WHO GLOBAL BENCHMARKING TOOL PLUS MEDICAL DEVICES (GBT+Medical Devices) FOR EVALUATION OF NATIONAL REGULATORY SYSTEM OF MEDICAL PRODUCTS

NATIONAL REGULATORY SYSTEM (RS): INDICATORS AND FACT SHEETS

Revision VI+MD version 1

March 2022

World Health Organization

Function:	**01- NATIONAL REGULATORY SYSTEM (RS)**
Description:	The National Regulatory System provides the framework that supports the World Health Organization (WHO) recommended regulatory functions. The National Regulatory Authority (NRA) is the institution in charge of assuring the quality, safety, and efficacy of medical products as well as ensuring the relevance and accuracy of product information. A sustainable, well-functioning regulatory system will ensure an independent and competent oversight of medical products.
Indicator:	**RS01 Legal provisions, regulations and guidelines required to define regulatory framework of national regulatory system (RS)**
Objective:	The objective of this indicator is to ensure that the legal basis defining the regulatory framework for the national regulatory system exists. The assessor should identify how the different pieces of the legislation are drafted and which organizations and institutions are consulted during this process, including the public, industry, non-governmental organizations and other interested parties. The assessor should identify the cases where the relevant legal provisions have been defined but the regulations have not been enacted and published, which may lead to legal uncertainty, misunderstanding or misinterpretation. The national regulatory system functions should be supported by appropriate and promulgated legislation.
Category:	01. Legal provisions, regulations and guidelines
Sub Indicator:	**RS01.01: Legal provision and regulations define the medical products that should be regulated.**
Maturity Level:	1
Scope:	1. Medicines 2. Vaccines

	3. Blood Products (whole blood, blood components and plasma derived medicinal products (PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should identify, within the existing legislation and regulations, the scope of regulatory activities and provisions for the products that should be regulated. Up to-date definitions for regulated medical products (e.g. medicines, biological products, and medical devices including in vitro diagnostics) should be used. It is not necessary to have a single (standalone) medical products law; however, a promulgated and enforced law should exist. If the base laws and regulations refer to the need for complementary regulation, it is important to access that information.
Objective:	The objective of this sub-indicator is to ensure the existence of legislation and regulations for the products that should be regulated. This should also include setting up the scope and mandate of the regulatory agency in charge of regulating medical products in the country.
Requirement:	Scope of regulated medical products
Evidence to review:	The assessor should request and review: 1. Promulgated legal provisions and regulations for the medical products that should be regulated.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885)., (1), (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1

	6. WHO - Good regulatory practices for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_products.pdf
Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There are no legal provisions or regulations defining the medical products that should be regulated. ⇒ ONGOING IMPLEMENTATION (OI): There are some legal provisions and regulations; or although they do not exist, demonstrable steps have been taken towards developing them. ⇒ PARTIALLY IMPLEMENTED (PI): The legal provisions and regulations defining the medical products that should be regulated were recently developed as draft but not yet promulgated and enforced. ⇒ IMPLEMENTED (I): The legal provisions and regulations defining the medical products are promulgated and enforced.
Limitations and remarks:	▪ In a short time, it may not be possible for the assessor to review all aspects that this indicator includes. Preferably the country profile or other documents that provide a good description of the regulatory landscape in the country should be studied beforehand. ▪ For blood and blood products, it is important that standards for preparation of blood for transfusion (e.g., collection of blood, donor selection, donor deferral and transfusion transmitted infection testing) should be referenced in legislation. ▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS01.02: Legal provision and regulations define the institutions that are involved as part of the regulatory system, as well as their mandates, functions, roles, responsibilities and enforcement powers.**
Maturity Level:	1
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should identify the legislation and regulations that define all institutions involved in medical product regulation including the relevant regulatory functions for each institution. The regulatory functions covered will depend on the scope of the regulatory system. The regulations should provide a clear mandate and define functions, roles, responsibilities and enforcement powers for each

	regulatory function in order to avoid overlapping of the respective empowerments. In the case of an assessment of a framework with multiple regulatory authorities, the sub-indicator should be fulfilled by each regulatory authority as well as any regional institution or authority. If different organizations at different level of the state are involved the assessor should review how the linkage among the organizations is defined in the law.
Objective:	The objective of this sub-indicator is to ensure that the legislation and institutional regulations provide clear mandates, functions, roles, responsibilities and enforcement powers for each section in order to avoid overlap of the respective empowerments. The same principle is applied if more than one institution is involved, or if different entities at different levels of the state are involved.
Requirement:	Institutions involved in the regulatory system
Evidence to review:	The assessor should request for and review: 1. List of agencies or authorities participating in the regulation of medical products, and the mandate for each. 2. Promulgated legal provisions and regulations establishing the regulatory system and defining the mandate for each of the institutions involved in the regulatory system. 3. Duties, responsibilities, level of competencies, mandates and enforcement powers established for each institution. 4. Documents that demonstrate that the role and scope of each institution is clear to all stakeholders involved, especially when there are complementary or shared responsibilities.
References:	1. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 2. National Drug Regulatory Legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications on Pharmaceutical Preparations: thirty- fifth report. World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885)., (78), (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1

	6. WHO - Good regulatory practices for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_products.pdf
Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There are no legal provisions or regulations defining the institutions involved as part of the regulatory system. ⇒ ONGOING IMPLEMENTATION (OI): There might be legal provisions and regulations defining the institutions involved as part of the regulatory system for some institutions but not all, or although they do not exist, demonstrable steps have been taken towards developing them. ⇒ PARTIALLY IMPLEMENTED (PI): The legal provisions and regulations defining the institutions involved as part of the regulatory system were recently developed as draft but not yet published officially. ⇒ IMPLEMENTED (I): The legal provisions and regulations defining the institutions involved as part of the regulatory system are published and available.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS01.03: When more than one institution or authority is involved in regulatory oversight, the regulations should define administrative arrangements and the channels of communication and coordination.**
Maturity Level:	2
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify the availability and implementation of regulations defining channels of coordination among different institutions when the National Regulatory Authority (NRA) is represented by more than one institution or authority. The assessor should verify that there are well-defined administrative mechanisms for clear coordination among the different institutions in order to

	avoid overlap of the respective empowerments. If different organizations at different levels of the state are involved, the assessor should review how the exchange of information is established and implemented.
Objective:	The objective of this sub-indicator is to ensure that the regulations define mechanisms for communication, coordination and management of regulatory activities and processes when more than one institution or authority is involved in the national regulatory system. If different entities at different levels of the state are involved, the same principle is applied.
Requirement:	Defined channels of coordination and an administrative mechanism
Evidence to review:	The assessor should request for and review: 1. List of agencies or authorities participating in the regulation of medical products and the mandate for each. 2. Published regulations defining the channels of coordination and an administrative mechanism when more than one institution or authority is involved in regulatory activities. 3. Record of communications and other related evidence that shows coordination and proper exchange of information. 4. Identified focal points for the purpose of coordination and exchange of information.
References:	1. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1
Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There are no regulations defining the administrative arrangements and the channels of communication and coordination when more than one institution or authority is involved in regulatory activities. ⇒ ONGOING IMPLEMENTATION (OI): There might be regulations defining the administrative arrangements and the channels of communication and coordination for some institutions or authorities but not for all, or although they do not exist, demonstrable steps have been taken towards developing them. ⇒ PARTIALLY IMPLEMENTED (PI): The regulations defining the administrative arrangements and the channels of communication and coordination were recently developed as draft but not yet published officially. ⇒ IMPLEMENTED (I): The regulations defining the administrative arrangements and the channels of communication and coordination, when more than one institution or authority is involved in regulatory activities, are published and available.
Limitations and remarks:	

Sub Indicator:	**RS01.04: All regulatory entities (central and decentralized ones) follow non- contradictory regulations, standards, guidelines and procedures.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should understand, for the different administrative levels, the policy and administrative organization for each of the organizational structures, as well as their responsibilities and mandates. The assessor should verify if legislation defines whether activities are centralized or whether they have been decentralized to other agencies or authorities (states, provinces, others). If decentralized, assessor should verify that they follow non-contradictory regulations, standards, guidelines, and procedures. Assessor should check the availability and implementation of such non-contradictory regulations, standards, guidelines and procedures in all levels of the regulatory bodies. In addition, there should be a mechanism in place to manage the possible changes to any related regulations, standards, guidelines and procedures. Guidelines for regulatory activities should be developed and/or adopted and regularly updated. All regulatory bodies should apply these guidelines.
Objective:	The objective of this indicator is to ensure that activities conducted by decentralized entities follow updated regulations, standards, guidelines, and procedures that are in agreement with the central authority of the country. This ensures that regardless of the entity or place where regulatory activities are taking place, the same principles and standards will be followed by all relevant parties. It also allows those regulatory bodies to have clarity on their roles and responsibilities.
Requirement:	Updated and non-contradictory regulations, standards, guidelines and procedures for all regulatory bodies.
Evidence to review:	The assessor should request for and review: 1. List of all regulatory bodies(central and decentralized ones) participating in the regulation of medical products and the mandate for each. In case of medical devices including in vitro diagnostics, the assessor should request for a list of testing laboratories and Conformity Assessment Bodies appointed by the NRA or other NRA's in other countries under the same legislation (i.e., regional entities). 2. The legislation and regulations that establish that all regulatory bodies (central and decentralized ones) should follow non-

	contradictory regulations, standards, guidelines, and procedures. 3. The identity of the individual or group responsible for monitoring of adherence to these principles (item2). 4. Documented evidence that procedures and mechanisms are in place to manage changes and inform all involved parties. 5. Documented evidence that procedures and mechanisms are in place to ensure guidelines are developed, regularly updated and available to all regulatory bodies.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1
Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There are no legal provisions or regulations defining that all regulatory entities (central and decentralized ones) follow non-contradictory regulations, standards, guidelines and procedures. ⇒ ONGOING IMPLEMENTATION (OI): There might be legal provision and regulations that regulatory entities (central and decentralized ones) follow non-contradictory regulations, standards, guidelines and procedures for some entities but not all, or although they do not exist, demonstrable steps have been taken towards developing them. ⇒ PARTIALLY IMPLEMENTED (PI): The legal provisions and regulations defining that all regulatory entities (central and decentralized ones) follow non-contradictory regulations, standards, guidelines and procedures were recently developed as draft but not yet published officially. ⇒ IMPLEMENTED (I): The legal provisions and regulations that all regulatory entities (central and decentralized ones) follow non-contradictory regulations, standards, guidelines and procedures are published and available.

Limitations and remarks:	
Sub Indicator:	**RS01.05: Legal provisions and relevant regulations to take actions on recall, suspension, withdrawal, destruction and decommissioning of substandard and falsified (SF) medical products.**
Maturity Level:	1
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify the availability of legal provisions and regulations supporting regulatory enforcement actions related to SF medical products, including recall, suspension, withdrawal, destruction, decommissioning and Field Safety Corrective Actions and field safety notices for medical devices including in-vitro diagnostics. In addition, the assessor should ensure that the NRA has authority to withhold or withdraw products from the market as well as from use in clinical trials.
Objective:	The objective of this indicator is to ensure that adequate provisions and mechanisms exist and have been enacted to handle actions on recall, suspension, withdrawal, destruction, decommissioning of SF medical products. This should include their destruction and a requirement for the manufacturers, distributors, or marketing authorization holders to participate in the recall of unsafe, defective or inappropriately labelled products. In the case of medical devices including, in vitro diagnostics provisions and mechanisms for Field Safety Notices and Field Safety Corrective Actions should be in place. Possible actions include the suspension of a marketing authorization, the recall of certain batches, issuance of warnings in national drugs bulletins, or issuance of a separate warning sent out to a list of institutions and key persons dealing with handling of medical products. NRA should have authority to withdraw products from the market and from clinical development or clinical trials.
Requirement:	Legal provisions and/or regulations for regulatory actions against SF medical products.
Evidence to review:	The assessor should request for and review: 1. Promulgated and enforced legal provisions and regulations to take actions on recall, suspension, withdrawal, destruction and decommissioning of SF medical products. In case of medical devices including in vitro diagnostics assessor should check if there are provisions and regulations for Field Safety Notices and Field Safety Corrective Actions.

	2. Guidance for manufacturers, importers, exporters and distributors on how to handle a recall including product destruction. 3. Procedures for handling quality defects (e.g., notifications of suspected quality defects or batch recalls by the company) and procedure for handling product problems in the case of including, focal points, defined responsibilities, deadlines and records. 4. List of recalls performed and documented reports. For medical devices including in vitro diagnostics, assessor should request for records on FSN and FSCA
References:	1. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 2. Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics, https://apps.who.int/iris/handle/10665/337551 3. IMDRF terminologies for categorized adverse event reporting (AER): terms, terminology structure and codes, Edition 4. http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-200318-ae-terminologies-n43.pdf and it`s updated annexes in Edition 5; http://www.imdrf.org/documents/documents.asp 4. Decommissioning of medical devices WHO Technical Series; 2019 https://apps.who.int/iris/bitstream/handle/10665/330095/9789241517041-eng.pdf?sequence=1&isAllowed=y
Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There are no legal provisions or regulations to take actions on recall, suspension, withdrawal and/or , destruction of SF medical products. Field safety corrective action (FSCA) and field safety notice (FSN) in case of medical devices including in vitro diagnostics ⇒ ONGOING IMPLEMENTATION (OI): There might be some legal provisions and regulations to take actions on recall, suspension, withdrawal and/or destruction of some SF medical products. In case of medical devices including in vitro diagnostics provisions and regulations for Field Safety Notices and Field Safety Corrective Actions. but not all, or although they do not exist, demonstrable steps have been taken towards developing them. ⇒ PARTIALLY IMPLEMENTED (PI): The legal provisions and regulations to take actions on recall, suspension, withdrawal and/or destruction of SF medical products. In case of medical devices including in vitro diagnostics provisions and regulations for Field Safety Notices and Field Safety Corrective Actions were recently developed as draft but not yet published officially. ⇒ IMPLEMENTED (I): The legal provisions and regulations to take actions on recall, suspension, withdrawal and/or destruction of SF medical products. In case of medical devices including in vitro diagnostics provisions and regulations for Field Safety Notices and Field Safety Corrective Actions are published and available.

Limitations and remarks:	▪ See also Market Surveillance and Control (MC) function ▪ See also Regulatory Inspection (RI) function ▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs). ▪ For medical devices, the term destruction may not apply and therefore terminologies such as replacement and decommissioning may be considered depending on manufacturers recommendations.
Sub Indicator:	**RS01.06: Legal provisions and regulations define requirements of transparency and dissemination of information to the public and relevant stakeholders.**
Maturity Level:	2
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should check whether the legal basis requires the mandated institutions to provide information to public and relevant stakeholders. The assessor should verify whether legislation and regulations are publicly available, and that channels of communication exist for this purpose.
Objective:	The objective of this sub-indicator is to ensure that legislation, regulations and other relevant information, such as administrative and regulatory decisions, reports and lists of authorized and unauthorized medical products, are publicly available. This public availability will ensure that those governed by the regulations, as well as society in general, can be aware of the information and utilize it as appropriate. In order to perform adequately and in a timely manner, the NRA should have proper channels of communication in order to respond to the needs, obligations and priorities.
Requirement:	Legal provisions for transparency and dissemination of information.
Evidence to review:	The assessor should request for and review: 1. Laws, regulations, other regulatory provisions, methodologies, and procedures establishing that legislation and regulations are to be made public. 2. Public information from websites or in official bulletins or other legal publications.

	3. Evidence for the availability and use of electronic or other platforms or means that allow external communications regarding the regulations. 4. Direct forms of dissemination such as letters and emails. 5. Documentation of feedback after dissemination and publication (e.g., acknowledgments of receipt, complaints, or questions).
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. Good governance for medicines: Model framework. Updated version 2014. WHO (110) (https://www.who.int/medicines/areas/governance/ggm_modelframe_updated/en/) 6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 7. Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics, https://apps.who.int/iris/handle/10665/337551
Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There are no legal provisions or regulations to define requirements of transparency and dissemination of information to the public and relevant stakeholders. ⇒ ONGOING IMPLEMENTATION (OI): The legal provisions and regulations to define requirements for transparency and dissemination of information to the public and relevant stakeholders were recently developed as draft but not yet published officially and implemented. ⇒ PARTIALLY IMPLEMENTED (PI): The legal provisions and regulation to define requirements for transparency and dissemination of information to the public and relevant stakeholders, and these were recently published and/or implemented.

	⇒ IMPLEMENTED (I): The legal provisions and regulations to define requirements of transparency and dissemination of information to the public and relevant stakeholders are published and available.
Limitations and remarks:	
Sub Indicator:	**RS01.07: Development of the regulations involves the NRA responsible for their implementation and enforcement.**
Maturity Level:	1
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that legislation and regulations ensure that the development of the legal provisions involves the regulatory authority responsible for their implementation and enforcement. The legal provisions also should establish the legal basis for enforcement of such laws and regulations. The purpose of the legislation is therefore the same as that of the drug /medical devices policy: to ensure that only safe, effective, quality drugs and medical devices are produced/manufactured, imported and distributed, and that these products are made available, managed effectively, and used appropriately. When writing the law, the practicalities of future enforcement should be kept in mind. If there are no strategies, facilities and resources for implementation and enforcement, legislation on its own will achieve nothing. A law with modest aims and objectives that is properly enforced is preferable to a more comprehensive one that cannot be implemented. As a good practice, development of the legal provisions should involve the regulatory authority responsible for their implementation and enforcement. In addition, the assessor should check if suitable timelines for the implementation of newly adopted regulations and guidelines are practiced. The suggested timeline for adoption of new internationally recognized guidelines (e.g., guidelines from World Health Organization (WHO) or International Conference on Harmonization or International Medical Devices Regulators Forum) ranges from 6 to 12 months; however, it is recognized that guideline implementation, might be extended over a longer period.
Objective:	The objective of this sub-indicator is to ensure that the development of the legal provisions involves the regulatory authority responsible for their implementation and enforcement. A well-formulated enforcement strategy is one that provides correct incentives for the regulated subjects as well as appropriate guidelines for enforcement. Furthermore, the enforcement strategy should be designed to minimize both the monitoring effort and the costs for the regulated subjects and the public sector. The

	importance of the enforcement phase is to ensure the quality and effectiveness of regulatory policy and delivery, to reduce the overall level of regulatory burdens imposed on businesses and citizens, and to increase incentives for compliance by private actors.
Requirement:	Involvement of the regulatory system in the development of regulations
Evidence to review:	The assessor should request for and review: 1. Legal provisions supporting different regulatory activities; 2. Records of process.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1
Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no evidence that the development of regulations involves the regulatory authority responsible for their implementation and enforcement. ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence but demonstrable steps have been taken towards this. ⇒ PARTIALLY IMPLEMENTED (PI): The regulatory authority responsible for its implementation has developed a draft but it has not yet been promulgated and enforced. ⇒ IMPLEMENTED (I): The regulations are developed with the involvement of the regulatory authority responsible for their implementation and enforcement.

