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HEALTH EMERGENCIES AND LEGAL PREPAREDNESS: A COMPARATIVE PERSPECTIVE

Monday 14th October 2024
Plesso Belmeloro, Via Andreatta 8, Aula H

15:00-15:15 - Welcome
Prof. Federico Casolari - Director of the Department of Legal Studies, University of Bologna

15:15-15:30 - Opening Address
Prof. Emanuele Sommario - Sant'Anna School of Advanced Studies, Pisa

15:30-16:50 - Session I – Australia, China, and Canada
Chair - **Prof. Giacomo Di Federico** - Department of Legal Studies, University of Bologna

Australia and legal preparedness in case of public health emergencies
Prof. Marco Rizzi - Law School, University of Western Australia

China and legal preparedness in case of public emergencies
Prof. Wang Qingbin - China University of Political Science and Law

Canada and legal preparedness in case of public health emergencies
Dr. Candice Ruck - University of British Columbia

16:50-17:15 - Coffee Break

17:10-18.30 - Session II – United States, African Union and European Union
Chair - **Prof. Alceste Santuari** - Department of Sociology and Business Law, University of Bologna

United States and legal preparedness in case of public health emergencies
Prof. William Sage - Law School, Texas A&M University

The African Union and legal preparedness in case of public health emergencies
Prof. Ben K. Twinomugisha - School of Law, Makerere University

The European Union and the post-pandemic reforms to tackle future PHEICs
Prof. Giacomo Di Federico - Department of Legal Studies, University of Bologna

18:30-19.00 – Debate

Online participation at the following link: https://teams.microsoft.com/l/meetup-join/19%3ameeting_ZDA5ZmIzNDEtNjJiZS00ZTRjLWEwNWMtMmU3ODNiZTY5MWZi%40thread.v2/0?context=%7b%22Tid%22%3a%22e99647dc-1b08-454a-bf8c-699181b389ab%22%2c%22Oid%22%3a%22348a1240-2cd6-446a-8d02-4629b84ec64c%22%7d
Meeting ID: 392 310 978 585 **Passcode**: cLQVXB

HEAL JEAN MONNET MODULE

HELP
HEALTH EMERGENCIES and LEGAL PREPAREDNESS
PRIN 2022

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EVENT REPORT

HEALTH EMERGENCIES AND LEGAL PREPAREDNESS: A COMPARATIVE PERSPECTIVE

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15:00-15:15 - Welcome

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

Prof. Casolari explained that this event is organized as part of the HELP project ('Health Emergencies and Legal Preparedness'). The project is a Research Project of National Relevant 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 the Scuola Superiore Sant'Anna (Institute of Law, Politics, and Development–DIRPOLIS).

One of the event's key objectives is to compare monitoring efforts carried out by various international organizations, both regional and global, as well as by specific countries. The aim is to share experiences from different regions and countries to understand better the legal frameworks that can enhance legal preparedness (LP) for pandemics. The seminar's approach involves working towards a common platform by examining the experiences of the most affected countries, territories, and the European Union, which has responded to emergencies in creative ways.

LP for public health emergencies (PHEs) is a topic extensively studied and discussed at the supranational level. It has been elevated in the political priorities of the European Commission's Presidency and is also a point of discussion at the level of the Presidency of the Council of the European Union.

Prof. Giacomo Di Federico - Department of Legal Studies, University of Bologna

Prof. Di Federico described the idea behind the project, which is to address the new topic of LP. One of the main objectives is to better investigate what LP is and to gain insight into how this concept has been applied around the world.

Concerning the background and expertise of the three main members of the HELP project, he briefly recalled:

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- Prof. Sommario, unit coordinator of the International Disaster Law Project and the Jean Monnet Module on European and International Human Rights Standards in Disaster Settings; holder of the Jean Monnet Chair on European and International Human Rights Standards in Conflicts and Disasters; part of the ILA Committee on Human Rights in Times of Emergency; member of the Editorial Board of the Yearbook of International Disaster Law and author of several publications on the topic of international law and disaster management.
- Prof. Di Federico, unit coordinator of the Jean Monnet Module on Health Protection in Europe: Actors and Legal Instruments (HEAL); responsible for the course of European Health Law (in Italian and English); member of the Global Health Security Agenda (GHSA); author of a book and numerous publications on European health law.
- Prof. Casolari, member of the Editorial Committee, Yearbook of International Disaster Law, and author of a few publications in international and supranational law on disaster management and the Union's response to the pandemic crisis.

15:15-15:30 - Opening Address

Prof. Emanuele Sommario - Sant'Anna School of Advanced Studies, Pisa

Prof. Emanuele Sommario addressed a specific issue: the identification of the concept of LP. In particular, the Professor focused on how this concept has been developed mainly in one jurisdiction (namely the US, where this concept emerged in the late 1990s and early 2000s) and showed how international fora have adopted and refined this definition, providing us with what can now be considered a working definition.

