Public Health and The Rule of Law

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Abstract

The rule of law is a sustainable system of laws, institutions, rules and community engagement that gives accountability to both government and private actors, fair laws that protect fundamental rights, open government and accessible justice. In a strong rule of law society, these four principles intersect to ensure that citizens have efficient, transparent and accountable institutions that can defend freedom, ensure public safety, including public health, and facilitate prosperity.

Evidence suggests a positive correlation between the rule of law and public health – countries with a better rule of law enjoy lower maternal and infant mortality rates, longer life expectancy and a lower incidence of chronic diseases. The rule of law fosters trust in institutions and supports a social contract between citizens, both of which are essential for resolving a public health crisis such as the COVID–19 pandemic in which a collective approach is the only way to keep and control the disease.

Keywords: Rule of Law; Health; Public Crisis; Chronic Diseas; Public Safety.

Introduction

The European Rule of Law Mechanism provides a process for an annual dialogue involving the European Commission, the Council of Europe, and the European Parliament, together with Member States, national parliaments, civil society and other stakeholders in the field of the rule of law. The Rule of Law Report is the basis of this new process [1].

One of the objectives of the European mechanism on the rule of law is to stimulate inter–institutional cooperation and to encourage all the institutions of the European Union to contribute to it according to their own institutional roles. This objective reflects a long–term interest of both the European Parliament and the Council. The Commission also invites national parliaments and authorities to discuss the report and encourages the involvement of other stakeholders at national and European level.

The report on the rule of law and the necessary work with member states is carried out annually under the mechanism and will serve as a basis for discussions in the European Union. They have the role of preventing, at the same time, the appearance or distortion of problems. Identifying early situations as soon as possible and with the mutual support of the Commission, other Member States and stakeholders, including the Council of Europe and the Venice Commission, could help Member States find solutions to their problems, to maintain and protect the state right.

The annual report established by the European Commission on the rule of law monitors significant developments, both positive and negative, which have a particular impact on the rule of law in member countries. The report is structured on four pillars: the judicial system, the anti–corruption framework, media pluralism and other institutional aspects related to the system of checks and balances in the rule of law. Of course, this balance must also be found in the field of health.

The Treaty on the Functioning of the European Union (TFEU) emphasized the importance of health policy, stipulating that "a high level of protection of human health shall be ensured in the definition and implementation of all Community policies and actions" as explicitly stated in Article 168 paragraph (1) of the TFEU. The primary responsibility for the protection of health and, in particular, health systems remain with the Member States. However, the European Union plays an important role in improving public health, preventing and managing diseases, mitigating sources of danger to human health and harmonizing health strategies between Member States.

Public health policy

Public health policy has recently taken center stage in European

policy–making, with the European Parliament making cancer one of the priority areas for action since the start of the 9th legislature following the onset of the COVID pandemic –19 and with the Commission's announcement warning that it is acting in the direction of a European Union with a much stronger population health. This fact was imposed especially in the conditions in which the situations created by the pandemic were a priority.

In the field of public health, the European Union aims to:

- Protecting and improving the health of European Union citizens;
- Supporting the digitization of health systems and infrastructure, as well as their modernization;
- Improving the resilience of health systems across Europe;
- The preparation of the European Union states to prevent and address better prepared, future pandemics.

Historically, EU health policy has its origins in health and safety provisions, later developing as a result of the free movement of people and goods within the internal market, which necessitated public health coordination. Various factors, including the bovine spongiform encephalopathy ("mad cow disease") crisis at the end of the last century, made health and protection high on the political agenda. The establishment of specialized agencies such as the European Medicines Agency (EMA) in 1993 and the creation of the European Center for Disease Prevention and Control (ECDC) in 2004 demonstrate the growing commitment of the European Union to health policy. Public health has also benefited from action in policy areas such as the environment and food, among many others. The establishment of the European Chemicals Agency (ECHA) in 2006 under REACH for the evaluation and registration of chemicals and the creation of the European Agency for Food Safety (EFSA) in 2002 were also proof of multidisciplinary efforts aimed at improving the health of European citizens.