Limitations and remarks:	▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs). ▪ For blood products, the regulations or their adaptations should take into consideration developments in the field of blood and related technologies.
Sub Indicator:	**RS01.08: The NRA consults or involves specific sectors of the civil society (such as non-governmental organizations (NGOs) representing health professionals, industry, consumers and patients) during the development or adoption of regulations and guideline.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify the development and application of a public and civil society consultation process prior to issuance of guidelines related to different regulatory activities. Specifically, assessor should: 1. Check whether the current and applicable legal and methodological bases for the development of regulations in the country require the participation of the NRA, industry, representatives of the health sector, patients, and NGOs. 2. Check whether a procedure/system is established to officially circulate or publish drafts in consultation with the public, the NRA, industry, representatives of the health sector, patients, and NGOs. 3. Assess evidence of how existing regulations were drafted, preferably those that were approved more than one year ago. Evaluate the extent to which they were circulated, and input was received from the NRA, industry, representatives of the health sector, patients, and NGOs. 4. Assess evidence that the time provided for consultation with the public, the NRA, industry, representatives of the health sector, patients, and NGOs was sufficient for review of the guidelines and response to comments. 5. Assess evidence for the existence of suitable timelines for the implementation of newly adopted regulations and guidelines. Preferably, these timelines should be specified in the public consultation process. The suggested timeline for adoption of new internationally recognized guidelines (e.g. WHO and International Conference on Harmonization guidelines, International Medical Devices Regulators Forum (IMDRF)) ranges from 6 to 12 months; however, it is recognized that the guideline implementation might be extended over a longer period.

Objective:	The objective of this indicator is to confirm that the regulations are developed through an interactive and participative process involving, among others, the NRA, industry, representatives of the health sector, patients, and NGOs. Assessor should note that the participants may vary according to the draft regulation or guideline under consideration; however, the consultation process ideally should be open to the public in accordance with good regulatory practices (GRP). As part of an open and transparent public policy, the development of regulations demands the participation of the general public as well as those regulated. From the earliest stages of developing a regulatory provision, consideration must be given to the viewpoints of those who must follow the standards that are set, those who are impacted by them, and those in general society. If regulations are approved without input from the key stakeholders involved, it is doubtful that they will be fully understood or successfully implemented.
Requirement:	Consults or involves specific sectors for the development or adoption of the guidelines
Evidence to review:	The assessor should request for and review: 1. Procedures for public and civil society consultation along with published drafts of guidelines; 2. Laws, regulations, guidelines, methodologies, or procedures establishing how regulations are prepared, who is invited to participate in the process, and who is consulted before approval; 3. Institutional records on the preparation of regulations and consultations carried out.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO - Good regulatory practices for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_pro

	ducts.pdf6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no evidence the NRA consults or involves specific sectors of the civil society (such as NGOs representing health professionals, industry, consumers and patients) during the development or adoption of regulations and guidelines. ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence but demonstrable steps have been taken towards this. ⇒ PARTIALLY IMPLEMENTED (PI): The regulatory authority responsible for its implementation has developed a draft but it has not yet been promulgated and enforced. ⇒ IMPLEMENTED (I): There is documented evidence the NRA consults or involves specific sectors of the civil society (such as NGOs representing health professionals, industry, consumers and patients) during the development or adoption of regulations and guidelines.
Limitations and remarks:	▪ The participation of all parties identified will vary depending on the type of regulation. The assessor should be mindful of why some may be excluded from the process for certain regulations. ▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS01.09: A guideline on complaints and appeals against regulatory decisions is available to the public.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should review if the possibility to appeal regulatory decisions, including those related to enforcement and inspection activities, is a fundamental aspect of the law. An efficient and effective enforcement system must provide readily accessible and transparent means for receiving complaints and appeals against regulatory decisions.

	The NRA should have implemented guidelines on review, evaluation, communication of complaints and appeals against regulatory decisions.
Objective:	The objective of this sub-indicator is to ensure that a mechanism exists to appeal regulatory decisions.
Requirement:	Complaints and appeals against regulatory decisions
Evidence to review:	The assessor should request for and review: 1. Guidelines for complaints and appeals related to different regulatory decisions.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf 5. MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization: IMDRF 2014http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-assessment-decision-process-141013.pdf#search=%22complaints%22 6. WHO -Good regulatory practices 6 for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_products.pdf 7. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1
Framework:	Structure/Foundation/Input

Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no guideline available on complaints and appeals against regulatory decisions. ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence of a guideline on complaints and appeals against regulatory decisions, but demonstrable steps have been taken towards its development. ⇒ PARTIALLY IMPLEMENTED (PI): There is a draft guideline on complaints and appeals against regulatory decisions but it is not yet implemented. ⇒ IMPLEMENTED (I): There is a documented and implemented guideline on complaints and appeals against regulatory decisions.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS01.10: Legal provision and/or regulations provides for classification and reclassification of medical devices and IVDs based on the associated potential harm and impact**
Maturity Level:	1
Scope:	Medical devices including in vitro diagnostics
Rationale	The universe of medical devices is diverse with wide variations in potential severity of harm to the patient or user. The risk class of a medical device is determined by factors such as level of invasiveness and the duration of the use in the body. The risk class of an IVD is determined primarily by the impact of an incorrect result, either on the health of the individual or on public health. The NRA allocates its resources and imposes controls proportional to the potential for harm associated with medical devices.
Description:	The assessor should identify within the existing legislation whether a scheme exists that defines the medical devices classification including a scheme for IVDs. Classification should also consider the technical, scientific and medical expertise of the intended user (layperson or healthcare professional). For IVDs, the risk classification depends both on the risk for the individual and for public health. The legislation should provide for a procedure for reclassification or adjustment of the classification rules of medical devices including IVD where appropriate.
Objective:	The objective of this sub-indicator is to ensure that the law includes a medical device classification scheme, based on internationally harmonized practice, to prove an efficient way of regulating each medical device according to its risk class. It should include

	provisions for the NRA to issue implementing acts and guidance on the classification of medical devices including IVDs. The manufacturer is responsible for determining the class of its devices and its decision may be challenged by the NRA.
Requirement:	Legal provision and/or regulations provides for classification and reclassification of medical devices and IVDs based on the associated potential harm and impact
Evidence to review:	The assessor should request for and review: 1. Promulgated legal provisions and regulations that define classification schemes for medical devices including IVDs.
References:	1. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 2. Principles of Medical Devices Classification. GHTF/SN77:2012 http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf 3. Principles of In Vitro Diagnostic (IVD) Medical Devices Classification, GHTF/SG1/N045:2008 http://www.imdrf.org/docs/ghtf/final/sg1/procedural-docs/ghtf-sg1-n045-2008-principles-ivd-medical-devices-classification-080219.pdf#search=%22risk%20classification%20IVD%22 (a new version is currently published for public consultation) 4. Development of medical device policies" https://apps.who.int/iris/bitstream/handle/10665/44600/9789241501637-eng.pdf?sequence=1&isAllowed=y
Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There are no legal provisions or regulations defining classification schemes for medical devices including IVDs ⇒ ONGOING IMPLEMENTATION (OI): There are some legal provisions and regulations for classification or although they do not exist, demonstrable steps have been taken towards developing them. ⇒ PARTIALLY IMPLEMENTED (PI): The legal provisions and regulations defining classification schemes for medical devices including IVDs were recently developed as draft but not yet promulgated and enforced. ⇒ IMPLEMENTED (I): The legal provisions and regulations defining a classification schemes for medical devices including IVDs are promulgated and enforced and include options for reclassification.
Limitations and remarks:	▪ In a short time, it may not be possible for the assessor to review all aspects that this indicator includes. Preferably the country profile or other documents that provide a good description of the regulatory landscape in the country should be studied beforehand.

	▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS01.11: Legal provision and /or regulations provides for development of classification rules or adoption of such rules from internationally accepted guidance documents.**
Maturity Level:	1
Scope:	1. Medical devices including in vitro diagnostics
Rationale	It is widely accepted that medical devices including IVDs are separable into groups or classes, typically four, A, B, C and D, by applying a set of classification rules, and specifying separately the different conformity assessment procedures that should apply to each group of devices.
Description:	The assessor should identify the existing legislation and/or guidelines that define classification rules. The classification rules for medical devices depend on the features of the device. For IVDs, the risk classification depends both on the risk for the individual and for public health. The regulatory authority may develop explanatory guidance to help a manufacturer apply the rules. While the manufacturer has the primary obligation to classify its medical device, its decision may be challenged by the regulatory authority
Objective:	The objective of this sub-indicator is to ensure that legislation and/or guidelines define rules for the classification of medical devices including in-vitro diagnostics in accordance with harmonised (e.g. IMDRF) definitions that provide for different conformity assessment procedures for a manufacturer of these devices.
Requirement:	Classification rules for medical devices including IVDs
Evidence to review:	The assessor should request for and review: 1. Promulgated legal provisions and /or that describe the classification rules for determining the risk class of a medical device including IVDs according to harmonized definitions.
References:	1. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 2. Principles of Medical Devices Classification. GHTF/SN77:2012 p:// httwww.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf 3. Principles of In Vitro Diagnostic (IVD) Medical Devices Classification, IMDRF/IVD WG/N64/FINAL :2021http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-wng64.pdf

	4. Development of medical device policies https://apps.who.int/iris/bitstream/handle/10665/44600/9789241501637-eng.pdf?sequence=1&isAllowed=y 5. Global Medical Devices Nomenclature System (GMDN); www.gmdnagency.org
Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There are no legal provisions and/or guidance defining classification rules for medical devices including IVDs according to their risk class. ⇒ ONGOING IMPLEMENTATION (OI): There are some legal provisions and/or guidance or although they do not exist, demonstrable steps have been taken towards developing them. ⇒ PARTIALLY IMPLEMENTED (PI): The legal provisions and/ or guidance defining classification rules for medical devices including IVDs according to their risk class were recently developed as draft but not yet promulgated and enforced. ⇒ IMPLEMENTED (I): The legal provisions and/or guidance defining classification rules for medical devices including IVDs according to their risk class are promulgated and enforced.
Limitations and remarks:	▪ In a short time, it may not be possible for the assessor to review all aspects that this indicator includes. Preferably the country profile or other documents that provide a good description of the regulatory landscape in the country should be studied beforehand. ▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS01.12: Policy, regulations and or guidelines on reprocessing of single use medical devices**
Maturity Level:	1
Scope:	Medical devices excluding in vitro diagnostics
Rationale	A single-use medical device (SUMD) is intended to be used on an individual patient during a single procedure and then disposed of. SUMDs are designed and labelled for single use. They do not come with an appropriate instruction for cleaning, disinfecting or sterilization procedures after use and the manufacturer has not investigated any deterioration in performance if they are subject to reprocessing. The reprocessing of SUMDs should ensure an equivalent level of safety and performance to that of the corresponding initial SUMD following each reprocessing process.
Description:	The assessor should verify that a policy, regulations and/ or guidelines on the reprocessing of SUMDs is in place by the NRA. The NRA policy, regulation or guideline should be clear with regards to allowance or prohibition of reuse of SUMDs. If

	reuse of SUMDs is principally possible as per the NRA policies, regulations or guidelines, the regulatory authority should consider the following: reprocessing of a SUMD as labelled by its manufacturer is not permitted unless the reprocessed SUMD meets the same initial standards as those of the original manufacturer. To allow their reuse, the entity that reprocesses and distributes medical devices labelled by their original manufacturer for single-use only will be subject to the same requirements of safety, quality and performance as manufacturers of new devices. This applies equally to a health-care facility fully reprocessing SUMDs for reuse within its own facility.
Objective:	The objective of this sub-indicator is to ensure that the policy, regulations and/ or guidelines on reprocessing SUMD should only be permitted after appropriate risk–benefit analyses are performed on the potential risks.
Requirement:	Legislation, policy and/or guidelines on reprocessing of SUMDs
Evidence to review:	The assessor should request for and review: 1. Promulgated policy, regulations and/ or guidelines that define reprocessing of SUMDS
References:	1. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 2. Australian regulatory guidelines for medical devices (ARGMD), Single use devices (SUMDs), and the reuse of SUMDs. https://www.tga.gov.au/sites/default/files/devices-argmd-01.docx 3. Regulation (EU) 2017/745 of the European Parliament and the Council on medical devices. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745 4. Reprocessing of Single-Use Devices. USFDA Archived content. http://wayback.archive-it.org/7993/20170111015341/http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/default.htm 5. Notice to Stakeholders- Health Canada's Regulatory Approach to Commercial Reprocessing of Medical Devices Originally Labelled for Single Use. 2016. https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/update-notice-stakeholders-regulatory-approach-commercial-reprocessing-medical-devices-originally-labelled-single-use.html

	6. Reprocessing and reuse of single-use medical devices in China: a pilot survey. British Medical Journal Public Health, 19, 461 (2019) //bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-019-6835-9 7. Development of medical device policies" https://apps.who.int/iris/bitstream/handle/10665/44600/9789241501637-eng.pdf?sequence=1&isAllowed=y
Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There are no legal provisions, policy, regulations and/ or guidelines s defining the conditions for the reprocessing of SUMDs ⇒ ONGOING IMPLEMENTATION (OI): There are some legal provisions, policy, regulations and/ or guidelines for the reprocessing of SUMDs or although they do not exist, demonstrable steps have been taken towards developing them. ⇒ PARTIALLY IMPLEMENTED (PI): The legal provisions and regulations defining the conditions for the reprocessing of SUMDs the were recently developed as draft but not yet promulgated and enforced. ⇒ IMPLEMENTED (I): The legal provisions and regulations defining the conditions for the reprocessing of SUMDs
Limitations and remarks:	▪ In a short time, it may not be possible for the assessor to review all aspects that this indicator includes. Preferably the country profile or other documents that provide a good description of the regulatory landscape in the country should be studied beforehand. ▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS01.13: Policy, regulations and/ or guidelines on refurbishment of medical devices**
Maturity Level:	1
Scope:	Medical devices excluding in vitro diagnostics
Rationale	Some medical devices, typically durable electromedical devices, are meant to be reused many times over a long design life. Refurbishing can be described as a restoration of a device to a condition of safety and performance that is comparable to its condition when new. This includes reconditioning, repair, installation of certain software and/or hardware updates that do not change the intended use of the original device, and replacements of worn parts. In adopting a policy on refurbishing, the regulatory authority

	should clearly state that the entity responsible for refurbishing or third party must meet the same requirements for safety and performance as applied to the original medical device.
Description:	The assessor should verify that a policy, a regulation and/ or a guideline on the refurbishing of medical devices is in place. The policy, regulation or guidelines should describe the conditions for refurbishing medical devices and assigns responsibility to either the original manufacturer or an entity or organization that refurbishes the medical device.
Objective:	The objective of this sub-indicator is to ensure that the policy, regulations and/ or guidelines on the refurbishment of medical devices should be enacted.
Requirement:	Legislation, policy and/or guidelines on refurbishing of medical devices
Evidence to review:	The assessor should request for and review: 1. Promulgated policy, regulations and/ or guidelines that define the conditions for refurbishing medical devices.
References:	1. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 2. Development of medical device policies" https://apps.who.int/iris/bitstream/handle/10665/44600/9789241501637-eng.pdf?sequence=1&isAllowed=y 3. Regulatory Framework for control of refurbished medical devices; Asia Pacific Economic Cooperation; 2012
Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There are no legal provisions, policy, regulations and/ or guidelines defining the conditions for refurbishing medical devices. ⇒ ONGOING IMPLEMENTATION (OI): There are some legal provisions, policy, regulations and/ or guidelines or although they do not exist, demonstrable steps have been taken towards developing them. ⇒ PARTIALLY IMPLEMENTED (PI): The legal provisions and regulations defining the conditions for refurbishing medical devices were recently developed as draft but not yet promulgated and enforced. ⇒ IMPLEMENTED (I): The legal provisions and regulations defining the conditions for refurbishing medical devices are promulgated and enforced

Limitations and remarks:	▪ In a short time, it may not be possible for the assessor to review all aspects that this indicator includes. Preferably the country profile or other documents that provide a good description of the regulatory landscape in the country should be studied beforehand. ▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Indicator:	**RS02 Arrangement for effective organization and good governance.**
Objective:	The objective of this indicator is to ensure that arrangements for effective organization and good governance are in place. Good governance is an essential factor for economic growth and sustainable development at all levels and within all sectors of society. The term Good Governance is increasingly used to emphasize the need for governance to operate with due regard for the rule of law and especially in a manner that is free of corruption. There is also growing consensus on the major characteristics of good governance. Good governance is participatory, consensus-oriented, accountable, transparent, responsive, effective, efficient, equitable, inclusive, and follows the rule of law.
Category:	02. Organization and governance
Sub Indicator:	**RS02.01: The structure and line of authority among, and within, all institutions that participate in the regulatory system is defined, documented and implemented.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that legislation or institutional regulation defines the structure and line of authority among, and within, all institutions that participate in the regulatory system. If more than one institution is involved, the legislation or institutional regulation should provide for clear coordination and avoid overlap of the regulatory activities. If different organizations at different level of the state are involved, the assessor should review the linkage among the organizations and evaluate how the exchange of information is established and implemented.

