Regulatory Health Authorities Collaboration and its Impact: Developing New Reliance Models

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ABSTRACT

Regulatory health authorities' collaboration is crucial in addressing the complexities of drug approval and health policy implementation. By working together, these authorities can improve efficiency, ensure patient safety, and facilitate timely access to necessary medical products. International cooperation also promotes regulatory harmonization, which can enhance global health outcomes. Collaboration among regulatory health authorities is essential for the efficient approval of medical products. The regulatory approval of medical products in countries with limited regulatory resources can be lengthy, which often compromises patients' timely access to much-needed medicines. Therefore, effective collaboration helps streamline processes and minimize delays. The impact of regulatory collaboration extends beyond individual countries; it contributes significantly to global health. Over the past 30 years, many national drug regulatory authorities have embarked on a process of gradual harmonization of all the technical aspects of studies, processes, and tests that generate the data necessary for decisions on drug approval. This harmonization supports better health outcomes worldwide. As the global landscape of public health evolves, regulatory authorities are required to adapt their practices. At a time when the world continues to be gripped by one of the most significant pandemics in history, medical regulators are understanding, more than ever, the value of effective regulation and coordination among themselves. This adaptability will shape the future of public health responses.

KEYWORDS: Regulatory authorities, Public Health Emergencies (PHE), European Medicines Agency (EMA), Marketing authorization, Collaboration, National regulatory authorities (NRAs), WHO.

1. INTRODUCTION

In today's interconnected world, collaboration and cooperation among regulatory health authorities have become increasingly crucial in ensuring the safety, efficacy, and quality of healthcare products and services. Regulatory authorities play a pivotal role in safeguarding public health by implementing guidelines, standards, and policies that govern the development, approval, and distribution of biomedical products [1]. During times of crisis or turbulent environments, the impact of regulatory authorities' actions becomes even more significant. In such scenarios, strict regulation imposed by regulatory authorities can potentially destabilise the supply chain system, underscoring the need for a collaborative approach between supply chain actors and regulatory bodies [2].

Collaborative regulation, which emerges from the collaboration between supply chain stakeholders and regulatory authorities, can help maintain a balanced and sustainable supply chain while ensuring appropriate safety standards are met [3]. This approach allows for open communication, shared decision-making, and the alignment of interests to address complex challenges effectively [4].

Public Health Emergencies (PHE) have had repercussions on health systems on a global scale, and timely access to new health technologies is a challenge for health policy [5]. Regulatory authorities must adapt to these challenges through robust collaboration to ensure healthcare systems remain responsive and effective during crises. During health emergencies, such as pandemics, collaboration between regulatory authorities is imperative for the rapid assessment and approval of vaccines and treatments. Multi-stakeholder interactions have evolved at product and policy levels, addressing the current and future landscape of interactions between companies and regulatory authorities [6]. This collaboration is critical for ensuring safe and effective products reach the public quickly.

2. IMPACT OF REGULATORY HEALTH AUTHORITIES' COLLABORATION

The collaboration among regulatory health authorities plays a crucial role in improving public health outcomes, enhancing the efficiency of drug approval processes, and fostering access to high-quality medicines. By embracing international cooperation and regulatory reliance practices, these authorities can address emerging health challenges and ensure timely access to essential medical products [7].

2.1. Importance of Collaboration

The collaboration among regulatory health authorities is essential for improving patients' access to medicines. The World Health Organization (WHO) advocates for reliance practices to enable national regulatory authorities (NRAs) to enhance access to medicines through cooperative efforts [8]. This collaboration allows regulatory bodies to share knowledge, streamline processes, and align standards, ultimately benefiting patients and healthcare systems.

2.2. Impact on Drug Approval Processes

New anticancer therapies have led to substantial improvements in prognosis across many cancers; however, commercial access to a drug is not possible until it has received regional regulatory approval from bodies such as the FDA, EMA, and others [9]. By collaborating, regulatory health authorities can reduce the time it takes for drugs to be approved for market access, which is vital for providing timely treatment options to patients.

2.3. Global Health Initiatives

To promote global health, regulatory agencies are tasked with increasing access to high-quality and effective medicines, particularly in low- and middle-income countries. For example, the European legislation introduced a collaboration tool aimed at supporting access to medications [10]. This shows the importance of regulatory harmonization across countries to meet public health needs.

