS to respect general principles of EU law and fundamental human rights. Rules on, for example, transparency; accountability; and subsidiarity must be respected.

Some new or revised powers with relevance to LP: Reg. 2022/2371 on serious cross-border threats to health now includes the formal legal power to declare a public health emergency. The declaration, once made, has clearly delineated (though also non-exhaustive) legal effects for the EU institutions. Art. 5(1) obliges the EC to prepare a Union prevention, preparedness and response plan. Artt. 5, 8, and 9 concern the Union and national preparedness plans assessment. There is an ongoing cycle of reporting, analysis, recommendation, which is yet to get fully under way. The obligation for MS to produce national preparedness plan is a significant change, which has been welcomed by academics, because it potentially fills a compliance gap for the International Health Regulations.

There is legal work ongoing integrating various relevant national and EU-level communicable diseases systems. The EU should also consider legal powers to revitalise or reintroduce platforms or processes that were introduced to respond to the COVID-19 pandemic, for example, the Passenger Locator Forms Exchange Platform or the European Federation Gateway Service. The continued use of contractual legal forms, using the EU's strength from its scale as a global market player, is part of LP. Here the HERA work on joint procurement, using the Joint Procurement Agreement for Medical Countermeasures 2014, is key.

There is also less obvious work that has been done and is underway. Legal provisions that incentivise re-shoring of medical/health system capacities in the EU are part of LP. Some examples of new EU law paving the way for this, and incentivising European-based supply routes, include the new Regulation on Substances of Human Origin (final act signed 13 June 2024, awaiting publication in OJ); and the proposed new Medicines Regulation and Directive, likely to be adopted in 2025. There are legal provisions balancing benefits from scale of health data at EU level (e.g., the new AI Act, the proposed European Health Data Space); and law enabling EU funding of preparedness and resilience work (e.g., EU4Health).

There are then areas of broader EU law where preparedness may not be considered explicitly. For instance, it is worth considering the extent to which EU law on state aid to industry supports pandemic preparedness. Another area to highlight in this regard is the EU free movement of people law. Procedural rules were not followed during the pandemic. The EC relied on soft law, rather than enforcing hard law obligations. One of the key things to be done to be prepared for future pandemics is citizen education. There was a lot of disinformation during the pandemic.

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The EU's competencies in the area of education are limited, maybe there could be a role in this for Horizon Europe, or the EU's structural funds. Finally, there is a big area where should be done in terms of the EU's LP: the EU's engagement with the rest of the world. The key policy instrument here is the EC Global Health Strategy, adopted in November 2022.
A preliminary assessment of all this leads to a conclusion that many of the legal and policy developments are good developments but they are not enough if the EU wants to be serious about LP.
To conclude with some proposals for discussion, the EU should consider a cross-cutting LP obligation, to respond to the dispersed nature of sites where LP is necessary. There should be an ongoing work stream on LP, with an LP process and checklist, overseen by the EC, with a transparent platform hosted on the EU's website that shows a traffic lights scoreboard. Equality should be explicitly mainstreamed in all LP work. The institutional framework should be strengthened with the Health Security Council to increase political 'gravitas' to provide leadership in a complex regulatory environment. And, probably most crucially, LP should be not only for the EU but the entire world.

The expansion of EU power in Public Health
Prof. Anniek De Ruijter, Professor of Health Law and Policy, University of Amsterdam
Prof. De Ruijter addressed the expansion of EU power in public health. The EU's power in the area of public health is expanding (empirical question). Whether we should expand EU power in the field of public health is more a normative question. When we talk about power in health, we should take into account the nature of this power. Power is often described in a relational manner, it is the authority to do things. Here we talk about the power that is created through the law. Power in politics is about answering the question 'Who gets what, when?'. We talk about power also in terms of the rule of law. All power is bound by law.
Power in health is political, scientific (professional expertise), legal & institutional.
1. Political (disease and state formation). Public health has been key to the centralization of the power of the modern State. Cholera led to the collectivizing of risks and solidarity. Health law is about the relationship of power and care between citizens and the State.
2. Scientific (professional communities). The involvement of the professional communities in health contributed to policymaking. Professional communities organise themselves close to institutions. These professional communities share a set of values, and their contribution is based on them. These people share language and values. These communities have a strong personal component, they know each other. They are invited to policymaking because they have experience in health politics.
3. Legal (self-regulation, institutional). As far as law-making in health is concerned, there is a lot of self-regulation of the professions, or through guidance and protocols. At the same time, health ministries are often the weakest link in government. However, the legal power of health will probably grow, since it is linked to the economy.
Power has grown around these three levels, alongside EU integration.

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With regards to the legal power of the EU in public health, the EU is characterised by a system of 'conferred' lawmaking powers. Power is conferred to the EU to harmonise national laws. There are exclusive, shared and supporting competencies, and each sector concerns some specific fields (e.g., internal market, agriculture and fisheries are examples of shared competencies). The key articles to take into account in the area of health are Art. 9 TFEU and Art. 168 TFEU. Harmonisation is prohibited (Art. 168(5)(7) TFEU) with the exception of medicines, blood, veterinary, plant health,, and 'incentive measures' for cross-border threats.

