Table A4.2 Improved regulatory systems for targeted health products (medicines, vaccines, medical devices including diagnostics)

Rationale	National Regulatory Authorities are the gatekeepers of the supply of medicines and other health products, mandated to ensure their quality, safety, and efficacy. They work within a legal framework and set of regulatory functions spanning the product lifecycle, from clinical trials oversight, marketing authorization and registration, licensing establishments, regulatory inspections, testing products, post-marketing surveillance, and safety monitoring. However, many countries still lack this basic building block of a well-functioning health system Resolution WHA67.20 emphasized the WHO mandate and requested both WHO and Member States to invest more in this area and to address all health products and technologies, particularly in low and middle-income countries. According to WHO database on regulatory systems strengthening activities, about 70% of member states have suboptimal regulatory systems, and especially the low- and middle-income countries. The situation in these countries can be extremely challenging. NRAs are often overburdened and under-staffed, with fragmented structures or insufficient legal and regulatory frameworks resulting into infiltration on the market of substandard and falsified (SF) medical products. SF medical products undermine public health goals, causes deaths, promotes antimicrobial resistance, erodes public confidence on health care services and workforce.
Mandate (WHA resolution, SDG)	WHA67.20 on Regulatory Systems Strengthening for medical products (2014)
Definition	Improved regulatory capacity measured against GBT indicators and implementation of recommendations according to their Institutional Development Plans for each of the health product streams (medicines, vaccines, medical devices and in vitro diagnostics)
Numerator	Maturity level achieved per product stream
Denominator	The highest maturity level achievable as per GBT as per product
Preferred data sources	Benchmarking reports and implementation of Institutional Development Plans (IDPs) according to WHO GBT
Other data sources	N/A
Disaggregation	N/A
Frequency of data collection	Annually
Limitations	Readiness of countries to invest in regulatory systems strengthening based on international good regulatory practices
Data type	Numerical or % implementation of GBT indicators
Related links	WHO global benchmarking tool for evaluation of national regulatory system of medical products (revision VI) Manual for benchmarking of the national regulatory system of medical products and formulation of institutional development plans (who.int) Evaluating and publicly designating regulatory authorities as WHO listed authorities Operational guidance for evaluating and publicly designating regulatory authorities as WHO listed authorities Manual for the performance evaluation of regulatory authorities seeking the designation as WHO listed authorities

Source: WHO Results Framework: Outcome Indicators Fourteenth General Programme of Work *(1)*.

Reference

1. Metadata WHO Results Framework: Outcome Indicators Fourteenth General Programme of Work (GPW14). Geneva: World Health Organization; 2024. (https://cdn.who.int/media/docs/default-source/documents/ddi/gpw14-results-framework_outcome-indicators_metadata.pdf, accessed 29 April 2025).