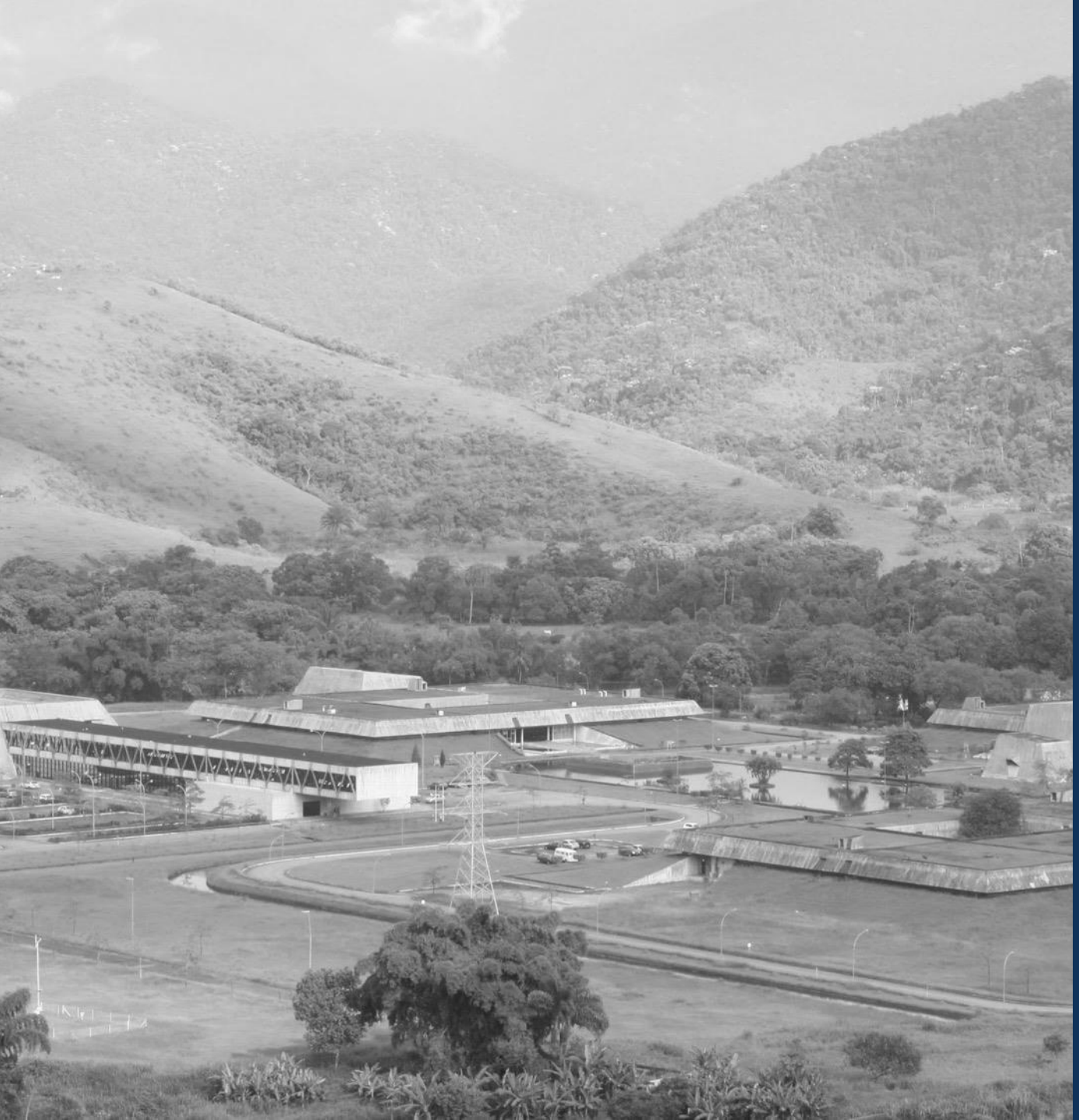
QUALITY INFRASTRUCTURE IN BRAZIL -

TIPS Development Dialogue 27-Sep-2021

National Institute of

Metrology, Quality and Techology

INMETRO



INMETRO and Brazil's quality infrastructure (QI)

INMETRO is a federal agency linked to SEPEC in the Ministry of Economy. INMETRO is the executive body of CONMETRO, and its mains competencies are:

- Scientific and industrial metrology
- Legal metrology
- Conformity assessment
- Accreditation body
- Executive Secretary of CONMETRO and its technical advisory committees, and
- Supervisor of Certification Inspection and Verification Bodies.