Despite the lack of a clear legal basis, public health policy developed in several directions long before the adoption of the TFEU. Medicines legislation has already been introduced since 1965 to guarantee high standards in pharmaceutical research and industry harmonize national drug licensing procedures and introduce rules on advertising, labeling and distribution. The medical and public health research programs date back to 1978 and have covered issues such as health issues influenced by age, environment and lifestyle, radiation risks and analysis of the human genome, focusing especially on major diseases. Member States have agreed to provide mutual assistance in the event of disasters and extremely serious diseases: "mad cow disease" provides a striking example of one form of cooperation and assistance. The emergence of drug addiction, diseases such as cancer and AIDS/HIV (among others) as major health problems, together with the increasingly free movement of patients and medical staff within the EU, puts public health even higher on the agenda EU.

The Maastricht Treaty of 1992, which created the European Union, introduced public health into the founding treaty. The scope is quite limited, but it has created a clear legal basis for the adoption of health policy measures. The Treaty of Amsterdam in 1997 further strengthened the provisions and, while primary competence in health matters still rests with the Member States, the role of the EU has become more prominent. The EU could now adopt measures to ensure (and not simply 'contribute to' as before) a high level of human health protection, and member states could cooperate on any causes of danger to human health.

In 1993, the Commission published a Communication on the Framework for Action in Public Health, which identified eight areas for action, including health promotion, cancer, medicines and rare diseases. This was the predecessor of multi–year public health programs. The conclusion of the first program was that a more horizontal, interdisciplinary approach was needed where EU action could bring more added value. This approach was considered for the development of subsequent programs, namely the EU Public Health Program 2003–2008, the Health Program 2009–2013 and the Third Health Program 2014–2020, the current EU health program (2021–2027).

In recent years, institutions have focused on three dimensions with direct implications for public health policies:

1) Consolidation of the inter–institutional framework

The role of the Parliament, as a legislator (as a co–decision body alongside the Council), has been strengthened with regard to aspects related to health, environment and consumer protection. The way the Commission launches legislative initiatives has been adapted, with standardized consultation procedures between services, establishing new rules on comitology and dialogue with civil society and experts. Finally, the role played by the relevant agencies (EMA, ECDC, ECHA, EFSA) was strengthened and the implementation of health programs was entrusted in 2005 to the Executive Agency for Health and Consumers (EAHC).

2) The need to strengthen the ability to react quickly

The current COVID–19 pandemic has re–emphasized the need for the EU to have a rapid response capacity to respond to serious health threats in a coordinated manner, especially at a time when international transport rapid facilitates the spread of diseases. To this end, in September 2021 the Commission established a new European Health Emergency Preparedness and Response Authority (HERA).

3) The need for better coordination of health promotion and disease prevention

The aim of these actions is to address the root causes of poor health related to personal lifestyle and economic and environmental factors (pollution from pesticides, heavy metals, endocrine disruptors). Actions will involve, among other things, close coordination with other EU policy areas, such as environment, transport, agriculture, and economic development. In addition, the actions will involve closer consultation of all stakeholders and greater openness and transparency in the decision–making process. In this sense, the European Parliament placed the need for a more coordinated European approach to fighting cancer on the political agenda at the beginning of the current 9th legislature.

Current issues and future challenges

Health comes first in all areas of action

Synergies between the different fields of action enable health issues to be addressed in their wider context. The "Farm to Fork" strategy will contribute to the production of not only sustainable food, but also healthier food products; The Zero Pollution Action Plan will create cleaner and healthier living spaces; The proposed "EU Health" program (2021–2027), together with other funds

and programs, will help to address health issues from different perspectives. Climate change mitigation also includes addressing health problems caused or exacerbated by climate change, such as increased deaths from heat waves and natural disasters, as well as changing modes of infection for water–borne diseases and transmitted by insects, snails, or other cold–blooded animals.

The "Health in all policies" (HIAP) approach, codified in the TFEU and the Charter of Fundamental Rights of the European Union, responds to the cross–sectoral nature of public health issues and aims to integrate health–related aspects into all relevant policies (Articles 9 and 168(1)) of the TFEU; Article 35 of the Charter).

In second place is disease prevention and health promotion.

Cancer is the second leading cause of death in the EU. Its consequences are felt not only at the individual and family level, but also at the level of national healthcare systems, budgets and economic productivity. To place this subject among the priorities of the political agenda, the Parliament established a special commission for the fight against cancer (BECA). Responding to an initiative of the European Parliament, the Commission presented the European plan to fight cancer, which covers prevention, early diagnosis, treatment, and monitoring.