It is therefore relevant to consider the concept of LP as an evolving global health law in the context of other areas of international law. Indeed, the pandemic has highlighted the need for increased preparedness at global, regional, and national levels. In this context, the negotiation of the **Pandemic Treaty** and the revision of the **International Health Regulations** (IHR), which is expected to enter into force in September next year, have been and are being discussed in parallel. One of the key findings of the review committee tasked with revising the IHR was that the widespread inadequacy of public health capacity in several countries has severely hampered the ability to respond effectively to the global pandemic represented by COVID-19.

One of the earliest instances in which the concept of LP was introduced dates back to the 1988 Institute of Medicine report. In this report the IOM the need for states to enhance the legal framework to address emerging public health prices better and they should 'review the public health legislation to define authorities and responsibilities of all relevant health agencies clearly and to regulate coordination among them and possibly update such legislation to design more Disease Control measures adequate.

The idea of LP was further developed in the USA by some authors (notably Moulton). They defined Public Health Legal Preparedness (PHLP) as 'the readiness of a public health system or community, and of states and nations of the world, to respond to specified health threats'. In particular, it is 'a subset of public preparedness that relates to the attainment of legal benchmarks that were ascendant to enhance the preparedness of public health systems'. According to these authors, PHLP relies on coordination between different

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authorities (which should be provided with adequate implementation tools) and across sectors of jurisdiction to make this framework workable.

This framework has served as a point of reference for various international fora, such as the GHSA and the International Federation of the Red Cross (IFRC), which have attempted to define the concept of PHLP in recent years.

In 2023, the GHSA provided the first official definition of LP in the context of PHEs. The term is as follows: 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*'. The paper details the constitutive elements of LP, explaining that the **analysis** of existing legal instruments requires a preliminary **mapping** of these and an assessment of the quality of existing legal frameworks in terms of clarity, effectiveness, and completeness. The GHSA paper also includes two elements: 1) **legal surveillance**, as these frameworks change over time, and monitoring it is necessary; 2) the **capacity to coordinate** all actors involved in public health management activities across multiple sectors also considering the complex nature of the threats which originate from human-animal environmental interaction. Indeed, following the IFRC's approach LP is not seen as an outcome, but rather as a dynamic process that requires regular review through operational procedures and plans.

A key question is whether current international law obliges states to pursue LP in health emergencies. For instance, **Article 59.3 IHR** demands that 'if a State is not able to adjust its domestic legislative and administrative arrangements fully with these Regulations [...], that State shall submit a declaration to the Director-General (of WTO) regarding the outstanding adjustments and achieve'. This suggests that there is some kind of obligation to align the domestic legal system with the content of the IHR. Then **Article 44.1, lett. d), IHR**, which is entitled 'collaboration and assistance', provides 'States Parties shall undertake to collaborate, to the extent possible, in the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations'. Lastly, there is also **Article 63 of the WHO Convention** which sets out the duty for each member to communicate promptly to the Organization important laws, regulations, official reports, and statistics about health that have been published in the State concerned.' Looking at these provisions, one is forced to conclude that it is rather difficult to say that under current global health law, there are precise obligations set out in terms of LP for PHEs.

The idea that states should adapt their legal systems to PHEs also emerges from other branches of international law, namely:

1) **International Human Rights**, via negative and positive obligations: on the one side, states must refrain from torturing people or oppressing the right to liberty and, on the other side, they must take measures to prevent possible violations of human rights. For example, in interpreting Article 2 of the European Convention on Human Rights, the European Court of Human Rights (ECHR) established that states have a positive obligation to establish an effective normative framework against risks to human well-being and against potential violations of the right to life.

2) **International Disaster Law** (IDL), as the legal mechanisms used to respond to PHEs and other types of disaster tend to overlap, including the declaration of a state of disaster emergency and the use of emergency powers.

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For example, PHEs incorporate the definition of disaster developed by the International Law Commission in its recent draft articles on the protection of persons in disasters. Article 9 of the draft states that 'each State shall reduce the risk of disasters by taking appropriate measures, including through laws and regulations, to prevent, mitigate and prepare for disasters'. These draft articles would therefore be fully applicable to PHEs of a certain scale. The General Assembly is discussing whether this draft article should become a binding treaty.

In conclusion, regardless of the outcome of the current negotiations on a pandemic treaty, global health must work more in synergy with other areas of international law, in particular human rights or disaster law, as these areas also argue for the establishment of concrete obligations in terms of LP for PHEs.

15:30-16:50 - Session I – Australia, China, and Canada

Chair - **Prof. Giacomo Di Federico** **-** Department of Legal Studies, University of Bologna

Australia and legal preparedness in case of public health emergencies

Prof. Marco Rizzi - Law School, University of Western Australia

Prof. Marco Rizzi described Australia's reaction to the COVID pandemic, focusing on preparedness, the available instruments at the time, and those that were subsequently developed. He also discussed the pronounced reliance on mandatory vaccination policies, the issue of compensation for vaccine injury, and the intersection of these topics with legal frameworks.

