



World Trade Organization Agreement on Technical Barriers to Trade and Domestic Regulations

Advanced Training for Medical Device Regulators Around Critical and Emerging Technologies 2026

(June 2026)

WTO Agreement on Technical Barriers to Trade

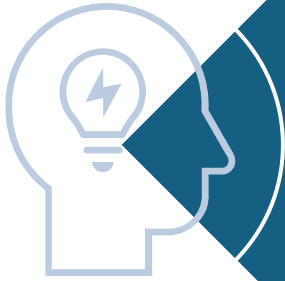
WTO:

- International organization that provides a legal and institutional framework for the implementation and monitoring of trade commitments made by WTO Member States
 - Provides a forum for members to negotiate trade agreements
 - Serves as a forum to resolve the trade disputes
 - Monitors how the agreements are being implemented

The WTO TBT Agreement:

- Aims to ensure that technical regulations, standards, and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade

Terms and Definitions



Technical Regulations

- Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which **compliance is mandatory**.



Standards

- Document **approved by a recognized body**, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which **compliance is not mandatory**.



Conformity Assessment Procedures

- Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled

Key TBT Principles

Use of International Standards

Transparency

Not more trade restrictive than necessary

Non-discrimination

RIGHT TO REGULATE: Balance Between Right to Regulate and Pursuit of Trade Liberalization

allowing Members to
fulfill legitimate
objectives
at levels they
consider appropriate



avoiding
[unjustifiable]
discrimination and
unnecessary barriers
to international trade

See also Preamble rec. 6, Art. 2.1, 2.2, 5.1.1, 5.1.2

Non-Discrimination Principles

Most-Favored Nation:

- Countries should treat all their trade partners equally
- No country should be “more favored” in terms of their imports.

National Treatment:

Eliminate “hidden” domestic barriers by according imported products treatment no less favorable than that accorded to products of national origin.

MFN and National Treatment

Article 2.1

Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment **no less favorable** than that accorded to **like products of national origin** and to **like products originating in any other country**

Article 5.1.1

Conformity assessment procedures are prepared, adopted and applied so as to grant access for suppliers of like products originating in the territories of other Members under conditions **no less favorable** than those accorded to suppliers of **like products of national origin** or **originating in any other country**

Trade Restrictiveness

Article 2.2

- Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, **technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective**, taking account of the risks non-fulfilment would create.

Article 5.1.2

- Conformity assessment procedures are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. This means, inter alia, that **conformity assessment procedures shall not be more strict or be applied more strictly than is necessary** to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks non-conformity would create.

Trade-Restrictiveness and Legitimate Objectives

Legitimate Objectives

- Protection of human health or safety
- The protection of animal or plant life or health
- The protection of the environment
- National security interests
- Prevention of deceptive practices
- Etc.

Elements of Consideration

- Scientific and technical information
- Related processing technology
- Intended end-uses of products
- Etc.

USE OF INTERNATIONAL STANDARDS

Use of International Standards

• Article 2.4

Where technical regulations are required and **relevant international standards** exist or their completion is imminent, **Members shall use them, or the relevant parts of them**, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.

• Article 5.4

In cases where a positive assurance is required that products conform with technical regulations or standards, and relevant guides or recommendations issued by **international standardizing bodies** exist or their completion is imminent, **Members shall ensure that central government bodies use them, or the relevant parts of them**, as a basis for their conformity assessment procedures, except where, as duly explained upon request, such guides or recommendations or relevant parts are inappropriate...

IMPLEMENTING TRANSPARENCY

**Process for Notification to the WTO of Regulatory
Actions**

Obligation to Implement Transparency

Establish and maintain	Establish and maintain a national enquiry point;
Publish	Publish draft regulations (technical regulations, or TRs) and conformity assessment procedures (CAPs) at an early appropriate stage;
Notify	Notify draft regulations/amendments to the World Trade Organization (WTO);
Allow	Allow for reasonable time for comments while amendments can still be introduced (60 days minimum, longer if possible);
Provide	Provide copies of relevant documents (upon request);
Take	Take written comments/discussions into account when developing the final regulation;
Allow	Allow a reasonable interval between publication and entry into force of the final TR or CAP so producers may adapt (6 months minimum, longer if possible).

ePing



ePing is an SPS & TBT notification alert system is a publicly available and self-subscribing service, whereby subscribers are able to receive email alerts regarding SPS and TBT notifications covering particular products and/or markets of interest to them.