Objective:	The objective of this sub-indicator is to ensure that the structure and line of authority among, and within, all institutions that participate in the regulatory system is implemented to ensure coordination and to avoid overlap of the respective empowerments.
Requirement:	Structure and line of authority
Evidence to review:	The assessor should request for and review: 1. Institutional founding documents along with evidence of implementation through procedures and respective records; 2. Organizational chart of NRA; 3. Procedures and human resources record forms of members and staff of the authority, their terms of reference and duration of office.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. Good governance for medicines: Model framework. Updated version 2014. WHO (110) (https://www.who.int/medicines/areas/governance/ggm_modelframe_updated/en/) 6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 7. WHO -Good Regulatory Practices for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_products.pdf
Framework:	Structure/Foundation/Input

Rating Scale:	⇒ NOT IMPLEMENTED (NI): The structure and line of authority among, and within, all institutions that participate in the regulatory system is not defined, documented and implemented. ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence that the structure and line of authority among, and within, all institutions that participate in the regulatory system are defined, documented and implemented but demonstrable steps have been taken towards its development. ⇒ PARTIALLY IMPLEMENTED (PI): There is a draft defining the structure and line of authority among, and within, all institutions that participate in the regulatory system but it is not yet implemented. ⇒ IMPLEMENTED (I): The structure and line of authority among, and within, all institutions that participate in the regulatory is defined, documented and implemented.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS02.02: Channels of communication and decision-making are clearly established among the structures, institutions, and departments forming the NRA.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify the existence and the actual use of communication and decision makings channels among different structures, institutions, and departments forming the NRA.
Objective:	The objective of this sub-indicator is to ensure that channels of communication and decision-making are clearly established among the structures, institutions, and departments forming the NRA. Supporting documentation should include the definitions for roles and responsibilities for each section, mechanisms for communication and coordination, and protocols for information and resource sharing. Collaborative agreements can assist in avoiding overlap and the duplication of efforts.
Requirement:	Presence of communication and decision-making channels

Evidence to review:	The assessor should request for and review: 1. Documentation for communication channels and decision making process among the structures, institutions, and departments; 2. Evidence of implementation through procedures and respective records.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1
Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): Channels of communication and decision-making are not clearly established among the structures, institutions, and departments that form the NRA. ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence that channels of communication and decision-making are established among the structures, institutions, and departments that form the NRA, but demonstrable steps have been taken towards their development. ⇒ PARTIALLY IMPLEMENTED (PI): There is a draft defining channels of communication and decision-making among the structures, institutions, and departments that form the NRA, but it is not yet implemented. ⇒ IMPLEMENTED (I): Channels of communication and decision-making among the structures, institutions, and departments that form the NRA are clearly defined, documented and implemented.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

Sub Indicator:	**RS02.03: Scientific and advisory committees exist to advise the NRA on topics of scientific and regulatory interest and on future objectives and strategies.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that: 1. there are legal provisions granting the NRA authority to convene outside experts and committees; 2. the scope of existing legal provisions authorizes the NRA to determine: a. the functions of the outside experts and committees; b. their role in the decision-making process; c. the circumstances under which they should be convened; 3. the NRA uses this authority to convene outside experts and committees
Objective:	The objective of this indicator is to ensure that the legal basis exists to convene outside experts and expert committees, to define their functions, (in particular, their role in the NRA decision-making process) and to define the circumstances under which they should be convened. Science and technology are evolving at a dizzying pace. Therefore, issues must be handled by multidisciplinary teams and it is impossible for the NRAs to have all the expertise needed to handle all issues. For this reason, it is highly recommended to have external experts and committees of experts available to help with the regulatory decision-making process. Nevertheless, advisory and scientific committees should not be considered as mandatory for the regulatory work. In this context, it should be noted that advisory and scientific committees add financial and administrative burden on the regulatory system. Legislation should give the NRA the authority to convene them in well-defined circumstances.
Requirement:	Scientific/advisory committees
Evidence to review:	The assessor should request for and review: 1. Laws, regulations, decrees, agreements, and other legal provisions conferring authority on the NRA to convene outside experts and

	expert committees, to define their functions, especially in the decision-making process, and to define the circumstances under which they should be convened. 2. Records, proceedings, and any other documents showing that the NRA makes use of the authority granted by the legislation.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1
Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): Scientific and advisory committees to advise the NRA on topics of scientific and regulatory interest and future objectives and strategies are not used or documented. ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence that scientific and advisory committees to advise the NRA on topics of scientific and regulatory interest and future objectives and strategies are used but demonstrable steps have been taken towards their implementation. ⇒ PARTIALLY IMPLEMENTED (PI): There is a draft defining scientific and advisory committees to advise the NRA on topics of scientific and regulatory interest and future objectives and strategies, but it is not yet implemented. ⇒ IMPLEMENTED (I): Scientific and advisory committees to advise the NRA on topics of scientific and regulatory interest and future objectives and strategies are used and documented.
Limitations and remarks:	▪ Advisory and scientific committees composed of external or internal experts should not be considered as mandatory for the regulatory work. Therefore, if there is a duly documented political or legal decision against the participation of outside experts

	and committees (e.g., due to their administrative or financial burden), this indicator should be rated Not Applicable. However, in this case, which is exceptional, the assessor should verify the availability of internal personnel with the expertise needed to take over the required regulatory activities without the need for internal or external expert committees. Availability of terms of reference for experts and expert committees would provide additional guidance to the assessor.
Sub Indicator:	**RS02.04: Independence of NRA from researchers, manufacturers, distributors and wholesalers, as well as from the procurement system.**
Maturity Level:	2
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should identify documented evidence that demonstrates the independence of NRA decision-making from researchers, manufacturers, distributors, wholesalers, procurement institutions and economic operators (in the case of medical devices including IVDs) and other government /non-government entities involved in acquiring different medical products. For example, the control laboratory of a manufacturer must not perform the quality testing on behalf of the NRA when quality testing is deemed necessary by the NRA (e.g. for the purpose of post-marketing surveillance or NRA lot release, if applicable). Another example is that the decision-making bodies should not include or be influenced by experts who represent institutions interested in marketing of medical products. If the Ministry of Health or other governmental authority is responsible for procuring medical products in the country, documented evidence should be provided that NRA decision- making is independent from the organization or office that is responsible for procuring the products. Aspects to consider when assessing whether the objectives of the indicator have been met: 1. Determine whether the duties assigned to the NRA include research, manufacture, or distribution of medical products and economic operators (in the case of medical devices including IVDs) and other government /non-government entities 2. Examine the hierarchical level of the NRA and verify that the NRA is independent of those involved in research, manufacturing, and distribution of product as well as from the procurement system.
Objective:	The objective of this indicator is to ensure that, consistently over time, the NRA operates independently of researchers, producers, distributors and other regulated parties. In order to discharge its duties fairly, the NRA must be independent of those regulated entities. Thus, the NRA may not be engaged in

	the activities that it regulates and may not be at a hierarchical level that is subordinate to those institutions that perform regulated activities. In some countries, the NRA historically has been responsible for manufacturing vaccines, which placed the NRA in the position of being judge and party to the matters before it, and thus compromising its independence and impartiality. Independence of the NRA decision-making process from influence by institutions, societies, and industries which may have direct or indirect interest in the NRA decisions is one of the key elements regarding the safe use of medical products and protection of public health.
Requirement:	Independence of NRA
Evidence to review:	The assessor should request for and review: 1. Organizational chart of the national regulatory system; 2. Functioning organizational chart of the NRA; 3. Documents defining mission and functions of the organizations within the national regulatory system.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 6. WHO - Good regulatory practices 6 for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_products.pdf

Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no evidence that the NRA is independent from researchers, manufacturers, distributors and wholesalers, as well as from the procurement system. ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence that the NRA is independent from researchers, manufacturers, distributors and wholesalers, as well as from the procurement system; however, demonstrable steps toward this have been taken. ⇒ PARTIALLY IMPLEMENTED (PI): There is evidence that some steps have been taken to establish the independence of NRA from researchers, manufacturers, distributors and wholesalers, as well as the procurement system, but it is not yet implemented. ⇒ IMPLEMENTED (I): There is documented evidence the NRA is independent from researchers, manufacturers, distributors and wholesalers, as well as from the procurement system.
Limitations and remarks:	▪ In case the manufacturer is part of the structure of the National Regulatory System, this must be taken into consideration when evaluating the independency. ▪ It is important to maintain good collaboration and communication between industry and academia while maintaining the independence of the regulatory system. Regulatory authorities (including national control laboratories) may be involved in scientific research activities. However, these research activities should not entail any conflict of interest with respect to regulatory oversight. Internal researchers with no conflicts of interest are not meant to be addressed by this sub-indicator and scoring the sub-indicator as "not implemented" should be excluded (unless justified for some other reason). On the other hand, if the regulatory authority is involved in research activities which conflict with the mandate to regulate medical products, the sub-indicator should be scored as “not implemented”. ▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Indicator:	**RS03 Strategic plan with clarified objective in place**
Objective:	The objective of this indicator is to ensure that the NRA has implemented and updated its strategic plan, including general objectives that are broken down into specific targets for various regulatory functions, and that are provided with defined time periods for implementation. The NRA should also ensure that adherence to the strategic plan is monitored periodically. Based on its mission and vision, and in accordance with the government’s policy, the NRA should adopt a coherent development strategy, update the strategy periodically, and monitor its implementation. This requires the availability of a detailed institutional development plan, including targets and deadlines, which complements the NRA strategy as stated in the NRA strategic plan. Setting an NRA strategy involves a complex process of development, implementation and monitoring. First, the strategy development process results in the formulation of the strategic plan. Second, activities aimed at achieving strategic objectives are implemented by

	the various entities of the NRA. Finally, the effect of these activities is monitored, and the regulatory work is adjusted if necessary. Throughout the process, careful planning and the involvement of the related parties are needed; at all times, the political dynamics have to be considered. A strategic plan without an implementation plan (also called institutional development plan) remains a dead document. Careful planning of the implementation steps and activities necessary to arrive at the expected outcome is important throughout the process. As evident, there are various types of plans. The first is probably the strategic plan (which may come under a higher national policy) to develop the strategic objectives themselves. After the strategic plan has been adopted, an implementation plan is needed; this implementation plan typically covers a 3 to 5-year period. This plan details the various activities for each of the strategic objectives. The implementation plan spells out what needs to be done and who is responsible, and then estimates the budget and proposes a time frame. If resources are insufficient without external input, a set of priority activities should be identified that can be executed within the existing resources. The implementation plan can be broken down into individual annual work plans for the NRA as a whole, or for the various units and departments.
Category:	03. Policy and strategic planning
Sub Indicator:	**RS03.01: A national medicines/medical devices policy, aligned with health policy, exists and is implemented.**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify the existence of national medicines /medical devices policy. A national medicines /medical devices policy, presented and printed as an official government statement, is important because it acts as a formal record of aspirations, aims, decisions and commitments. Without such a formal policy document, there may be no general overview of what is needed. As a result, some government measures may conflict with others, because the various goals and responsibilities are not clearly defined and understood. The policy document should be developed through a systematic process that incudes consultation with all interested parties. In this process the objectives must be defined, priorities must be set, strategies must be developed, and commitments must be built. A national medicines /medical devices policy cannot be developed in a vacuum; it must fit within the framework of a particular health care system, a national health policy and, perhaps, a programme of health sector reform. The goals of the national

	medicines /medical devices policy should always be consistent with broader health objectives, and policy implementation should help to achieve those broader objectives.
Objective:	The objective of this sub-indicator is to ensure that a national medicines /medical devices policy aligned with the health policy exists and it is implemented. A national medicines /medical devices policy is a commitment to a goal and a guide for action. It defines and prioritizes the medium to long-term goals set by the government for the pharmaceutical/medical devices sector and identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical/medical devices sector can be coordinated. The policy covers both the public and the private sectors and involves all the main actors in the pharmaceutical/medical devices field. A national drug/medical devices policy is needed for many reasons. The most important are: to present a formal record of values, aspirations, aims, decisions and medium to long-term government commitments; to define the national goals and objectives for the pharmaceutical /medical devices sector; to set priorities; to identify the strategies needed to meet those objectives; to identify the various actors responsible for implementing the main components of the policy; and to create a forum for national discussions on these issues.
Requirement:	National medicines policy/National medical devices policy
Evidence to review:	The assessor should request for and review: 1. National medicines policy; 2. National health policy; 3. National medical device policy; 4. Evidence for implementation of the drug/medical devices policy.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf)

	4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. Development of medical device policies" https://apps.who.int/iris/bitstream/handle/10665/44600/9789241501637-eng.pdf?sequence=1&isAllowed=y. 6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1
Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): A national medicines//medical devices policy, aligned with health policy is not defined, documented and implemented. ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence that a national medicines/medical devices policy, aligned with health policy, exists and is implemented but demonstrable steps have been taken towards its development. ⇒ PARTIALLY IMPLEMENTED (PI): There is a draft defining a national drug policy, aligned with health policy but it is not yet implemented. ⇒ IMPLEMENTED (I): A national drug policy, aligned with health policy is defined, documented and implemented.
Limitations and remarks:	▪ National drug/policy is the term broadly used, however national medicines policy and medical devices policy can also exist. ▪ In some countries the national medicines /medical devices policy can go to the cabinet or parliament for endorsement. In others, the policy will remain an administrative document that serves as a basis for implementation plans and changes in the law and regulations. In some countries the entire national drug policy document has become law. Although this is a powerful demonstration of political commitment, it can also cause problems, as future adjustments to the policy may become difficult. It is therefore recommended that only certain enabling components of the policy are incorporated into law, without too many operational details. ▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS03.02: The NRA has established and declared its vision, mission and strategic priorities.**
Maturity Level:	2

Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify: 1. The existence of legal provisions establishing that the NRA must have a Board, Management Committee, or administrative leadership body. 2. That the functions of the Board, Management Committee or administrative body include the establishment and/or adoption of strategic development plans, including its vision, mission and strategic priorities. 3. That such an administrative body exists in practice, that the administrative body is functioning, and that it approves and monitors the institution's strategic development plans, its vision, mission and strategic priorities.
Objective:	The objective of this sub-indicator is to ensure that the NRA has established and declared its vision, mission and strategic priorities. The general objectives of the national drug policy are access, quality and objective use. The policy should balance the various goals and objectives, and thus create a complete and consistent entity. For example, one objective is to provide access to assured source of medicines. Additionally, strategic development plans set out the means to achieve short, medium, and long-term goals, and to channel resources and activities toward achievement of same.
Requirement:	Vision, mission and strategic priorities
Evidence to review:	The assessor should request for and review: 1. Published or unpublished legal provisions on the leadership levels within the NRA; 2. Records, for the last three-time periods, of the proceedings of the administrative body that is responsible for adopting the institution's strategic development plans; 3. Strategic development plans 4. Organizational chart or other NRA document describing the Board or other administrative body.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2),

	(http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 2. Development of medical device policies" https://apps.who.int/iris/bitstream/handle/10665/44600/9789241501637-eng.pdf?sequence=1&isAllowed=y. 3. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1
Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): The NRA has not established and declared its vision, mission and strategic priorities. ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence that the NRA has established and declared its vision, mission and strategic priorities but demonstrable steps have been taken towards its development. ⇒ PARTIALLY IMPLEMENTED (PI): There is a draft document defining the NRA vision, mission and strategic priorities. ⇒ IMPLEMENTED (I): There is documented evidence that the NRA has established and declared its vision, mission and strategic priorities.
Limitations and remarks:	▪ The terminology for collegial administrative bodies and institutional strategic development plans may vary from country to country. ▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS03.03: A plan for achieving strategic objectives is developed, implemented and regularly updated.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs)

	4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that: 1. There are institutional strategic development plans and that they are updated (check last three versions or past three years). 2. The plan contains general and specific objectives, includes all basic regulatory functions, and establishes deadlines for carrying out actions or achieving expected results. 3. There is periodic monitoring of compliance with the plan.
Objective:	The objective of this indicator is to ensure that the NRA has implemented and updated its development plan, including the plan's general objectives that define specific targets and time periods for various regulatory functions. The NRA should also ensure that adherence to the development plan is monitored periodically. Based on its mission and vision, and in accordance with the government's policy, the NRA should adopt a coherent development strategy that is periodically updated and should then monitor its implementation. This requires the existence of an institutional development plan, as well as a strategy, including targets and deadlines, for following the plan.
Requirement:	Plan for achieving and updating strategic objectives
Evidence to review:	The assessor should request for and review: 1. The NRA's institutional development plans and their updates; 2. The NRA's annual plans; 3. Documents that describe the general and specific objectives and indicators; 4. periodic reports on compliance with the plans and objectives (which should be completed on at least an annual basis).
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf)

	4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. Development of medical device policies" https://apps.who.int/iris/bitstream/handle/10665/44600/9789241501637-eng.pdf?sequence=1&isAllowed=y. 6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1
Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): The NRA has not developed, implemented or regularly updated a plan for achieving strategic objectives. ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence that the NRA has developed, implemented or regularly updated a plan for achieving strategic objectives, but demonstrable steps have been taken towards its development. ⇒ PARTIALLY IMPLEMENTED (PI): There is a draft document defining a plan for achieving strategic objectives. ⇒ IMPLEMENTED (I): There is documented evidence that the NRA has developed, implemented and regularly updated a plan for achieving strategic objectives.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS03.04: Documented policies, procedures and mechanisms, including written criteria, are established for recognition and reliance on decisions of other NRAs (if applicable).**
Maturity Level:	2
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should identify if there are provisions or written criteria for recognition and reliance on other NRAs. The assessor should check the criteria, provisions, procedures, and decision-making processes related to this recognition process, along with a list of recognized NRAs.

Objective:	The objective of this sub-indicator is to ensure there are documented policies, procedures and mechanisms in place for recognition and reliance on other NRAs. For example, some countries will not have the mechanisms and resources that enable them to assess the medicines applications with their own expertise; such countries may use a system or mechanism of recognizing decisions of other NRAs. In that case the country may recognize certificates, reports or decisions from the foreign NRA (e.g. in the country of origin of the product) or from the WHO prequalification process. Other examples may include the functions such as regulatory inspections, clinical trials oversight, and lot release. If this is the case, the assessor should verify that written provisions and procedures are established that define who is allowed to recognize decisions, reports or certificates from other authorities. For this purpose, the NRA should create a list of the NRAs that may be recognized.
Requirement:	Recognition and reliance on other NRA's decisions
Evidence to review:	The assessor should request for and review: 1. Documentation for the mechanisms and procedures for recognition and reliance on other NRA's decisions; 2. Documentation for the policy that defines the criteria for recognition of foreign NRA inspections or regulatory decisions; 3. A list of recognized NRAs and supporting records.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO Good reliance practices in regulatory decision-making: high-level principles and recommendations https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS20_851_good_reliance_practices.pdf?ua=1 6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1

Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): The NRA has not established documented policies, procedures and mechanisms with written criteria for recognition and reliance on other NRA's decisions (if applicable). ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence that the NRA has established documented policies, procedures and mechanisms with written criteria for recognition and reliance on other NRA's decisions (if applicable) but demonstrable steps have been taken towards its development. ⇒ PARTIALLY IMPLEMENTED (PI): There is a draft document defining documented policies, procedures and mechanisms with written criteria for recognition and reliance on other NRA's decisions (if applicable). ⇒ IMPLEMENTED (I): There is documented evidence that the NRA has developed, implemented and regularly updated documented policies, procedures and mechanisms, with written criteria, for recognition and reliance on other NRA's decisions (if applicable).
Limitations and remarks:	If the country has enough resources to conduct all regulatory oversight with internal resources, this sub-indicator can be scored as not applicable.
Sub Indicator:	**RS03.05: The NRA is promoting good regulatory practices (GRPs)**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should evaluate if the NRA promotes, establishes and applies the principles of GRP to the regulation of medical products in different functions and areas. The principles on which regulatory systems may be established and by which they may be evaluated are legality, impartiality, consistency, proportionality, flexibility, effectiveness, efficiency, clarity and transparency.
Objective:	The objective of this sub-indicator is to ensure the NRA applies the principles of GRP to the regulation of medical products. GRPs are built on a foundation of transparency, good governance and sound policy-making. Public confidence in health products depends on confidence in the integrity of regulatory oversight. In order to meet their objectives of promoting and protecting public health,

	national regulatory authorities need to carry out their functions based on this set of principles. GRPs help to ensure that national regulatory systems, and international regulatory cooperation programmes, remain relevant, current and flexible as technology evolves and unforeseen needs and emergencies occur.
Requirement:	GRP
Evidence to review:	The assessor should request for and review: 1. Policies and regulations outlining the application of the principles of GRPs in the oversight of medical products; 2. Documents that provide examples of the application of the principles of GRPs.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. Good regulatory practices: guidelines for national regulatory authorities for medical products., (112), (http://digicollection.org/whoqapharm/p/about/) and (http://apps.who.int/medicinedocs/en/) 6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 7. WHO Good Reliance Practices in regulatory decision-making: high-level principles and recommendations https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS20_851_good_reliance_practices.pdf?ua=1 8. WHO - Good regulatory practices for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_products.pdf