2.4. Enhancing Regulatory Capacity

The purpose of developing and adopting regulatory science for drug regulatory authorities is to enhance regulatory capacity by advancing the scientific approach for the evaluation of medicines [11]. Enhanced regulatory capacity ensures that health authorities can efficiently respond to emerging medical needs and leverage collaborations to implement best practices.

2.5. Addressing Health System Challenges

The COVID-19 pandemic has highlighted the necessity of strong collaboration among health authorities to address public health crises effectively [12]. This situation demonstrated that collaborative frameworks are vital for coordinating responses, managing resources, and integrating health functions to safeguard public health.

3. WHAT SPECIFIC EXAMPLES CAN YOU PROVIDE OF SUCCESSFUL COLLABORATIONS BETWEEN REGULATORY HEALTH AUTHORITIES?

Successful collaborations between regulatory health authorities are instrumental in enhancing public health outcomes and ensuring access to quality healthcare. Various international partnerships have demonstrated how shared knowledge, resources, and best practices can lead to more effective and efficient health responses, particularly during crises or in addressing complex health issues [13].

3.1. Examples of Regulatory Collaborations

One significant example is the formation of a consortium comprising regulatory authorities such as the Australian Therapeutic Goods Administration (TGA), Health Canada, Swissmedic, and the Singapore Health Sciences Authority (HSA). This consortium aimed to jointly address regulatory challenges by sharing expertise and harmonizing standards for drug evaluation and approval, thus improving the overall efficiency of regulatory processes [14].

3.2. Collaborative Efforts During Health Crises

During the COVID-19 pandemic, various health authorities collaborated globally to ensure swift vaccine distribution and public health safety measures. For instance, the CDC Foundation worked with partners in Zambia and Tanzania to tackle challenges concerning vaccination access and public hesitancy, demonstrating how strategic partnerships can effectively address urgent public health needs[15].

3.3. Implementation of Public Health Partner Authorities

In South Australia, the establishment of Public Health Partner Authorities (PHPAs) exemplifies successful cross-sector collaboration. These authorities, guided by the "Health in All Policies" approach, facilitate partnerships aimed at improving population health and wellbeing. By integrating public health considerations into policies across different sectors, PHPAs have achieved significant improvements in community health outcomes [16].

3.4. Collaboration in Response to the Opioid Crisis

Public health agencies have also played pivotal roles in convening partnerships to address the opioid crisis. These collaborations involve local and state-level health agencies working together with community organizations to develop and implement comprehensive strategies aimed at reducing opioid misuse and supporting recovery efforts [17].

3.5. Global Collaborations in Regulatory Science

Furthermore, global collaborations among health authorities have been strengthened through initiatives like the World Health Organization's efforts to improve drug promotion ethics, particularly in the context of online advertising [18]. By establishing stringent standards and promoting responsible advertising practices, regulatory authorities aim to safeguard public health, especially during crises. These examples illustrate the myriad ways regulatory health authorities collaborate to enhance public health, streamline processes, and respond effectively to challenges faced by healthcare systems globally. The integration of diverse perspectives and expertise through such partnerships fosters innovative solutions to complex health issues.

4. EMA ENGAGEMENT IN COLLABORATIVE PATHWAYS

The European Medicines Agency (EMA) plays a critical role in fostering collaborations that enhance the development and oversight of medicinal products through various adaptive pathways. This engagement enhances the scientific relevance of collaborative projects and supports the agency's mission to promote public health. EMA has significantly engaged in collaborative pathways aimed at improving drug regulation and access to medicines across different regions [19]. This engagement is reflected in various initiatives that facilitate multi-stakeholder dialogues and regulatory reliance between Europe and non-EU countries. The collaborative frameworks not only enhance harmonization but also allow for a more efficient review process for new medicines.

4.1. EMA's Role in Collaborative Pathways

The European Medicines Agency (EMA) interacts with many different stakeholders involved in the development of drugs, including academic researchers. EMA's engagement in external research projects benefits the consortia conducting them and supports the Agency's mission to foster scientific excellence and advance regulatory science. Furthermore, EMA has established an academia liaison office and created a framework for collaboration with academia [20].

