21 May 2021

Sandra Roussel
Assistant Secretary
Regulatory Policy Economic Division
Department of the Prime Minister & Cabinet

Dear Ms Roussel,

Submission from Medicines Australia: Consultation on Regulator Performance Guide

Thank you for the opportunity to respond to this consultation. This submission was brought together by Medicines Australia's Regulatory Affairs Working Group (RAWG) in consultation with our broader membership. Members of the RAWG are selected for their regulatory and industry experience, and bring a whole-of-industry perspective to the consideration of issues that stand to impact our sector.

Medicines Australia is the peak body representing the innovative, research-based, medicines industry in Australia. Medicines Australia's members have a broad and deep pipeline of innovative medicines, diagnostics, treatments and vaccines. Our members develop, manufacture, and supply critical medicines and vaccines available on the pharmaceutical benefits scheme (PBS), the Life Saving Drugs Program (LSDP), the national immunisation program (NIP) and companion diagnostics or other treatments available through the Medical Benefits Scheme (MBS) and National Blood Authority (NBA). Our membership comprises small, medium, and large Australian and multi-national companies. Many of the world's multi-national medicines manufacturers are members of Medicines Australia through their local affiliates. These local affiliates provide a critical worldwide connection that enables Australians to access globally developed breakthrough medicines and therapies.

Medicines Australia welcomes the Government's proposals for refreshing the regulator performance framework through a renewed Deregulation agenda. The Department of Health is the primary Commonwealth entity that regulates the pharmaceutical industry, including registration of medicines by the Therapeutic Goods Administration and reimbursement under the Pharmaceutical Benefits Scheme. Overall, Medicines Australia supports this updated Regulator Performance Guide. It is important that regulator's key performance indicators (KPIs) align measuring the experiences of the regulated so that systems, guidelines, policies and legislative frameworks can continually improve. This is particularly important for regulators working on a cost-recovery basis.

If we can be of any further assistance, please contact Anne-Maree Englund (Head of Strategic Policy Implementation, anne-maree.englund@medicinesaustralia.com.au) or Peter Komocki (Manger, Industry and Regulatory Policy, peter.komocki@medicinesaustralia.com.au).

Yours sincerely,

Anne-Maree Englund
Head of Strategic Policy Implementation
Medicines Australia

Consultation Feedback

Since the adoption of the current framework in 2014, Medicines Australia has provided feedback that the six outcomes based KPI's and associated measures do not measure the outcomes and 'customer experience' that matter to the medicines industry. Consequently, they have not been effective in driving the changes necessary to support innovation and reduce regulatory burden.

As a stakeholder whose views were sought prior to release of the current consultation, Medicines Australia would like to complement the Deregulation Taskforce on their genuine engagement and active listening. It is clear from the consultation that concerns raised by stakeholders have been reflected in the proposed principles of regulator best practice. These represent a simplified framework that will create greater accountability and transparency in areas that matter to industry. As with all principles based regulatory frameworks, however, the importance of implementing the principles as intended will be key to creating the optimal operating environment for industry. We look forward to working with the Department of Health as it seeks to implement this refreshed guidance.

Overall Medicines Australia supports all three principles outlined in the regulator performance guide as providing a fit for purpose framework. Appropriately implemented, the framework will enable continuous improvement and evolution to maintain a contemporary approach to regulation, one rapidly adaptable to the changing needs of industry operating in a competitive global environment.

Comments on individual principles are summarised below and we look forward to seeing the final framework to be released on 1 July 21.

Principle 1: Continuous improvement and building trust: regulators adopt a whole-of-system perspective, continuously improving their performance, capability and culture, to build trust and confidence in Australia's regulatory settings.

The adoption of a principle that specifically reflects the need to adopt a whole-of-system perspective is welcomed. For the medicines industry, the silos across different government departments working under different legislative frameworks can create unnecessary barriers for patients trying to access innovative and potentially lifesaving therapies. Cross collaboration across departments considering the end-to-end needs of patients is critical to reducing red tape.

Medicines Australia also considers the examples provided under Principle 1 are highly relevant to the medicines industry. Organisational culture is key to creating an optimal operating environment, whilst internal accountability is an important part of building a positive culture. The recognition of the importance of environmental scanning and monitoring of other jurisdictions are key elements to enable the evolution of the regulatory framework in parallel with changes in the global regulatory landscape. This avoids a 'reactive' approach to regulation to catch up with international best practice.

In the context of registering new medicines through the Therapeutic Goods Administration (TGA), and continued learnings during COVID, pragmatism, flexibility and minimising duplication to support global harmonisation of activities has reduced red tape and enabled a collaborative approach to maintaining medicines supply. Under the new performance framework, opportunities for increasing the capabilities of regulators to better understand the operational aspects of the industries they regulate, and vice versa, has the potential to drive changes that further reduce red tape. This in turn will benefit the medicines industry and the broader Australian community, which should have access to new vaccines, treatments and medicines sooner.

Principle 2: Risk-based and data-driven: regulators maintain essential safeguards, using data and digital technology to manage risks proportionately to minimise regulatory burden and to support those they regulate to comply and grow.

Medicines Australia has provided feedback for many years on the importance of access to accurate metrics that provide insights to identify pain points for both agencies and industry to inform continuous regulatory improvements. The lack of appropriate digital infrastructure and technology has been a major barrier in this respect. It is therefore pleasing to see the recognition of the need to adopt technology solutions and enhance digital literacy to better understand and manage risks. This in turn will enable an adaptable approach to regulation driven by data.

In combination with Principle 1, with the right culture and capabilities and clear identification and prioritisation of risk as outlined in Principle 2, the new performance framework allows regulators to provide the right public safeguards whilst avoiding being a barrier to growth and innovation. Regulation should therefore not result in red tape for the majority that behave appropriately and have well established compliance history, rather focus on ensuring that non-compliance is effectively mitigated. It will therefore be key that agencies implement all principles of the framework consistently and correctly to deliver the expected level of performance defined in the consultation.

Principle 3: Collaboration and engagement: regulators are transparent and responsive, implementing regulations in a modern and collaborative way.

The need for genuine collaboration and active listening is strongly endorsed by Medicines Australia as a priority for effective partnership and collaboration. Open dialogue and transparency from all parties can ensure the right level of regulation to support innovation, whilst delivering the right level of 'protection' to ensure public health and safety. In the field of medicine regulation, safety remains a paramount consideration.

Currently, a lack of transparency remains a barrier to effective partnership that would enable co-design of innovative approaches that support industry growth and provide appropriate protection of the community. The concept of 'regulatory sandboxes' is therefore welcomed as an illustration of activities that would meet the government expectations of a best practice regulator under the new framework.

In summary, we look forward to working with relevant agencies across the Department of Health as they adopt the principles outlined in the Regulator Performance Guide. If implemented as intended we strongly believe the refreshed framework will lead to better mutual understanding and collaboration, reduce red tape, enable a more proactive and timely approach to aligning regulation with international best practice and support the health and welfare and economic growth of the Australian community.