



THE JOURNEY TO RESILIENCE

A GLC4HSR Learning Series

***Peer to Peer Learning
Series, Session 4:***
**Health Regulation:
Building Regulatory
Systems that
Protect People
while Enabling
Innovation**

24th September 2026

2:00 – 3:30 PM IST



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Strong health systems depend not only on financing, service delivery and workforce capacity, but also on effective governance. Among the core governance functions, health regulation plays a critical role in ensuring that health services, medicines, medical devices, diagnostics, digital health technologies and health professionals are safe, effective, ethical and accountable.

The fourth session of The Journey to Resilience, the peer-to-peer learning series convened by the Global Learning Collaborative for Health Systems Resilience (GLC4HSR), examined health regulation as a core function of health-system governance. The session marked the beginning of a deeper exploration of regulation within the governance series, following earlier discussions on assessment and monitoring, policy formulation, and decision-making during and after public health emergencies.

The discussion recognised that regulation is becoming increasingly complex. Digital health, artificial intelligence, new medicines and medical devices, cross-border healthcare, changing models of health professional education, and expanding private-sector participation are creating regulatory questions that cannot always be addressed through traditional approaches

**The central question was therefore not simply how to regulate, but:
How can regulatory systems protect people without unnecessarily
constraining innovation?**

Dr. N. Krishna Reddy, CEO, ACCESS Health International, moderated the session and set the broader context for understanding regulation as a governance function that operates across different levels and components of the health system. The discussion then examined three areas in greater depth: regulation of health professional education, regulation of medicines and medical devices, and regulation of digital health, health data, and artificial intelligence.

Regulation as a Core Governance Function



Opening the session, Dr. N. Krishna Reddy situated health regulation within the broader purpose of the GLC4HSR governance learning series.

The series seeks to move beyond abstract descriptions of governance and examine the functions and institutional mechanisms through which health systems are actually governed. Regulation, like assessment, monitoring and policy decision-making, operates across different stages of health-system development and has implications for health-system strength, health security and resilience.

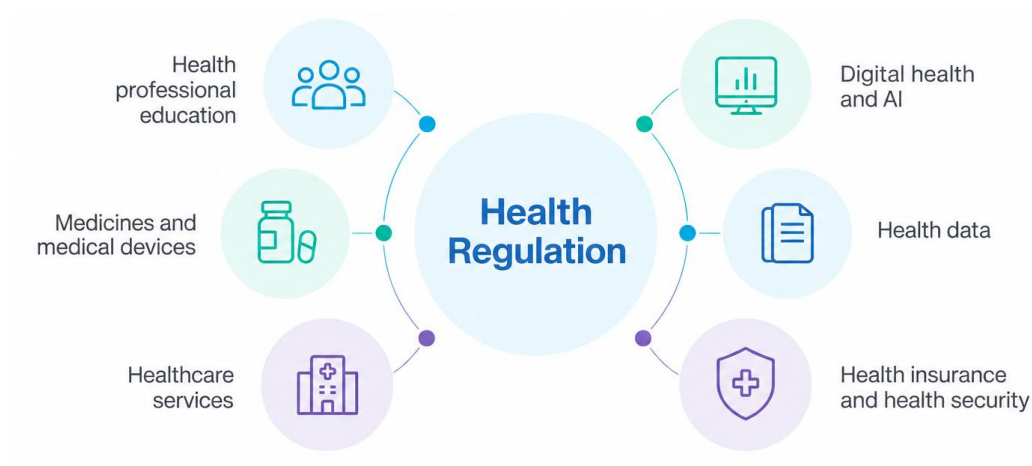
Dr. Reddy emphasised that regulation should not be understood as a static function. It operates during routine periods, during preparedness for public health emergencies, and during crises themselves. The experience of COVID-19 demonstrated the need for regulatory systems to be capable of adapting to rapidly changing circumstances and supporting timely responses to emerging risks.

This is particularly important because regulation touches virtually every part of the health system. It determines, among other things, who is qualified to provide care, how health professionals are educated and licensed, how medicines and medical devices are assessed, how health data are managed, and how emerging technologies are governed.

Regulation should not be looked at as a static function. It may need some changes in light of the experience with the recent COVID pandemic and ongoing crises, so that regulatory systems can prepare themselves for ongoing or future public health emergencies.

Given the breadth of the subject, the session was positioned as a curtain raiser for a broader exploration of health regulation. The intention was not to provide a comprehensive review of every regulatory domain, but to introduce some of the complexities involved and identify areas where regulatory systems may need reform.