4.2. Improving Regulatory Science

To achieve the goals set in the EMA Regulatory Science to 2025 reflection documents, the Agency has increasingly engaged with academia2. This collaboration aims to increase understanding of EMA's public health role among academic stakeholders and to facilitate the translation of academic research into methodologies that meet EMA's standards2. Moreover, EMA collaborates on advancing the field of regulatory science by fostering the development of new biomarkers, endpoints, and methodologies [21].

4.3. Participation in External Projects

EMA contributes to several external research projects that are coordinated by academic institutions and that address issues pertinent to regulatory science. These projects are often set up within the context of the EU Horizon 2020 framework, involving large consortia comprised of public and private stakeholders working toward shared objectives [22]. The criteria employed by the Agency to decide on participation include the project's relevance for EMA's strategic aims and the anticipated added value EMA can offer.

4.4. Challenges and Adaptations

Project coordinators and EMA experts reported that the SARS-CoV-2 pandemic negatively impacted many projects, with delays being a common issue. Interviews indicated that while some projects fell behind schedule, nearly all participants believed their projects were on track to accomplish their objectives within the necessary timeframes [23]. The pandemic also highlighted the need for efficient multi-stakeholder cooperation, indicating areas where regulatory science can improve.

4.5. Communication and Collaboration

EMA's working relationships with project consortia are generally described positively, with both EMA staff and project coordinators expressing satisfaction with the collaborative efforts2. However, some coordinators have encountered difficulties in obtaining timely feedback or responses from their EMA contact points [24]. Maintaining effective communication is crucial to ensure that both parties can deliver the expected outcomes within established timelines.

4.6. Collaborative Frameworks

The EMA is involved in several key collaborative frameworks, including the EUMedicines4all procedure, the WHO collaborative registration procedure, and the OPEN initiative. These initiatives primarily focus on enabling non-EU countries to benefit from EMA's assessments, thereby fostering international cooperation and regulatory reliance5. The EMA's collaboration includes exchanges with authorities from countries such as Australia, Canada, Japan, and Switzerland, promoting shared evaluations while maintaining the autonomy of individual agencies [25].

4.7. Importance of Early Dialogue

Early dialogue and collaboration have fundamentally shaped many of EMA's activities, ranging from cancer treatment advancements to digital transformation initiatives. This emphasis on multi-stakeholder engagement has been crucial in aligning various parties involved in the regulatory process, ensuring that diverse perspectives are considered during decision-making [26]. The collaboration extends beyond European borders, proactively seeking input from multiple stakeholders to enhance the regulatory landscape globally.

4.8. Implementation of Regulatory Pathways

Implementing new collaborative regulatory pathways has become a focal point for the EMA, particularly in the aftermath of the COVID-19 pandemic. The agency anticipates that international collaboration will play an increasingly prominent role in future pharmaceutical regulations, as reflected in the proposals for overhauling EU pharmaceutical legislation5. The EMA supports initiatives like the OPEN pathway, which not only improves the scientific evaluation process but also contributes to more efficient access to effectively regulated medicines [27].

5. WHAT SPECIFIC PROJECTS HAVE THE EMA BEEN INVOLVED IN RECENTLY THAT HIGHLIGHT THEIR COLLABORATIVE EFFORTS?

The European Medicines Agency (EMA) has engaged in several collaborative projects that illustrate its commitment to enhancing regulatory science and drug development through partnerships with various stakeholders. These initiatives not only aim to improve drug safety and efficacy but also focus on the integration of real-world data and adaptive methodologies in clinical practices [28]. Through these initiatives, the EMA exemplifies a proactive approach in fostering partnerships that are vital for addressing the complexities of modern drug development and ensuring public health safety.

5.1. Collaborative Research with Stakeholders

The EMA has been increasingly involved in multi-stakeholder research projects, particularly in collaboration with academic institutions and regulatory agencies. These efforts help in addressing complex regulatory challenges associated with medicinal product development. EMA's engagement in such collaborative initiatives emphasizes the importance of incorporating diverse expert perspectives in regulatory decision-making [29].

5.2. The conect4children (c4c) Network

In recent years, EMA has been part of the pan-European network called conect4children (c4c), which focuses on improving clinical trial facilitation for pediatric medicines. This network, funded by the Innovative Medicines Initiative, aims to enhance the recruitment and retention of pediatric patients in clinical trials, ensuring that safe and effective treatments are developed for younger populations [30].