In addition, users can search notifications, share notifications, upload additional information and participate in discussions.



ePing also offers an Enquiry Point Management Tool to facilitate domestic as well as international information sharing and discussion.

Regulator Perspective of the WTO TBT Committee

- Implementation:
 - Inter- and intra-agency coordination
 - Be a part of the broader conversation
 - E.g., Thematic sessions
 - ePing is a tool for anyone, including regulators



Good Regulatory Practices (GRP)

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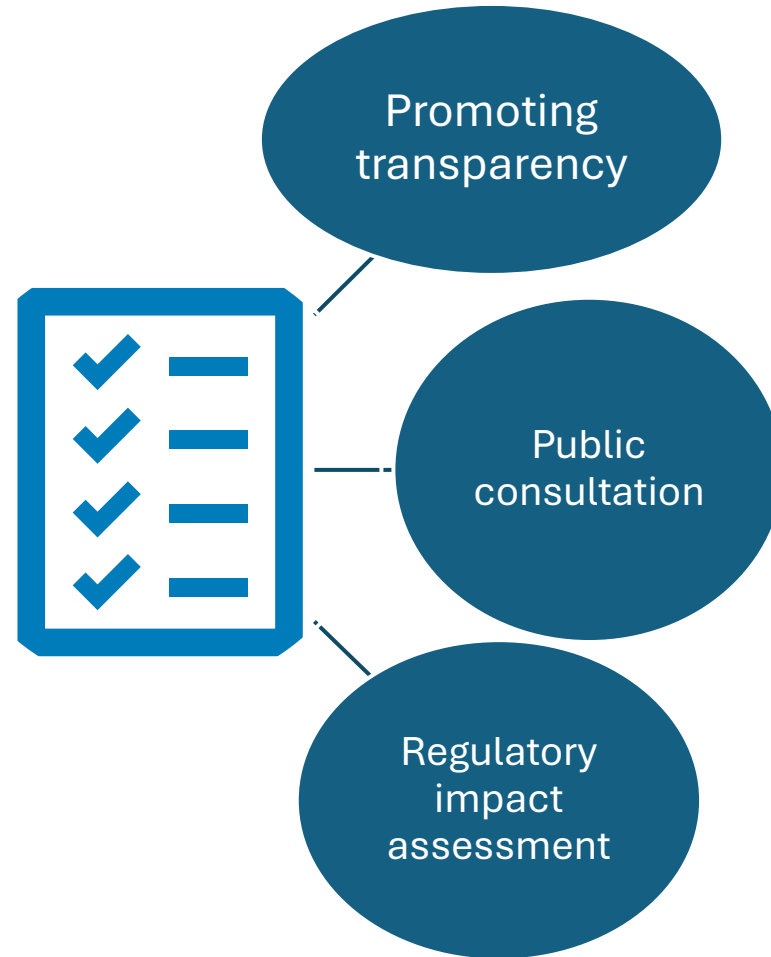
GRP Supports WTO TBT Agreement

“Good Regulatory Practice (GRP) can contribute to the improved and effective implementation of the substantive obligations under the TBT Agreement. Effective implementation through best practices is seen as an important means of avoiding unnecessary obstacles to trade.”

