Good Regulatory Practices

Benefits and implications for the health sector

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Importance

Why focus on improving business regulation through GRP?

Prevent regulatory surprises and failures

That come from:

- Poor design.
- Lack of consultation with private sector.
- State capture.
- Good intentions, poorly analyzed.

The size of regulatory burden

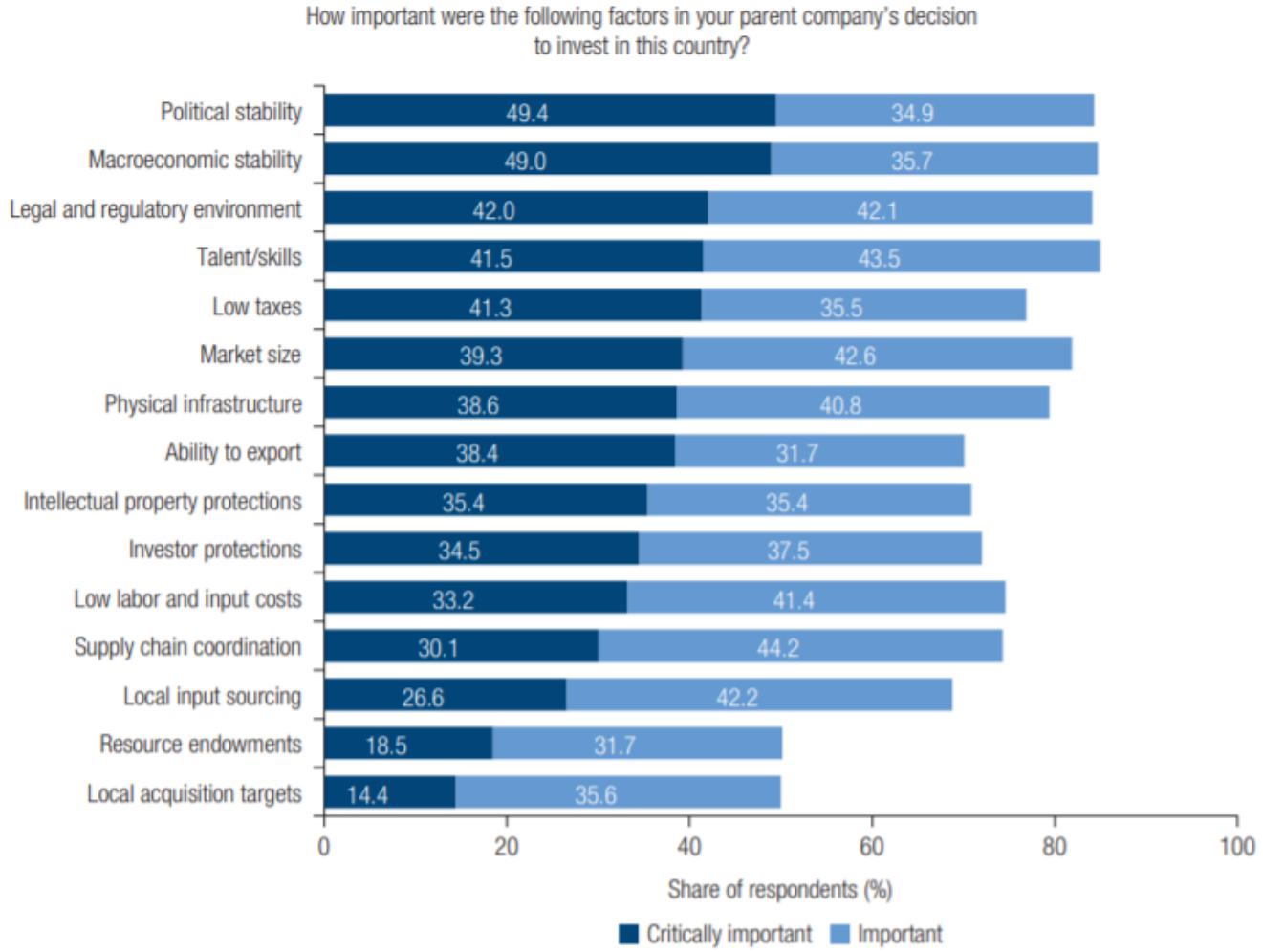
- Mexico: 3.4% of national GDP;
  : 1.3% of state GDP; and
  : 3.4% of municipal GDP.
- DR: 5.5% of national GDP.
- US: $1.9 trillion dollars, the estimated cost of federal regulation.

Investment decision factor

- Legal and regulatory environment among top 3 factors for FDI decisions.
- Only behind political and macroeconomic stability.

Source: WB's Global Investment Competitiveness Report 2019-2020.