Before explaining this legal framework, it is important to understand Australia's context as a federation, which suffers from what constitutional lawyers call the 'Washminster mutation'. In other words, the Australian system combines elements of the Washington system (federalism) and the Westminster system (parliamentary governance). The parliamentary systems are dominated by the executive branch, with limited scope for judicial review.

In the context of the pandemic response, it quickly became apparent that, from the perspective of preparedness, institutions were ill-equipped to handle the extraordinary disruption caused by the pandemic. There was a complete lack of coordination between states and the federal government, both horizontally (between states) and vertically (between states and the federal government). This became evident, for example, when the federal government enacted provisions under the **Biosecurity Act** allowing the closure of borders or the limitation of arrivals. Further disruption occurred in decisions regarding schools: some states kept schools open, while others closed them.

In response to this chaotic start, the government established the **National Cabinet**. This informal coordinating group brings together the Prime Minister (the Head of State) and State Premiers (Heads of Government). The National Cabinet has been maintained as a coordinating body between federal and state executives. However, despite its aim to coordinate responses, as the pandemic intensified, less affected eastern states chose to close their internal borders. This created the paradox of a federal government in charge of external borders, while state governments controlled internal borders. Additionally, the requirements for entering one state differed from those of another, with state governments

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deciding internal border measures while the federal government controlled the number of overseas arrivals.

This lack of LP and a coherent legal framework for rationalizing key policy decisions left many important decisions to individual states. Moreover, there was very limited recourse for individuals affected by these decisions, with the ability to challenge them in court being almost non-existent.

One of the most extreme examples of this chaos was when, during the second wave, the federal government decided to close its borders not only to foreign arrivals but also to its citizens returning from certain hotspots, such as India. The lack of such a specific entitlement in the Australian Constitution led to a tense situation where citizens were deprived of the right to return to their own country and had no legal recourse to challenge this decision.

In managing the crisis, the Australian government initially aimed to maintain a COVID-free or COVID-reduced environment, relying heavily on border measures. These measures were implemented through two types of legislation: public health acts and emergency management acts. PHEs were not always treated with specific instruments but fell under broader emergency categories.

Later in the pandemic, as Australia increasingly felt the impact of the virus, the country began to rely heavily on vaccines as the primary tool for pandemic management. The obligation to be vaccinated, especially for workers (affecting at least 75% of the workforce), was established by administrative acts. This is significant for judicial review because, as an administrative decision rather than legislative, it could not be disallowed by Parliament, making judicial review much more difficult. Overnight, 75% of the workforce faced the obligation to be vaccinated within a certain period to maintain employment.

In the absence of clear legal principles on how such powers could be used, these decisions became highly political. Only two states, Queensland and Victoria, have state-level Bills of Rights, which provide some protection of fundamental rights. There were several challenges to mandatory vaccination, with the only successful legal case based on the **Human Rights Act**. The presence of human rights legislation acts as a counterbalance to executive power.

Without a clear legal framework to define and limit the use of such powers, decisions became highly political. The lack of a culture focused on balancing different fundamental rights increases the risk of significant oversight, leading to policies that can be successfully challenged in court.

What does this have to do with preparedness? LP includes providing a coherent and reliable framework to ensure that measures taken in response to an emerging health threat are predictable. The risk is that the response to a health threat may become excessively subject to political expediency.

Finally, despite its heavy reliance on mandatory vaccination, Australia initially did not have a no-fault compensation scheme for vaccine-related injuries. Concerns about vaccine side effects, such as the increased risk of thrombosis linked to the AstraZeneca vaccine and risks of pericarditis associated with mRNA vaccines, led the federal government to establish a vaccine claims scheme. However, this scheme was overly rigid, with inefficient processes that were too slow to respond, defeating one of its primary goals: to provide prompt

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compensation.

In terms of preparedness, this lack of clarity and efficiency in the compensation scheme adds another layer of complexity. If governments mandate therapeutic measures, there is an obligation to provide relief for the rare cases of severe side effects. This obligation is heightened when countermeasures are fast-tracked, as was the case with COVID-19 vaccines. Ensuring safety nets for those negatively affected is essential to maintaining public trust and social cohesion.

In conclusion, Australia is a country that relies heavily on political processes. Compared to jurisdictions like the European Union, it has limited legal instruments for protecting the Rule of law during PHEs.

China and legal preparedness in case of public emergencies

Prof. Wang Qingbin - China University of Political Science and Law

Prof. Wang Qingbin discussed China's legal responses to PHEs.

China has established a comprehensive legal response to PHEs. Overall, the guiding principle of China's legal response mechanism for PHEs is to prioritize the people and their lives while aiming to prevent and mitigate significant risks in the public sector; it emphasizes protecting public interests while also focusing on safeguarding citizens' rights.

China has issued regulations on emergency response to PHEs, establishing a response mechanism that includes prevention, emergency preparedness, and treatment for major infectious diseases, outbreaks of diseases of unknown origin, and cases of mass poisoning.

In 2011, the regulations on emergency response to PHEs were revised for further refinement. In 2024, China is researching and reviewing the law on the responses to PHEs, aiming to provide better legislative support for responding to such events.

