

RECOMMENDATIONS

NOVEMBER 2019 • REGULATING MEDICINES IN A GLOBALIZED WORLD: THE NEED FOR INCREASED RELIANCE AMONG REGULATORS

RECOMMENDATION 1

The committee recommends a strategy that leverages the support of each stakeholder group in the following manner:

- All regulatory authorities, especially well- and moderately well-resourced regulatory authorities, should increase information-sharing and the transparency of each other's regulatory activities across the lifecycle of medicines in ways that can facilitate more efficient agency resource allocation and decision-making for all regulators, and reduce the burden of redundant regulatory activities on regulators, patients, and industry.
- All regulatory authorities, especially well- and moderately well-resourced regulatory authorities, should be allowed to share their work products in essentially unredacted form (i.e., full reports without parts of the report expunged, except for personal privacy information) with other regulatory authorities so assessment and inspection information can be made available to other regulators, especially lower-resourced regulators, to enable access to quality, useable regulatory information by a greater number of regulatory authorities for addressing global public health needs. In this respect, policymakers, and the U. S. Congress in particular, should weigh the challenges and opportunities involved with empowering their respective medicines regulatory authorities to share complete unredacted inspection reports (for example good manufacturing practice reports) with other regulatory authorities that would facilitate learning, aid in decision-making, reduce the use of limited resources on redundant inspections, decrease the burden on industry of redundant inspections, and strengthen the overall global public health infrastructure for safe and effective quality medicines.
- Lower-resourced regulatory authorities should consider the risks and benefits of unilateral recognition of regulatory decisions of trusted regulatory authorities when doing so facilitates better public health decision-making in the context in which the regulatory authority functions.
- Industry should support the recognition and reliance efforts of regulatory authorities by encouraging regulatory authorities to share less-redacted or, better, unredacted reports with their trusted regulatory authority partners, and by showing a willingness to share regulatory decision-making relevant health-related data and/or information more publicly for a global public good and to reduce their own burden of redundant oversight.
- Patient and consumer groups should support the recognition and reliance efforts of regulatory authorities by advocating for a "public health protection and promotion" framing of all such recognition and reliance arrangements of medicines regulatory authorities and for their increased use.

RECOMMENDATION 2

Policymakers, including lawmakers, should explore empowering regulators to expand the scope and substance of future Mutual Recognition Agreements (MRAs) that address issues related to the safety, efficacy, and manufacturing quality of medicines, and to ensure that these MRAs are primarily designed, developed, and implemented by medicines regulators. Policymakers will also need to ensure that regulators have adequate resources for these tasks.¹

¹Murray Lumpkin, Lembit Rago and Katherine Bond did not fully concur with this recommendation because they believe it still leaves the negotiation, oversight and finalization of MRAs related to medicines regulation to trade negotiators, rather than empowering medicines regulators to design, develop, conclude, and implement these specific medicines regulatory MRAs on their own. They believe that is the only way to ensure that public health is the sole focus of the negotiation and agreement and that it is negotiated and concluded in the collaborative public health atmosphere that exists between medicines regulators and not the competitive business dynamic that pervades and shades trade negotiations

RECOMMENDATION 3

The committee recommends that regulators consider increasing the current scope of both formal and less formal reliance arrangements, including Mutual Recognition Agreements (MRAs), and that policymakers encourage regulatory authorities to explore formal and informal opportunities for reliance with other trusted regulatory authorities that give regulators greater flexibility in responding to challenges affecting their responsibility in overseeing the quality, safety, and efficacy of medicines throughout the lifecycle of the medicine. Potential areas identified for scope exploration include good laboratory practice (GLP), good clinical practice (GCP), good pharmacovigilance practices (GPvP) inspections reports, pre-clinical assessment reports, bioequivalence assessment reports, and a wider scope of product classes covered by such arrangements.

RECOMMENDATION 4

Regulatory authorities in the United States (US) and the European Union (EU) should immediately implement provisions noted in the current MRA (e.g., the so-called “third-country” good manufacturing practice [GMP] inspection reports) and regulatory authorities should begin considering the potential for expanding the EU-US MRA to include reliance in areas beyond GMP and a broader scope of products under the current GMP provisions.

RECOMMENDATION 5

Regulatory authorities, with guidance from their governmental leaders, should undertake determining whether current limitations on sharing regulatory work products with other regulatory authorities are still fit-for-purpose to help protect and promote public health; to reduce the burden of regulatory redundancy on patients, industry, and regulators; to allow regulators globally to best utilize the limited technical and financial resources currently available to them to meet their public health mandates; and to bring needed quality medicines to patients domestically and globally as efficiently as possible.

RECOMMENDATION 6

When an agreement is being developed, the regulatory authorities should co-create a results framework with clear indicators/metrics and processes for monitoring and measuring the results and impacts of formal and informal recognition and reliance arrangements that could enhance understanding of their public health and other benefits and associated regulatory efficiencies, and enable benefit-risk and cost-benefit analysis of formal and less formal recognition and reliance arrangements over time.

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