FIGURE O.12 The Legal and Regulatory Environment Was among the Top Three Factors for FDI in 2019



Source: Computation based on 2019 GIC Survey.
Note: Affiliates of multinational enterprises (MNEs) were surveyed in 10 middle-income countries: Brazil, China, India, Indonesia, Malaysia, Mexico, Nigeria, Thailand, Turkey, and Vietnam. FDI = foreign direct investment.

Obligations from modern trade agreements

- Examples include:
  - USMCA.
  - CPTPP.
  - Pacific Alliance.
  - Bilateral agreements between US-Ecuador; US-Brazil; Chile-Uruguay and Brazil-Chile.


What constitutes GRP?
Where to start?

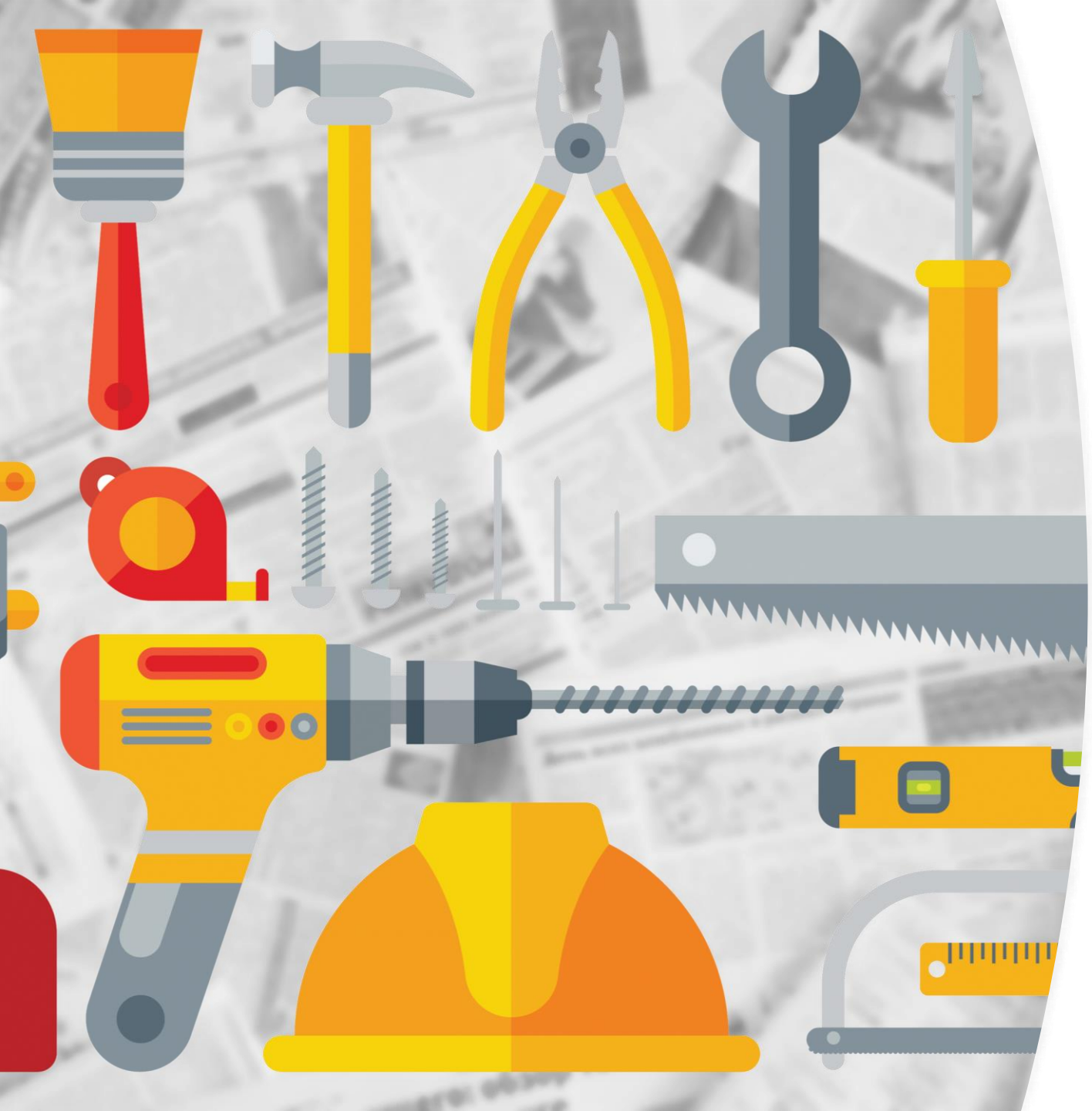
What is GRP?

It **improves the quality of regulation** (*achieve public policy objectives more effectively*), through:

Adoption of **institutions, policies, principles, procedures and tools** when planning, designing, implementing and evaluating regulation.