Dr. Reddy identified three areas for particular attention during the session: health professional education, health goods such as medicines and medical devices, and digital health, health data, and artificial intelligence. Other areas, including clinical service regulation, health insurance, and consumer grievance mechanisms, were identified for future discussions.



Regulating Health Professional Education



Prof. Bhuputra Panda, Director and Professor, KIIT University; Senior Advisor, ACCESS Health International, examined the regulation of health professional education within countries and across national borders.

He framed regulation of professional education as an assurance chain connecting population needs, education, individual competencies and permission to practise. The regulatory question therefore extends beyond whether an individual has completed a particular curriculum or obtained a degree. It also concerns whether that individual possesses the competencies required to practise safely and effectively.

This becomes particularly important as health systems increasingly rely on a wider range of health professionals. In addition to doctors and nurses, health systems depend on allied health professionals and other cadres whose education, certification and professional roles also require appropriate standards and oversight.

Prof. Panda explained that regulation involves legitimate authority, standards, oversight and enforcement mechanisms that determine who may practise, who may be licensed, how qualifications are recognised, and what requirements professionals must meet.

In India, he noted, the regulatory framework has evolved through different institutions and legislative arrangements. The National Medical Commission, for example, has responsibility for standards related to medical education, while other health professional cadres have different or evolving regulatory arrangements.

Professional education regulation is essentially a public interest assurance chain that connects the population in terms of their needs, education in terms of quality and competencies at the individual level.

This creates a significant challenge for areas such as public health and health management education, where there can be considerable variation in curricula across institutions. Prof. Panda pointed to the absence of a single strong regulatory mechanism with the authority to establish and enforce standardised curricula for some of these professions.

The discussion highlighted an important distinction between setting standards and enforcing them. A regulatory framework is only effective when institutions have the capacity and authority to implement, monitor, and continuously improve those standards.

From Curricula to Competencies

A central theme of Prof. Panda's contribution was the need to move towards competency-based approaches to health professional education.

Traditional approaches can place considerable emphasis on whether an individual has completed a prescribed curriculum and obtained a qualification. However, increasingly complex health systems require professionals to demonstrate the knowledge, skills and competencies necessary to practise effectively in changing environments.

This has implications both within countries and across borders.

Prof. Panda noted that regulatory systems in different countries vary considerably in how they assess professional competence and maintain standards after initial qualification. In some settings, continuing assessment and requirements for professional updating form an important part of the regulatory framework.

The discussion therefore raised a broader question: how can countries establish comparable standards of competence while retaining the ability to respond to their own health-system needs?

This becomes particularly relevant during public health emergencies, when countries may need to mobilise health professionals rapidly across regions or borders. Differences in licensing requirements, qualifications and professional standards can become barriers to workforce mobility at precisely the time when additional capacity may be required.

The session therefore highlighted the potential value of greater cooperation and alignment around health professional education standards, while recognising the complexity of achieving this across different legal, educational and health-system contexts.



Regulation Across Countries and Regulatory Capacity

The discussion also highlighted substantial variation in regulatory capacity both within countries and across countries.

Prof. Panda described how differences in institutional capacity can result in wide variation in the quality and relevance of professional education. Institutions may operate with very different levels of academic, administrative and regulatory capacity, even when they offer programmes with similar titles.

This creates a challenge for national systems seeking to establish consistent standards and for countries seeking to recognise qualifications obtained elsewhere.

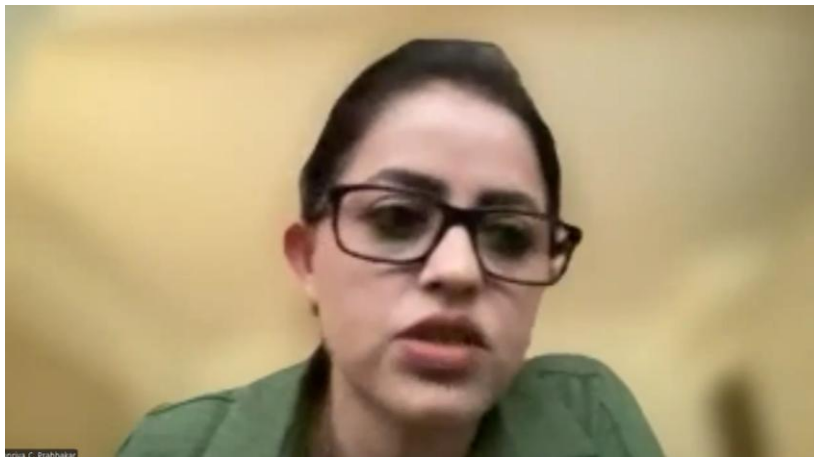
Dr. Reddy connected this issue to the wider question of regulatory capacity. The same challenge appears across different regulatory domains: some countries have highly developed institutions with established systems of assessment, enforcement and continuous improvement, while others continue to develop the institutional capacity required to perform these functions effectively.

