

# Pharmaceutical Products

Version:52

DescriptionThis is a versionDescription

## Policy Laws and Governance

indicatorName	An institutional development plan of the national medicines regulatory authority based on the results of the GBT exists
Pss Insight Indicator	PLG01
Definition	<p>The Global Benchmarking Tool (GBT) represents the primary means by which the World Health Organization (WHO) objectively evaluates regulatory systems, as mandated by WHA Resolution 67.20 on Regulatory System Strengthening for medical products. The tool and benchmarking methodology enables WHO and regulatory authorities to:</p> <ul style="list-style-type: none"><li>11 identify strengths and areas for improvement;</li><li>facilitate the formulation of an institutional development plan (IDP) to build upon strengths and address the identified gaps;</li><li>prioritize IDP interventions; and</li><li>monitor progress and achievements.</li></ul>
Topic	Policy Laws and Governance
assessmentQuestions	<p>Has the country completed at least 1 GBT assessment? (institutional development plan)</p> <p>Has the country developed and published an institutional development plan as a result of the last GBT exercise? (institutional development plan)</p>
indicatorName	A progress report on the institutional development of the national medicines regulatory authority published
Pss Insight Indicator	PLG02

Definition	<p>The Global Benchmarking Tool (GBT) represents the primary means by which the World Health Organization (WHO) objectively evaluates regulatory systems, as mandated by WHA Resolution 67.20 on Regulatory System Strengthening for medical products. The tool and benchmarking methodology enables WHO and regulatory authorities to:</p> <ul style="list-style-type: none"> <li>· identify strengths and areas for improvement;</li> <li>· facilitate the formulation of an institutional development plan (IDP) to build upon strengths and address the identified gaps;</li> <li>· prioritize IDP interventions; and</li> <li>· monitor progress and achievements.</li> </ul> <p>Countries should report progress towards the goals and system improvements documented in the institutional development plan.</p>
Topic	Policy Laws and Governance
assessmentQuestions	<p>Has the country completed at least 1 GBT assessment? (progress report on the institutional development)</p> <p>Has the country developed and published an institutional development plan as a result of the last GBT exercise? (progress report on the institutional development)</p> <p>Has the country published a progress report for the institutional development plan? (progress report on the institutional development)</p>
indicatorName	Submission of national data to the Global Antimicrobial Resistance Surveillance System (GLASS)
Pss Insight Indicator	PLG03
Definition	<p>Launched in October 2015, the Global Antimicrobial Resistance Surveillance System (GLASS) is being developed to support the global action plan on antimicrobial resistance. The aim is to support global surveillance and research in order to strengthen the evidence base on antimicrobial resistance (AMR) and help informing decision making and drive national, regional, and global actions.</p>
Topic	Policy Laws and Governance
assessmentQuestions	Has the country submitted data to GLASS within the past 12 months?
indicatorName	Updated National Action Plan on the containment of antimicrobial resistance
Pss Insight Indicator	PLG04

Definition	<p>In May 2015, the Sixty-eight World Health Assembly adopted the global action plan on antimicrobial resistance. The goal of the global action plan is to ensure, for as long as possible, continuity of successful treatment and prevention of infectious diseases with effective and safe medicines that are quality-assured, used in a responsible way, and accessible to all who need them.</p> <p>The World Health Assembly also urged all Member States to develop and have in place by 2017, national action plans on antimicrobial resistance that are aligned with the objectives of the global action plan.</p>
Topic	Policy Laws and Governance
assessmentQuestions	<p>Has the country developed and published a national action plan on the containment of antimicrobial resistance?</p> <p>What is the year of the most recent update or revision of the action plan?</p>
indicatorName	Number of PSTA assessments within the last five years
Pss Insight Indicator	PLG07
Definition	<p>WHO has developed the PSTA assessment tool to assist countries with the assessment of the public availability of key documentation that facilitates accountability of the pharmaceutical system. This document is intended for policy makers and concerned stakeholders with an interest in improving governance in the pharmaceutical system as well as for those who will carry out an assessment.</p> <p>The assessment results are intended to be used to:</p> <ul style="list-style-type: none"> <li>· Identify strengths and weaknesses with regards to transparency of pharmaceutical information</li> <li>· Inform priority setting</li> <li>· Develop targeted policy interventions</li> <li>· Periodically to monitor progress</li> </ul> <p>The main focus of the assessment is on transparency and accountability in the public sector. Other sectors are included in the assessment when relevant for accountability.</p>
Topic	Policy Laws and Governance
assessmentQuestions	Number of PSTA assessments within the last five years