Cancer has been tackled at European level through a series of initiatives. For example, there are recommendations in force at EU level regarding national screening programs for breast cancer, cervical cancer, and colorectal cancer, but also regarding the target population, participation in screening exams, and monitoring of positive or uncertain results varies greatly from one Member State to another. Parliament's BECA Committee is currently highlighting the need to achieve greater equity across the Union in access to cancer screening and treatment programs.

The EU Joint Action on Mental Health and Wellbeing ran from 2013–2018 and created a European framework for action on mental health and well–being. With suicide being the second leading cause of death in the 15–29 age group, prevention, awareness, non–stigmatization, and the ability to get help in cases of depression, self–harm and suicide risk remain of major importance. Mental health in schools and the workplace also requires special attention. Although the duration of the joint action was limited, mental health has received renewed attention in the context of the current COVID–19 pandemic.

As regards communicable diseases, the legislation in force (Decision 1082/2013/EU) aims to provide the framework to address cross–border threats to health: the ECDC has put in place an early warning and response system, and the Committee on EU health security coordinates measures to combat disease outbreaks and epidemics. In these cases, cooperation with the UN World Health Organization (WHO) is essential, as can be seen in the case of the recent outbreak of the coronavirus pandemic (Sars–CoV–2;2019; coronavirus disease; Covid–19) at the end of 2019/beginning of 2020. Numerous ad hoc measures have been adopted under emergency procedures and can be followed on a special EUR–Lex webpage as well as on the Commission's coronavirus response webpage.

Initiative

Among the main regulatory initiatives were:

- Regulation (EU) 2020/1043 of the European Parliament and of the Council of 15 July 2020 on the conduct of clinical trials and the supply of medicinal products for human use containing genetically modified organisms or consisting of genetically modified organisms and intended to treat or prevent disease caused by the coronavirus (COVID–19).

- Commission Communications entitled "EU Strategy on COVID–19 Vaccines" and "Preparing for COVID–19 Vaccination Strategies and Vaccine Deployment";

- Council Recommendation of 13 October 2020 establishing common criteria and a common framework for travel measures in response to the COVID–19 pandemic. The recommendation aims to help Member States make decisions based on the epidemiological situation in each region.

- During 2020, the Commission continued to take further steps to help increase resilience in several areas in all Member States. Among the measures are linking national contact applications, expanding travel exemptions, more extensive testing and securing vaccine stocks. The COVID–19 Pandemic Response Package includes:

- The Commission's communication regarding additional measures to respond to the COVID–19 pandemic.

- Communication of the Commission regarding testing strategies for COVID–19.

- The Commission's recommendation regarding the use of rapid antigenic tests.

- Under the auspices of a communication entitled "Building a European Health Union:

Drugs, alcohol, and tobacco use are lifestyle factors that have a serious impact on human health and combating them is a major concern for public health policy. The Tobacco Products Directive (Directive 2014/40/EU; applicable from 2016) and the Tobacco Products Directive (Council Directive 2011/64/EU) were important steps in this process.

In December 2020, the Council approved the new EU Drugs Strategy for the period 2021–2025. The document establishes a global policy framework and sets strategic priorities for the EU's illicit drug policy under three main axes: reducing the supply of drugs, reducing the demand for drugs and addressing the harmful effects of drugs. Efforts to revise the 2006 EU Alcohol Strategy appear to be currently stalled.

The EU Action Plan on Childhood Obesity 2014–2020 is an important step in streamlining the various measures to combat obesity. although the mid–term evaluation showed further potential to strengthen the system, while the Council found that the program was not sufficiently effective.

Third, the changes in society as well as the demographic transition were analyzed.

Recent demographic trends have brought even more problems to health policy. The aging of the EU population, the demand to maintain quality of life in old age and the sustainability of health systems require a response. In 2020, the WHO launched the Decade of Healthy Ageing, and in this context the Commission published a Green Paper on population aging in January 2021.

Recent migration crises and the arrival of large numbers of migrants from outside the EU led to the adoption of an action plan on the integration of third–country nationals in 2016. The action plan addresses, among other things, the health–related

disadvantages faced by migrants, including access to health services. In 2020, the Commission presented the European Agenda on Migration and the new Pact on Migration and Asylum, which aims to further streamline European policies in this area.