This disparity raises the importance of international cooperation, shared standards, capacity development and mechanisms for mutual recognition and reliance.

The objective is not necessarily to create one identical regulatory model for every country. Rather, it is to establish sufficient confidence in the quality and competence of regulatory systems so that countries can cooperate more effectively, particularly when health professionals or health products cross borders.

The governance problem becomes whether one jurisdiction can trust another jurisdiction for the same candidate or individual when he or she wants to go outside and practise the profession that he or she has been trained to practise.

Regulating Digital Health, Health Data and Artificial Intelligence



Supriya C. Prabhakar, Technical Head – Digital Health, Technology Application and Services, ACCESS Health International, examined one of the fastest-evolving areas of health regulation: digital health, health data and artificial intelligence.

She began by highlighting how digital health is changing the way health systems deliver care, generate and use knowledge, and involve organisations outside the traditional boundaries of the health sector.

This creates a more complex regulatory environment. A single digital health intervention can involve professional regulation, healthcare service regulation, product regulation, data protection, cybersecurity and infrastructure requirements simultaneously.

For example, a patient receiving a virtual consultation supported by an AI-based recommendation and a shared electronic health record may experience a single episode of care. Behind that experience, however, multiple regulatory responsibilities may apply.

Professional rules may govern the clinician. Service regulation may address quality of care. Product regulation may apply to software. Data protection rules may govern the collection and use of information. Infrastructure requirements may determine whether the service is secure and reliably available.

The challenge, therefore, is not simply the existence of multiple regulations but how those regulatory responsibilities connect with one another.

A credible regulatory system should bring together clear authority with sound evidence and the capacity to respond to circumstances as they change.

Regulation Must Keep Pace with Evolving Technology

A major issue highlighted by Supriya was that digital technologies, particularly AI-based systems, do not necessarily remain static after they are initially assessed.

A technology may be developed and validated for a particular population, language, clinical setting, or dataset, but subsequently be deployed in a different context. AI models may also be updated as software evolves.

This creates a challenge for traditional regulatory approaches that rely heavily on assessment at a single point in time.

Regulation therefore needs to consider continuous oversight, reassessment, and validation as technologies change and as their uses expand.

The same issue applies to cross-border data flows. Health information can move between jurisdictions, raising questions about which authority has responsibility for the data, who may access it, and which legal requirements apply.

The discussion emphasised that there is unlikely to be one universal regulatory model for digital health. Different jurisdictions have adopted different approaches depending on their legal, institutional and health-system contexts. The more important question is how regulatory systems can provide clarity about responsibilities while remaining sufficiently adaptable to technological change.

Health Data: Rights, Uses and Accountability

The regulation of health data introduces another layer of complexity because the same information can serve multiple legitimate purposes.

Public trust grows when people have a reason to believe that innovation serves their interest and that institutions can act when something goes wrong.

Health data may be required for continuity of care, public health activities, research, service improvement or technological development. Each use can raise different questions about legal authority, consent, safeguards and accountability.

Supriya emphasised that the collective benefits of health-data use need to be considered alongside individual rights.

The existence of a potential public or commercial benefit does not automatically make every use of health data appropriate. Regulatory frameworks need to clarify when information can be accessed, for what purposes, under what safeguards, and with what mechanisms for oversight and redress.

This also makes grievance and remedy mechanisms important. Individuals need understandable pathways through which they can question how their data have been used, while institutions need the capacity to detect, investigate and address potential breaches.

The broader issue is institutional accountability. Health authorities, data protection bodies, medical device regulators and professional bodies may each have legitimate responsibilities, but no single institution may have complete visibility across the entire digital health ecosystem.

Effective regulation therefore depends on clear mandates and coordination between institutions.



Regulation of Medicines and Medical Devices



Mariam Ghobrial, Manager – Life Sciences, ACCESS Health International, examined the regulation of medicines, vaccines and medical devices from a national, regional and global perspective.

She began by outlining the fundamental purposes of regulation: protecting patients, ensuring safety, quality and efficacy, while also enabling innovation, availability and investment.

The discussion then moved to the challenges created by fragmented regulatory systems, particularly in regions where multiple national regulatory authorities operate across relatively interconnected markets.