In recent years, China's legal response mechanism to PHEs has already demonstrated distinctive characteristics in the following three aspects:

1) **A stable, flexible, professional, and inclusive management system** for PHEs has been established, focusing on the unified coordination between the central and local governments and emphasizing the participation of society as a whole.

China's public health emergency management system has insisted on **stability** in responding to PHEs. The model has been adopted where the Communist Party of China leads the government is responsible and various departments collaborate to ensure a unified and effective response. This system maintains a top-down traditional hierarchical administrative model. It extends to the smallest unit of social governors to respond effectively to PHEs. This top-down management system is not rigid or inflexible; it demonstrates strong **vitality** vertically and horizontally.

The central government sends specialized personnel to the outbreak site to provide guidance and supervision.

China's public health emergency management system is highly **professional** in responding to PHEs. China places great importance on expert scientific advice in order to make efficient

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decisions quickly with professionals. These experts provide recommendations on the severity of PHEs and appropriate emergency response measures.
The emergency management system showed considerable **inclusiveness** following the outbreak of the pandemic. In addition to the participation of various levels of government and experts, China encourages autonomous organizations, enterprises, and citizens to take part in the response efforts.

2) A comprehensive and responsive emergency management mechanism for PHEs has been established.

Governments at all levels in China carry out long-term risk source management, investigate and record the risks and sources that may cause a PHE, carry out a regular risk assessment, and regularly supervise the management and use of risk sources. This system includes an overarching plan from the central government and local government. These plans are coordinated and interconnected across various categories.

Key institutions (such as healthcare facilities, nursing homes, and educational institutions) regularly conduct drills for the emergency response plan to ensure their effectiveness in the event of a PHE. For instance, a comprehensive monitoring and early warning system has been established. Risk monitoring points have been set up in various locations such as health care facilities, schools, and pharmacies, and transportation helps to collect information on unexpended disease outbreaks. If a potential risk is identified, institutions can report it directly by phone or online, and individuals can also make reports. If the government confirms the risk, it will disclose transparently the information to the public.

The Chinese government adopts emergency response measures based on the severity of the risk. In particular, these measures establish the principle of administrative urgency to effectively mitigate the risk of PHEs: the government can implement urgent measures to quickly control the situation. This system emphasizes the protection of citizens' rights during emergency responses. The principle of proportionality is applied prioritizing scientific accuracy to achieve the greatest impact with minimal cost. Efforts are made to reduce the impact on social production and citizens' lives, thereby safeguarding the rights of businesses and individuals. For example, local governments provide care for vulnerable groups (such as minors, the elderly, the disabled, the women) during public health crises, ensuring essential medical services for severe patients; additionally, psychological intervention centers are established to offer timely support after the crisis ends. The government promptly deletes collected personal information to protect privacy, a practice included in the 2024 draft law.

3) China is focusing on a **robust liability system for PHEs** in response to illegal activity by government departments professional organizations units and individuals during PHEs.

China has established strict legal responsibilities. Authorities attempt to provide a system of accountability for the failures of national agencies. Additionally, there is a strong crackdown on practices such as price gouging, and violations of citizens' privacy during a PHE aimed at better protecting citizens' legal rights and safeguarding the public interest.

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In today's global context, PHEs have become an issue that requires a collective response.

Canada and legal preparedness in case of public health emergencies

Dr. Candice Ruck - University of British Columbia

Dr. Candice Ruck discussed how the Canadian health system is structured, what is the background that informed the legal situation in Canada, and what were the legal tools used during the pandemic.

Like Australia, Canada is a federal system, consisting of 10 provinces and three territories. The balance of power between the provinces and the federal government in Canada historically shifts very heavily towards the provinces, even for healthcare. In other words, the provinces have near total autonomy when it comes to the actual implementation and the structure of the health systems within their borders.

Federally, Canada has a publicly funded, single-payer healthcare system known as Medicare, guided by the **Canada Health Act** (enacted in 1984). This Act outlines a financial transfer system from the federal government to provinces, built around five principles, including public administration, accountability, and accessibility. Provinces voluntarily follow the Act's principles, as non-compliance entails the risk of suspension of federal funding. While provinces contribute through local taxes, most funding originates from federal transfers, creating a strong incentive for adherence. This structure has generally been effective for over 40 years.

Due to the provinces' autonomy, Canada has significant variations in provincial health system structures, ranging from centralized to decentralized models, with differing levels of authority granted to health ministers versus public health officers. Although this system generally functions well, national PHEs expose its weaknesses, as seen during the 2003 SARS outbreak. SARS, a coronavirus similar to COVID-19, primarily spread in healthcare facilities, highlighting a gap in Canada's preparedness.

After SARS the federal government set up a Commission to inquire into the response because it was largely considered a failure. There was little to no cooperation between the federal and provincial governments. At one point travel advisories were issued against Canada because there was no way to accurately tell how many cases there were since the provincial government wouldn't share that information with the federal government.

The Commission issued several recommendations. Many of them were adopted by the federal government, but at the time the most significant for the future of public health preparedness in the country was the passing of the **Public Health Agency of Canada Act**.

