

Conformity Assessment – Ensuring Compliance with International Obligations: Checklist

Marina Egydio de Carvalho

MDRC Project Tier 1 Lead

S T A N D A R D S A L L I A N C E - P H A S E 2



Overview

- Background – Conformity assessment
- Activity Focus: Dive into the checklist



Conformity Assessment Procedures – Key aspects

Countries' use of conformity assessment procedures (CAPs) is a key area of work for the Technical Barriers to Trade (TBT) Agreement.

CAPs are used to determine whether products fulfil the requirements established by relevant technical regulations or standards and are vital for trust in trade.

CAP give consumers confidence in the integrity, safety and trustworthiness of products.

Add value to manufacturers' marketing claims, and, ultimately, to products themselves



Conformity Assessment Procedures:

Include testing, sampling, inspection and certification, as well as accreditation (of laboratories carrying out tests, for example)

TBT Agreement seeks to avoid CAPs that unnecessarily hinders trade. One factor that might influence the choice of the appropriate CAP is the level of risk posed by products not conforming with relevant specifications

Under the TBT Agreement, members are free to choose the PAC, provided they do not restrict trade beyond what is necessary



PAC - Background strategy

Non-
discrimination

Necessity

Use of
international
Standards



Checklist – What is it?

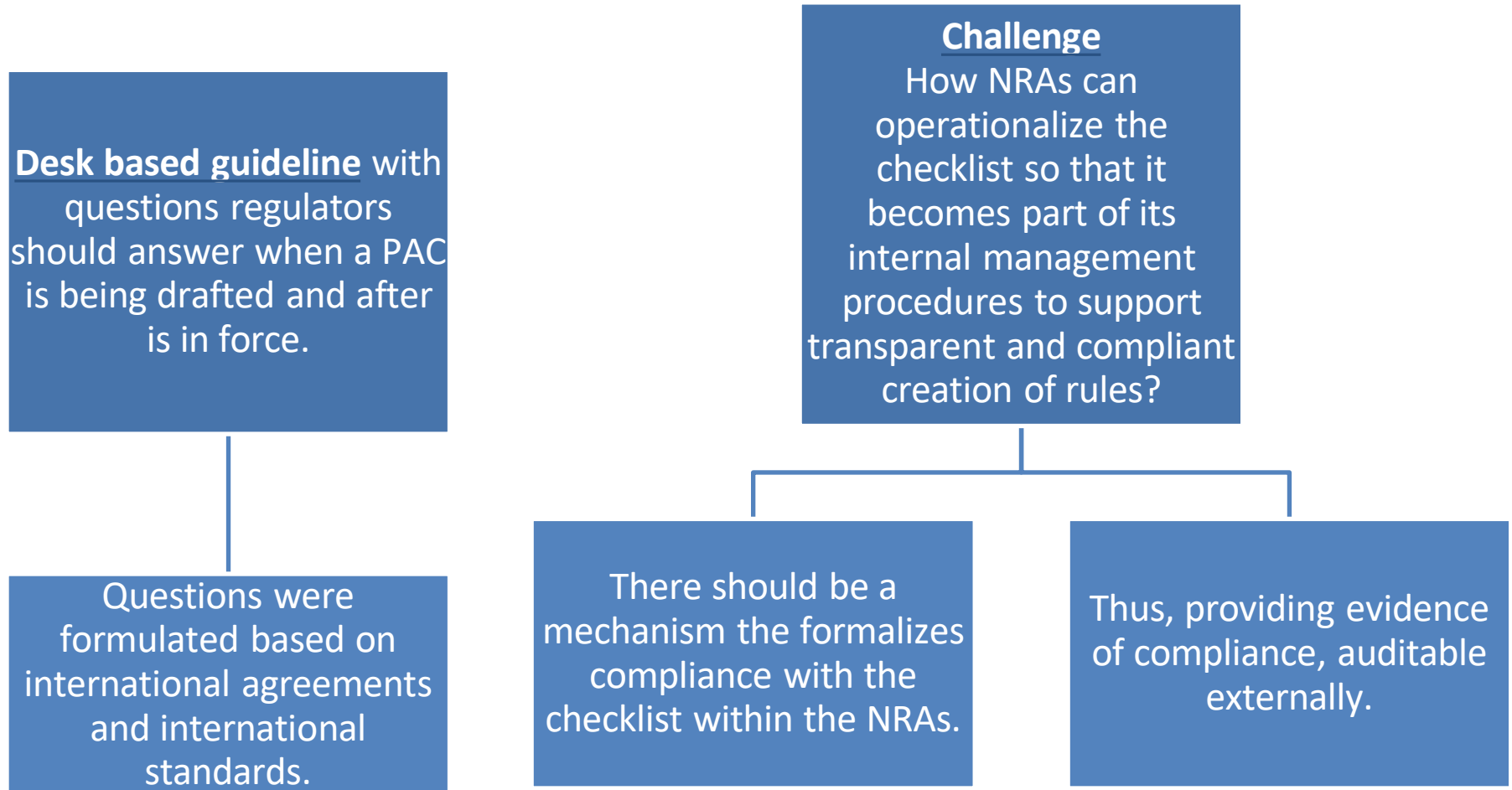
BRIDGE to connect the work of the medical device NRA with the GRP/TBT/WTO rules.