5.3. Inclusion in Real-World Data Initiatives

EMA is also actively involved in leveraging real-world data (RWD) to contextualize efficacy findings for investigational therapies. By participating in studies that assess the use of RWD-derived external controls, EMA aims to enhance the robustness of clinical trial outcomes and inform regulatory decisions [31].

5.4. Marie Skłodowska-Curie Symposium Collaborations

Another notable initiative includes EMA's participation in the Marie Skłodowska-Curie Symposium on Cancer Research and Care. This symposium promotes collaborations between cancer researchers and care providers across Europe and North America. Such forums facilitate knowledge exchange and collective advancements in cancer treatment and care strategies [32].

5.5. Continuous Improvement in Regulatory Science

EMA's ongoing commitment to regulatory science is reflected in its collaborations on various external research projects aimed at improving methodologies related to drug evaluation and safety monitoring. These projects contribute not just to regulatory frameworks but also to the overall improvement of health outcomes through evidence-based approaches [33].

6. HOW DOES THE EMA PRIORITIZE WHICH COLLABORATIVE PROJECTS TO UNDERTAKE?

The European Medicines Agency (EMA) prioritizes its collaborative projects through a structured evaluation process that considers the relevance of the project to its strategic objectives, the impact on public health, and the potential for added scientific value. This systematic approach ensures that resources are allocated efficiently to projects that will contribute significantly to regulatory science and drug development.

6.1. Strategic Alignment

The EMA assesses potential collaborative projects based on their alignment with its strategic goals and public health priorities. Projects that address pressing regulatory challenges, emerging health issues, or that facilitate the development of methodologies relevant to drug evaluation are prioritized. This strategic framework helps guide the Agency in focusing on high-impact projects that can enhance patient safety and treatment efficacy [34].

6.2. Stakeholder Engagement

Another important aspect of project prioritization is stakeholder engagement. The EMA evaluates projects that involve collaboration with diverse stakeholders, including academic institutions, pharmaceutical companies, and healthcare practitioners. Initiatives that foster broad participation and gather multi-disciplinary expertise are often favored, as they can facilitate comprehensive approaches to complex regulatory challenges [35].

6.3. Scientific Value and Feasibility

The EMA takes into consideration the scientific value and feasibility of proposed projects. Each initiative is evaluated for its potential to generate new data or insights that can improve regulatory practices [36]. This includes assessing the methodologies proposed and whether they are practical within the expected timeframe and resource availability.

6.4. Impact on Public Health

A primary consideration for EMA is the project's potential impact on public health. Collaborative efforts that aim to address significant health concerns or that can potentially lead to new treatment options are prioritized higher. The urgency and scope of health issues they address play a crucial role in deciding the projects that will move forward [37].

6.5. Evaluation Criteria

Lastly, the EMA has established specific evaluation criteria for determining which projects to undertake. This includes assessing prior collaborations, expected outcomes, and alignment with ongoing regulatory science initiatives. The effectiveness of past projects also informs future prioritization decisions, fostering a cycle of continuous improvement [38].

By utilizing these strategies, the EMA effectively prioritizes its collaborative projects, helping ensure they meet both regulatory demands and public health needs.

7. HOW DO THESE COLLABORATIONS TYPICALLY OVERCOME CULTURAL AND REGULATORY DIFFERENCES?

Collaborations between regulatory health authorities and other stakeholders often face cultural and regulatory differences, which can hinder effective communication and operational efficiency. However, these challenges can be overcome through various strategies that promote understanding, alignment of practices, and shared objectives. These strategies include fostering cultural competence, leveraging technology, developing aligned regulatory frameworks, and enhancing communication channels.

7.1.Fostering Cultural Competence

One of the primary ways to overcome cultural differences in collaborations is by fostering cultural competence among team members. Cultural competence involves understanding, respecting, and effectively interacting with people from diverse backgrounds. This capability is crucial in ensuring that all parties can collaborate effectively and navigate potential misunderstandings that may arise from cultural disparities [39].

7.2. Leveraging Technology

The use of technology plays a significant role in bridging gaps created by cultural and regulatory differences. For instance, digital platforms facilitate real-time communication and information sharing, making it easier for teams across different geographical and cultural backgrounds to remain aligned in their objectives and operations [40]. This technological engagement minimizes delays, enhances collaboration, and allows for quick adaptations in the face of regulatory changes.