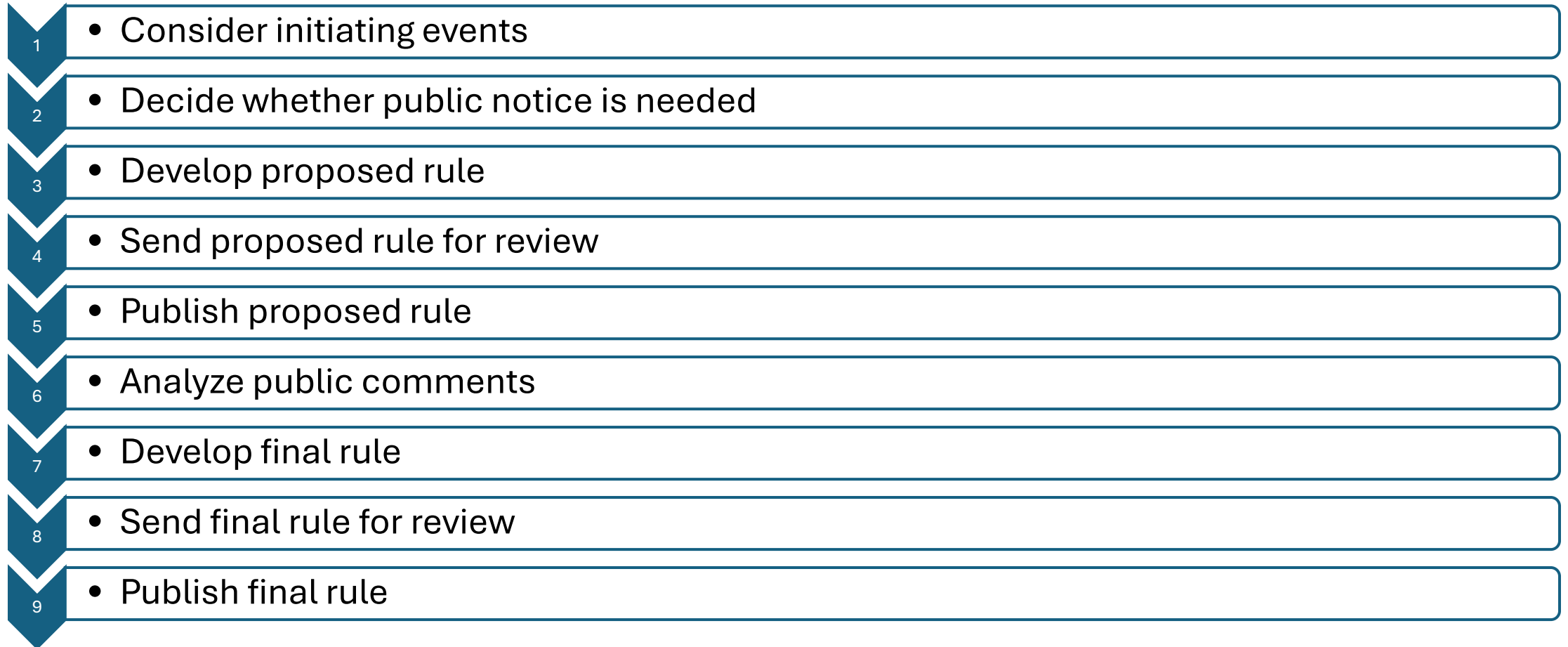
Source: Decisions and Recommendations Adopted by the WTO Committee on Technical Barriers to Trade Since 1995 (G/TBT/1/Rev.15)

GRPs

- Internationally recognized processes and procedures that improve the quality and cost-effectiveness of domestic regulations
- Three general principles for the use of GRPs in the rulemaking process include the following:



