

## STRATEGIC PLAN

### WHO Coalition of Interested Parties (CIP) Network

January 2023 – December 2027

#### INTRODUCTION

#### BACKGROUND

Resolution WHA67.20 on Regulatory system strengthening for medical products, which was approved by the Sixty-seventh World Health Assembly in May 2014, recognizes that effective regulatory systems are an essential component of health system strengthening, contribute to better public health outcomes, and are necessary to the implementation of universal health coverage. The Resolution also recognizes that inefficient regulatory systems can be a barrier to access, to safe, effective and quality medical products.

WHO's objectives in the area of regulatory system strengthening are to:

1. promote cooperation on regulatory matters, convergence and transparency through networking, coordinating, collaborating, work-sharing and reliance; and
2. build capacity in Member States consistent with good regulatory practices.

These objectives are intended to facilitate access to safe, effective and quality medical products by assisting countries reach and sustain a level of regulatory oversight that is effective, efficient and transparent. WHO understands that an increasing number of entities are involved in efforts to strengthen regulatory systems at country-, regional or global level. WHO also recognizes the value of networks, collaboration and coordination (particularly given limitations in resources) in achieving the aforementioned objectives, in enhancing the effectiveness of regulatory support outcomes and, conversely, in avoiding fragmented or uncoordinated support to Member States.

The World Health Organization (WHO) since 2021, has established the network for regulatory systems strengthening, named the “**Coalition of Interested Parties**” (CIP) (hereafter referred to as, “CIP”, the “CIP Network”, the “Network”). The CIP provides a framework for collaboration between WHO and participants in the CIP Network in order to provide more effective support to regulatory strengthening activities, with a view to enhancing access to safe, effective and quality medical products. Please refer to <https://www.who.int/publications/m/item/terms-of-reference-for-the-coalition-of-interested-parties>.

Based on Resolution WHA67.202, the WHO five-step capacity building model will also guide the roles and activities of the Network participants. The Network's governance structure will be comprised of a Global Steering Group (GSG) at the global level, as well as by Regional Steering Groups (RSGs) that may also be established at each WHO Region. Each of the GSG and RSGs will, in turn, be supported by a Secretariat from WHO.

The CIP Network Strategic Plan will be endorsed by the GSG. The CIP Network GSG is required to establish, approve, monitor, review and facilitate the Network's overall strategic direction, priorities and effectiveness as well as identify and approve recommendations on areas for improvement concerning the activities of the Network at the global, regional and/or country levels. The progress made on the activities in order to achieve the overarching objectives of the Network will be continuously monitored and reflected in the GSG annual report.

The overall performance of the CIP Network will be measured, and coordination efforts made in the context of the CIP Network should have a sustainable impact.

#### 01. Vision Statement

Health for all by enhancing regulatory capacity, consistency and sustainability with a view to enhancing access to safe, effective and quality medical products.

## 02. Mission Statement

To promote collaboration and alignment of partnership efforts to support regulatory system strengthening at national, regional and global level, through an agreed platform for robust coordination, transparency, communication and stakeholder engagement.

## 03. Aims and Objectives

The purpose of the Network is to establish and promote a unified strategic and coordinated approach to strengthening national and regional regulatory systems, thereby contributing to the implementation of Resolution WHA67.20 as well as the common objectives of the Network participants. The Network also aims to increase the effectiveness of collective efforts and desired impact in countries and regions. More specifically, the objectives of the Network include:

- a) the more effective use of resources directed at strengthening regulatory systems, consistent with good regulatory practices;
- b) enhancing the capacity, consistency and sustainability of regulatory support interventions;
- c) promoting the sharing and adoption of best practices between participants in the Network; and
- d) reducing burden on regulatory authorities caused by uncoordinated, duplicative and potentially incongruous support activities.