	9. Building an Institutional Framework for Regulatory Impact Analysis (RIA): Guidance for Policy Makers Version 1.1 2008 Regulatory Policy Division Directorate for Public Governance and Territorial Development. https://www.oecd.org/regreform/regulatory-policy/40984990.pdf
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): The NRA is not promoting the principles of GRP. ⇒ ONGOING IMPLEMENTATION (OI): There is no documented evidence the NRA is promoting the principles of GRP, but demonstrable steps have been taken towards its development. ⇒ PARTIALLY IMPLEMENTED (PI): There is a draft document defining the principles of GRP. ⇒ IMPLEMENTED (I): There is documented evidence that the NRA is promoting and applying accepted principles of GRP.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Indicator:	**RS04 Regulatory system is supported with leadership and crisis management plans**
Objective:	The objective of this indicator is to ensure that national regulatory authorities have the appropriate tools and institutional framework for co-coordinated action for management of crises. Getting a clear operational picture of the development of the crisis is the basis for decision-making both at operational and strategic levels. What happened, how many people are or might be affected, what are the issues at stake, how might the crisis develop, and what are the means in the operational field are a series of questions that leadership needs for making decisions. The complexities of modern crises often require the involvement of many actors, above and beyond emergency services. This approach demands effective coordination for a successful outcome. The need for coordination also raises significant public governance challenges, as crisis management functions are often exercised at sub-national levels but coordinated at the centers of governments. The capacity to coordinate crisis management is a fundamental element of good governance, as it tests the government's capacity to provide, in a timely manner, the appropriate responses required to protect citizens and businesses and to mitigate the impact of disasters. Crisis managers need to adapt their approaches to deal with a variety of different stakeholders that may have different interests, priorities, and values.
Category:	04. Leadership and crisis management

Sub Indicator:	**RS04.01: Leadership ensures that the strategic priorities and objectives are well known and communicated throughout the NRA.**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that the strategic priorities and objectives are defined and implemented. In the case of crisis management, harmonized systems and situation reports from all active operational entities should be gathered at a centralized location in order to inform the crisis cell (i.e., the group composed of high -level officials designated to be in charge and to respond, handle and manage crisis situations). Information and communication systems, as well as standard reporting protocols among the emergency response network, enable easier analysis and raise awareness of the situation. Ongoing work to address the challenge of public health emergencies has increasingly recognized the important role that public communication plays in their effective management.
Objective:	The objective of this sub-indicator is to confirm that strategic priorities and objectives are issued by senior management or the head of the institution. In addition, the assessor should verify that a development plan exists, and its implementation is supported by the senior management.
Requirement:	Strategic priorities and objectives communication
Evidence to review:	The assessor should request for and review: 1. Documents that verify that strategic priorities and objectives are available, distributed to different organizational levels and understood by the staff; 2. Records of relevant communications.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological

	Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 6. Medical Devices – Quality Management Systems – Requirements for regulatory purposes. ISO 13485:2016. https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100422_preview.pdf 7. WHO - Good regulatory practices for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_products.pdf 8. Building an Institutional Framework for Regulatory Impact Analysis (RIA): Guidance for Policy Makers Version 1.1 2008 Regulatory Policy Division Directorate for Public Governance and Territorial Development. https://www.oecd.org/regreform/regulatory-policy/40984990.pdf
Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): The strategic priorities and objectives are neither known nor communicated throughout the NRA. ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence that strategic priorities and objectives are known and communicated throughout the NRA, but demonstrable steps have been taken towards its development. ⇒ PARTIALLY IMPLEMENTED (PI): There is a draft document defining the strategic priorities and objectives and how to communicate them through the NRA. ⇒ IMPLEMENTED (I): There is documented evidence that the strategic priorities and objectives are known and communicated throughout the NRA.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

Sub Indicator:	**RS04.02: A rapid alert system/safety alert to for managing the threats by SF medical products and for recalling these products from the market/issuance of FSN and conducting FSCA.**
Maturity Level:	2
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify the existence of a nationwide rapid alert system to manage and react to SF medical products wherever identified. Such rapid alerts may or may not include an order to recall the concerned product or batch; however, the option for either limited or nationwide recalls should be available. In addition to product recalls, other possible actions in association with the rapid alert include, but are not limited to, suspension of distribution, quarantine in place, importation alert, FSN and FSCA for medical devices. Furthermore, the rapid alert/safety alert (with or without recall, FSN and FSCA) may be associated with suspension or withdrawal of the marketing authorization for the related product. In addition, the rapid alert system may entail different levels of implementation (and accordingly communication), for example, national level, state level, district level, main store, and others throughout the organizations involved in the distribution channel. The assessor should also review the related roles and responsibilities, points of contact, communication channels, and decision trees, including representative examples of rapid alerts/safety alerts issued over the last few years.
Objective:	The objective of this sub-indicator is to confirm the existence of a rapid alert/safety alert system that is able to manage threats posed by SF medical products and ensure a timely and proportionate response. The existence of SF medical products is an unacceptable risk to public health because they have the potential to harm patients and undermine confidence in medical products, healthcare professionals and health systems.
Requirement:	Management system of SF medical products
Evidence to review:	The assessor should request for and review: 1. Regulations and documented procedures that address the management of threats by SF medical products and recalls, FSN and FSCA of such products from the market; 2. Number of complaints received;

	3. Number of recalled medical products and number of FSN and FSCA in case of medical devices including IVDs; 4. Documentation that information is publicly available, that the media used (web page, official gazette or other NRA bulletin) are appropriate, and that the information is maintained and updated on a regular basis; 5. Guidance given to manufacturers, importers, exporters and distributors and economic operators on management of recalls, FSN and FSCA including the destruction of product (replacement, decommissioning or any other method as may be recommended by medical devices manufacturers); 6. Procedures and related records for handling quality defects, product problems (e.g. notifications of suspected quality defects, safety and performance problems and company batch recalls including FSCA) 7. List of recalls, FSN and FSCA performed and documented reports; 8. Procedures and records of the rapid alert//safety alert system including responsibilities, points of contact, communication channels and decision trees.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics https://apps.who.int/iris/handle/10665/337551 6. IMDRF terminologies for categorized adverse event reporting (AER): terms, terminology structure and codes, Edition 4 . http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-200318-ae-terminologies-n43.pdf and updated annexes in Edition 5; http://www.imdrf.org/documents/documents.asp International Medical Device Regulators Forum; 2020 and 2021 respectively. 7. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1
Framework:	Structure/Foundation/Input

Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no evidence of a rapid alert system/safety alert to react to and to manage threats by SF medical products. ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence of a rapid alert system/safety alert to react to and to manage threats by SF medical products; however, demonstrable steps have been taken towards its development. ⇒ PARTIALLY IMPLEMENTED (PI): There is a draft document defining a rapid alert system/safety alert to react to and to manage threats by SF medical products. ⇒ IMPLEMENTED (I): There is documented evidence of a rapid alert system/safety alert to react to and to manage threats by SF medical products.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS04.03: A rapid alert /Safety alerts and recall system /FSN &FSCA based on documented communication to the appropriate level of the distribution channel and with a feedback mechanism.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify how the alert /safety alerts and recall system/FSCA works, focusing on communications to the appropriate level across the distribution channel along with the confirmatory feedback mechanism. In a timely process, the decision taken by the NRA should be shared appropriately and should state the severity of the defect. Communications should be given to the entire supply chain and to all stakeholders using the fastest mode of communication available, which may include email, telephone, fax, text or other appropriate means. Immediately after the decision to recall or to conduct FSCA has been made, the licensee, or representative of licensee where the product is marketed, should inform the concerned regulatory authorities in the country in which any affected product batches were distributed. Further actions on recall should be undertaken according to the recall class and a feedback mechanism should be established.
Objective:	The objective of this sub-indicator is to ensure a system is in place to recall from the market/FSN and FSCA, promptly and effectively, products known or suspected to be defective. Recall is an action taken to withdraw and remove the medical products from distribution

	or use. For medical devices, such actions are usually taken by the manufacturer and not the NRA. The process should include corrective actions taken for deficiencies reported on quality, safety or efficacy. Recall operations should be capable of being initiated promptly down to the required level in the distribution channel and a feedback mechanism should be in place. Such actions should be notified via a field safety notice (FSN). In assessing the need for FSCA, the manufacturer may use the methodology described in the international standard ISO 14971. FSCAs may include: return of a medical device to the manufacturer or its representative, device modification, device exchange, device destruction, /decommission, advice given by the manufacturer regarding the use of the device (e.g. where the device is no longer on the market or has been withdrawn but could still possibly be in use, e.g. implants).
Requirement:	A rapid alert/safety alerts and recall system/FSN and FSCA
Evidence to review:	The assessor should request for and review: 1. Rapid alert/safety alerts and recall/FSN and /FSCA procedures along with the associated records and communications; 2. List of recalls/FSN and FSCA, examples of recalls //FSN and FSCA and recall notifications/FSNs.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics https://apps.who.int/iris/handle/10665/337551 6. IMDRF terminologies for categorized adverse event reporting (AER): terms, terminology structure and codes, Edition 4 . http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-200318-ae-terminologies-n43.pdf and updated annexes in Edition 5; http://www.imdrf.org/documents/documents.asp International Medical Device Regulators Forum; 2020 and 2021 respectively.

	7. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 8. Medical Devices Post Market Surveillance: Content of Field Safety Notices GHTF/SG2/N57R8:2006 http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n57r8-2006-guidance-field-safety-060627.pdf
Framework:	Process
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no evidence of a rapid alert/safety alert and recall system /FSCA based on documented communication to the appropriate level of the distribution channel and with a feedback mechanism. ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence of a rapid alert /safety alert and recall system/FSCA based on documented communication to the appropriate level of the distribution channel, but demonstrable steps have been taken towards its development. ⇒ PARTIALLY IMPLEMENTED (PI): There is a draft document defining a rapid alert/safety alert and recall system/FSCA based on documented communication to the appropriate level of the distribution channel. ⇒ IMPLEMENTED (I): There is documented evidence of a rapid alert/safety alert and recall system/FSCA based on documented communication to the appropriate level of the distribution channel and with a feedback mechanism.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS04.04: Recall/FSCA system based on documented confirmation that appropriate, batch-traceable action and/or destruction/decommission has been undertaken when necessary.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify the existence of documentation which covers the regulatory decisions related to product recalls or FSN and FSCA in case of medical devices including in vitro diagnostics, and which can provide sufficient evidence that proper actions have been taken. There should be written procedures describing the actions to be taken, including the need to consider a recall/ /FSCA in the

	case of a complaint concerning a possible product defect. If a product defect is discovered or suspected in a batch, consideration should be given to whether other batches should be checked to determine whether they have been also affected. In particular, other batches that may contain reprocessed product from the defective batch should be investigated. Where necessary, appropriate follow-up action, possibly including product recall/FSCA, should be taken after investigation and evaluation of the complaint. All decisions made, and all measures taken as a result of a complaint or detection of unqualified products should be recorded and referenced to the corresponding batch records. Complaints/ records should be regularly reviewed for any indication of specific or recurring problems that require attention and that might justify the recall//FSCA of marketed products. The competent authorities should be informed if a manufacturer or other relevant stakeholder is considering action following possibly faulty manufacture, product deterioration, or detection of any other serious quality problems with a product.
Objective:	The objective of this sub-indicator is to ensure that a recall system/FSCA exists, and the progress of the recall process/FSCA is monitored and recorded. Records include the disposition of the batches and/or destruction and for medical devices, decommissioning, and replacement and as may be suggested by the manufacturer when necessary.
Requirement:	Recall system/FSN and FSCA based on documented confirmation
Evidence to review:	The assessor should request for and review: 1. Documented evidence of the fate of recalled batches/FSCAs; 2. Documentation of reconciliation and recalls/FSCA success rate (i.e. comparison of actual recalled units versus distributed ones within a certain timeframe in case of medical devices comparison between FSCA and distributed products)).
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf)

	5. WHO good manufacturing practices for pharmaceutical products: main principles (51) (http://digicollection.org/whoqapharm/p/about/) and (http://apps.who.int/medicinedocs/en/) 6. Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics h https://apps.who.int/iris/handle/10665/337551 7. IMDRF terminologies for categorized adverse event reporting (AER): terms, terminology structure and codes, Edition 4 . http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-200318-ae-terminologies-n43.pdf and updated annexes in Edition 5; http://www.imdrf.org/documents/documents.asp International Medical Device Regulators Forum; 2020 and 2021 respectively. 8. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 9. Medical Devices Post Market Surveillance: Content of Field Safety Notices GHTF/SG2/N57R8:2006 http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n57r8-2006-guidance-field-safety-060627.pdf
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no evidence of a recall/FSCA system based on documented confirmation that appropriate, batch-traceable action and/or destruction/decommission has been undertaken when necessary. ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence of a recall/FSCA system based on documented confirmation that appropriate, batch-traceable action and/or destruction/decommission has been undertaken when necessary; however, demonstrable steps have been taken towards its development. ⇒ PARTIALLY IMPLEMENTED (PI): There is a draft document defining a recall/FSCA system based on documented confirmation that appropriate, batch-traceable action and/or destruction has been undertaken when necessary. ⇒ IMPLEMENTED (I): There is documented evidence of a recall/alert system based on documented confirmation that appropriate, batch-traceable action and/or destruction has been undertaken when necessary.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS04.05: Written criteria to cover circumstances in which the routine regulatory processes may not have to be followed in relation to crises and emergencies linked to a risk management plan.**

Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify the existence of a crisis risk management plan ready to be implemented in circumstances in which the routine regulatory processes may not be followed when responding to crises and emergencies (e.g. outbreaks, force majeure, and medical product shortages). In addition, the criteria should be defined in a written document to describe management of crises and emergencies. A crises and emergencies plan is a course of action developed to mitigate the damage caused by those events that could endanger an organization's ability to function. Such a plan should include measures that provide for the safety of personnel and, if possible, property and facilities. It should also include provisions to assess the severity of an incident and to implement steps to eliminate the problem. Development of the plan begins with a vulnerability assessment. The results of the assessment will show: 1. The likelihood of a situation occurring; 2. The means that are available to stop or prevent the situation; 3. The potential responses to a given situation. From this analysis, appropriate crisis and emergency management procedures can be established. At the planning stage, it is important to employ a multidisciplinary team approach. Communication, training and periodic drills will ensure adequate performance if the plan must be carried out.
Objective:	The objective of this sub-indicator is to ensure that procedures related to NRA response to relevant crises and emergencies have been developed, documented and tested prior to the occurrence of an event. Such procedures should be developed according to a risk management plan. An important element of any system for the prevention of major incidents is the establishment of an emergency plan. Crises and emergencies plans seek to minimize the consequences of a crisis or emergency and require the timely application of defined procedures by people with adequate training and resources.
Requirement:	Crises and Emergencies Plan
Evidence to review:	The assessor should request for and review: 1. Regulatory risk management plan to cover circumstances in which the routine regulatory processes may not be followed when

	responding to crises and emergencies; 2. Written documents that describe the process; 3. Any records of crises management.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=16. WHO - Good regulatory practices for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_products.pdf 6. Building an Institutional Framework for Regulatory Impact Analysis (RIA): Guidance for Policy Makers Version 1.1 2008 Regulatory Policy Division Directorate for Public Governance and Territorial Development. https://www.oecd.org/regreform/regulatory-policy/40984990.pdf
Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no evidence of written criteria to cover circumstances in which the routine regulatory processes may not be followed in relation to crises and emergencies. ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence of written criteria to cover circumstances in which the routine regulatory processes may not have to be followed in relation to crises and emergencies, but demonstrable steps have been taken towards its development.

	⇒ PARTIALLY IMPLEMENTED (PI): There is a draft document defining written criteria to cover circumstances in which the routine regulatory processes may not have to be followed in relation to crises and emergencies. ⇒ IMPLEMENTED (I): There is documented evidence of written criteria to cover circumstances in which the routine regulatory processes may not have to be followed in relation to crises and emergencies.
Limitations and remarks:	If routine regulatory processes are mandatory in all circumstance based on the regulation, the assessor should review how the country can handle an emergency condition in a timely manner, for example, by providing additional staff and resources that allow regulatory activities to be conducted under emergency conditions.
Indicator:	**RS05 Quality management systems (QMS) including the risk management principles are applied and realized.**
Objective:	The objective of this indicator is to confirm whether the NRA has implemented the main principles of a Quality Management System (QMS) which includes the application of risk management principles for all regulatory functions and which has been updated to include the required documentation. QMS is a valuable tool that helps NRAs to achieve greater credibility for their decisions and greater stability in their operations, to include systematic planning, control, and improved quality in all processes throughout all regulatory functions, and to ensure a comprehensive approach for all.
Category:	05. Quality and risk management system
Sub Indicator:	**RS05.01: Top management demonstrates commitment and leadership to develop and implement quality management system (QMS).**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The commitment and leadership with respect to QMS is demonstrated by: 1. taking accountability for the effectiveness of the QMS;

	2. ensuring that the quality policy and quality objectives are established for the QMS and that they are compatible with the visions, mandates and strategic directions of the organization; 3. ensuring the integration of the QMS requirements into the organization's business processes; 4. promoting the use of the process approach and risk-based thinking; 5. ensuring that the resources needed for the QMS are available; 6. communicating the importance of effective quality management and of conformance to the QMS requirements; 7. ensuring that the QMS achieves its intended results; 8. engaging, directing and supporting persons to contribute to the effectiveness of the QMS; 9. promoting continuous QMS improvement; 10. supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.
Objective:	The objective of this sub-indicator is to confirm the commitment and leadership from top management that is required for the proper development, implementation and maintenance of the QMS.
Requirement:	Leadership and commitment
Evidence to review:	The assessor should request for and review: 1. Documentation of the resources (financial, human, infrastructure, and equipment) allocated for the development, implementation and maintenance of QMS; 2. Communication aids that convey to all staff levels the importance of effective QMS 3. Documentation for top management involvement in the monitoring, review and continuous improvement of QMS.
References:	1. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization, 2015 sub-clause 5.1.1., (4), (https://www.iso.org/iso-9001-quality-management.html) 2. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 3. WHO guideline (2019) on the implementation of quality management systems for national regulatory authorities. *WHO Drug Information, 33* (3), 410 - 457. World Health Organization. https://apps.who.int/iris/handle/10665/330870
Framework:	Structure/Foundation/Input
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no evidence that top management demonstrates commitment and leadership to develop and implement QMS.

