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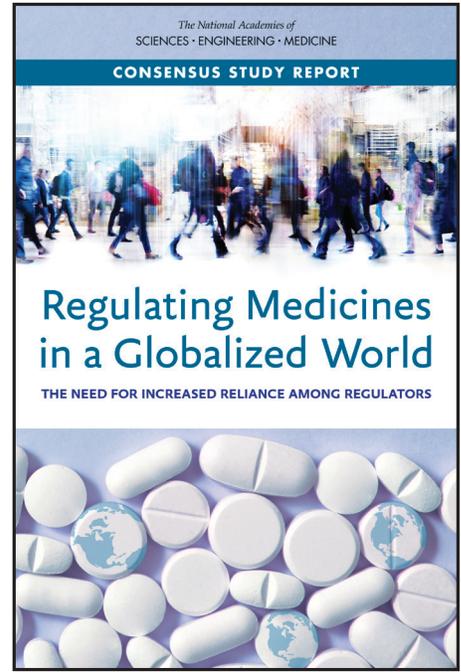
Regulating Medicines in a Globalized World: Need for Increased Reliance among Regulators

Promoting and protecting public health was, is, and always will be central to the missions of medicines regulatory authorities. How to achieve this goal without stunting innovation at a time of unprecedented advances in drug development and supply chain complexity, however, is a major challenge for regulatory authorities worldwide. For many, the answer lies within reliance. Maximizing reliance and cooperation efforts with other trusted regulators is key to ensuring the quality, safety and efficacy of medicines in today's globalized world.

It is within this context that the National Academies of Sciences, Engineering, and Medicine assembled an expert committee to examine the challenges and opportunities facing medicines regulatory authorities, particularly in the context of mutual recognition agreements and other forms of regulatory reliance. The resulting report, *Regulating Medicines in a Globalized World: The Need for Increased Reliance Among Regulators*, provides an overview of the landscape and presents the committee's strategy for improving regulatory cooperation in ways that place the public's interest at the center of its efforts.

ABOUT RECOGNITION AND RELIANCE

Within medicines regulation, recognition and reliance are both about leveraging the work and work products (e.g., inspection reports or scientific assessment reports) of other trusted regulatory authorities. Where they differ is the extent to which regulatory authorities are required by law to share information. In this regard, "recognition" is viewed as a more stringent form of reliance, with mutual recognition agreements (MRAs)—as part of trade agreements—being the most stringent form of recognition. While some view the stringency of recognition and reliance as a benefit to patients and public health, others view it as a potential risk; however, what is essential for any form of recognition or reliance is national sovereignty. Regulatory authorities may leverage the work or work products of other trusted authorities, but any information received will only contribute to informing regulatory decision-making, it will not replace a country's ability to come to its own conclusions, based on the needs of its people, after all the information is received about a medi-



cine. Tools to facilitate recognition and reliance across the product lifecycle are collectively called “arrangements.” They can be formal (like MRAs or memoranda of understanding) or informal (like scientific collaboration).

It is the committee’s view that recognition and reliance arrangements are now a 21st century best regulatory practice. Regardless of human technical and financial resources, regulators should make increased use of reliance and cooperation with other trusted regulators. No single regulatory authority has all the resources it needs to meet its public health responsibilities in their entirety. Given the critical nature of this challenge, impediments to entering into and using informal and formal recognition and reliance arrangements in regulating medicines, must be removed.

THE COMMITTEE’S RECOMMENDATIONS

In an environment of limited human and financial resources and at a time of unprecedented globalization and societal requests for faster approvals of drugs, medicines regulators have felt the pressure to stretch their finite resources. To that end, regulators have undertaken a wide range of activities geared toward helping each other manage a growing workload by leveraging those limited resources. This view is reflected in the conclusion and six recommendations made by the committee, that includes a strategy for leveraging the support of each stakeholder group with an expressed interest in ensuring the quality, safety and efficacy of medicines in a single jurisdiction and as a global public health good. Regulatory authorities require the support of industry, patients, and governments to realize the maximum benefits of any

recognition or reliance arrangement. Each of these stakeholder groups has a role to play in supporting efforts to enhance cooperation between and among regulatory authorities with the aim of improving public health. This is the essence of the committee’s recommended strategy.

The committee identified key opportunities in the following areas:

Improving Public Health Through Better-Designed MRAs

MRAs have usually been developed in the context of trade negotiations with the dual aim to reduce technical barriers to trade as well as promote public health. To prioritize what should be the public health aims and focus of these arrangements, the committee believes that medicines regulators, with their public health background, are ideally situated persons to increase the scope and substance of interagency reliance. It is this shared, common interest, that makes medicine regulators well-suited to develop, design and implement the substance of such regulatory agreements in the future.