Key pieces of a GRP system

- GRP policy: backed up by a legal mandate.
- Institutions: policy coordination body and regulatory agencies.
- GRP tools: from planning to design, implementation and evaluation.
- Predefined procedures and guidelines: to produce/review BR.
- Business regulations themselves.
- Digital systems for regulatory delivery.



Main GRP tools

G

R

P

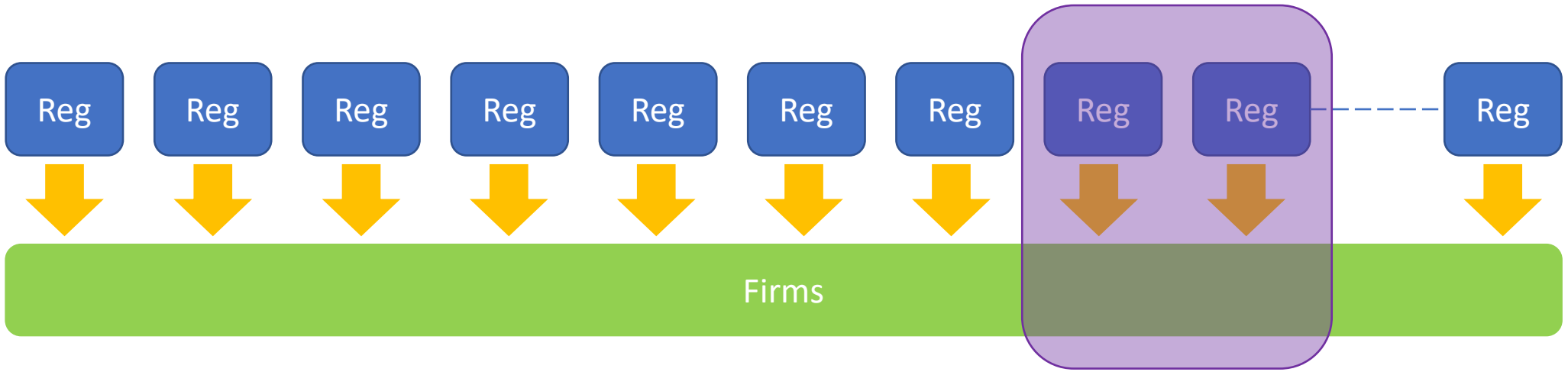
- Transparency and access to regulatory information.
- Regulatory Plans.
- Ex ante RIA.
- Private sector consultation.
- Administrative simplification or red tape reduction (digitizing procedures, BPR, etc.).
- Ex post review of existing regulation.

GRP means going beyond your industry

But, why?

- Focused on regulation from a specific sector/industry.
- With great technical/sector lenses but lacking methodological approaches in the design or review of regulation (RIA, public consultation or ex post evaluation).
- Still affected by the rest of the business regulatory environment.

Better regulation sector focus



GRP and the health sector

From GRP to access to good medical products and devices (1)

- Countries need a health system with medical products and devices that are safe, effective and of consistently assured quality.
- The medical products and devices sector is one of the most regulated industries because of the impact it has on health and society.

WHA 67.20: “inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products”.

From GRP to access to good medical products and devices (2)

- GRP incentivizes sound, affordable, efficient regulation of medical products.
- This is achieved by conducting regulatory impact assessments, public consultation periods, review of existing regulation...

Colombia: pilotos evaluación ex post regulación sector salud

- Proyecto mejora regulatoria – IFC.
- Enfoque uso evidencia para análisis de impacto normativo ex ante y ex post.
- 6 evaluaciones ex post como experiencias piloto en Colombia.
- 2 con MinSalud/Invima:
  - Decreto 677 de 1995: registros, licencias, control de calidad y vigilancia sanitaria de medicamentos.
  - Decreto 3249 de 2006: suplementos dietarios.

What can businesses in the health sector do?

Be proactive

- Engage at different stages of the regulatory cycle…
- … especially early in the process when regulations are just plans.

Informed engagement

- Bring evidence to the policy/regulatory discussion.
- Invest collectively in think tanks or research centers led by the private sector.

Malaysia – the private sector as copilot of GRP policy

"GRP is all about public-private collaboration... GRP introduction in Malaysia is a manifestation of this." "In the old times, policies and regulations were made under the assumption that the Government knew the best way. However, today's Government cannot ensure it knows everything. Therefore, it needs to consult the private sector and work together to develop better policies."

"PEMUDAH advocated for the introduction of public consultation as a core element of the National Policy on the Development and Implementation of Regulations."

– YBhg. Tan Sri Saw Choo Boon, former private sector co-chair of PEMUDAH

PEMUDAH: Special Task Force to Facilitate Business.

- Proactive public-private collaboration.
- No more regulation than needed.
- Share leadership, both at high and technical levels.

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