## 04. Guiding Principles of the CIP Network

The following principles will guide the work of the Network:

- a) Coordination between WHO and the Network participants to support the strengthening of regulatory systems is essential to enabling complementary, coherent action and optimal outcomes in Member States;
- b) The sharing and use of confidential and/or proprietary information in connection with the implementation of the Network's activities will be subject to the Network participants': (i) obtaining the prior written consent of the owner of such confidential and/or proprietary information which may include, without limitation, the relevant national regulatory authorities (NRAs) and/or Ministries of Health (MOHs); and (ii) prior signature of, and compliance with the terms and conditions contained in, the Confidentiality Undertaking set forth in Annex I to these TORs;
- c) The CIP Network's support is directed at the country and/or regional level(s), and will be coordinated through the designated Network country and/or regional focal persons from each participating organization;
- d) The work of the Network will be conducted in a manner that is objective and impartial, without favour to any Network participant or other party, and that avoids actual or apparent conflicts of interest, unfounded bias or improper influence of stakeholders;
- e) Through the CIP Network, and under WHO leadership, a neutral platform will be established to facilitate open discussions regarding the needs of the NRA, interests of CIP members and technical and financial resources available to provide support and have sustainable impact for regulatory systems in Member States;
- f) Operationalization of the coordinated Network support for regulatory system strengthening in a country or region must be led by the NRA(s) if it is to have the desired country impact;
- g) The nature and scope of technical and/or financial support provided in the context of the CIP Network in a particular country or region is guided by the WHO five-step capacity building model (Figure 1) and will be set forth in an agreed written plan of support, referred to as the Support Plan;
- h) The Support Plan will, among other things, define the roles and responsibilities of each CIP Network member based on its competencies, and establish the specific activities, expected outcomes, priorities, timelines and available resources under such Support Plan;

- i) Areas of technical and/or financial support will be categorized according to the regulatory functions and overarching enabling system defined by the WHO Global Benchmarking Tool; and
- j) Technical and financial support will be coordinated and aligned with the Institutional Development Plans (IDPs) developed following benchmarking activities using the WHO Global Benchmarking Tool.

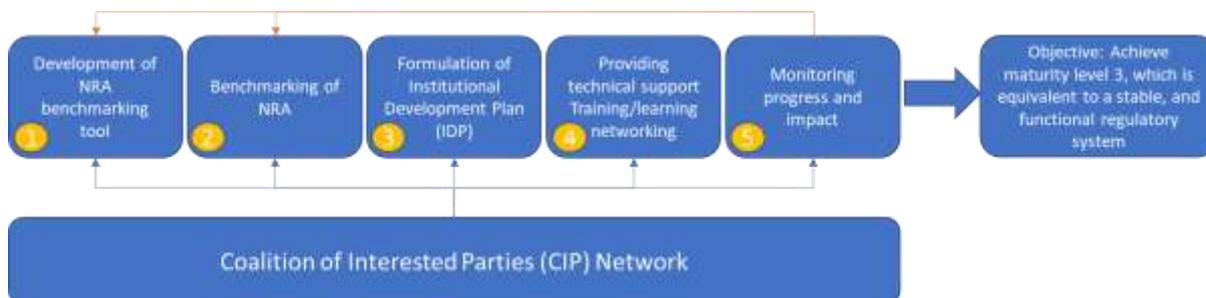


Figure 1. WHO five-step capacity building model.

## 05. Implementation

The Network's governance structure will be comprised of a Global Steering Group (GSG) at the global level, as well as Regional Steering Groups (RSGs) that may also be established at each WHO Region. Each of the GSG and RSGs will, in turn, be supported by a Secretariat.

Time-limited working groups may be established to undertake work related to the Network's activities or the development of products of the Network, in each case, globally and/or within the relevant region and in alignment with the operational plan.

An operational plan will be developed to complement the CIP Network Strategic Plan. The operational plan will cover a two-year period to account for realistic timeframes for regulatory progress.

In line with Section 7.2 and 7.3 of the CIP Network Terms of Reference, CIP members shall demonstrate commitment to provide ongoing support to the Network's regulatory system strengthening activities and demonstrated engagement in regulatory strengthening activities. CIP members are required to actively participate in, observe and support the Network's purpose, objectives, guiding principles, work and activities and attend and actively participate in annual and ad hoc Network meetings. CIP members shall provide technical and/or financial support to countries and/or regions, provide input into annual GSG/RSG Support Plans and participate in global, regional and/or national CIP coordination efforts.