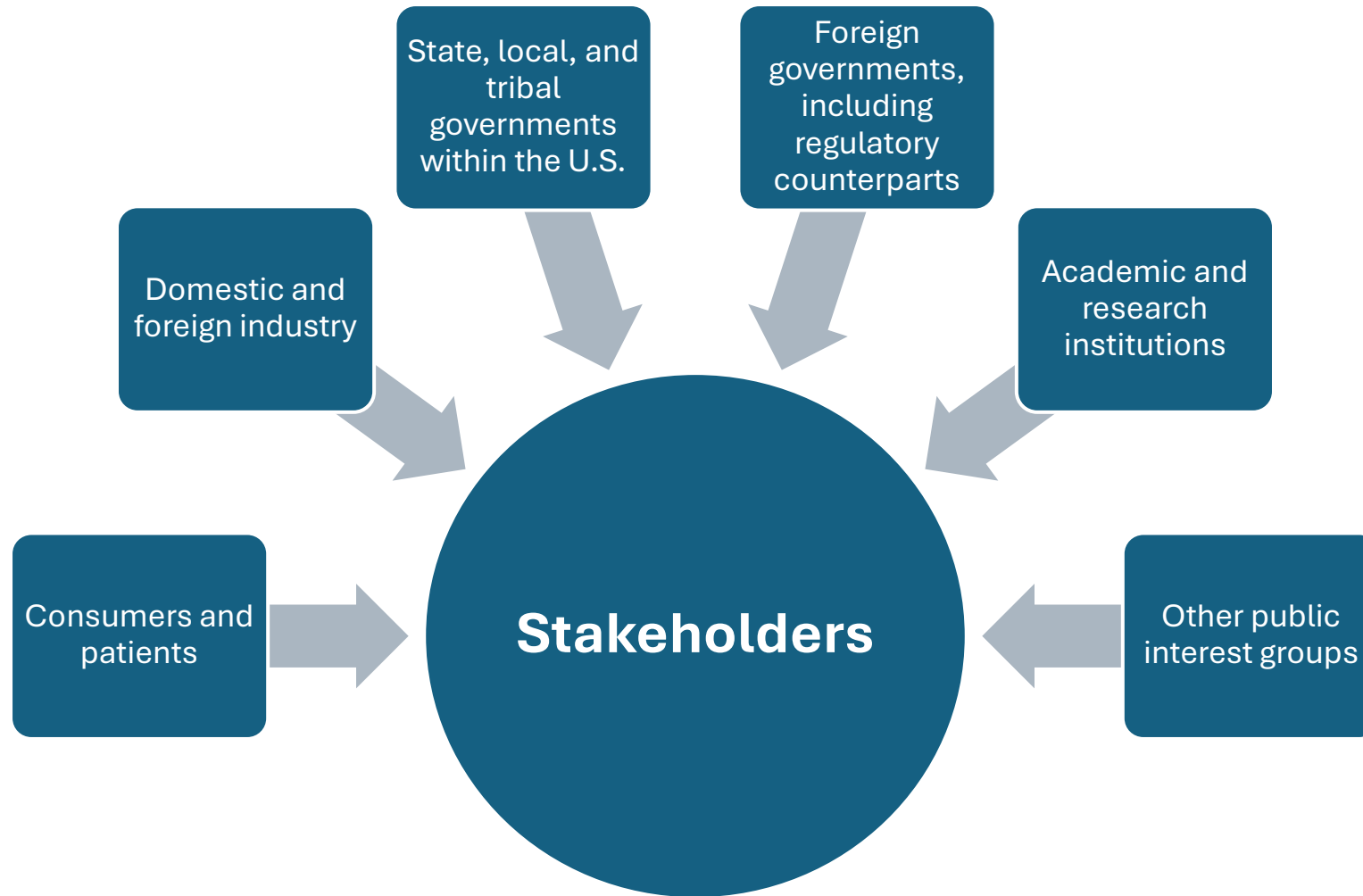
Rulemaking Process



Identifying Regulatory Priorities



Stakeholders



Developing a Draft Regulation



Reviewing Draft Regulation



Draft regulations are subject to an intensive review process.



The Office of Management and Budget (OMB) coordinates interagency review of significant and economically significant rules.



[Reginfo.gov](https://www.reginfo.gov) provides information on regulatory actions currently under 12866 review.



Stakeholders may request [12866 meetings](#) with OIRA to discuss a rule under review.

Public Consultation Process

Open Comment Period

- Publish the draft regulation in the Federal Register
- Open a docket at [regulations.gov](https://www.regulations.gov)
- Alert the appropriate U.S. point of contact to notify the corresponding WTO committee
- Extend comment period (case-by-case basis)
- Hold listening sessions, public meetings, or public workshops to support commenting process