7.3. Aligning Regulatory Frameworks

Aligning regulatory frameworks among collaborating entities is essential to overcome regulatory differences. This can involve harmonizing standards, sharing best practices, and engaging in mutual recognition agreements that simplify regulatory compliance across jurisdictions. Such alignment reduces the complexity of navigating multiple regulations, thereby facilitating smoother collaboration and quicker project implementation [41].

7.4. Enhancing Communication Channels

Effective communication is fundamental in overcoming both cultural and regulatory differences. Establishing clear communication channels and protocols allows stakeholders to express their concerns, clarify expectations, and share updates transparently. Regular meetings, collaborative tools, and a culture of open dialogue can further strengthen these communication efforts, ensuring that all parties remain on the same page throughout the collaboration process [42].

7.5. Continuous Training and Development

Ongoing training and development initiatives can significantly contribute to overcoming challenges posed by cultural and regulatory differences. By investing in training programs that emphasize cultural awareness and regulatory compliance, organizations equip their teams with the necessary skills to navigate complex international landscapes effectively [43]. This proactive approach fosters a culture of learning and adaptation, enhancing the overall effectiveness of collaborations.

7.6. Building Relationships and Trust

Finally, building strong relationships and trust among collaborators is vital for overcoming challenges. Trust can lead to more open communication and willingness to compromise, which are essential elements for successful collaborations. Establishing personal connections, understanding each other's values and working styles, and engaging in team-building activities can help cultivate a collaborative environment that transcends cultural and regulatory boundaries [44]. These strategies illustrate how collaborations can successfully navigate cultural and regulatory differences, paving the way for effective partnerships that ultimately benefit all stakeholders involved.

8. WHAT SPECIFIC TECHNOLOGIES ARE MOST EFFECTIVE FOR ENHANCING COLLABORATION ACROSS CULTURAL AND REGULATORY DIVIDES?

Technologies that enhance collaboration across cultural and regulatory divides play a vital role in fostering effective communication, transparency, and efficiency among stakeholders. Key technologies contributing to this objective include digital communication platforms, cloud-based collaboration tools, blockchain technology, and artificial intelligence [45]. Each of these technologies addresses specific challenges posed by cultural and regulatory differences, facilitating smoother interactions and better alignment among collaborators.

8.1. Digital Communication Platforms

Digital communication platforms, such as video conferencing tools and messaging applications, are essential for bridging cultural divides. These platforms enable real-time interactions, fostering a sense of immediacy and personal connection among team members from diverse backgrounds. Effective communication is fundamental to organizational success, influencing productivity, collaboration, and conflict resolution within the workplace [46]. By allowing for face-to-face dialogue, these tools help overcome language barriers and cultural misunderstandings.

8.2. Cloud-based Collaboration Tools

Cloud-based collaboration tools, such as Google Workspace and Microsoft 365, facilitate seamless document sharing and collaborative editing across multiple geographic locations. These tools promote transparency and real-time data sharing, enabling teams to work together efficiently despite regulatory differences. The adoption of digital platforms and tools that facilitate real-time communication, transparency, and data-driven decision-making across supply chains is essential [47]. By centralizing access to shared resources, these tools ensure that all participants have up-to-date information, which is critical for informed decision-making.

8.3. Blockchain Technology

Blockchain technology serves as a powerful tool for enhancing transparency and trust in collaborative environments, particularly in supply chain management. By providing secure and immutable records of transactions, blockchain helps to align stakeholders on critical compliance and regulatory standards. The globalization of trade has introduced complexities in supply chain management, necessitating effective information sharing for enhanced transparency and collaboration [48]. Blockchain ensures that all parties have access to the same information, thereby reducing discrepancies caused by regulatory differences.

8.4. Artificial Intelligence

Artificial intelligence (AI) plays a crucial role in processing vast amounts of data and providing analytics that facilitate decision-making in collaborative efforts. AI-driven tools can help identify potential cultural or regulatory barriers in communication, suggesting tailored strategies for overcoming them. Implementing AI-driven analytics for predictive insights can improve supplier engagement, trust, and performance [49]. This ability to analyze and interpret data helps organizations adapt their approaches based on specific cultural contexts and regulatory environments.