The CIP Network will initiate coordination activities in priority countries. The following criteria shall be considered when determining the priority countries for CIP coordination efforts:

1. Countries with several partners i.e., CIP members and non-CIP members
2. Countries targeted by CIP members
3. National regulatory authorities engaged in benchmarking activities using the WHO GBT, where well formulated IDPs are available. For the purposes of carrying out the CIP Network's regulatory strengthening activities, NRAs are required to give consent to the WHO and the CIP Network members for the exchange and maintenance of information, in confidence, related to the NRA and/or their activities.
4. Targeting countries identified as regional leaders in order to leverage spill-over effect onto other countries in the region
5. Countries more vulnerable to emergency situations

6. Countries engaged in regional reliance structures
7. Countries earmarked for vaccine manufacturing or as technology hubs
8. Countries lacking partner support
9. National regulatory authorities that have reached maturity level 3 and may require support to maintain the achieved maturity level

Communication strategies for internal and external communication may be determined and implemented as required. The CIP SharePoint may be used as the central point for internal communication. External communication and engagement shall be undertaken to inform a wider audience of the outputs, success and challenges of CIP Network activities. Publication of reports and other information products from the Network should be in peer-reviewed journals and in accordance with open access policy. The annual reports of the GSG and relevant RSGs shall be publicly available.

CIP Network activities should be monitored and reported on to advance the accountability and sustainability of the activities of the Network. Accountability will be monitored through the quantification of completed support activities and supportive evidence of outcomes of such activities.

#### 06. Strategic priorities, Goals and Objectives (SMART)

Strategic Priority	Goal	Objective	Performance indicator
1. Strengthen country and regional regulatory systems	1.1. Strengthen national regulatory capacity to ensure quality, safety and efficacy of medical products	1.1.1. Enhance external support for regulatory systems strengthening at global, regional and national levels	<ul style="list-style-type: none"> <li>▪ Number of CIP members active at global, regional and national level</li> </ul>
		1.1.2. Prioritize targeted countries for CIP implementation	<ul style="list-style-type: none"> <li>▪ Mapping of CIP member activities at global, regional and national level</li> <li>▪ Development of annual work plan</li> <li>▪ List of countries and regions by priority to support</li> <li>▪ Mapping of CIP member competencies</li> </ul>
		1.1.3. Optimize and expand regulatory strengthening and capacity building	<ul style="list-style-type: none"> <li>▪ Number of activities at global, regional and national levels</li> <li>▪ Number of activities across 10 activity types</li> </ul>
2. Increase the impact of the CIP Network support to	2.1. Improve targeting and alignment of CIP	2.1.1 Facilitate improved coordination of	<ul style="list-style-type: none"> <li>▪ Number of coordination efforts</li> </ul>

countries and regions	Network support activities	CIP members; and external partners at national level, where relevant	
	2.2. Enhance monitoring of the impact of CIP Network support activities	2.2.1. A validated evidence-base to assess the outputs and outcomes of CIP Network support activities	<ul style="list-style-type: none"> <li>▪ Progression of maturity of regulatory system</li> <li>▪ Progression of maturity of regulatory function</li> <li>▪ Percentage IDP implementation</li> <li>▪ Timelines for IDP implementation</li> </ul>

## 07. Key Performance Indicators

The following performance indicators will be used to identify measures for determining the output of the CIP Network at global, regional and national level:

Metrics:

*Quantitative*

1. Number of CIP members active at global level and regional level
2. Number of activities at global, regional and national level
3. Number of activities across 10 activity types:
  - 3.1. Grant: Meaning a quantity of money (award), i.e., financial assistance, given for a specific purpose to support regulatory system strengthening
  - 3.2. Training: Constitutes a basic concept in human resource development concerned with developing a particular skill to a desired standard by instruction and practice.
  - 3.3. Technical assistance: Meaning the provision of technical assistance to support implementation.
  - 3.4. Study tour: Meaning an educational trip designed to help a group of people learn more about another country's regulatory system.
  - 3.5. Workshop: Meaning a presentation, meeting, or educational session where people learn or work on a specific topic, task, or creative project, and are actively involved in the process.
  - 3.6. Tool/product: Meaning the development of a tool for data collection or ICT tool / development of a product such as a training module
  - 3.7. Twinning: Meaning the voluntary partnership agreement between a CIP member and a National Regulatory Authority/regional initiative for the purposes of sustainable capacity building, where capacity building is considered as the development of competencies to perform regulatory activities in line with a stable, well-functioning and integrated regulatory system.
  - 3.8. Document: Meaning the development of documents such as legal frameworks, guidelines, SOPs, process flows, work instructions, job descriptions etc.
  - 3.9. Report/manuscript: Meaning the publication of a manuscript in a peer-reviewed journal or publication of a recognised report.