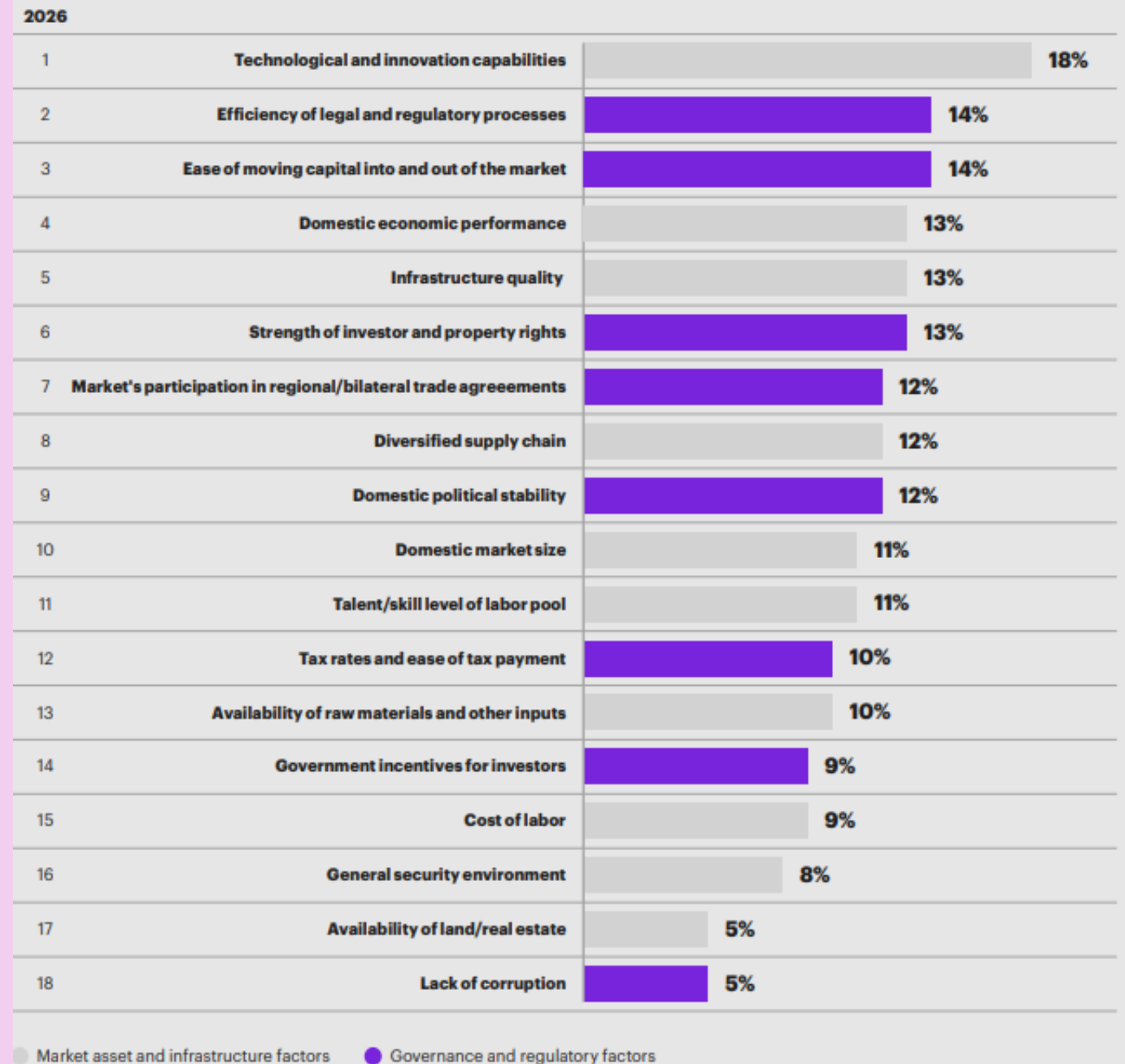
Post Public Consultation

- Consolidating form, duplicate, and out-of-scope comments
- Identifying issues and categorizing comments by topic
- Preparing high-level summaries of comments (including specific data or recommendations)
- After considering substantive comments, drafting the final rule and clearly referencing any changes within comment response

GRP creates:

- Market-friendly atmosphere
- Political stability
- Assurances of predictability and consistency

According to the 2026 Kearney Foreign Direct Investment Confidence Index, **Efficacy of Legal and Regulatory Processes** was the one of the highest factors in determining investment intentions.



GRP in U.S. Trade Agreements:

Agreements:

- United States-Mexico-Canada Agreement (Chapter 28)
- Brazil Protocol on Trade Rules and Transparency
- Ecuador Protocol on Trade Rules and Transparency
- Multiple Agreements on Reciprocal Trade (ARTs)

Benefits:

- Regulatory actions are a frequent trade irritant
- Contribute to more informed policy decisions and improve the quality and cost-effectiveness of government regulation
- Form the foundation for a stronger trading relationship
- Benefits: transparency, predictability, accountability, facilitate trade