INMETRO is also the official monitoring body for compliance with the principles of OECD Good Laboratory Practice.

CONMETRO is the co-ordinating body of the Brazilian QI. The President of INMETRO is the Executive Officer of CONMETRO (Executive Secretary) and it is chaired by the Secretary of SEPEC. Ministries and also private sector organisations (ABNT and trade associations) are represented in CONMETRO.

INMETRO`S LABORATORY CAMPUS

Dimensions of the scientific campus

1,7 million m^2

(52,7 Thousand m^2 Constructed area)

Number of Laboratories

52

Buildings in the Campus

55

Inmetro System`s workforce

6.500

professionals, around the country

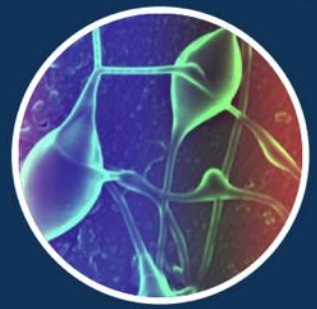
INMETRO`s competences

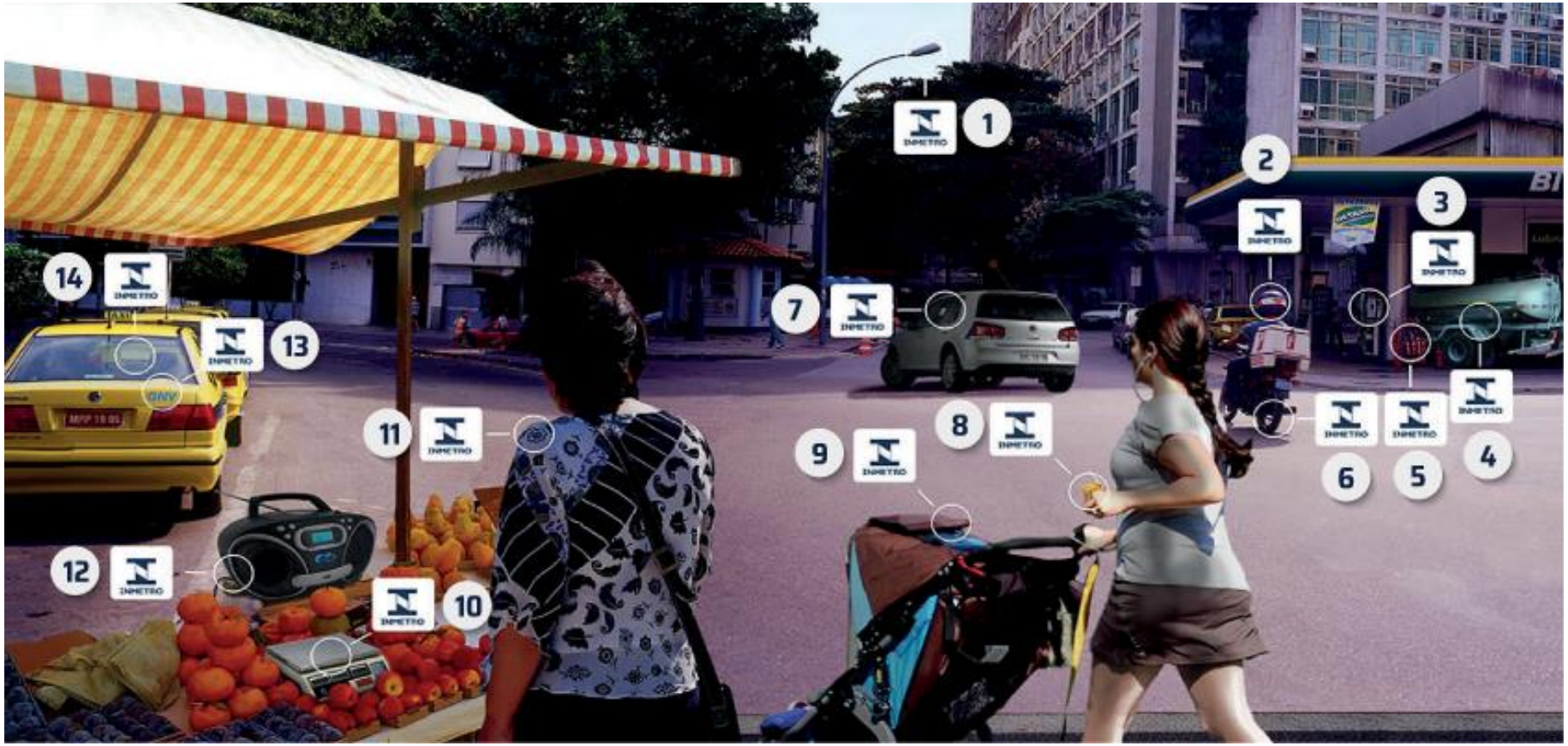
INMETRO

- Scientific and Industrial Metrology
- Metrology applied to Life Sciences
- Legal Metrology
- Conformity Assessment and e Safety of Products
- Accreditation
- International Affairs / Technical Barrier to Trade and Cooperation