In 2015, Parliament called for action to reduce inequalities among children in areas such as health and the introduction of a child guarantee in the context of an EU plan to tackle child poverty. In June 2021, the Council adopted the Commission's proposal to establish a European Child Guarantee. As a next step, Member States are expected to submit national plans to the Commission by March 2022, outlining how they will implement the Child Guarantee by 2030 [2].

Fourth, but not least, action was taken on medication.

The new regulation on clinical trials from 2014 became applicable at the beginning of 2022. In the field of medical devices and in vitro diagnostic devices, two new regulations will gradually replace the three existing directives in the coming years.

Access to affordable medicines and tackling drug shortages will be high on the political agenda in the coming years, particularly considering Brexit. The review of legislation on medicines for children and rare diseases, as well as the directives on blood, tissues and cells, will pave the way for possible future changes. The European Parliament has already expressed its concern about vaccine hesitancy and declining vaccination rates and expressed its view on the European One Health Action Plan on antimicrobial resistance; these aspects will remain essential in the years to come.

Fifthly, the digitization of everything that means health at the European level is in the foreground.

Information and communication technologies improve the entire life cycle of health problems, from prevention through diagnosis to treatment, monitoring and management of health and lifestyle. Digitization of the healthcare sector is part of the EU's digital single market strategy and has enormous potential; to give results, several measures are being prepared [3].

The 2018 Communication on the Digital Transformation of Health and Personal Care Services in the Digital Single Market identifies citizens' access to their health data, including cross–border, as priorities; personalized medicine through common data infrastructures of the European Union, enabling researchers and other health professionals to pool resources across the European Union; and empowering citizens with digital tools for user feedback and patient–focused support (mobile health solutions, personalized medicine). The infrastructure of digital e–health services will provide the necessary physical network [4]. A legislative proposal on the European health data space was foreseen as early as the fourth quarter of 2021 [5].

Sixthly, cross–border healthcare was considered, with the 2011 Directive on the application of patients' rights in cross–border healthcare establishing the conditions under which a patient can go to another EU [6] country to receive healthcare and the conditions for its reimbursement.

And seventh, health technology assessment (HTA)

In 2018, the Commission presented a proposal to strengthen cooperation at EU level between Member States for the assessment of medical technologies. ETM assesses the added value of new or existing medical technologies–drugs, medical devices and diagnostic tools, surgical procedures, as well as

measures to prevent, diagnose or treat diseases–compared to other medical technologies. Parliament and the Council formally adopted it by the end of 2021.

The European Parliament has consistently promoted the establishment of a coherent public health policy. It has also actively sought to consolidate and promote health policy through numerous opinions, studies, debates, written statements, and own initiative reports on numerous issues. At the start of the current legislature, Parliament took on a more active agenda–setting role, insisting that the fight against cancer should become an absolute priority of EU health policy. In view of the crisis caused by the COVID–19 [7] pandemic, the Parliament has taken an active role in promoting a coordinated European response and underlined the need to engage in much closer cooperation in the field of health to create a European Union of Health.

The Committee for the Environment, Public Health, and Food Safety (ENVI) is the main representative of the Parliament in terms of health–related issues, constituting more than 10% of the total legislative activity of the Parliament [8]. Several parts of the upcoming European Green Deal package will also have a direct or indirect impact on health, such as the clean and circular economy strategy, the zero–pollution objective, the food chain sustainability objective, and the net neutrality objective climatic. The related legislation will be adopted by Parliament as co–legislator. Parliament also exercises its right of scrutiny by verifying and possibly objecting to delegated and implementing acts proposed by the Commission in relation to previously adopted legislation.

ENVI's Health Working Group plays an active role in promoting exchanges between MEPs and subject matter experts on the most topical health issues by organizing thematic workshops.

Conclusion

The European institutions did their best to keep afloat the correlation between the requirements of the rule of law and the public health seriously affected by the pandemic crisis, in the conditions in which the Member States aligned themselves with the European legal requirements.

But the pandemic also presents a unique opportunity to catalyze reforms that will help rebuild the trust citizens need for good governance to work effectively, particularly in areas critical to fighting the pandemic and protecting public health in the long term long. In this way, strengthening the rule of law is an essential building block for a healthy society and deserves priority attention and resources during the recovery and reconstruction stages that follow.

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Conflict of interest

Authors declare that there is no conflict of interest.

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