Has this limited 'competence' (legislative power) limited EU law-making in the field of health? It is true that the competence of the EU in health is limited but the EU can use soft law, guidelines, recommendations. It can also adopt legislation that affects health using other legal bases, such as internal market, agriculture, and free movement of workers.

Why does this matter? Soft modes of governance are characterised by unclear democratic processes. In addition, limited EU power disconnects national and EU political processes in health. At the national level, there are the health departments and attached know-how of professional communities. At the EU level, if the 'driving seat' is the internal market, agriculture (etc), then different national representation and policy expertise are invited.

Should the EU have more power? Should the EU have a stronger legal basis for health? There are vast differences in quality and safety across European health systems, and also from an organizational point of view. This consideration would go against the idea of more EU competencies in the area of health. However, we also have common underlying values and principles. Despite the defensive nature of Art. 168(5) and (7) TFEU, 'common safety concerns in public health matters' is a shared competence.

A stronger legal basis would have effects both on the Council and the EC. There is a Council configuration for health, the EPSCO Council (Employment, Social Policy, Health and Consumer Affairs). Paradoxically, if the EU has more power, there could be a stronger national representation. As far as the EC is concerned, DG SANTE would have more power to make proposals (it is worth remembering the Bolkeinstain Services Directive whose draft was proposed by DG MARKT).

In any case, the use of conferred legal power is limited by the principle of subsidiarity (Art. 5(3) TEU). Subsidiarity requires a political choice on whether Union action will achieve an outcome that the MS acting alone could not achieve. In other words, the discussion on subsidiarity is a political one. The assessment of whether legislation is useful for reasons of health is different when health is ancillary to other policy objectives. To conclude, the advantages of more EU competences in health would be the stronger overall political representation in health, both nationally and in the EU. Health departments and communities would be no longer circumvented at EU level. There would be an improved substantive political discussion on the need for EU intervention (subsidiarity).

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Digitalisation in health presents several challenges. The EC took the opportunity to propose various pieces of legislation in this field. It is possible to think about topics such as the Health Technology Assessment (HTA), substances of human origin, and compulsory licensing. The scientific scenario is also changing. For instance, companies are no longer researching chemical molecules but biological ones and are using more self-engineering.

Another key issue in this context regards technology and personalised care for patients. Technology is the driver of reshaping the relationship between healthcare providers and the patient. Technology can improve the ability to gather, analyse, manage and conserve health data. This raises various critical issues, such as the privacy of sensitive data.

Technology enables the connection between the healthcare provider and the patients. Through telemedicine, the healthcare treatment could be improved by putting directly in touch the patient with the healthcare provider. Telemedicine could also enable the real-time connection of data. Mobile devices are the patient's companion. What is the patient's interest in using telemedicine? Telemedicine could be used to monitor a patient after surgery, to monitor a chronic disease (as a result, this would lead to less use of nurses); to support the patient remotely in case of minor injuries. Telemedicine offers the possibility to be followed by your healthcare provider when you are outside your place of living.

However, digitalisation presents some loopholes. We do not have specific rules concerning telemedicine. We do not have common standards. This makes it difficult to reach the target of digitalisation. Anyway, digital health has experienced an evolution. In 2018, the EC adopted a Communication on the digital transformation of health and care (COM(2018) 233 final).

Digitalization cannot be limited to telemedicine but also it should expand to other tools that personalise health improvements. The idea is to use digitalisation to customise health services, taking into consideration the features of every individual. Digital therapies are addressed in an annex by the Medical Device Regulation (Regulation (EU) 2017/745). For instance, some devices stimulate healthy behaviours by telemonitoring. Think about anxiety, depression, eating disorders and similar conditions. You can use these devices as a game which can push the individual to healthy behaviours. Most of these programmes are used in combination with therapy.

However, we do not have specific legislation on digital therapies. The problem is that you do not have clinical trials on digital therapies. The risk is that the system does not work. The questions then are: Who has to assess digital therapies? Who should reimburse it? One solution might be to have a system where the therapy is not reimbursed and monitored for one year. Then if it is demonstrated that that the service is profitable to the patient, the State reimburses it.

12:00-12:30 Debate

The event ended with an interesting debate that touched upon several issues. The speakers talked about whether the EU should or should not settle for soft governance in health. Some noted that soft law is problematic because it affects transparency and accountability. There was

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a thorough discussion on the consequences of more EU power in health. It was claimed that more EU power might empower national health representatives. However, the EU should be very careful with interfering with MS in the area of health. It was observed that national parliaments might need more time to react to proposals. In addition, the relationship between the declaration of public health emergency under the WHO International Health Regulations (IHR) and the declaration of emergency at the EU level was discussed. It was clarified how the ECDC could support countries. Their support could be remote (e.g., the country needs help with some parts of the preparedness plan) or in-country (e.g., after-action reviews). The ECDC can also offer support in crisis times offering professionals such as epidemiologists and data managers. In the end, it was claimed that one of the best ways to prepare for the next health emergency is to reduce poverty and strengthen national healthcare systems.

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