Mariam used the African regulatory landscape to illustrate this challenge. Multiple national regulatory authorities can create duplication in assessments and increase the time and resources required for products to reach patients.

This becomes especially significant during public health emergencies, when regulatory processes can become bottlenecks affecting access to medicines, vaccines and other health technologies.

It is not only about quality, safety and efficacy. It is about availability—the product, the high-quality product, safe and effective, is available to the patient.

Harmonisation and Regulatory Reliance

One response to regulatory fragmentation is harmonisation.

Mariam discussed the work of the International Council for Harmonisation and its efforts to align technical requirements for pharmaceutical development and assessment. Harmonised approaches can reduce duplication in clinical and non-clinical requirements and create greater consistency in the way technical information is submitted and assessed.

The Common Technical Document was presented as an example of how standardisation can improve consistency across regulatory submissions.

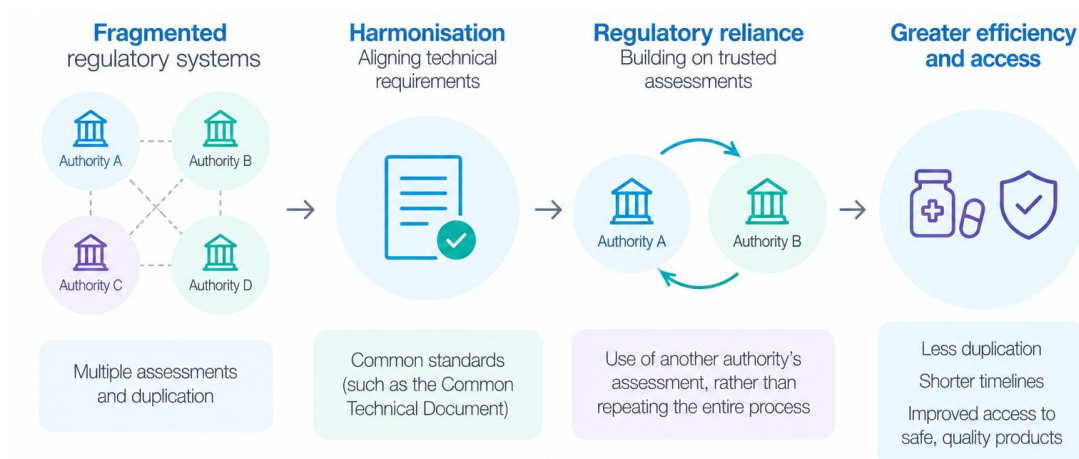
However, harmonised technical requirements are only useful when regulatory authorities have the capacity to assess the information effectively.

This led to a second important concept: regulatory maturity.

Mariam described the WHO Global Benchmarking Tool as a mechanism for assessing the maturity and capabilities of national regulatory authorities. The framework examines multiple regulatory functions and helps identify strengths, gaps, and areas where capacity development may be required.

The discussion highlighted that regulatory strengthening is therefore not simply about establishing rules. It also requires institutions with the technical expertise, systems, and resources needed to implement those rules.

Reliance is one regulatory authority depending on another regulatory authority in the assessment, not redoing the assessment from the beginning. So it builds on trust.



Building Trust Between Regulatory Authorities

The next step beyond harmonisation is regulatory reliance.

Reliance allows one regulatory authority to make use of the assessment or work conducted by another trusted authority rather than repeating the entire process independently.

Mariam described examples involving regulatory inspections, vaccine batch release and product assessments, as well as regional arrangements that allow countries to build on assessments conducted by other authorities.

Such approaches can reduce duplication, shorten timelines and support access while maintaining regulatory safeguards.

However, reliance ultimately depends on trust between regulatory institutions.

For one authority to rely on another, it must have confidence in the quality, transparency and consistency of the other authority's regulatory processes.

This creates a direct connection between regulatory maturity, international cooperation and access to health products.

Medical Devices and Evolving Regulatory Models

Mariam also highlighted the distinct regulatory considerations associated with medical devices.

The discussion contrasted major regulatory approaches used in the United States and European Union, including differences in classification, approval pathways, timelines, and post-market requirements.

Unlike medicines, many medical devices can evolve through technological changes and product updates, creating their own challenges for regulatory oversight.

The discussion therefore reinforced a broader message from the session: regulatory systems need to be sufficiently robust to protect people while remaining responsive to the characteristics of the technologies and products they regulate.

Regulation, Trust and Public Interest

Across the three presentations, a common theme emerged: regulation is ultimately about public trust.