	⇒ ONGOING IMPLEMENTATION (OI): There is no evidence that top management demonstrates commitment and leadership to develop and implement QMS, but demonstrable steps have been taken in this direction. ⇒ PARTIALLY IMPLEMENTED (PI): Some resources (financial, human, infrastructure and equipment) have been allocated for the development, implementation, and maintenance of QMS. ⇒ IMPLEMENTED (I): There is documented evidence that top management demonstrate commitment and leadership to develop and implement QMS.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS05.02: Quality policy, objectives, scope and action plans for establishment of the QMS are in place and communicated to all levels.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that top management has established, implemented and maintained a quality policy that: 1. is appropriate to the purpose and context of the NRA and supports its strategic direction; 2. provides a framework for setting quality objectives; 3. includes a commitment to satisfy applicable requirements; 4. includes a commitment to continued improvement of the QMS; 5. is communicated to all levels across the organization. The assessor should verify that the quality policy: 1. Is available and is maintained as documented information; 2. is communicated, understood and applied within the NRA; 3. is available to relevant interested parties, as appropriate. The assessor should verify that the NRA has established quality objectives for functions, levels and processes needed for the QMS.

	The quality objectives should: 1. be consistent with the quality policy; 2. be measurable; 3. take into account applicable requirements; 4. be relevant for conformity of products and services and for enhancement of customer satisfaction; 5. be monitored; 6. be communicated; 7. be updated as appropriate. The NRA should maintain documented information on the quality objectives. When NRA is planning how to achieve its quality objectives, the NRA should determine: 1. what will be done; 2. what resources will be required; 3. who will be responsible; 4. when it will be completed; 5. how the results will be evaluated.
Objective:	The objective of this sub-indicator is to confirm that a policy statement to support QMS is issued by senior management or the head of institution, that a development plan exists, and that implementation of the plan is supported by senior management. The quality policy should be communicated to all levels across the organization.
Requirement:	Quality policy, objectives, scope, and action plans
Evidence to review:	The assessor should request for and review: 1. Evidence that the quality policy is available, distributed to different levels of the organization and understood by the staff; 2. Evidence that quality objectives are documented and communicated to all levels; 3. Evidence that there is agreement on the scope of QMS application; 4. Evidence that the action plan for QMS establishment and maintenance is available and regularly updated.
References:	1. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization, 2015 sub-clause 5.2.1, 5.2.2 , 6.2., (4), (https://www.iso.org/iso-9001-quality-management.html) 2. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1

	3. WHO guideline (2019) on the implementation of quality management systems for national regulatory authorities. *WHO Drug Information, 33* (3), 410 - 457. World Health Organization. https://apps.who.int/iris/handle/10665/330870
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): The NRA has no quality policy for the establishment of the QMS. ⇒ ONGOING IMPLEMENTATION (OI): The NRA is taking steps toward the quality policy for the establishment of a QMS and there is documented evidence of this. ⇒ PARTIALLY IMPLEMENTED (PI): The quality policy for the establishment of the QMS was recently established, a quality system policy was implemented less than a year ago, or there is a QMS, but it does not yet cover all regulatory functions. ⇒ IMPLEMENTED (I): The NRA has all of the aforementioned elements, and consistently maintains documentation of the results of related activities over time.
Limitations and remarks:	▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs). ▪ For blood products, the QMS policy statement should make reference to and be aligned with international standards.
Sub Indicator:	**RS05.03: Organizational chart, with roles and responsibilities to establish the QMS are defined and in place.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that top management assign the responsibility and authority for: 1. ensuring that the QMS conforms to the requirements of international standards; 2. ensuring that the processes are delivering their intended outputs; 3. reporting on the performance of the QMS and on opportunities for improvement, in particular to top management; 4. ensuring the promotion of customer focus throughout the NRA; 5. ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented.

Objective:	The objective of this sub-indicator is to confirm that top management ensures that responsibilities and authorities for relevant roles are assigned, communicated, understood, and followed within the NRA in order to establish and maintain the QMS.
Requirement:	Organizational roles, responsibilities and authorities
Evidence to review:	The assessor should identify the entities that are in place to establish, implement or maintain the QMS. The different responsibilities should be identified and assigned. So, the assessor should check and evaluate that the: 1. Organizational chart is documented and authorized; 2. Responsibilities & authorities for processes are assigned; 3. Job descriptions that include roles, responsibilities, and authorities for each block in the organizational chart have been written and approved
References:	1. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization, 2015 sub-clause 5.3., (4), (https://www.iso.org/iso-9001-quality-management.html) 2. WHO Guidance on Human Resource for medical devices,https://apps.who.int/iris/bitstream/handle/10665/255261/9789241565479-eng.pdf;jsessionid=565B180CA9F7408720856799FEDAB0A8?sequence=1 3. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 4. WHO guideline (2019) on the implementation of quality management systems for national regulatory authorities. 5. *WHO Drug Information, 33* (3), 410 - 457. World Health Organization. https://apps.who.int/iris/handle/10665/330870
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There are no defined roles and responsibilities (with or without organizational chart) to establish the QMS. ⇒ ONGOING IMPLEMENTATION (OI): There is no organizational chart, with defined roles and responsibilities to establish the QMS, but demonstrable steps have been taken towards its development. ⇒ PARTIALLY IMPLEMENTED (PI): The organizational chart, with defined roles and responsibilities to establish the QMS, was recently developed. ⇒ IMPLEMENTED (I): There is an organizational chart, with defined roles and responsibilities, and the QMS is established.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

Sub Indicator:	**RS05.04: Enough competent staff is assigned to develop, implement and maintain the QMS.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify whether the NRA: 1. Has determined the adequate number of staff to implement and maintain QMS; 2. Has determined the necessary competence of NRA personnel doing work that affects the performance and effectiveness of the QMS; 3. Has ensured that these personnel are competent on the basis of appropriate education, training, skills and experience; 4. Has taken actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken, where applicable; 5. Has retained appropriate documented information as evidence of competence.
Objective:	The objective of this sub-indicator is to ensure the NRA provides the human resources (i.e., with respect to number and competence of personnel) necessary for the effective implementation of its QMS and for the operation and control of its processes. Necessary competence for personnel performing work significantly influences the work output and outcome.
Requirement:	Sufficient human resources and competency
Evidence to review:	The assessor should evaluate and verify if adequate competent (i.e., with respect to education, training, skills and experience) human resources has been designated and assigned to develop, implement and maintain QMS. The assessor should check and evaluate the following: 1. Criteria for the necessary personnel competence (e.g., competency matrix for each function); 2. Staff training plan (addressing recruitment, on-the-job training and other actions to achieve the necessary competencies); 3. Appropriate training records and system for retention of these records.
References:	1. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization, 2015 sub-clause 7.1.2, 7.2., (4), (https://www.iso.org/iso-9001-quality-management.html)

	2. WHO Guidance on Human Resource for medical devices, https://apps.who.int/iris/bitstream/handle/10665/255261/9789241565479-eng.pdf;jsessionid=565B180CA9F7408720856799FEDAB0A8?sequence=1 3. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 4. WHO guideline (2019) on the implementation of quality management systems for national regulatory authorities. *WHO Drug Information, 33* (3), 410 - 457. World Health Organization. https://apps.who.int/iris/handle/10665/330870 5. Competence, Training, and Conduct Requirements for Regulatory Reviewers: IMDRF 2016 http://www.imdrf.org/consultations/cons-requirements-regulatory-reviewers.asp
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): The NRA does not have adequate competent staff (education, training, skills and experience) to develop, implement and maintain the QMS. ⇒ ONGOING IMPLEMENTATION (OI): The NRA has recently developed the plan to recruit adequate competent staff; however, the plan has not been implemented. ⇒ PARTIALLY IMPLEMENTED (PI): The NRA recently recruited the adequate number of the staff to develop, implement and maintain the QMS and their training programmes or competency building activities are ongoing. ⇒ IMPLEMENTED (I): The NRA has had a sustained number of competent staff (education, training, skills and experience) assigned to develop, implement and maintain the QMS.
Limitations and remarks:	▪ Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed personnel, as well as the hiring or contracting of competent personal. Regarding effectiveness of training please refer to sub-indicator RS05.14 ▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS05.05: The NRA establishes mechanisms to continually improve the QMS.**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines

	3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	Continuous improvement is a constant theme of a QMS. QMS continuous improvement can be achieved through different complementary approaches including, for example, management review, customer feedback, and process and product evaluation. The NRA should continually work to improve the adequacy and effectiveness of the QMS. The NRA should consider the results of analyses and evaluations, and the outputs from management reviews, to determine if there are needs or opportunities that should be addressed as part of continual improvement.
Objective:	The objective of this sub-indicator is to ensure that the NRA establishes, implements, maintains and continually improves the QMS. The NRA should identify the processes needed for developing and maintaining the QMS and should adopt the mechanisms necessary to ensure continued improvement.
Requirement:	Continual improvement
Evidence to review:	The assessor should evaluate and verify whether the NRA has established, documented and implemented a QMS, and has worked continually to improve its effectiveness through management review. The assessor should check and evaluate the following: 1. mechanisms of QMS periodic monitoring and evaluation and ways for figuring out and addressing identified gaps; 2. availability of resources needed for QMS continual improvement; 3. availability of documentation related to addressing risks, opportunities and outputs from management review; 4. availability of documents that describe processes for QMS and regulatory system evaluation and that identify processes that require optimization; 5. availability of documents to improve the processes and address QMS gaps.
References:	1. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization, 2015 sub-clause 10.3., (4), (https://www.iso.org/iso-9001-quality-management.html) 2. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 3. WHO guideline (2019) on the implementation of quality management systems for national regulatory authorities. *WHO Drug Information, 33* (3), 410 - 457. World Health Organization. https://apps.who.int/iris/handle/10665/330870

	4. Competence, Training, and Conduct Requirements for Regulatory Reviewers: IMDRF 2016 http://www.imdrf.org/consultations/cons-requirements-regulatory-reviewers.asp
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): The NRA has no mechanism for continuous improvement of the QMS. ⇒ ONGOING IMPLEMENTATION (OI): The NRA is taking steps toward the establishment of a mechanism for continuous improvement of the QMS and there is documented evidence of this. ⇒ PARTIALLY IMPLEMENTED (PI): The NRA's mechanism for continuous improvement of the QMS was recently established. ⇒ IMPLEMENTED (I): The NRA has established mechanisms to continually improve the QMS and consistently maintains documentation of the results of related activities over time.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS05.06: The NRA has identified its regulatory processes, determined their interactions and defined the methods needed to control these processes.**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that the NRA determines the processes needed for the QMS and their application. The NRA should: 1. determine the regulatory inputs required and the outputs expected; 2. determine the sequence (i.e. regulatory workflow including all related steps assigned to each unit within NRA and those assigned to other stakeholders e.g. industry) and interactions among these processes; 3. determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes; 4. determine the resources needed for these processes and ensure their availability; 5. assign the responsibilities and authorities for these processes; 6. address the risks and opportunities;

	7. evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results; 8. improve the processes and the QMS. To the extent necessary, the NRA should: 1. maintain documented information to support the operation of its processes; 2. retain documented information to provide confidence that the processes are being carried out as planned. The NRA should apply controls to the design and development process to ensure that: 1. the results to be achieved are defined; 2. reviews are conducted to evaluate the ability of the results of design and development actions to meet requirements; 3. verification activities are conducted to ensure that the design and development of the regulatory outputs (e.g. approved marketing authorizations) meet the input requirements (e.g., marketing authorization standards and regulations); 4. validation activities are conducted to ensure that the resulting products and services (e.g. laboratory testing) meet the requirements for the specified application or intended use (e.g. pharmacopeial standards, ISO standards and other internationally recognized guidance for medical devices including in vitro diagnostics); 5. necessary actions are taken on problems determined during the reviews or verification and validation activities; 6. documented information of these activities is retained. The NRA should implement production and service provisions under controlled conditions. Controlled conditions should include, as applicable: 1. the availability of documented information that define: a) the characteristics of the products to be produced, the services to be provided, or the activities to be performed; b) the results to be achieved; 2. the availability and use of suitable monitoring and measuring resources; 3. the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met; 4. the use of suitable infrastructure and environment for the operation of processes; 5. the appointment of competent personnel with any required qualifications; 6. the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; 7. the implementation of actions to prevent human error; 8. the implementation of release, delivery and post-delivery activities. Design and development reviews, verifications and validations have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

Objective:	The objective of this sub-indicator is to confirm the organization has established, implemented and maintained a design and development process that is appropriate to ensure the subsequent provision of products and services. The NRA should establish methods and tools to monitor proper implementation.
Requirement:	Operation
Evidence to review:	The assessor should request and review evidence for: 1. availability of processes list; 2. availability of different regulatory processes flowcharts including process controls and interactions with other processes.
References:	1. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization, 2015 sub-clause 4.4, 8.3, 8.5.1., (4), (https://www.iso.org/iso-9001-quality-management.html)
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): The NRA has not identified its regulatory processes. ⇒ ONGOING IMPLEMENTATION (OI): The NRA is taking steps toward the establishment of its regulatory processes and there is documented evidence of this. ⇒ PARTIALLY IMPLEMENTED (PI): The NRA has recently identified its regulatory processes, determined their interactions and defined the methods needed to control these processes. ⇒ IMPLEMENTED (I): The NRA has identified its regulatory processes and determined their interactions, and there is documented evidence that the regulatory processes are under control.
Limitations and remarks:	▪ The implementation of this requirement can be evaluated with more detail under each function. ▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS05.07: Requirements for documentation management as well as traceability of regulatory activities are established.**
Maturity Level:	2
Scope:	1. Medicines 2. Vaccines

	3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify the NRA's QMS includes: 1. documented information required by the applicable International Standard; 2. documented information determined by the organization to be necessary for the effectiveness of the QMS. The assessor should check that the NRA, when creating and updating documented information, ensures that: 1. identifications and descriptions (e.g. a title, date, author, or reference number) are appropriate; 2. format (e.g., language, software version, and graphics) and media (e.g. paper or electronic) are appropriate; 3. reviews and approvals are suitable and adequate. The assessor should verify that documented information required by the QMS and by the applicable International Standard should be controlled to ensure that information is: 1. available and suitable for use, where and when it is needed; 2. adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). With respect to the control of documented information, the assessor should check that the NRA addresses the following activities, as applicable: 1. distribution, access, retrieval and use; 2. storage and preservation, including preservation of legibility; 3. control of changes (e.g. version control); 4. retention and disposition. The assessor should confirm that documented information of external origin that the NRA considers to be necessary for QMS planning and operation is appropriately identified and controlled. The assessor should verify that documented information retained as evidence of conformity is protected from unintended alterations and remains available and accessible. Procedures should identify those personnel who have permission and authority to view and change the documented information, and those personnel who have permission only to view the documented information.
Objective:	The objective of this sub-indicator is to ensure the NRA has a suitable document control procedure for the organization, identification, storage, protection, retrieval, retention, and disposition of documents (i.e., procedures and records).

Requirement:	Documented information
Evidence to review:	The assessor should evaluate and verify this requirement by reviewing: 1. Record control procedures; 2. Record control system, including identification of records, safeguard of records, retrieval of records, retention of records for defined periods, and destruction of obsolete records; 3. Mechanisms for ensuring adequate documentation of different regulatory activities and availability of and easy access to such documentation; 4. Examples of records; 5. Records access, archiving, retention, and disposition.
References:	1. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization, 2015 sub-clause 7.5., (4), (https://www.iso.org/iso-9001-quality-management.html) 2. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 3. WHO guideline (2019) on the implementation of quality management systems for national regulatory authorities. *WHO Drug Information, 33* (3), 410 - 457. World Health Organization. https://apps.who.int/iris/handle/10665/330870 4. Competence, Training, and Conduct Requirements for Regulatory Reviewers: IMDRF 2016 http://www.imdrf.org/consultations/cons-requirements-regulatory-reviewers.asp
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): The NRA has no requirements for documentation management or cannot trace its regulatory activities and decisions. ⇒ ONGOING IMPLEMENTATION (OI): The NRA is taking steps toward the establishment of its requirements for documentation management and traceability of regulatory activities; however, there is no documented evidence for this. ⇒ PARTIALLY IMPLEMENTED (PI): The NRA has recently identified its requirements for documentation management and traceability of regulatory activities. ⇒ IMPLEMENTED (I): The NRA has identified its requirements for documentation management and traceability of regulatory activities and there is documented evidence of the same.
Limitations and remarks:	▪ The extent of documented information for a QMS can differ from one organization to another due to: 1. the size of NRA and the scope of its mandate with respect to types of activities, processes, products and services; 2. the complexity of processes and their interactions;

	3. the competence of personnel; 4. technical resources and technologies available. ▪ Records must remain legible and identifiable throughout their retention period. ▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS05.08: External and internal issues including relevant potential risks are defined and assessed periodically for proper risk mitigation.**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that the NRA monitors and reviews information about external and internal issues. Issues can include positive and negative factors or conditions for consideration. Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local. Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization. The assessor should confirm the NRA considers the issues and requirements referred to the organization when planning for the QMS. The risks and opportunities need to be addressed in order to: 1. give assurance that the QMS can achieve its intended result(s); 2. enhance desirable effects; 3. prevent, or reduce, undesired effects; 4. achieve improvement. The assessor should verify the NRA has planned: 1. actions to address these risks and opportunities; 2. steps to: a) integrate and implement the actions into its QMS processes; b) evaluate the effectiveness of these actions. The assessor should check that actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of products and services.