INMETRO`s competences

INMETRO

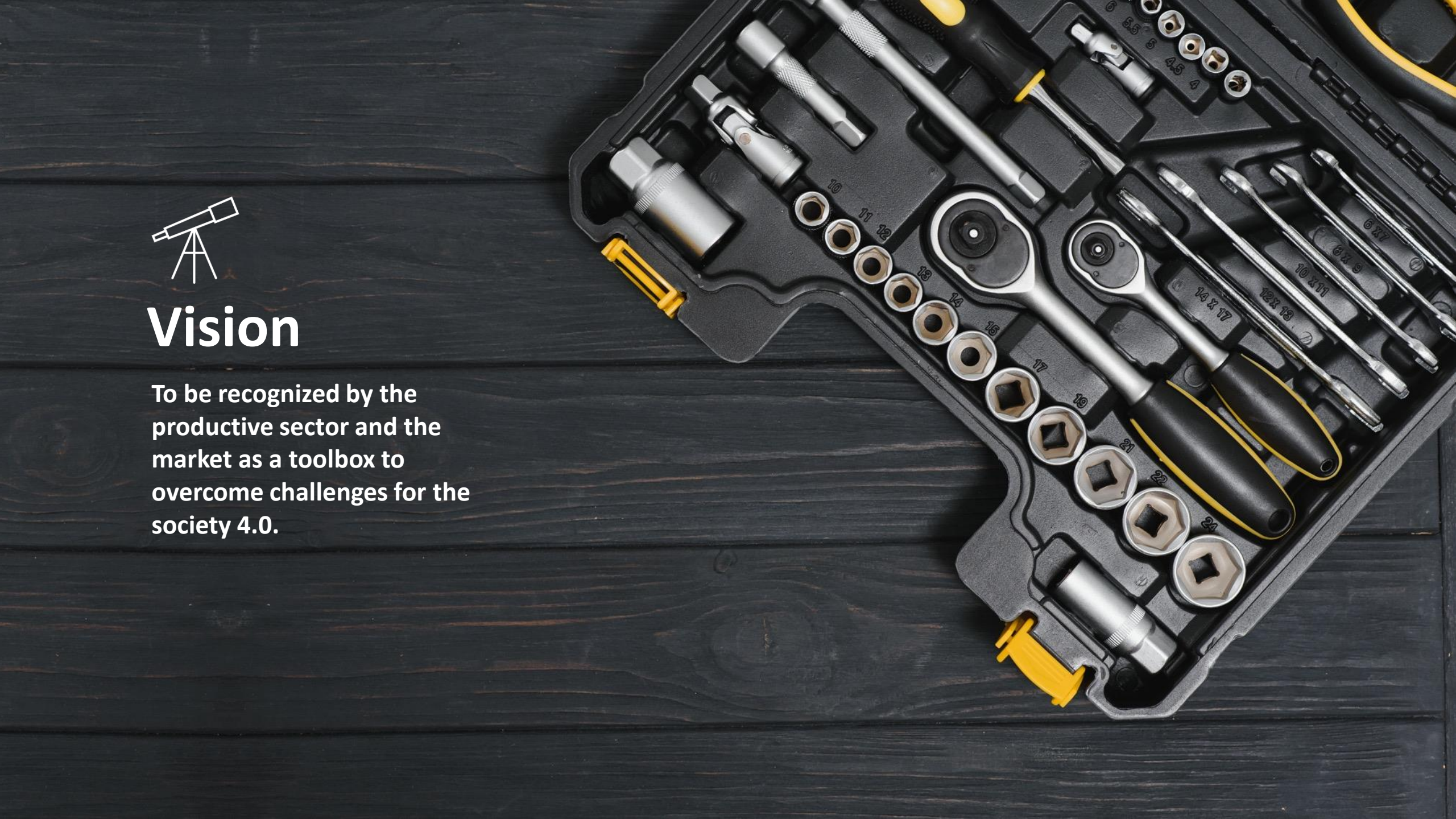




1- Mandatory certification of public lighting fixtures;
2- Conformity assessment of helmets;
3- Metrological Technical Regulation of Fuel Pumps;
4- Volumetric verification of tank trucks;
5- Conformity assessment of fire extinguishers;
6- Brazilian Tire Labeling Program (performance criteria);
7- Brazilian Vehicle Labeling Program (fuel consumption);
8- Pre-Packaged Goods (packaged and measured without the presence of the consumer);
9- Conformity assessment of children's strollers;
10- Technical-Metrological Regulation of Weighing Instruments (Weighing Scales);
11- Technical Regulation of Textile Product Labeling;
12- Brazilian Labeling Program (noise);
13- Quality Technical Regulation on Vehicle Safety Inspection of Automotive Road Vehicles with Vehicle Natural Gas Systems (CNG); and
14- Technical-Metrological Regulations of Taximeters.

MISSION

To provide quality infrastructure solutions that add trust, quality and competitiveness to products and services made available by Brazilian organizations for the economic prosperity and well-being of our society.



Vision

To be recognized by the productive sector and the market as a toolbox to overcome challenges for the society 4.0.

OBJECTIVES

Modernisation of Inmetro`s Regulatory Model

- Ser estável e perene, abrangente e que acompanhe a evolução das expectativas da sociedade e do mercado
- Superar os problemas identificados no modelo atual
- Ser um instrumento de proteção e dinamização do mercado e facilitador dos negócios

PRINCÍPIOS

1. Abrangência
2. Foco em objetivos e resultados
3. Flexibilidade
4. Compatibilidade
5. Isonomia
6. Harmonização
7. Responsabilização dos fornecedores e baseado em riscos
8. Evolução da Fiscalização para Vigilância do mercado
9. Agilidade
10. Viabilidade

