Pharmaceutical Products

Version: 116

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Information

Indicator Name	Existence of a policy or strategy that sets standards for collection and management of pharmaceutical information
Pss Insight Indicator	IM01
Topic	Information
Assessment Questions	Does the policy or strategy set standards for: Data collection? Existence of a policy or strategy that sets standards for collection and management of pharmaceutical information Does the policy or strategy set standards for: Reporting procedures? Does a policy or strategy exist to set standards for the pharmaceutical information system? Does the policy or strategy set standards for: Data management? Are there specific targets set for each indicator? Does a national set of indicators for the pharmaceutical system exist? Are data analyzed and reports disseminated at least once per year?
Indicator Name	Data on safety, efficacy, and cost effectiveness of medicines available and used to inform essential medicines selection
Pss Insight Indicator	IM02
Topic	Information

Assessment Questions	Based on the last meeting's minutes or documentation of the last discussion on selecting essential medicines, was safety used to inform the discussion and final decision: Based on the last meeting's minutes or documentation of the last discussion on selecting essential medicines, was efficacy used to inform the discussion and final decision: Data on safety, efficacy, and cost effectiveness of medicines available and used to inform essential medicines selection Based on the last meeting's minutes or documentation of the last discussion on selecting essential medicines, was cost-effectiveness used to inform the discussion and final decision

Regulatory Systems

Indicator Name	% of dispensing facilities inspected each year
Pss Insight Indicator	RS03
Topic	Regulatory Systems
Assessment Questions	What is the last calendar year for which data on dispensing facilities inspected are available? In the reference year, what is the total number of registered dispensing facilities or retail outlets that were inspected)? % of dispensing facilities inspected each year In the reference year, what is the total number of licensed pharmaceutical dispensing facilities or retail outlets registered in the country?
Indicator Name	Average number of days for decision making on a medicine application for registration
Pss Insight Indicator	RS04
Topic	Regulatory Systems

Assessment Questions	If the country does not routinely collect this information, enter the total number of business days taken to review the previous 10 applications for registration of a NEW pharmaceutical product Average number of days for decision making on a medicine application for registration If the country does not routinely collect this information, enter the total number of business days taken to review the previous 10 applications for registration of a GENERIC pharmaceutical product If the country tracks the average number of days taken to review an application for new pharmaceutical product registration, please enter the current value here If the country tracks the average number of days taken to review an application for generic pharmaceutical products registration, please enter the current value here
Indicator Name	% of medicines on the EML that have at least one registered product available.
Pss Insight Indicator	RS05
Topic	Regulatory Systems
Assessment Questions	% of medicines on the EML that have at least one registered product available. If the country tracks this information, enter the percentage of EML medicines that have at least one product registered. Total Number of medicines on the EML If the country does not track this information, obtain the latest copies of both the national EML and the registered products list to perform the comparison. Number of Medicines on EML with corresponding registered product