	Options to address risks can include avoiding risks, taking risks in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences of the risk, sharing the risk, or retaining risk by informed decision. Opportunities can lead to the adoption of new practices, launching new products, addressing new customers, building partnerships, and using new technology and other desirable and viable possibilities to address the needs of the organization or its customers.
Objective:	The objective of this sub-indicator is to ensure the organization determines external and internal issues that are relevant to its purpose and strategic direction and that may affect its ability to achieve the intended QMS result. When planning for the QMS, the NRA should consider the issues and requirements and determine the risks and opportunities that need to be addressed in the context of the organization. The issues and requirements should be reconsidered periodically to determine if the risks and opportunities that need to be addressed in the context of the organization have changed and require action. The NRA should identify issues that may eventually impact the regulatory performance in a negative way and develop actions and steps needed to implement the mitigation strategy. Such strategies can provide assurance that the QMS can achieve its intended results.
Requirement:	Actions to address risk and opportunities
Evidence to review:	The assessor should evaluate and verify the integration of this requirement by reviewing: 1. Evidence for identification of potential risks for each process, and for creation of a list of potential risks; 2. Methodology and SOPs for risk analysis with examples of some potential risks (e.g., calculations of likelihood and severity and creation of risk index); 3. Evidence for availability of risk mitigation action plan or strategy to control the potential risks based on its risk assessment.
References:	1. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization , 2015 sub-clause 6.1, 4.1., (4), (https://www.iso.org/iso-9001-quality-management.html) 2. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 3. WHO guideline (2019) on the implementation of quality management systems for national regulatory authorities. *WHO Drug Information, 33* (3), 410 - 457. World Health Organization. https://apps.who.int/iris/handle/10665/330870 4. Competence, Training, and Conduct Requirements for Regulatory Reviewers: IMDRF 2016 http://www.imdrf.org/consultations/cons-requirements-regulatory-reviewers.asp
Framework:	“Structure/Foundation/Input”

Rating Scale:	⇒ NOT IMPLEMENTED (NI): The NRA has not identified or prioritized potential risks and opportunities or defined essential processes for risk mitigation. ⇒ ONGOING IMPLEMENTATION (OI): The NRA is taking steps towards the identification and prioritization of potential risks and opportunities and defining essential processes for risk mitigation, and there is documented evidence of this. ⇒ PARTIALLY IMPLEMENTED (PI): The NRA has recently identified and prioritized potential risks and opportunities, defined essential processes and developed SOPs for risk analysis and risk mitigation plan. ⇒ IMPLEMENTED (I): The NRA has identified and prioritized potential risks and opportunities, defined essential processes, and implemented SOPs for risk analysis. There is a mitigation action plan or strategy to control the potential risks based on its risk assessment.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS05.09: The externally provided products and services relevant to regulatory activities are controlled through established mechanisms.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that the organization has determined the controls to be applied to externally provided processes, products and services when: 1. products and services from external providers are intended for incorporation into the organization's own products and services; 2. products and services are provided directly to the customers by external providers on behalf of the organization; 3. a process, or part of a process, is provided by an external provider as a result of a decision by the NRA. The NRA should retain documented information of these activities and any necessary actions arising from the evaluations. The NRA should ensure that externally provided processes, products and services do not adversely affect the NRA's ability to consistently deliver conforming products and services to its customers. The assessor should verify the NRA should:

	1. ensure that externally provided processes remain within the control of its QMS; 2. define both the controls that it intends to apply to an external provider and those that it intends to apply to the resulting output; 3. take into consideration: a) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements; b) the effectiveness of the controls applied by the external provider; 4. determine the verification steps, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements. The NRA should ensure the adequacy of requirements prior to their communication to the external provider. The NRA should communicate to external providers its requirements for: 1. the processes, products and services to be provided; 2. the approval of: a) products and services; b) methods, processes and equipment; c) the release of products and services; 3. competence, including any required personnel qualifications, and the need to establish terms of reference addressing confidentiality and potential conflicts of interest (as per RS06.04 and RS09.06); 4. the external providers' interactions with the NRA; 5. the controls and monitoring of the external providers' performance that will be applied by the NRA; 6. verification or validation activities.
Objective:	The objective of this sub-indicator is to confirm the NRA ensures that externally provided processes, products and services conform to requirements. The NRA should determine and apply criteria for the evaluation, selection, performance monitoring, and re- evaluation of external providers. These criteria should be based on their ability to provide processes or products and services in accordance with established requirements. An example of externally provided services is outsourced laboratory testing which should ideally be controlled through a quality agreement (with defined roles and responsibilities) between the responsible unit within the NRA (contract giver) and the external laboratory (contract acceptor). Another example of externally provided product is the information provided by the regulated sector. In the latter example, it should be noted that some of the main outputs from an NRA include those that establish parameters, rules and services for regulated industry, and thus these actors from the regulated sector can be considered both as suppliers and customers of the NRA services. This depends on the direction of the workflow. In all cases, as part of the QMS establishment within the NRA, services, products and customers should be well-defined and controlled.
Requirement:	Control of externally provided process, products and services

Evidence to review:	The assessor should evaluate and verify this requirement by reviewing: 1. List of externally provided products and services (e.g., tests, audits, or assessments) that are relevant to regulatory activities; 2. Availability and appropriateness of criteria for selection, evaluation, and re-evaluation of suppliers and outsourcing organizations; 3. Availability of list of approved suppliers and outsourcing organizations; 4. Availability of evaluation records of suppliers and outsourced organizations.
References:	1. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization, 2015 sub-clause 8.4., (4), (https://www.iso.org/iso-9001-quality-management.html) 2. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 3. WHO guideline (2019) on the implementation of quality management systems for national regulatory authorities. *WHO Drug Information, 33* (3), 410 - 457. World Health Organization. https://apps.who.int/iris/handle/10665/3308704 Competence, Training, and Conduct Requirements for Regulatory Reviewers: IMDRF 2016 http://www.imdrf.org/consultations/cons-requirements-regulatory-reviewers.asp 4. IMDRF Medical Device Single Audit Program (MDSAP) https://www.fda.gov/medical-devices/medical-device-single-audit-program-mdsap/imdrfmdsap-wg-and-gthf-documents
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): The NRA does not have a list of regulatory-relevant externally-provided products and services. ⇒ ONGOING IMPLEMENTATION (OI): The NRA does not have a list of regulatory-relevant externally-provided products and services and has not defined criteria for selection, evaluation, and re-evaluation of suppliers and outsourcing organizations, but there are some demonstrable steps. ⇒ PARTIALLY IMPLEMENTED (PI): The NRA has recently identified the list of regulatory-relevant externally-provided products and services and has defined criteria for selection, evaluation, and re-evaluation of suppliers and outsourcing organizations. ⇒ IMPLEMENTED (I): The NRA has a list of regulatory-relevant externally-provided products and services, has defined criteria for selection, evaluation, and re-evaluation of suppliers and outsourcing organizations, and has records of evaluations.
Limitations and remarks:	

Sub Indicator:	**RS05.10: A mechanism to evaluate the satisfaction of internal and external customers and other interested parties is in place for system improvement.**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that the NRA monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled. The NRA should determine the methods for obtaining, monitoring and reviewing this information. Mapping or identifying the customers and other stakeholder is essential for the proper implementation of this sub-indicator. Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, and warranty claims. A procedure should be in place for performing these activities.
Objective:	The objective of this sub-indicator is to ensure the organization implements an effective customer satisfaction process to record and evaluate outcomes. Effective arrangements for communicating customer feedback and complaints should be in place.
Requirement:	Customer satisfaction
Evidence to review:	The assessor should evaluate and verify the implantation of this requirement by reviewing: 1. Results of customer satisfaction measurement by means of surveys, complaints analysis and claims analysis; 2. Actions taken with each unsatisfied customer (complaints or claims). 3 Identification of customers and stakeholders
References:	1. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization, 2015 sub-clause 9.1.2., (4), (https://www.iso.org/iso-9001-quality-management.html)
Framework:	"Output".

Rating Scale:	⇒ NOT IMPLEMENTED (NI): The NRA does not perform customer satisfaction measurement by means of surveys, complaints analysis and claims analysis. ⇒ ONGOING IMPLEMENTATION (OI): The NRA does not perform customer satisfaction measurement by means of surveys, complaints analysis and claims analysis, but there are some demonstrable steps taken towards this end. ⇒ PARTIALLY IMPLEMENTED (PI): The NRA has recently implemented customer satisfaction measurement by means of surveys, complaints analysis and claims analysis. ⇒ IMPLEMENTED (I): There is documented evidence that the NRA performs customer satisfaction measurement by means of surveys, complaints analysis and claims analysis and that actions are taken to deal with unsatisfied customers.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS05.11: Internal and external audits of the QMS are established and conducted at planned intervals.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that the NRA: 1. plans, establishes, implements and maintains an audit programme which specifies the frequency, methods, responsibilities, planning, and reporting requirements, and which takes into consideration the importance of the processes concerned, changes affecting the NRA, and the results of previous audits; 2. defines the audit criteria and scope for each audit; 3. selects auditors and conducts audits to ensure objectivity and impartiality of the audit process; 4. ensures that the results of the audits are reported to relevant management; 5. takes appropriate correction and corrective actions, if necessary, without undue delay; 6. retains documented information as evidence of the implementation of the audit programme and the audit results.
Objective:	The objective of this sub-indicator is to ensure that internal and external audits are planned at regular intervals to provide information on whether the QMS conforms to the organization’s own requirements and is effectively implemented and maintained.

Requirement:	Internal audit
Evidence to review:	The assessor should evaluate and verify implementation of auditing system by reviewing: 1. Internal audit procedures; 2. Audit schedules; 3. Records of auditors' qualifications and competence; 4. Audit records; 5. Root cause analyses and corrective actions to prevent recurrence of non-conformities observed during audits.
References:	1. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization, 2015 sub-clause 9.2 (4) (https://www.iso.org/iso-9001-quality-management.html) 2. ISO 19011: 2018 Guidelines for auditing management systems., International Organization for Standardization., (117), (https://www.iso.org/standard/70017.html) 3. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 4. WHO guideline (2019) on the implementation of quality management systems for national regulatory authorities., WHO Drug Information, 33 (3), 410 - 457. World Health Organization. https://apps.who.int/iris/handle/10665/330870 5. Competence, Training, and Conduct Requirements for Regulatory Reviewers: IMDRF 2016 http://www.imdrf.org/consultations/cons-requirements-regulatory-reviewers.asp 6. IMDRF Medical Device Single Audit Program (MDSAP). https://www.fda.gov/medical-devices/medical-device-single-audit-program-mdsap/imdrfmdsap-wg-and-gthf-documents
Framework:	"Process"
Rating Scale:	NOT IMPLEMENTED (NI): The NRA has not established internal and external audits of the QMS at planned intervals. ONGOING IMPLEMENTATION (OI): The NRA has not established internal and external audits of the QMS at planned intervals, but some demonstrable steps have been taken. PARTIALLY IMPLEMENTED (PI): The NRA has recently established internal and external audits of the QMS at planned intervals but these are not yet implemented. IMPLEMENTED (I): There is documented evidence that the NRA has established and implemented internal and external audits of the QMS at planned intervals and acts on non-conformities in a timely manner.

Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS05.12: Corrections, corrective actions, and other actions for risk mitigation and overall improvement, are implemented and documented and their effectiveness is verified.**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that when a nonconformity occurs, including any arising from complaints, the NRA should: 1. react to the nonconformity and, as applicable: a) take action to control and correct it; b) deal with the consequences; 2. evaluate the need for action to eliminate the cause of the nonconformity, in order that it does not recur or occur elsewhere, by: a) reviewing and analyzing the nonconformity; b) determining the causes of the nonconformity; c) determining if similar nonconformities exist or could potentially occur; 3. implement any action needed; 4. review the effectiveness of any corrective action taken; 5. Update, if necessary, risks and opportunities determined during planning; 6. make any required changes to the QMS. Corrective actions should be appropriate taking into consideration the effects of the nonconformities encountered. The NRA should retain documented information as evidence of: 1. the nature of the nonconformities and any subsequent actions taken; 2. the results of any corrective action
Objective:	The objective of this sub-indicator is to ensure the NRA determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction. These should include improving products and

	services to meet requirements and to address future needs and expectations, as well as correcting, preventing or reducing undesired effects. The goal of these actions is to improve the performance and effectiveness of the QMS. Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.
Requirement:	Appropriate correction and corrective actions are taken for observed non-conformities .
Evidence to review:	The assessor should evaluate and verify the status of corrective actions and actions for risk mitigation and for overall improvement, as well as the implementation of these actions and documentation of their effectiveness. The assessor should request for and review: 1. Evidence of implementing corrections, corrective actions & preventive actions; 2. Corrections and corrective action procedures with example of records; 3. Preventive action procedures with examples of records, if any.
References:	1. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization, 2015 sub-clause 10.2., (4), (https://www.iso.org/iso-9001-quality-management.html) 2. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 3. WHO guideline (2019) on the implementation of quality management systems for national regulatory authorities. *WHO Drug Information, 33* (3), 410 - 457. World Health Organization. https://apps.who.int/iris/handle/10665/330870 4. Competence, Training, and Conduct Requirements for Regulatory Reviewers: IMDRF 2016 http://www.imdrf.org/consultations/cons-requirements-regulatory-reviewers.asp 5. IMDRF Medical Device Single Audit Program (MDSAP) https://www.fda.gov/medical-devices/medical-device-single-audit-program-mdsap/imdrfmdsap-wg-and-gthf-documents
Framework:	"Process"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): The NRA has not implemented corrections, corrective actions, and other actions to mitigate risks. ⇒ ONGOING IMPLEMENTATION (OI): The NRA has not implemented corrections, corrective actions, and other actions to mitigate risks, but some demonstrable steps have been taken. ⇒ PARTIALLY IMPLEMENTED (PI): The NRA has recently implemented corrections, corrective actions, and other actions to mitigate risks but these are not documented. ⇒ IMPLEMENTED (I): The NRA has implemented and documented corrections, corrective actions, and other actions for risk mitigation and overall improvement. The effectiveness of these actions is verified.

Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS05.13: Top management reviews and documents the organization's QMS at planned intervals (i.e., management review).**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that management reviews should be planned and carried out taking into consideration: 1. the status of actions from previous management reviews; 2. changes in external and internal issues that are relevant to the QMS; 3. information on the performance and effectiveness of the QMS, including trends in: a. customer satisfaction and feedback from relevant interested parties; b. the extent to which quality objectives have been met; c. process performance and conformity of products and services; d. nonconformities and corrections, corrective actions and preventive actions; e. monitoring and measurement results; f. audit results; g. the performance of external providers; 4. the adequacy of resources; 5. the effectiveness of actions taken to address risks and opportunities; 6. opportunities for improvement. The outputs of the management review should include decisions and actions related to: 1. opportunities for improvement; 2. any need for changes to the QMS; 3. resources need. The organization should retain documented information as evidence of the results of management reviews.

Objective:	The objective of this sub-indicator is to ensure that top management reviews the organization's QMS at planned intervals, to ensure its continued suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.
Requirement:	Management review is being performed
Evidence to review:	The assessor should evaluate and verify that top management monitors the QMS at planned intervals by review of the following: 1. Management review procedures; 2. Management review periodicity; 3. Management review records; 4. Management review inputs (e.g., audit results and customer satisfaction reports) as well as outputs (e.g., decisions, corrections, corrective actions and preventive actions),
References:	1. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization, 2015 sub-clause 9.3., (4), (https://www.iso.org/iso-9001-quality-management.html) 2. WHO Guidance on Human Resource for medical devices, https://apps.who.int/iris/bitstream/handle/10665/255261/9789241565479-eng.pdf;jsessionid=565B180CA9F7408720856799FEDAB0A8?sequence=1 3. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 4. WHO guideline (2019) on the implementation of quality management systems for national regulatory authorities. WHO Drug Information, 33 (3), 410 - 457. World Health Organization. https://apps.who.int/iris/handle/10665/330870 5. Competence, Training, and Conduct Requirements for Regulatory Reviewers: IMDRF 2016 http://www.imdrf.org/consultations/cons-requirements-regulatory-reviewers.asp 6. 5. IMDRF Medical Device Single Audit Program (MDSAP); https://www.fda.gov/medical-devices/medical-device-single-audit-program-mdsap/imdrfmdsap-wg-and-gthf-documents
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): The NRA top management does not review and document the organization's QMS at planned intervals (i.e., management review). ⇒ ONGOING IMPLEMENTATION (OI): The NRA top management does not review and document the organization's QMS at planned intervals (i.e., management review), but some demonstrable steps have been taken.

	⇒ PARTIALLY IMPLEMENTED (PI): The NRA has recently implemented management reviews at planned intervals, but these are not documented. ⇒ IMPLEMENTED (I): The NRA top management reviews and documents the organization's QMS at planned intervals (i.e., management review).
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS05.14: A mechanism is established to evaluate and demonstrate the effectiveness of training activities.**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify the NRA reviews and evaluates whether planned training meets their objectives. In addition, NRA should evaluate the learning effectiveness of trained staff.
Objective:	The objective of this sub-indicator is to ensure the NRA has established a mechanism to evaluate and demonstrate the effectiveness of training activities. For the purpose of this sub-indicator, training is not confined to QMS training activities but extends to all training activities (e.g., technical, management, and soft (i.e., interpersonal)) skills. Training is one of the key elements for building and developing personnel competencies. In order to ensure proper conduct of training programs, training evaluations must be performed. Training evaluations may cover single or multiple trainings, with or without focus on individual trainees. Pre and/or post training examination is one form of evaluation of individual training effectiveness. Other evaluation mechanisms include, for example, evaluation of the individual and overall performance of trainees, and evaluation of behavioral changes in the trainees. Training effectiveness evaluation is essential for ensuring that training objectives are met, and that participating staff has benefited from it.
Requirement:	Evaluation of competency and training activities effectiveness
Evidence to review:	The assessor should evaluate and verify the effectiveness of training by reviewing: 1. Standard operating procedures (SOPs) for evaluation of the effectiveness of the training and actions taken; 2. Samples of training evaluation records and analyses.

References:	1. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization, 2015 sub-clause 7., (4), (https://www.iso.org/iso-9001-quality-management.html) 2. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 3. WHO guideline (2019) on the implementation of quality management systems for national regulatory authorities. WHO Drug Information, 33 (3), 410 - 457. World Health Organization. https://apps.who.int/iris/handle/10665/330870 4. Competence, Training, and Conduct Requirements for Regulatory Reviewers: IMDRF 2016 http://www.imdrf.org/consultations/cons-requirements-regulatory-reviewers.asp
Framework:	"Output"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no mechanism established to evaluate and demonstrate the effectiveness of training activities. ⇒ ONGOING IMPLEMENTATION (OI): Mechanisms/procedures to evaluate and demonstrate the effectiveness of training activities have not been implemented; however some demonstrable steps have been taken. ⇒ PARTIALLY IMPLEMENTED (PI): mechanisms/procedures to evaluate and demonstrate the effectiveness of training activities has been recently implemented. ⇒ IMPLEMENTED (I): Records to evaluate and demonstrate the effectiveness of training activities are available and maintained over time.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Indicator:	**RS06 Human resources to perform regulatory activities.**
Objective:	The objective of this indicator is to ensure that all entities within an NRA are adequately resourced with a trained, experienced and skilled workforce that is empowered to fully perform their regulatory functions. This will ensure that regulatory processes and activities are performed in accordance with international best practices. The government should take responsibility for planning and overseeing the development of the necessary human resources. The strategies chosen should realistically reflect the needs and capacity of the country, and an adequate budget should be allocated. Consideration of the following aspects will help to ensure the development of a human resources policy that is supportive of the national drug policy and national regulatory system implementation. Planning should be initiated at an early stage and should consider short, medium and longer-term needs. A quantitative analysis of the human resources needed (including a realistic estimate of the attrition rate) may help to set priorities. Financial planning should match the financial resources with priority needs. Good

	planning and appropriate lead times will help to ensure that sufficient number of competent staff is available. Plans should include a career development policy and measures to retain staff in the service. The assessor should evaluate this general approach for the NRA by reviewing the human resources chapters of each regulatory functions and the education, skills, experience and training of the staff employed to perform the regulatory activities.
Category:	06. Resources (HR, FR, infrastructure and equipment)
Sub Indicator:	**RS06.01: The NRA has the power to select and recruit its own staff following documented procedures based on its own written criteria (i.e., education, training, skills and experience).**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify the role and responsibilities of the NRA in the selection of the personnel in its workforce. Assessor should verify that the NRA is involved in the framing of the recruitment criteria as per the requirements of the job or function. Key policy issues include: 1. government responsibility for planning and overseeing the development and training of the human resources needed; 2. definitions for minimum education, training, skills and experience requirements for each category of staff; 3. career planning and team building in government service; 4. the need for external assistance (i.e., national and international). 5. NRA's power to select and hire their own staff;
Objective:	The objective of this sub-indicator is to ensure that human resources development policies and strategies ensure that sufficient competent and motivated personnel are available to implement the components of the national regulatory system. Lack of motivation or appropriate expertise has been a decisive factor in failures to implement an effective and efficient national regulatory system.
Requirement:	Autonomy to select and recruit its own staff

Evidence to review:	The assessor should request for and review: 1. Regulations that give power to NRA to select and hire their own staff; 2. Documented recruitment procedures that are based on its own written criteria (i.e., education, training, skills and experience).
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO Guidance on Human Resource for medical devices, https://apps.who.int/iris/bitstream/handle/10665/255261/9789241565479eng.pdf;jsessionid=565B180CA9F7408720856799FEDAB0A8?sequence=1 6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 7. IMDRF N40 FINAL: 2017. Competence, Training, and Conduct Requirements for Regulatory Reviewers. Link: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170316-competence-conduct-reviewers.pdf.
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): The NRA has no policies and no power to select and recruit its own staff. ⇒ ONGOING IMPLEMENTATION (OI): There is no regulation that gives NRA the power to select and recruit its own staff however some demonstrable steps have been taken. ⇒ PARTIALLY IMPLEMENTED (PI): Documented procedures for recruitment based on NRA's own written criteria (i.e., education, training, skills and experience) have been recently drafted but not yet implemented.