- 3.10. Human resource: Meaning the placement of a human resource to perform a routine regulatory function within a National Regulatory Authority.
4. Number of coordination efforts
  - 4.1. Number of CIP facilitated agreements with coordinated partner commitment
  - 4.2. Mapping of coordination efforts, identifying and addressing gaps, overlaps and synergies
  - 4.3. Global: GSG meetings
  - 4.4. Regional: RSG meetings
  - 4.5. National: CIP Coordination meetings, meetings between NRA and CIP member
5. Number of activities conducted for purposes of carrying out the CIP Network's regulatory strengthening activities:
  - a. Number of conferences, workshops, training interventions, people trained, placements, consultations
  - b. Number of products/tools (such as digital tools, training modules/materials, sustainability frameworks, accountability frameworks) and how these may be shared with or applied to other countries or within the region
6. Additional metrics considered at NATIONAL level, in the context of WHO led benchmarking using the Global Benchmarking Tool (GBT):
  - a. Timelines for IDP implementation
  - b. Percentage IDP implementation
  - c. Progression of maturity of regulatory function
  - d. Progression of maturity of regulatory system

#### *Qualitative*

1. Collect success stories including micro-narratives from NRAs
2. Survey: Pre and Post intervention
3. Survey: Satisfaction of NRA, CIP member and WHO Country office after the intervention

#### **08. Reporting**

The quantitative and qualitative data on CIP engagement at global, regional and national level will be collected through the following mechanisms:

#### *Quantitative:*

1. Mapping of CIP member activities at global, regional and national level
2. CIP Toolkit: Support Plan  
The Support Plan contained in the CIP Toolkit has been developed to document the technical and financial support directed at selected IDPs. The Support Plan identifies the targeted regulatory function and IDP, contains a description of the support provided/activity performed by the CIP member, the timeline and the associated budget. CIP members are required to populate the Support Plan in agreement with NRAs receiving support. The Support Plan should be updated, by the CIP members. The NRA cGBT datafile should be updated in line with actions taken through CIP member support and upload the relevant evidence onto the NRA RSS SharePoint. The NRA is responsible for submitting the updated Support Plan and cGBT datafile to the WHO CIP focal person every 6 months.
3. Additional quantitative data considered at NATIONAL level, in the context of WHO led benchmarking using the Global Benchmarking Tool (GBT):  
NRAs are required to update the GBT datafile as activities are completed/support is provided and IDPs are implemented. In this way NRAs will be able to report on the percentage of IDP

implementation and the progression of maturity level for a specific regulatory function and/or for the overall regulatory system.

The quantitative data collected on CIP engagement may be used to contribute towards the reporting on the output of the CIP Network. For this reason, it is critical that CIP members ensure that the CIP Toolkit is used to formalise the support provided.

*Qualitative:*

1. Record success stories
2. Surveys

Reports on CIP member engagement at global, level will be prepared annually by the CIP Network Secretariat and will be ratified by the CIP Network GSG at the annual GSG meeting. Reports on CIP member engagement at regional and national level will be prepared annually by the RSG Secretariat and will be ratified by the CIP Network RSG at the annual RSG meeting. The RSG will review and provide recommendations to the GSG concerning revisions to the Network's regional operating procedures.

**09. Review**

The CIP Network Strategic Plan approved by the GSG and will be reviewed every two years and updated where necessary, to ensure that it remains relevant, agile, responsive and aligned to the evolving needs of the CIP Network and external environment.