The Public Health Agency of Canada (PHAC). The latter was created as a semi-autonomous body, positioned alongside rather than under Health Canada, the federal health ministry. The PHAC's head was given deputy minister status to enhance the agency's authority. Another key position, the **Chief Public Health Officer** of Canada, was created with a dual role: advising the government and acting as a public watchdog. However, these roles sometimes conflicted, despite their intent to bolster the PHAC's autonomy.

Due to the division of powers between federal and provincial governments, PHAC's authority over provinces remains purely advisory, unable to mandate actions. To improve collaboration, the Pan-Canadian Public Health Network was established, involving the Chief Public Health Officer and provincial/territorial counterparts, meeting regularly on public health issues.

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For emergencies, Canada developed the Federal/Provincial/Territorial Public Health Response Plan for Biological Events. This framework coordinates roles and responsibilities between federal and provincial levels during emergencies. Each province has its own pandemic plan, and federally there is the Canadian Pandemic Influenza Response Plan for technical guidance. The FPT framework, however, is not technical but sets out cooperation structures.

During emergencies, a special advisory committee, formed by members of the **Pan-Canadian Public Health Network** (including chief public health officers from all levels), manages response efforts. This committee also oversees three specific advisory committees focusing on technical guidance, communications, and other pandemic aspects. So, the chief public health officers from the federal-provincial and territorial levels oversee 3 different advisory committees to address different aspects of the pandemic technical advisory committee.

All these structures work together to coordinate a pandemic response, compensating for previous failures. It has been suggested that some overcorrection may have occurred, with overlapping issues among various bodies and structures. However, during COVID-19, the response was more cohesive than what had been seen during SARS.

One key take-aways from SARS that was not addressed concerned adequate financial investments to develop a tool for the digital integration of case numbers and other health data across provinces and at the federal level. The inability to share data easily was a significant limit during SARS. Efforts were made, but they weren't successful, mainly because participation was voluntary, and never legislatively mandated. Provinces have always been wary of anything that could reduce their authority or autonomy, including access to data. This reluctance remains the biggest obstacle to an integrated digital data system, and it hampered Canada's response to COVID-19.

When COVID-19 struck, the **Special Advisory Committee** was established. However, initially, no substantial action was taken by the federal government. As a signatory to the International Health Regulations (IHR), Canada resisted calls for border restrictions, considering them a potential violation of IHR obligations.

Once the pandemic was declared, the federal government took several measures—without transferring powers to the provinces. The federal government's role in a PHE is largely restricted to border control, financial aid, and vaccine procurement. The first federal actions focused on these areas. Numerous amendments, orders-in-council, and new legislation were passed, aiming to restrict movement across national borders and provide temporary economic relief. Canada spent generously on economic relief during the pandemic. Legislation was also passed to expedite access to COVID-related medical devices, including test kits, initially and later, antivirals and vaccines. This was done very quickly, with parliamentary debate largely suspended. There was strong support for the government in the early days, and provinces and the federal government worked cohesively.

However, this unity began to fray in late 2020 and particularly in 2021 as successive COVID-19 waves hit. Provinces responsible for healthcare delivery had autonomy in setting social distancing and other PHE related measures, resulting in inconsistencies. Pandemic fatigue and differing provincial responses increased discord nationwide. Although initial cohesion

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gradually disintegrated, by late 2021 provinces started introducing various forms of vaccine passports at their own pace and with their own rules.
Like in Australia, vaccination was not legally mandated, but unvaccinated people faced significant restrictions. These restrictions further heightened the discord experienced across the country.

An interesting aspect of the federal government's legal powers during COVID-19 is the potential use of the **Emergencies Act** to override provincial autonomy. The Emergencies Act, passed in 1988 to replace the former War Measures Act, is the only legal instrument that the federal government can use to supersede provincial control. The War Measures Act had been applied in the past for some harsh measures, including the internment of Japanese citizens during the Second World War.
The new Act was designed to clarify the types of emergencies under which it could be invoked and to ensure it was more in line with the Charter of Rights and Freedoms.
When COVID-19 emerged in 2020, the Emergencies Act had never been used. Its stated legislative purpose is to compensate for the absence of other laws in special situations, and it authorizes the federal government to take extraordinary temporary measures in response to emergencies.
In April 2020, the federal government sent letters to provincial governments requesting input on using the Emergencies Act for COVID-19. While the Act mandates that provinces must be consulted, their agreement is not required – the federal government can impose the Act unilaterally.
However, the provinces unanimously opposed its use, arguing that it was unnecessary. The federal government weighed this and recognized that, while it had the power to enact the Emergencies Act, the provinces would still be responsible for healthcare implementation within their borders. Given the federal government's lack of infrastructure to override provincial authority directly in healthcare, they decided that voluntary provincial cooperation was more beneficial, and a federal state of emergency was not declared at the beginning of the pandemic, leaving each province free to decide and implement its response.
In 2022, the Emergencies Act was invoked in response to the **Freedom Convoy occupation** in Ottawa. This allowed the federal government to freeze protest organizers' bank accounts and suspend the right to assembly – an action that raised concerns under the Canadians' Charter rights. These measures dissolved the occupation relatively quickly, but the invocation of the Emergencies Act raised unprecedented questions about judicial oversight.
The Canadian Civil Liberties Association and the Canadian Constitution Foundation both challenged the federal government in Court over this use of the Act. Last year, the Federal Court ruled that the threshold for using the Emergencies Act had not been met. The federal government is appealing the ruling, and there is currently no decision on that appeal. This situation has set a legal precedent in Canada, raising critical questions about the extent to which the government can unilaterally determine its uses of the Emergencies Act without judicial review. It also questions whether the Act, despite being intended to align with the Charter, could potentially override Charter rights with minimal accountability in the future.