	⇒ IMPLEMENTED (I): The NRA has the power to select and recruit its own staff and there are documented procedures and records based on its own written criteria (i.e., education, training, skills and experience).
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS06.02: A periodic staff appraisal system is established to review performance and competencies, to identify training needs, and to agree on performance targets.**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that a periodic staff appraisal system is established to review performance and competencies, to identify training needs and to agree on performance targets. For each category of personnel, the nature and extent of their involvement, as well as their roles and responsibilities should be clearly defined. This will make it possible to decide on the discipline and level of training required for each category. There should be a number of minimum educational and training requirements for each category. In addition, there is need to evaluate the competency and performance of staff members at defined intervals, to ensure the adequacy of expertise needed to perform regulatory functions.
Objective:	The practical and theoretical training of human resources involved in drug regulation, as well as the continuous updating of their skills, are key components of good NRA performance. This provides consistency and ensures that the agency’s actions will be based on the latest scientific developments.
Requirement:	Assessment of human resource capability (e.g., number proportionate to tasks, possession of appropriate skills and education, identification of training needs) along with periodic staff appraisal for performance evaluation
Evidence to review:	The assessor should request for and review: 1. SOP or any written procedure to define periodic staff appraisal system, interval of evaluation and performance targets for each function;

	2. List of personnel trained in the last three years; 3. Records for re- evaluation of staff.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO Guidance on Human Resource for medical devices, https://apps.who.int/iris/bitstream/handle/10665/255261/9789241565479eng.pdf;jsessionid=565B180CA9F7408720856799FEDAB0A8?sequence=1 6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 *7. IMDRF N40 FINAL: 2017. Competence, Training, and Conduct Requirements for Regulatory Reviewers.* Link: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170316-competence-conduct-reviewers.pdf.
Framework:	"Process"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no SOP or any written procedure to define a periodic staff appraisal system. ⇒ ONGOING IMPLEMENTATION (OI): There is no SOP or any written procedure to define a periodic staff appraisal system; however some demonstrable steps have been taken. ⇒ PARTIALLY IMPLEMENTED (PI): The SOP or any written procedure to define periodic staff appraisal system has been recently drafted but is not yet implemented. ⇒ IMPLEMENTED (I): There is a documented and implemented SOP or any written procedure to define periodic staff appraisal system, interval of evaluation and performance targets for each regulatory function.

Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS06.03: A documented policy or procedure for the appointment and recruitment of external experts is available.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that there is a policy for appointment of external experts, evaluate whether the selection process uses an unbiased selection panel, and assess whether the process is transparent. The results of such selection should be made public. When assessing whether the objectives of the indicator have been met, assessor should consider 1. whether the NRA has a documented policy for the recruitment and selection of external experts; 2. if there is no such policy, how the NRA demonstrates the ability to base its decisions on current scientific developments; 3. whether the policy is applied.
Objective:	The objective of this sub- indicator is to ensure the NRA has a documented policy or procedure for the appointment and recruitment of external experts. This policy or procedure should have defined criteria for the selection of experts. Selection process should be conducted by a competent panel and decisions should be made public. Outside experts and expert committees are mechanisms that allow the NRA access to expertise on a particular topic. Such a practice is recommended in light of the rapid pace of progress in science and technology, which means that no NRA can have staff with sufficient first-hand, up-to-date knowledge in all fields. External experts are an extension of the NRA's staff, and therefore must meet the same requirements for competence, experience and education as in- house staff, especially given the implicit risks because they are not an internal and integral part of the NRA, and thus are not subject to the same work-related laws and regulations. Therefore, it is good regulatory practice to establish a policy with defined criteria for recruitment of experts, creation of selection panels, and publication of final decisions.
Requirement:	Recruitment of external experts

Evidence to review:	The assessor should request for and review: 1. Public information from the internet, bulletins, publications, or other official documents; 2. Supporting documentation, including notices for external experts, records of selection meetings, appointments, and contracts.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1
Framework:	"Process"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no policy for the appointment, recruitment and selection of external experts. ⇒ ONGOING IMPLEMENTATION (OI): A circulated draft of such a policy is available, or there is evidence that proposals have been made. ⇒ PARTIALLY IMPLEMENTED (PI): The policy was approved recently (less than one year ago), and these concepts were only recently incorporated into external experts' contracts or other documents. ⇒ IMPLEMENTED (I): The NRA has and consistently applies a policy for the recruitment and selection of external experts.
Limitations and remarks:	

Sub Indicator:	**RS06.04: Documented mechanism to handle potential conflicts of interest for internal and external experts and committee members, to gather declarations of interest and to guarantee the update of these declarations for all regulatory functions.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should review the procedure for declaration of interests by experts and verify whether the same criteria are applied in case of internal or external experts and committee members for all regulatory functions. Assessor should consider the following aspects when assessing whether the objectives of the indicator have been met: 1. whether there is a conduct policy for external experts and expert committees; 2. if there is such a policy, whether it establishes terms of reference regarding confidentiality and potential conflicts of interest; 3. whether the policy is applied.
Objective:	The objective of this sub-indicator is to ensure that there is a mechanism in place to manage potential conflicts of interest for internal and external experts and expert committees. Outside experts and committees on which they serve are an extension of the NRA's work; therefore, they must meet the same criteria as those applied to staff involved in regulatory functions. Since they do not work at the NRA and generally perform other tasks, potentially with and for those regulated, there is a risk of conflicts of interest that are different from those faced by civil servants. For this reason, the NRA must apply a special conflict of interest policy when hiring outside experts.
Requirement:	Managing potential conflicts of interest of internal and external experts and committee members
Evidence to review:	The assessor should request for and review: 1. Public information on the internet, bulletins, or other official documents; 2. Code of conduct for experts; 3. Contracts for external experts;

	4. Expert committee rules and special exclusions; 5. Examples of declarations of interest, as well as examples of deferrals due to potential conflicts of interest
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 6. WHO Guidance on Human Resource for medical devices, https://apps.who.int/iris/bitstream/handle/10665/255261/9789241565479eng.pdf;jsessionid=565B180CA9F7408720856799FEDAB0A8?sequence=1 7. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 8. IMDRF N40 FINAL: 2017. Competence, Training, and Conduct Requirements for Regulatory Reviewers. Link: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170316-competence-conduct-reviewers.pdf.
Framework:	"Process"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): The NRA has no internal mechanism to handle conflicts of interest for internal and external experts and committee members. ⇒ ONGOING IMPLEMENTATION (OI): There is documented evidence that steps have been taken to develop a rule or policy and internal mechanisms and procedures to handle conflicts of interest, but they are not available or have not yet been implemented. ⇒ PARTIALLY IMPLEMENTED (PI): A rule or policy and mechanism to handle potential conflicts of interest were recently established (less than one year ago), but there is not sufficient, robust evidence of the NRA's work in this area.

	⇒ IMPLEMENTED (I): The NRA has a rule or policies, mechanisms, and procedures to handle potential conflicts of interest for internal and external experts and committee members, and they are periodically updated and applied consistently over time.
Limitations and remarks:	
Indicator:	**RS07 Financial resources to perform regulatory activities.**
Objective:	The objective of this indicator is to ensure that whether or not a public system operates with cost-recovery, decentralized medical products budgets or other systems, the system should be well-designed and provided with resources sufficient to run regulatory activities properly. Financial planning should match the financial resources with priority needs. The assessor should identify if the NRA has sustainable funding. The assessor should find out if the NRA is funded by the Government, by the fees collected for the services provided or by donor sources. The availability of an adequate budget is essential to provide salaries that will attract personnel with the required training and experience, as well as the facilities and infrastructure needed. The NRA should have the authority to collect and utilize internally the funds that it generates.
Category:	06. Resources (HR, FR, infrastructure and equipment)
Sub Indicator:	**RS07.01: Sources of funding are established for the NRA and affiliated institutions to carry out all regulatory functions.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that sources of funding needed to carry out all functions are available for the NRA and the affiliated institutions. The process or mechanism for obtaining funding should be reviewed. Assessor should evaluate the following when assessing whether the objectives of this indicator have been met: 1. Identify the sources of funding for the NRA (e.g., the government, fees collected for services provided by the NRA, grants, or a combination of these or other sources) and determine if they are sustainable.

	2. Determine whether the NRA has annual budgets. If so, determine whether they cover execution of all regulatory functions. Budgets for at least two years should be reviewed.
Objective:	The objective of this sub-indicator is to confirm that the NRA has sources of funding that allow it to perform its regulatory functions under stable conditions. For an NRA to maintain adequate performance, the agency must have sustainable funding. The budget must allow it to operate satisfactorily and perform all regulatory and oversight duties with sufficient specialized personnel.
Requirement:	Existence of fee system or an equivalent mechanism for stable funding.
Evidence to review:	The assessor should request for and review: 1. Applicable regulations; 2. Annual NRA budget for at least two years; 3. Funding agreements; 4. NRA annual reports on activities and budgets.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization, 2015, (4), (https://www.iso.org/iso-9001-quality-management.html) 6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1
Framework:	“Structure/Foundation/Input”

Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no evidence of stable sources of funding, or no budget is established for performing all regulatory functions. ⇒ ONGOING IMPLEMENTATION (OI): There is evidence of steps being taken to systematize the sources of funding for the NRA and allocate a budget periodically. ⇒ PARTIALLY IMPLEMENTED (PI): There are sources of funding, but they have not been stable during the past three years. The NRA stated that certain functions or indicators (i.e., under this or other modules) cannot be implemented due to budget constraints. ⇒ IMPLEMENTED (I): The NRA has defined sources of funding and has been executing a budget for the performance of all its regulatory functions over time.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS07.02: The amounts collected for fees, taxes, tariffs or dues payable for the services provided are defined and publicly available.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that the amounts of fees, taxes, tariffs or dues payable for the services provided are defined and that this information is publicly available. Fees, taxes, tariffs or dues are a financial charge imposed upon a taxpayer (an individual or legal entity).
Objective:	The objective of this sub-indicator is to ensure that for purposes of transparency, the NRA or the responsible authority in the country should define the amounts of fees, taxes, tariffs or dues payable for the services provided by the NRA and should make this information available to the public.
Requirement:	Fees, taxes, tariffs

Evidence to review:	The assessor should request for and review: 1. Documentation showing fees, taxes, tariffs or dues payable for the services provided; 2. Documentation demonstrating public availability of this information.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 6. WHO - Good regulatory practices for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_products.pdf
Framework:	“Structure/Foundation/Input”
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no public list, although fees are charged for services. ⇒ ONGOING IMPLEMENTATION (OI): The list is awaiting approval from the governing institutions, and there is evidence that such a proposal has been submitted. ⇒ PARTIALLY IMPLEMENTED (PI): The list was recently published (i.e., less than a year ago), or a list was published more than a year ago but it does not include all services. ⇒ IMPLEMENTED (I): There is a list with the rates of all NRA services that require payment. This rate list is consistently applied, is updated periodically, and was published digitally or printed less than a year ago.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

Sub Indicator:	**RS07.03: There are provisions relating to reduction or exemption of dues, taxes, tariffs or fees in defined situations for public health interest.**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should check that there are provisions in the NRA to waive or reduce the fees and taxes in cases of public health interest, for example, to guarantee the availability of medical products. The NRA should define the criteria for specific circumstances, as well as necessary actions.
Objective:	The objective of this sub-indicator is to ensure that provisions exist to facilitate and improve access to medical products and to guarantee the availability of medical products in defined situations (e.g., shortages, emergencies, or outbreaks) through reductions or exemptions in dues, taxes, tariffs or fees. This information should be publicly available.
Requirement:	Possibility for reduction or exemption of dues, taxes, tariffs or fees
Evidence to review:	The assessor should request for and review: 1. The provisions in the NRA to waive or reduce the fees and taxes in emergency situations; 2. Examples of tax exemptions or reductions under emergency conditions or other relevant situations.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical

	Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 6. WHO - Good regulatory practices for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_products.pdf
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There are no provisions relating to reduction or exemption of dues, taxes, tariffs or fees in defined situations for public health interest. ⇒ ONGOING IMPLEMENTATION (OI): The provisions are awaiting approval from the governing institutions, and there is evidence that such a proposal has been submitted. ⇒ PARTIALLY IMPLEMENTED (PI): The provisions were recently published (i.e., less than a year ago), but there are no examples of tax exemption or reduction to show. ⇒ IMPLEMENTED (I): There are provisions relating to reduction or exemption of dues, taxes, tariffs or fees in defined situations for public health interest and there are examples of their application.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS07.04: The NRA has authority to manage the funds allocated and/or generated internally.**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics

Description:	The assessor should verify that the NRA has the authority to manage the funds allocated and/or generated internally. The assessor also should determine the percentage of these funds that are used by the NRA for its functions.
Objective:	The objective of this sub-indicator is to ensure the NRA has the authority to manage allocated or internally-generated funds to finance regulatory activities. This authority plays an important role in enhancing the autonomy and independence of the NRA.
Requirement:	Authority to manage the funds allocated and/or generated internally.
Evidence to review:	The assessor should request for and review 1. Provisions that give authority to NRA to manage allocated funds and to collect and use the funds generated internally; 2. Mechanisms or processes in place to manage these funds; 3. Records of funds that are generated by NRA and the percentage that are used internally.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf)
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): The NRA does not have the authority to manage the allocated or internally generated funds. ⇒ ONGOING IMPLEMENTATION (OI): There is evidence of steps being taken to enable the NRA to manage the allocated or internally generated funds. ⇒ PARTIALLY IMPLEMENTED (PI): The NRA is recently able to manage allocated or internally generated funds or the NRA, with some constraints or limitations, has the authority to manage allocated or internally generated funds.

	⇒ IMPLEMENTED (I): The NRA has the full authority to manage the allocated or internally generated funds.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS07.05: The NRA periodically publicizes its budget.**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should check that the NRA publicizes its budget periodically (i.e., at least once per year). The assessor should review publicly available budgets, both an overall budget as well as a budget broken down by regulatory function and/or medical products.
Objective:	The objective of this sub-indicator is to ensure that the NRA periodically publicizes its budget to demonstrate transparency, prevent corruption, and build trust between the public and the NRA.
Requirement:	NRA periodically publicize its budget
Evidence to review:	The assessor should request for and review: 1. Provisions requiring the NRA to publicize its budget periodically; 2. Records of published budgets.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical

	Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO guidance on Good Regulatory Principles (GRP). t https://www.who.int/docs/default-source/medicines/norms-and-standards/current-projects/qas16-686-rev-3-good-regulatory-practices-medical-products.pdf?sfvrsn=ccb041db_2 6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1
Framework:	"Output".
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no provision stating the NRA periodically publicizes its budget. ⇒ ONGOING IMPLEMENTATION (OI): There is evidence of steps being taken to systematize the publication of the NRA budget. ⇒ PARTIALLY IMPLEMENTED (PI): The provisions were recently published (i.e., less than a year ago), but there are no examples of NRA budget publication. ⇒ IMPLEMENTED (I): There are provisions stating the NRA periodically publicizes its budget and there are records of published budgets available for two years.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Indicator:	**RS08 Infrastructure and equipment to perform regulatory activities.**
Objective:	The objective of this indicator is to ensure that resources and infrastructure are available to the national regulatory authority in order to perform regulatory activities adequately. A well-resourced authority backed with adequate drug legislation and regulations is needed to ensure the delivery of regulatory activities.
Category:	**06. Resources (HR, FR, infrastructure and equipment)**
Sub Indicator:	**RS08.01: The workspace and work environment provided for performing the regulatory activities are adequate.**
Maturity Level:	2

Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that "work environment" under which work is performed (including physical, environmental and other factors) is adequate to perform regulatory activities. Infrastructure includes, as applicable: 1. buildings, workspaces and associated utilities; 2. lighting and ventilation in the workspaces;
Objective:	The objective of this sub-indicator is to ensure the NRA provides and maintains the minimum infrastructure needed to achieve conformity to service requirements and conduct regulatory activities. The organization should determine and manage the work environment (workspace) and the environmental conditions needed for employees to perform their daily activities.
Requirement:	Suitable workspace and work environment
Evidence to review:	The assessor should request for and review: 1. Number of staff and the number of offices to which they are assigned; 2. Quality of workspace; 3. Lighting and ventilation in the workspace; 4. Supporting services (e.g., transportation and communication systems).
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf)

	5. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization, 2015 (4) (https://www.iso.org/iso-9001-quality-management.html) 6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 7. WHO - Good regulatory practices for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_products.pdf
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is inadequate workspace and work environment to perform regulatory activities. ⇒ ONGOING IMPLEMENTATION (OI): There is evidence of steps being taken to ensure adequate workspace and work environment to perform all regulatory activities. ⇒ PARTIALLY IMPLEMENTED (PI): There is adequate workspace and work environment in some areas but not for all regulatory functions. ⇒ IMPLEMENTED (I): The NRA provides adequate workspace and work environment for all regulatory activities.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS08.02: The workspace and work environment provided for performing the regulatory activities includes essential requirements.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify the "work environment" including the essential requirements to perform regulatory activities. The assessor should verify that there is enough space for secure storage of documents and an easily accessible archive. In addition, some specific regulatory activities require specific workspace (e.g., laboratory facilities). The archival of the documents should be verified.