Whether the subject is the competence of a health professional, the safety of a medicine, or the responsible use of AI and health data, people need confidence that regulatory institutions can identify risks, act when problems arise, and protect the public interest.

Dr. Reddy highlighted this connection during the discussion, noting that public trust in governance systems is an important determinant of health-system resilience. The regulatory function therefore cannot be separated from broader questions of institutional credibility and accountability.

At the same time, the speakers emphasised that regulation should not become an unnecessary barrier to access or innovation.

The challenge is to create regulatory systems that are proportionate, evidence-informed, transparent and capable of adapting to change.

The Challenge of Regulatory Capacity

A broader question raised during the discussion was how countries with limited regulatory capacity can strengthen their systems.

The speakers highlighted that significant disparities exist not only between countries but also between institutions within the same country.

Some regulatory systems have sophisticated technical capabilities and established mechanisms for assessment, surveillance and enforcement. Others may have gaps in institutional capacity, technical expertise, infrastructure or implementation.

International cooperation can therefore play an important role in strengthening regulatory capacity.

For health professional education, this may involve greater alignment of competency standards and recognition mechanisms. For medicines and medical devices, it may involve harmonisation, reliance and capacity-building initiatives. For digital health, it may involve sharing regulatory experience and developing approaches that can respond to rapidly changing technologies.

Regulation During Public Health Emergencies

The discussion also returned to the relationship between regulation and health-system preparedness and resilience.

During a public health emergency, regulatory decisions can have immediate consequences for access to diagnostics, medicines, vaccines, medical devices, technologies and health professionals.

Regulatory systems therefore need to be prepared before a crisis occurs.

Dr. Reddy highlighted the importance of having appropriate legal and regulatory provisions already in place so that emergency measures can be activated when needed, rather than requiring systems to create new mechanisms during a crisis.

This is particularly relevant for emergency approvals, regulatory reliance, movement of health professionals, data access and use, and accelerated assessment of new technologies.

The broader lesson is that regulatory resilience is built during routine periods.



Key Insights

The fourth session of The Journey to Resilience brought together perspectives from health professional education, digital health, health data, medicines and medical devices to examine regulation as a core governance function.

- **Regulation is a core governance function:** Health regulation extends across professional education, healthcare services, medicines and medical devices, digital health, health data and health security. It is not a static function and needs to evolve alongside health systems, technologies and emerging risks.
- **Effective regulation requires institutional capacity:** Strong regulatory standards are only effective when institutions have the authority, technical expertise, resources and systems needed to implement, monitor and enforce them. Strengthening regulatory capacity is therefore as important as developing regulatory frameworks.
- **Regulation must evolve with technology:** Digital health and AI are creating new regulatory challenges that cut across professional, product, service, data and infrastructure regulation. As technologies evolve after deployment, regulatory approaches need to support continuous oversight, reassessment and adaptation.
- **Cooperation can strengthen regulatory systems and access:** Harmonisation, mutual recognition and regulatory reliance can reduce duplication, strengthen regulatory capacity and support access to medicines, medical devices and health professionals across jurisdictions. Such approaches depend on trust in the quality and consistency of regulatory systems.

Key Insights

- **Regulation must balance protection and innovation:** The purpose of regulation is not simply to create rules, but to protect people while enabling responsible innovation and access. Regulatory approaches need to be proportionate, evidence-informed and responsive to changing circumstances.
- **Trust and resilience are central to effective regulation:** Credible regulatory institutions can strengthen public confidence in health services, products and technologies. Stronger regulatory systems, in turn, contribute to health-system resilience by enabling systems to anticipate risks, respond to emergencies and adapt to change.

A Final Reflection

The discussion ultimately reframed health regulation as more than a system of rules and compliance requirements. It is a core governance capability that shapes how health systems protect people, manage risk and respond to change.

For health professional education, effective regulation helps ensure that those entering the health workforce have the competencies required to practice safely and effectively. For medicines and medical devices, it creates systems through which safety, quality and efficacy can be assessed while improving access and enabling innovation. For digital health and AI, it provides the institutional safeguards needed to manage technologies that are rapidly evolving and increasingly embedded in healthcare delivery.

Across these different domains, the same principle emerged: regulation must be capable of adapting to changing circumstances without losing sight of its fundamental purpose—protecting people and serving the public interest.

As the Journey to Resilience continues, the discussion provides a foundation for examining other dimensions of health regulation, including healthcare services, health insurance, consumer protection, and other regulatory functions that contribute to stronger, safer, and more resilient health systems.