TOOL to support national regulators in developing PAC that comply with international law and assures consistency with general and international practices.

DEVELOPED by the Medical Device Regulatory Convergence Project (MDRC), jointly with MDRC government partners.



Checklist – how it works?



Checklist – Advantages?

- Easy flow of trade
- Compliance with international rules
- Cost efficiency
- Availability of products



Checklist – Focus (1)

- **National Treatment – TBT 5.1.1.; 6.1. and 6.4.**
 - Participation of conformity assessment bodies (CAB) from other territories under same conditions?
 - Acceptance of results from other countries' CAB?
 - Conformity assessment procedures are made under same rules and timing?
 - Confidential information are treated equally regardless if national or imported products?



Checklist – Focus (2)

- **Explanations and Information – TBT 5.2.1.; 5.2.2.; 5.2.3.; 5.2.4 and 5.2.8**
 - Transparency for detailing a conformity assessment procedure?
 - Publication of a processing period?
 - How it ensures that confidential information is protected?
 - Are there procedures for reviewing complains, are they publicly available and dully explained?
 - Does the NRA publish rules regarding acceptance of results from other CAB (including from third countries)?
- **Subcontracting**
 - Does the CAB allow for subcontractors (including from third countries)?



Checklist – Focus (3)

- **Accreditation - TBT 5.2.2 and 6.1**
 - How the CAB deals with CAB from other countries and the results published by them?
 - Are there procedures that facilitates Mutual Recognition Arrangements?
- **Conformity Assessment Selection – TBT 5.1.2. and 5.2.2.**
 - Are there assessment of risks for each selected scheme?
 - Are procedures based on scientific and technical information?
 - Are there evaluation of incidence of non-compliance?
 - Are there assessment for alternative approaches?
 - How costs are calculated, evaluated and applied?
 - Costs can be explained?
 - Are duplicative CAP avoided?



Checklist – Standard Operational Procedures (SOP)

More Executive Operating Procedures can be implemented by the NRA that meet many of the elements of the checklist, without meeting manually use it for every action they take.

The MDRC is working with the NRA to implement such SOP to operationalize the checklist in an efficient manner, taking into consideration NRA Resources

Raise awareness and address the checklist



Contact Information Standards Alliance

Sandra Ligia González

Executive Secretary

slgonzalez@standardsalliance-mdrc.org

Marina Carvalho

Staff Lead on International Trade and GRP

marvalho@standardsalliance-mdrc.org

Steven Bipes

Vice President, Global Strategy and Analysis

AdvaMed

SBipes@AdvaMed.org

S T A N D A R D S A L L I A N C E - P H A S E 2