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At present, Canada's legislative system is in a state of limbo – awaiting both the ruling on the Emergencies Act appeal and a potential Commission to guide future legislative changes for pandemic preparedness.

16:50-17:15 - Coffee Break

17:10-18.30 - Session II – United States, African Union and European Union

Chair - **Prof. Alceste Santuari - **Department of Sociology and Business Law, University of Bologna

United States and legal preparedness in case of public health emergencies

Prof. William Sage - Law School, Texas A&M University

Prof. William Sage discussed the experience of the United States during the pandemic period. The speech highlighted the systemic issues in U.S. healthcare and public health systems, how they were exacerbated by the COVID-19 pandemic, and the legal and policy changes necessary to address these failures in the future.

Authors Evan Anderson and Scott Burris wrote an essay on the failures of U.S. health policy and public health policy during the COVID-19 pandemic. They pointed out that the United States has essentially unlimited financial resources and represents about 4% of the world's population, yet it suffered nearly 20% of the global mortality from COVID-19, with well over 1,000,000 American lives lost.

The arguments they present for explaining these failures include:

1. **Political Factors:** During the COVID-19 pandemic, ineffective leadership at various government levels appeared at times to almost sabotage the public health response.
2. **Mismanagement of Resources:** Over time, the United States has neglected, depleted, and under-supported its public health infrastructure. Although the U.S. spends nearly five trillion dollars on healthcare, less than 1% of that amount goes toward public health, and this funding has not increased substantially despite the implementation of the Affordable Care Act in 2010 or the onset of the COVID-19 pandemic. In other words, while there is ample funding, budget allocation is skewed, with far more spent on healthcare than on general health.
3. **Ineffective Institutions:** Key institutions, such as the CDC (Centers for Disease Control) and the FDA (Food and Drug Administration), lacked the flexibility and responsiveness required during the COVID-19 crisis. These failures are exacerbated by the fact that public health authority exists at both state and local levels within the 50 states, resulting in a fragmented network rather than a cohesive system.
4. **Gap Between Healthcare and Public Health:** A significant divide exists between healthcare spending and investment in public health preparedness and general population well-being. The U.S. healthcare system focuses more on medical care than on maintaining overall health.
5. **Legal Failures:** the legal readiness at the start of the COVID-19 pandemic can be questioned. Relevant legal actors came together to draft, debate, enact, and adopt thousands of emergency laws—some from executive branch officials (like

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governors), others from state legislatures and the federal government. Most of these new rules, however, were narrowly focused on COVID-19 and did not address future pandemic preparedness. During COVID-19, the public health sector steeped in its scientific methods and deference to scientific authority failed to consider how people would react, resulting in policies that lacked the desired public health impact.

6. **Healthcare System Inadequacies:** The U.S. healthcare system is largely driven by hospitals, where serious illnesses are treated, and hospitals are financed mainly by private insurance payments rather than public health funds. Private insurance often reimburses hospitals at a much higher rate than Medicare (for the elderly) or Medicaid (for low-income patients). Financial survival for hospitals depends heavily on privately insured patients who can afford elective, non-emergency procedures. For example, during COVID-19, New York City hospitals faced financial strain when they were overburdened with Medicare and Medicaid patients who needed critical care.
7. **Social Injustice and Health:** the connection between social injustice and health outcomes should also be taken into consideration. The COVID-19 pandemic revealed how deeply embedded inequalities in U.S. society, including racial and socioeconomic disparities, negatively impact on public health. Health and justice are linked, with systemic injustices impacting public health at every turn during the pandemic. Over the last 20 years, American health scholars and policymakers have increasingly acknowledged the importance of social determinants of health—the non-medical factors that influence well-being and longevity. However, rather than addressing these as societal issues, the tendency has been to treat them as scientific observations, shifting the focus away from social and economic reform.
8. **Constitutional and Legal Challenges:** Over the past two decades, the U.S. Supreme Court has broadened the interpretation of freedom of speech to include corporate entities, allowing them to express views through speech or political contributions, while also protecting them from being compelled to convey government messages. This expansion makes it difficult for the government to counter misinformation effectively. Additionally, the Court has restricted the powers of administrative agencies and expanded religious freedom protections, limiting governmental actions in public health when they might conflict with religious practices. This legal shift profoundly affects public health responses and underscores the importance of legal frameworks that genuinely support public health initiatives.