VISÃO

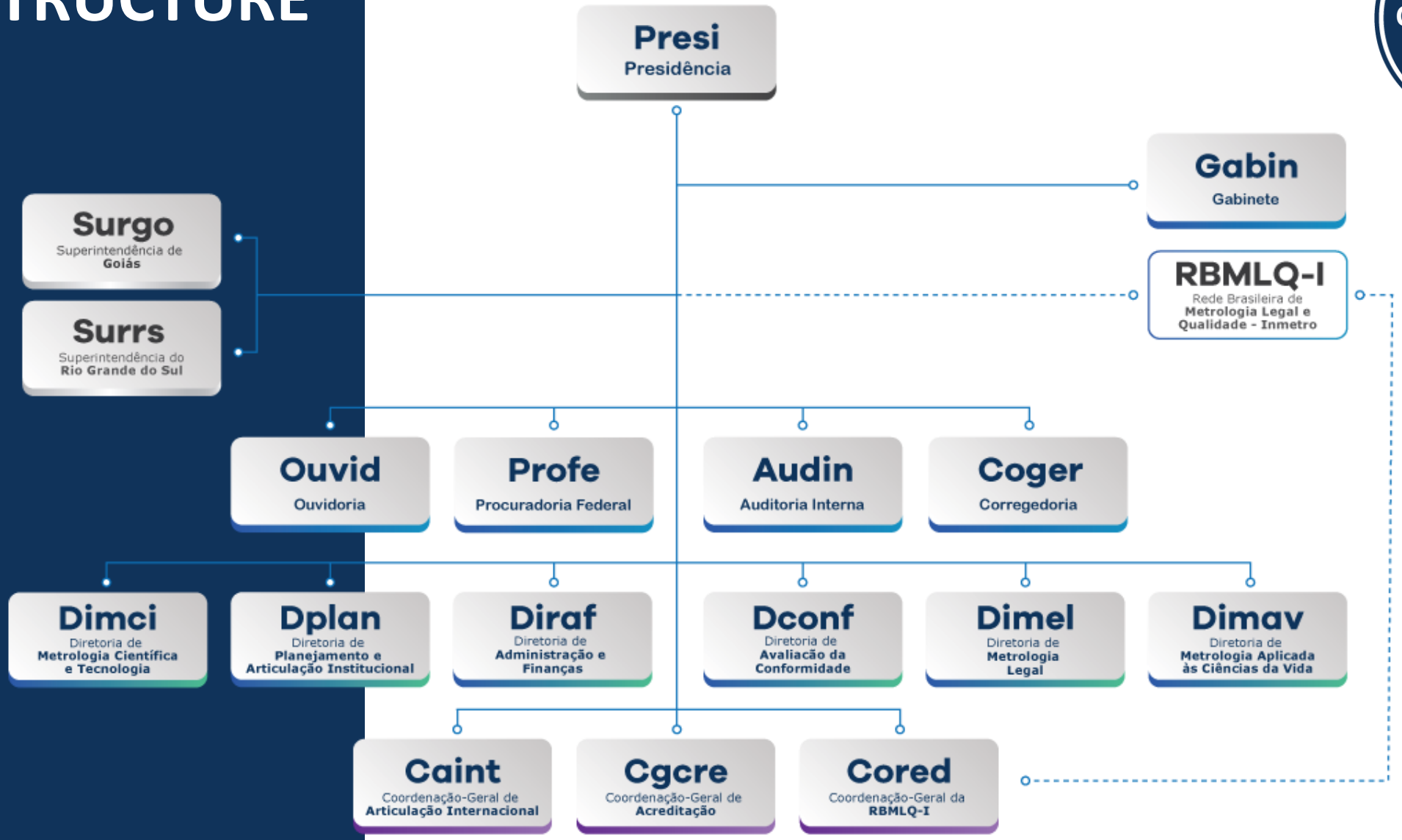
Entende-se que este modelo deve atender à seguinte visão de futuro para o modelo regulatório: Modelo regulatório, como parte da Infraestrutura da Qualidade, que atende às expectativas da sociedade, assegura um mercado seguro e dinâmico, é flexível e acolhe a inovação, promove a competitividade e potencializa a digitalização (Indústria 4.0).

DIRECTIVES

1. Processo regulatório
2. Responsabilização do fornecedor
3. Uso de Avaliação da Conformidade
4. Requisitos essenciais e uso de normas técnicas
5. Vigilância de Mercado
6. Abordagem de avaliação e gestão de riscos
7. Impacto e resultados regulatórios
8. Alinhamento e harmonização internacional
9. Governança
10. Implementação