8.5. Project Management Software

Project management software, such as Asana and Trello, is instrumental in aligning teams from different cultural and regulatory backgrounds. These tools allow for clear task assignments, timelines, and accountability, ensuring that all team members understand their roles and responsibilities [50]. The increased clarity in project management helps to mitigate misunderstandings that may arise due to cultural differences, facilitating smoother collaboration across diverse teams.

8.6. Training and Development Technologies

Finally, technologies that facilitate training and development focused on cultural competence and regulatory compliance can significantly enhance collaboration. Online learning platforms can offer courses tailored to help employees understand diverse cultural contexts and regulatory landscapes, thereby fostering a more inclusive and knowledgeable workforce [51]. By investing in ongoing training programs, organizations can equip their teams with the necessary skills to navigate complex international landscapes effectively.

By leveraging these technologies, organizations can improve their collaboration efforts across cultural and regulatory divides, enhancing overall operational efficiency and teamwork effectiveness.

9. ROLE OF PATIENTS AND PATIENT ADVOCACY GROUPS

Patients and patient advocacy groups play an essential role in the European Medicines Agency (EMA) project prioritization process. Their involvement ensures that regulatory activities align closely with patient needs and preferences, enhancing the effectiveness and relevance of drug development and approval processes [52].

9.1. Inclusion in Regulatory Committees

Patients and patient advocacy groups are represented in various EMA committees, such as the Committee for Orphan Medicinal Products (COMP) and the Paediatric Committee (PDCO). Their participation allows for direct input into the assessment of orphan designations and pediatric investigation plans (PIPs), ensuring that patient perspectives are integrated into the decision-making processes.

9.2. Feedback on Regulatory Documents

Patient involvement extends to the review of EMA documents intended for public use, including package leaflets, safety communications, and summaries of medicines. This feedback helps to ensure that the information provided is clear and relevant, reflecting patient priorities and improving overall communication.

9.3. Identification of Patient Priorities

Patient advocacy groups assist in identifying key priorities that reflect the concerns and needs of the patient community. This collaborative relationship aids the EMA in understanding which therapeutic areas or conditions require urgent attention, influencing project selection in a way that emphasizes patient-centricity [53].

9.4. Participation in Public Consultations

The EMA encourages public participation, allowing patients and advocacy groups to share their experiences and insights during consultations. Such engagement not only influences the prioritization of projects but also fosters a more transparent and inclusive regulatory environment that considers diverse patient experiences [54].

9.5. Legislative Support for Patient Engagement

Legislative frameworks such as the Twenty-First Century Cures Act in the United States mandate the inclusion of patient experience data in regulatory decision-making, echoing similar efforts within the EMA. Such initiatives reinforce the importance of patient voices and ensure that their insights shape regulatory processes from the outset, enhancing project relevance and prioritization. Through these mechanisms, patients and advocacy groups significantly contribute to the EMA's project prioritization process, ensuring that it is responsive to real-world health needs and circumstances.

10.FUTURE DIRECTIONS FOR COLLABORATIVE EFFORTS

As the health landscape evolves, regulatory health authorities must continue to foster international collaboration to adapt to new challenges, such as digitalization and emerging diseases [55]. Investing in regulatory partnerships will be essential for ensuring that regulatory bodies can meet future demands and enhance the overall effectiveness of health systems. Despite the advancements in collaborative pathways, the EMA and related stakeholders face challenges regarding regulatory reliance. Concerns have been raised about the adequacy of faster approval processes and the necessity of maintaining high standards for the safety and efficacy of medicines [56]. Looking ahead, the EMA continues to advocate for the implementation of WHO’s Good Reliance Practices as a means to enhance regulatory efficiency and improve access to quality medicines [57].

11.CONCLUSION

Overall, the EMA's engagement in collaborative pathways represents a critical evolution in the regulatory landscape. The globalization of traditional medicines and the increasing international supply chains have further highlighted the importance of transparent, science-based quality standards and the need for regulatory convergence across different national jurisdictions. Regulatory collaboration and the sharing of best practices can contribute to the worldwide availability of traditional medicines based on appropriate standards. By fostering partnerships with various international regulatory bodies, the EMA aims to improve cross-border harmonization and expedite access to innovative treatments for patients worldwide while also addressing the associated challenges to ensure regulatory robustness.

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