The African Union and legal preparedness in case of public health emergencies

Prof. Ben K. Twinomugisha - School of Law, Makerere University

Prof. Ben K. Twinomugisha discusses the significant public health challenges facing the African Union (AU) member states, particularly in the context of emerging health emergencies. The speaker highlighted the African Union's role in addressing these challenges, which are exacerbated by weak health systems, inadequate infrastructure and low vaccination coverage across the continent.

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The African Union comprises 55 member states and grapples with a range of PHEs, including outbreaks of diseases such as Ebola, yellow fever, and monkeypox. These emergencies are complex and multifaceted, necessitating a comprehensive and collaborative response. Traditional health issues like malaria and tuberculosis, alongside the impacts of climate change, further complicate the public health landscape in Africa.
Legal frameworks to address PHEs are often fragmented, reflecting the colonial history of many African nations. While many countries have laws and policies in place, challenges persist in their enforcement due to limited resources.

The **African Centre for Disease Control** (Africa CDC) plays a pivotal role in supporting member states by establishing early warning systems and emergency operation centers for PHEs. However, the effectiveness of these systems varies significantly across the continent.
Uganda is highlighted as an example of a country that has successfully navigated public health crises, including COVID-19, by activating its public health emergency operations and establishing swift communication and coordination mechanisms. Uganda has a history of effectively managing health crises, such as Ebola and COVID-19, supported by an established public **health emergency operations center**. This center, activated during crises, coordinates public health responses and has been crucial in managing outbreaks through surveillance, contact tracing, and community engagement. Three points are particularly relevant:

1. **Emergency Operations**: the Ugandan government has implemented a well-structured public health response during COVID-19, which included establishing task forces and mobilizing resources to manage the crisis. Despite the government's efforts, challenges persist due to inadequate healthcare infrastructure, which has limited the availability of essential medical supplies and services.
2. **Human Rights Considerations**: throughout the COVID-19 response, Uganda faced tensions between enforcing public health measures and protecting individual rights. While necessary for public safety, some restrictions led to concerns over human rights abuses. Activists emphasized the need for safeguards to ensure that public health interventions do not imppinge on individual’s freedoms disproportionately.
3. **Community Engagement and Communication**: Uganda's public health strategy relied heavily on community engagement through various media channels, ensuring that the population was informed about health measures. This approach has been pivotal in promoting compliance with health interventions, especially during lockdowns and vaccination campaigns.

Despite Uganda's successes, the challenges of resource allocation, infrastructure, and human rights protection remain pressing issues. In addressing PHEs, the African Union should prioritize the following actions:

- **Strengthening Legal Frameworks**: member states need to adopt and implement comprehensive legal frameworks to guide public health emergency responses, ensuring compliance with international regulations.
- **Capacity Building**: there is a need for investments in health infrastructure and human resources, including training health professionals and improving

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surveillance systems.

- **Establishing Emergency Operation Centers**: every member state should establish functional public health emergency operation centers to enhance preparedness and response capabilities for future health crises.
- **Promoting Human Rights**: safeguarding human rights should be central to public health responses, ensuring that measures taken during health emergencies are proportionate and respect individual freedoms.

The need to balance public health measures with human rights protection is crucial, as restrictive measures during health emergencies can lead to tensions regarding civil liberties.

In conclusion, the establishment of robust legal frameworks and operational centers across African Union member states to enhance preparedness for PHEs is essential. Learning from Uganda's experience, collaborative efforts are needed among member states to address the ongoing challenges posed by PHEs.

The European Union and legal preparedness in case of public health emergencies

Prof. Giacomo Di Federico - Department of Legal Studies, University of Bologna

Prof Giacomo Di Federico discussed how the European Union has responded to COVID-19. In particular, the aim was to better understand how LP facilitates prevention, detection, and rapid response to PHEs.

From an EU perspective, the pandemic has made clear the absolute need to coordinate the member states' action on health matters to create a health governance system capable of anticipating and responding to cross-border threats and sharing skills, knowledge and expertise.

These objectives are both at the heart of the idea, put forward by the President of the Commission, of a **European Health Union** but they are also pivotal elements of global health.

On the one hand, the Treaty recognizes that Member States retain the sole power and responsibility for the definition of their health policy and the organization and delivery of health services. On the other hand, the EU Council (i.e., the representatives of the Member States, usually health ministers) and the European Parliament Members (elected directly from the citizens) can only adopt incentive measures to promote monitoring, early warning of and response to major cross-border health scourges, but cannot harmonize the laws and regulations of the Member States. The same applies when the legislator intervenes to promote rapid and effective operational cooperation between national authorities responsible for civil protection. It should also be borne in mind that the Council of the EU has been given the power to decide on appropriate measures "in a spirit of solidarity" and in particular, if serious difficulties arise in the supply of certain products as medical countermeasures.