STRUCTURE

INMETRO`s Central Units



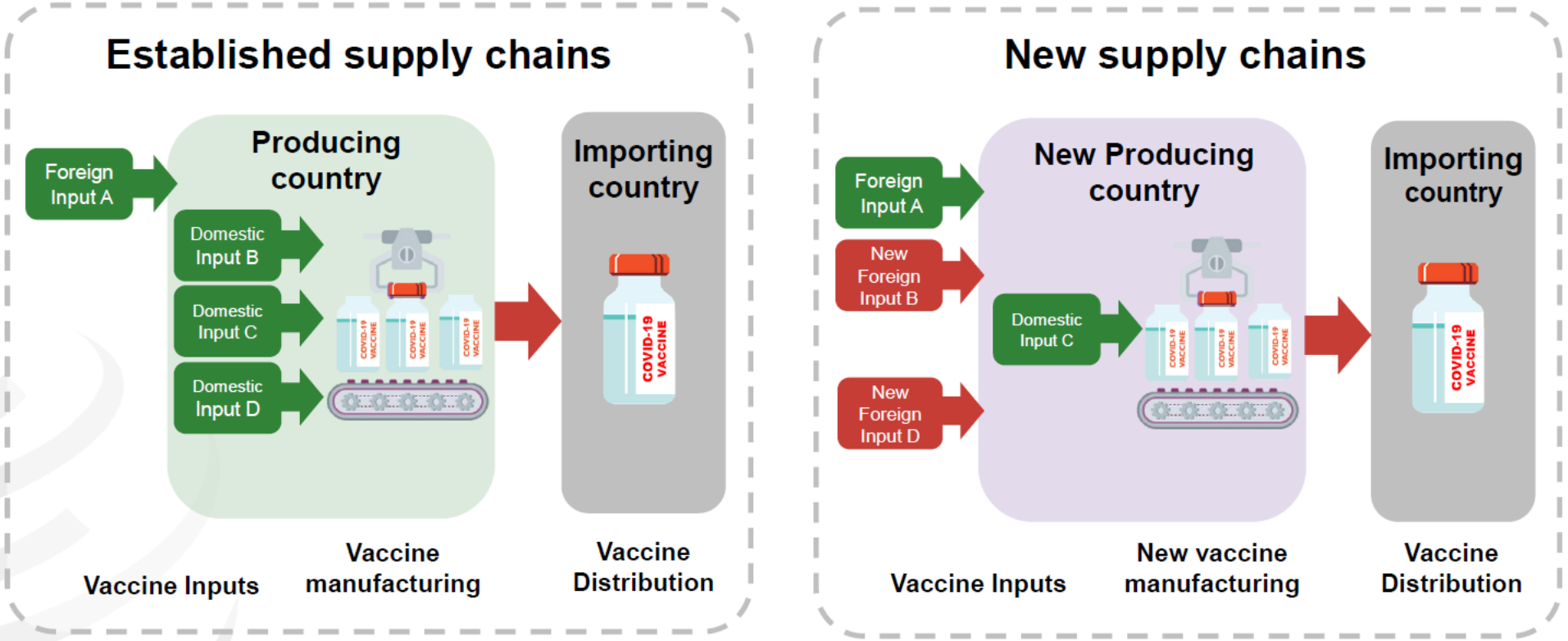
ONDE ESTAMOS

INTERNATIONAL COOPERATION

Main partnerships

Inmetro maintains partnerships with similar institutions on all continents. There are dozens of cooperation MoUs in force.

Vaccine supply chains are increasingly complex and relying on international trade



Source: WTO Secretariat

Research topics to QI and NMI:

1 - Quantitative measurements;

2- Reference materials for quality control;

3 - Data for comparative evaluation;

4 - Leadership and technical advice for national and international standards development efforts; etc.

Smoothening trade on critical vaccine inputs

A few ideas for action

National level

- Establish a **communication channel** with vaccine manufacturers and other relevant stakeholders so they can inform about the bottlenecks (e.g. National Committee on TF)

- National dialogue with manufacturers / relevant stakeholders to understand the **current conditions** for trade in critical vaccine inputs

- Consider to accelerate the implementation of the most relevant **TFA provisions**

- Examine **best practices** from other Members / explore additional measures

- Improve the granularity of trade data to facilitate monitoring trade in the relevant products

-Other?

International Cooperation

- Monitor / exchange information on **emerging bottlenecks** as identified by vaccine manufacturers and other relevant stakeholders; tackle them

- Monitor / exchange information on best practices to **facilitate trade** on critical vaccine inputs

- Improve **data collection** of trade on critical vaccine inputs so the international community can better monitor trade in these products; find ways to have more granularity in the data collection

- Other?

Source: WTO Secretariat

There is an opportunity to develop a Technology Roadmap for the vaccines developed and under development for covid-19, with a focus on the quality infrastructure necessary for the production factors, identifying the main international trends in their technological and market aspects of the vaccine sector from the supply chain, focusing on their infrastructure aspects of the necessary quality. Technological trends are related to the quality of raw materials used, the technologies involved that depend on precise instrumentation in terms of measurement, inputs` chemical compositions, physicochemical properties and other quality requirements. Market trends refer to economic agents (companies, universities and partnerships) in the sector. It is expected that the mapping reached at the end will guide the actions of international technical cooperation in metrology and conformity assessment, applicable to guaranteeing the quality infrastructure in Brazil for the production of vaccines.

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