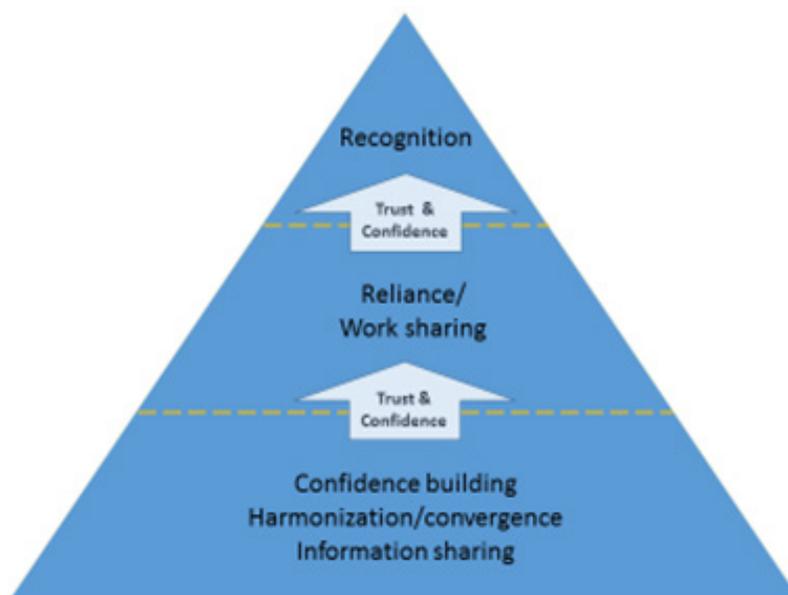


FIGURE 1-1 Building confidence and trust from and for greater reliance.

Responding to Evolving Science and Technology

More agile reliance arrangements would be better suited to meet challenges associated with a rapidly evolving science, technology, and the global medicines regulatory landscape. MRAs and other reliance arrangements should be expanded to include new areas, increasing the current scope of both formal and informal reliance arrangements. In this way, regulatory authorities can better meet the challenges associated with the globalized production of medicines, as well as the growing need to address the medicine requirements during public health emergencies.

Better Utilization of the European Union–United States MRA

The EU–US MRA, as currently written, narrowly applies only to areas involving good manufacturing practice (GMP) and then only to a limited range of products. The EU–US MRA could be expanded to go beyond its currently limited focus to a broader GMP focus and to other regulatory activities, including enacting provisions like third-country inspections. These aspects taken together would allow for greater product coverage.

Information Sharing Among International Medicines Regulators

Without a unified platform and a standard format for reporting, the sharing of assessment and inspection reports can be challenging. Some regulators share assessment, inspection, and other reports with other regulators with whom legally authorized appropriate confidentiality agreements exist. The U.S. Food and Drug Administration and Congress should work to determine whether existing confidentiality restrictions are still fit-for-purpose in the 21st-century globalized environment and whether modifications are needed to meet public health goals.

Evaluating Public Health Impacts of Reliance and Recognition Arrangements for Medicines

Evaluating the impacts of formal and informal reliance and recognition arrangements on public health, on the use of regulatory and industry resources, and on the essential regulatory competencies of regulatory authorities is challenging because of a dearth of frameworks, metrics, and data for use in such evaluations. Creating a results framework with clear indicators/metrics and processes for monitoring and measuring the results of recognition and reliance arrangements could enhance understanding of their various impacts, especially on public health, and enable benefit-risk and cost-benefit analysis of formal and less formal recognition and

reliance. Including specific evaluations of public health and other goals, metrics, and mandates in the text of future formal and less formal recognition and reliance arrangements would contribute to developing a robust body of knowledge regarding their impacts and overall utility.

To read the full text of the committee's recommendations, visit [nationalacademies.org/RegulatoryReliance](https://www.nationalacademies.org/RegulatoryReliance).

CONCLUSION

Recognition and reliance arrangements are important tools for helping regulatory authorities of all resource levels address the public health challenges posed by the increasing complexity of medicines and their globalized supply chains. All authorities would benefit from increased use of formal and informal recognition and reliance arrangements in conducting activities designed to meet their public health mission. In the committee's view, regulation through such arrangements can now be considered a 21st-century "best regulatory practice."

Committee on Regulating Medicines in a Globalized World: Need for Increased Reliance among Regulators

Alastair Wood (Chair)

Vanderbilt University

David Beier

Bay City Capital

Thomas Bollyky

Council On Foreign Relations

Katherine Bond

US Pharmacopeia

David Cockburn

European Medicines Agency

Elizabeth Golberg

Harvard Kennedy School

Lawrence Gostin

Georgetown University

Gavin Huntley-Fenner

Huntley-Fenner Advisors, Inc

Barbara Koremenos

University Of Michigan

Murray Lumpkin

Integrated Delivery Bill And
Melinda Gates Foundation

Lembit Rago

Council For International Orga-
nizations Of Medical Sciences

Study Sponsor

U.S. Food and Drug Administration

Study Staff

Patricia Cuff

Study Director (from April
2019), Senior Program Officer

Monica Whitley

Study Director (until August
2019)

Daniel Flynn

Research Associate

Inez Adams

Research Associate

Kelly Choi

Senior Program Assistant
(from April 2019)

Natalie Lubin

Senior Program Assistant
(until April 2019)

Julie Pavlin

Director, Board On Global
Health

To read the full report, please visit
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