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The Union has exercised its competencies and has developed a plan to build a true **European Health Union**. This effort has been criticized in the legal literature insofar as many have suggested that the Union has acted ultra vires to respond to the crisis.
The most important acts that have been adopted are not related to the provision of health care but to the protection of public health.

1. Firstly, a health emergency preparedness and response authority, the **Health Emergency Preparedness and Response Authority**_(HERA) was created as an internal service of the European Commission.
2. Second, the mandates of the **European Medicines Agency** (EMA), which conducts clinical trials and authorizes vaccines, and the **European Centre for Disease Prevention and Control** (ECDC) have been strengthened.
3. Thirdly, the **legal framework on serious cross-border health threats** and the **rules on the Union's civil protection mechanism** have been revised.
4. Fourthly, a **new regulation** has been adopted specifically to ensure the supply **of critical relevant crisis medical countermeasures** in the event of a public health emergency at the Union level.

The Union has tried to comply with international standards and strengthen its legal preparedness, even though public health and providing health services remains a national competence. It is not just a question of guaranteeing security, it is also a question of guaranteeing fundamental rights and guaranteeing the existence and proper functioning of the internal market. Indeed there are a number of questions to be tackled: is there an ad hoc regime for PHEs? Which subjects are legitimized to declare a state of emergency? When can the applicable regime be activated and what kind of coordination between the competent public authorities is ensured? Are there monitoring and early warning mechanisms for shortages of medical products or devices? How is access to the protective equipment and medical supplies needed during a pandemic guaranteed? The post-pandemic legal reform has addressed all these concerns.

The first reaction of the Member States was to **close their borders**. This immediately creates a problem for the Union, which is the disintegration of the single market. One must accept that member states are free to close their borders because there is no enforcement system at the EU level to stop them from doing so. So, at that point, the focus was more on trying to ensure that there was some kind of circulation of at least essential workers, but also critical materials. The free movement of workers or individuals has been solved by the creation of a COVID certificate. The Union could never impose compulsory vaccination - that is a matter for the Member States.

The second response to COVID-19 was **strengthening the legal framework** for more prevention, preparedness, and response.

The health package presented by the Commission and swiftly adopted by the EU legislator rests on three main pillars:

- **First pillar**: the new Regulation on the response to serious cross-border health threats, complemented by the decision to set up HERA and the strengthening of the mandate of the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC);

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- **Second pillar**: the regulation reforming the decision on the Union's civil protection mechanism and facilitating the management of resources voluntarily contributed by Member States (ambulances, helicopters, aircraft, and also medical teams);
- **Third pillar**: the new regulation on a framework of measures to be activated in the event of PHEs; it's a question of making medical countermeasures available on the market.

Looking at the reform as a whole, three main objectives have been achieved:

1) Firstly, to increase the **decision-making capacity** of both the existing bodies and to create new bodies, acting upon scientific evidence. This means that it is important to involve experts in the process but also to involve stakeholders. For example, when HERA activates its emergency mode to retrieve material relevant to a crisis, it will at some point confront itself and discuss with representatives of the industry.

2) The second objective of the reform is to improve the **monitoring and detection capacity**. The new mandate of the ECDC foresees the creation of a network of reference laboratories in all the Member States, but also the creation of dedicated services and new IT tools such as the European Shortage Monitoring Platform and the new Vaccine Monitoring Platform. In this way the monitoring mode has been decentralized, with the possibility for the competent bodies to upload information and this information is then shared within the Union. It is important to mention, among the IT tools, a tool that supports health protection: the European Health Data Space. The idea is to gather all the available electronic data (for example, medical records): and share for research purposes.

3) Third objective: strengthening **response capacity**. Immediately after the WHO declaration of a public health threat of international concern, a number of emergency task forces were set up: one within the ECDC and one within the EMA. An EU Civil Protection Knowledge Network was also established under the EU Civil Protection Mechanism.

Four novelties are particularly noteworthy to appreciate the added value of this reform package:

1) the development of a **Union health preparedness plan** based on pre-determined key elements: planning for multi-sectoral cooperation, security surveillance, monitoring, early warning communication, and overview of production capacities.

2) the strengthening of the role of the ECDC to offer **technical and policy making support** before, during and after sanitary crisis.

3) the Commission is entrusted with the task of **declaring a public health emergency** (in liaison with the WHO and with the support of an advisory committee of independent experts from the Member States) whenever there is a threat of biological, chemical, environmental, or even unknown origin

4) the Council is competent to activate an ad hoc framework for the **procurement and purchase of medical countermeasures** and the activation of a health crisis board

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Over the last 20 years, following several health crises and several amendments to the Treaties, the Union has equipped itself with an increasingly comprehensive framework of rules applicable to health emergencies. Despite the limited competencies of the Union in the field of public health protection, Member States have understood that certain problems can only be solved at the supranational level. So, beyond the formal division of competencies, there is a common intention to work together to solve cross-border health-related problems. Also, what is emerging is the idea that the Union will set indicators and benchmarks (for example, for planning or epidemiological surveillance) and this means that member states – despite the lack of harmonization - are de facto forced to act in line with common European rules.

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