	Infrastructure includes, as applicable: 1. process equipment (both hardware and software); 2. supporting services (servers and information systems); 3. archives; 4. workspace for specific regulatory activities, e.g., laboratories.
Objective:	The objective of this sub-indicator is to ensure the NRA provides the work environment needed to conduct regulatory activities in an efficient manner. The organization should determine and manage the work environment needed to achieve conformity to product requirements.
Requirement:	Essential requirements available in workspace and work environment
Evidence to review:	The assessor should request for and review: 1. Workspace and security access for storage of documents (paper and electronic); 2. Archives; 3. List of needed equipment, as well as availability of this equipment (e.g., process equipment and supporting services)
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization, 2015 (4) (https://www.iso.org/iso-9001-quality-management.html) 6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1

	7. WHO - Good regulatory practices for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_products.pdf
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): The workspace and work environment that are provided for performing the regulatory activities do not include the essential requirements as specified in this fact sheet. ⇒ ONGOING IMPLEMENTATION (OI): A plan to meet the essential requirements as specified in this fact sheet exists for the workspace and work environment that are provided for performing the regulatory activities, but it is not yet implemented. ⇒ PARTIALLY IMPLEMENTED (PI): There is evidence that steps and actions have been taken for the workspace and work environment that are provided for performing the regulatory activities to meet the essential requirements as specified in this fact sheet, but it does not yet meet all essential requirements. ⇒ IMPLEMENTED (I): The workspace and work environment that are provided for performing the regulatory activities are verified to include the essential requirements as specified in this fact sheet.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS08.03: The equipment provided for performing the regulatory activities is adequate.**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify the equipment provided for the performance of regulatory activities is adequate to perform these activities (i.e., taking into consideration the types of activities to be performed and the number of staff allocated).
Objective:	The objective of this sub-indicator is to ensure the NRA provides and maintains adequate equipment as part of the infrastructure needed to achieve conformity to service requirements and to perform regulatory activities.

Requirement:	Equipment provided for performing regulatory activities is adequate
Evidence to review:	The assessor should request for and review: 1. List of needed equipment (e.g., computers and printers) and its availability; 2. Indication that the available equipment fulfil the minimum requirements for such equipment; 3. List of functional equipment and its maintenance.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization, 2015 (4) (https://www.iso.org/iso-9001-quality-management.html) 6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 7. WHO - Good regulatory practices for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_products.pdf
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is insufficient equipment to perform regulatory activities. ⇒ ONGOING IMPLEMENTATION (OI): There is evidence of steps being taken to ensure adequate equipment to perform all regulatory activities.

	⇒ PARTIALLY IMPLEMENTED (PI): There is adequate equipment available in some areas but not enough to cover all regulatory functions. ⇒ IMPLEMENTED (I): The NRA provides adequate equipment for all regulatory activities.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Indicator:	**RS09 Mechanisms exist to promote transparency, accountability and communication.**
Objective:	The objective of this indicator is to ensure that NRA's general practices and policies dealing with transparency issues are established in procedures and outcomes. On this matter the assessor could undertake interviews outside the NRA, for example, with stakeholders' representatives, to collect information on how the NRA is perceived or operates. Information is a key pre-requisite for communication. Adequate and effective communication plays a fundamental role for exchanging information, informing relevant stakeholders, and preventing misunderstanding. When regularly communicating both internally and externally, organizations remain more transparent. Accountability is the process through which an organization makes a commitment to respond to and balance the needs of stakeholders in its decision-making processes and activities. The assessor should verify that the information and documents are updated for all sub-indicators. Documented evidence to be studied: 1. Reporting and communication policy; 2. Annual or periodic reports; 3. NRA web page or website.
Category:	08. Transparency, accountability and communication
Sub Indicator:	**RS09.01: The NRA participates in regional and/or global networks to promote convergence and harmonization efforts and expand its collaboration in the regulatory field.**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines

	3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should check the global, regional and/or sub-regional networks joined by the relevant NRA. Only those networks which promote convergence, harmonization, collaboration and reliance among the NRAs or related institutions (e.g. pharmacovigilance centers) should be considered. Active participation in meetings, seminars, committees, and adoption of decisions and recommendations by the networks should be verified.
Objective:	The objective of this indicator is to ensure the participation of the NRA in regional or global networks. These networks can serve as a forum for sharing information, exchanging experiences on technical issues and best practices, and facilitating assistance between NRAs. They can contribute to efforts to promote convergence of international regulatory requirements and practices, as well as harmonization efforts.
Requirement:	Involvement of the NRA in regional and/or global networks to promote convergence and harmonization efforts in regulatory requirements and practices
Evidence to review:	The assessor should request for and review: 1. Global, regional and/or sub-regional network memberships and agreements; 2. Minutes of meetings of these networks, documentation of high level decisions (e.g. guidelines adaptation), and records of communications.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf)5. WHO Global Model Regulatory Framework for medical devices

	including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 5. WHO - Good regulatory practices for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_products.pdf 6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no evidence that the NRA participates in a regional and/or global network. ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence that the NRA participates in regional and/or global networks but demonstrable steps have been taken towards this. ⇒ PARTIALLY IMPLEMENTED (PI): The NRA has participated in some meetings, seminars, or committees but there is no evidence of adoption of decisions or recommendation by the networks. ⇒ IMPLEMENTED (I): There is documented evidence of NRA participation in regional and/or global networks.
Limitations and remarks:	▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs). ▪ For blood products, the NRA should have the ability to participate in international risk management activities when needed. This includes, for example, access to epidemiological data and the capacity and expertise to perform respective risk assessments. Documented procedures for sharing risk information internationally should be in place; records of the information exchanged with international partners should be kept. The NRA should conduct data gathering and/or have access to comprehensive externally gathered adverse event data on blood donations and transfusions (i.e., haemovigilance data) that can be shared with other NRAs and benchmarked against similar reporting in other NRAs.
Sub Indicator:	**RS09.02: The information on laws, regulations guidelines and procedures is publicly available and is kept duly updated.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs)

	4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that all relevant laws, regulations, guidelines and procedures are publicly available and duly updated. Some other information related to internal procedures and decision making may be for internal use only. Assessor should verify the availability of document control mechanisms and procedures for updating the documents at a regular frequency. The assessor should verify that there is public access to non-classified information unless otherwise justified for well-specified reasons as provided by law (such as protection of privacy or ensuring fairness of procurement procedures).
Objective:	The objective of this sub-indicator is to ensure that medical products laws, regulations, guidelines and procedures are available and accessible to stakeholders and the general public. Openness and transparency are key ingredients for building the accountability and trust which are necessary for the functioning of organization and for good governance.
Requirement:	Laws, regulations, guidelines and procedures are publicly available.
Evidence to review:	The assessor should request for and review: 1. Publicly available laws, regulations, guidelines and procedures; 2. Mechanisms in place for information sharing (e.g., website or other public communications); 3. Written procedures describing the process.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. Good governance for medicines: Model framework. Updated version 2014. WHO, (110), (https://www.who.int/medicines/areas/governance/ggm_modelframe_updated/en/)

	6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 7. WHO - Good regulatory practices for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_products.pdf
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no evidence that the information on laws, regulations guidelines and procedures is publicly available and is kept duly updated. ⇒ ONGOING IMPLEMENTATION (OI): The information on laws, regulations guidelines and procedures is not publicly available or kept duly updated but demonstrable steps have been taken towards this. ⇒ PARTIALLY IMPLEMENTED (PI): There is some information publicly available but not from all types of documents, or information is not kept duly updated. ⇒ IMPLEMENTED (I): The information on laws, regulations guidelines and procedures is publicly available and is kept duly updated.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS09.03: Information on decisions related to regulatory activities is available to the public.**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that all relevant information and summary reports that serve as the bases for regulatory decisions for different functions are available and that final decisions are communicated to the public.

Objective:	The objective of this sub-indicator is to ensure that relevant documents that support positive or negative NRA decisions are publicly available, and that final decisions are communicated to the public. Evidence-based decisions and honesty regarding the facts and principles considered in the regulatory decision-making process greatly enhance public trust. A basic component of transparency in the work of NRAs is based on whether its decisions are published, and whether the relevant information is quickly and easily accessible to those regulated and to the general public. Regulatory decisions include approvals or denials; unless prohibited by specific legal provisions, decisions to not approve (i.e., denials) should also be published.
Requirement:	NRA decisions are accessible to the public
Evidence to review:	The assessor should request for and review: 1. Provisions or guidelines describing the public communication process; 2. List of publicly available final decisions and supporting documents and reports related to different regulatory processes (e.g., marketing authorizations, clinical trials, inspections, market surveillance, pharmacovigilance, and licensing); 3. Relevant documents from website or other mechanisms used to publish the information.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. Good governance for medicines: Model framework. Updated version 2014. WHO (110) (https://www.who.int/medicines/areas/governance/ggm_modelframe_updated/en/) 6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1

	7. WHO - Good regulatory practices for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_products.pdf
Framework:	"Output"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): No regulatory decisions are published. ⇒ ONGOING IMPLEMENTATION (OI): There is evidence that a process is underway for the publication of regulatory decisions. ⇒ PARTIALLY IMPLEMENTED (PI): Regulatory decisions began to be published recently (i.e., less than a year ago). ⇒ IMPLEMENTED (I): The NRA systematically publishes the positive and negative regulatory decisions.
Limitations and remarks:	▪ In some countries, legislation may not allow the publication of negative regulatory decisions. In this case, the assessment of this sub-indicator should be limited to the publication of positive regulatory decisions (e.g. marketing authorizations granted or Good Manufacturing Practice compliance assessments). ▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS09.04: Information on marketed medical products, authorized companies and licensed facilities is publicly available.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that lists identifying all authorized products and all licenses issued to manufacturers, importers, wholesalers and other institutions engaged in manufacture, control, distribution, or marketing of medical products are published and publicly available. Experience in countries has demonstrated that informing consumers and public interest groups on regulation of medicines enhances political support for the regulatory process, promotes NRA transparency and accountability, and shields them from negative external influence.

Objective:	The objective of this sub-indicator is to ensure that information on NRA decisions is available to the public. Such transparency can help to reduce conflicts of interest and corruption. In addition, public availability of a list of approved products may prevent use of any unregistered products.
Requirement:	Information on marketed medical products, authorized companies and licensed facilities is publicly available
Evidence to review:	The assessor should request for and review: 1. Guidelines which describe the information that should be publicly available; 2. Publicly available information on marketed products and authorized companies and facilities.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 6. WHO - Good regulatory practices for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_products.pdf
Framework:	"Output".
Rating Scale:	⇒ NOT IMPLEMENTED (NI): No information on marketed medical products, authorized companies and licensed facilities is published. ⇒ ONGOING IMPLEMENTATION (OI): There is evidence that a process is underway for the publication of some regulatory decisions on marketed medical products, authorized companies and licensed facilities.

	⇒ PARTIALLY IMPLEMENTED (PI): Regulatory decisions on marketed medical products, authorized companies and licensed facilities began to be published recently (i.e., less than a year ago). ⇒ IMPLEMENTED (I): The NRA systematically publishes the positive and negative regulatory decisions on marketed medical products, authorized companies and licensed facilities and there is evidence available for more than 2 years.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS09.05: All publicly available information is periodically reviewed and maintained.**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that public information is reviewed on regular basis so that the latest updates are currently available to the public.
Objective:	The objective of this sub-indicator is to ensure the NRA considers and defines specific intervals for reviewing and maintaining the publicly available information. As part of this process, the NRA should consider the risks linked to different categories of information.
Requirement:	Publicly available information is reviewed and maintained.
Evidence to review:	The assessor should request for and review: 1. A guideline for publication of information that describes the types of information to be published, specifies the format for publication, identifies the persons responsible, and defines the frequency for updating; 2. Records documenting that these procedures are followed.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological

	Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 6. WHO - Good regulatory practices for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_products.pdf
Framework:	"Output".
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no evidence that publicly available information is periodically reviewed and maintained. ⇒ ONGOING IMPLEMENTATION (OI): The publicly available information is not periodically reviewed and maintained but demonstrable steps have been taken towards this. ⇒ PARTIALLY IMPLEMENTED (PI): There is some information publicly available but not from all types of documents or information is not kept duly updated. ⇒ IMPLEMENTED (I): The publicly available information is periodically reviewed and maintained.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS09.06: Appropriate mechanisms exist for management of confidential information.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs)

	4. Medical devices including in vitro diagnostics
Description:	The assessor should identify the written procedures for the management of confidential information for internal staff, external experts and members of advisory committees. A written document and established mechanisms should explain which information should be kept confidential and how this should be done. The mechanisms should be explicit regarding the means used by the NRA to keep confidentiality, including administrative, physical and technical controls. It is very important to define how information can be shared within and outside the NRA.
Objective:	The objective of this sub-indicator is to ensure that the NRA has appropriate mechanisms and procedures for management of confidential information. Confidential Information refers to any documents, materials or information (whether in written, oral, electronic or any other format) which are of a confidential, proprietary, personal or non-public nature. Such confidential information may belong to either (i) the NRA or (ii) any third party collaborating with the NRA or to whom the NRA owes a duty of confidentiality (including, but not limited to, manufacturers, marketing authorization holders and clinical investigators). Confidential information must be protected from unauthorized access to safeguard the privacy or security of an individual or organization.
Requirement:	Adequate management of confidential information
Evidence to review:	The assessor should request for and review: 1. Written documents that describe management of confidential information; 2. Documentation that there is adequate infrastructure to keep the confidential information, e.g., locked rooms or secure computerized systems.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116),

	(http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. Good governance for medicines: Model framework. Updated version 2014. WHO (110) (https://www.who.int/medicines/areas/governance/ggm_modelframe_updated/en/) 6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 7. WHO - Good regulatory practices for regulatory oversight of medical products https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS16_686_rev_3_good_regulatory_practices_medical_products.pdf
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no evidence that the NRA has an appropriate mechanism to manage confidential information. ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence that the NRA has an appropriate mechanism to manage confidential information but demonstrable steps have been taken towards this. ⇒ PARTIALLY IMPLEMENTED (PI): The NRA has developed a draft document to manage confidential information but it has not yet been implemented. ⇒ IMPLEMENTED (I): There is documented evidence that the NRA has an appropriate mechanism to manage confidential information.
Limitations and remarks:	▪ Confidential information means any documents, materials or information (whether in written, oral, electronic or any other format) which are of a confidential, proprietary, personal or non-public nature. Such confidential information may belong to either (i) the NRA or (ii) any third party collaborating with the NRA or to whom the NRA owes a duty of confidentiality (including, but not limited to, manufacturers). ▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS09.07: A code of conduct, which includes management of conflicts of interest, is published and enforced for internal and external staff, including members of the advisory committees.**
Maturity Level:	3
Scope:	1. Medicines 2. Vaccines

	3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify the existence of a written, published and enforced code of conduct for internal staff and for external experts and members of advisory committees. The main issues are related to the independence of all experts involved in the regulatory processes and to the management and prevention of potential conflicts of interests (see also RS06.04).
Objective:	The objective of this sub-indicator is to ensure the NRA has established codes of conduct based on professionalism, institutional values, and ethical principles. This is a mechanism to prevent unethical behavior by public servants and external staff (including members of the advisory committees) in the performance of their duties. Studies by Transparency International indicate that governments which have established a framework for good governance, based on codes of conduct, ethical principles and other key components of an integrity system, are listed among the countries with very low levels of corruption. There is a logical and consistent link between values, principles and a code of conduct. A code of conduct attempts to articulate in concrete terms the application of ethical principles. The normative base for the code of conduct is the framework of institutional values.
Requirement:	Code of conduct
Evidence to review:	The assessor should request for and review: 1. A guideline describing the code of conduct for the NRA; 2. Records of signed conflict of interest forms.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf)

	5. Good governance for medicines: Model framework. Updated version 2014. WHO (110) (https://www.who.int/medicines/areas/governance/ggm_modelframe_updated/en/) 6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no evidence that a code of conduct, including management of conflicts of interest, is published and enforced for internal and external staff, including members of the advisory committees. ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence that a code of conduct, including management of conflicts of interest, is published and enforced; however, demonstrable steps have been taken towards this. ⇒ PARTIALLY IMPLEMENTED (PI): The NRA has developed a draft document but it has not yet been implemented. ⇒ IMPLEMENTED (I): There is documented evidence that a code of conduct, including management of conflicts of interest, is published and enforced.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS09.08: The NRA uses computerized systems to process information, manage records, and analyze data.**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that the NRA makes appropriate use of automation and effectively manages its databases to process information and generate good quality and readily accessible reports. "E-government" refers to the use of information and communication technologies to promote more efficient and effective government, facilitate more accessible government services, allow greater public access to information, and make government more accountable to citizens. The assessor should verify the utilization of electronic systems and workstations by the NRA to handle these activities, which may be repetitive in nature. In general, e-governance would be required to be checked.

Objective:	The objective of this sub-indicator is to ensure the NRA manages computerized systems for information processing, records management, and data analysis. This sub-indicator measures the NRA's handling of automated data management systems, use of safeguards to protect data integrity, and development of integrated networks. Under this indicator, the degree to which these objectives are achieved is also assessed. E-governance can play a facilitating role.
Requirement:	Computerized systems to automate repetitive activities are used by the NRA
Evidence to review:	The assessor should request for and review: 1. Evidence for availability of electronic systems and workstations; 2. Evidence for availability of required software for conducting regulatory activities; 3. List of processes that use computerized systems; 4. Databases in use or under in development within the NRA; 5. Databases and systems in use that can be consulted by those regulated and the general public.
References:	1. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 2. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 3. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf)
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no evidence that the NRA uses computerized systems for information processing, records management, and data analysis. ⇒ ONGOING IMPLEMENTATION (OI): There is no evidence that the NRA uses computerized systems for information processing, records management, and data analysis, but demonstrable steps have been taken towards this. ⇒ PARTIALLY IMPLEMENTED (PI): The NRA has started to use computerized systems for information processing, records management, and data analysis but this has not been applied in all regulatory processes.

	⇒ IMPLEMENTED (I): There is documented evidence that the NRA uses computerized systems for information processing, records management, and data analysis.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS09.09: The NRA has its own web page with timely information that gives public access to related legal provisions, guidelines and decisions.**
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics
Maturity Level:	3
Description:	The assessor should check that the NRA web page serves as a platform for sharing timely information and for providing public access to legal provisions, guidelines and decisions.
Objective:	The objective of this sub-indicator is to ensure the NRA's website plays an active role in effective and timely communication of information required to be publicized (see also RS09.02).
Requirement:	Website
Evidence to review:	The assessor should request for and review: 1. NRA website and information available on it; 2. NRA communication policy; 3. Written documents describing how frequently information provided on the website should be reviewed and updated.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2),

	(http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1
Framework:	"Structure/Foundation/Input"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): The NRA does not have a website with timely information that gives public access to related legal provisions, guidelines and decisions. ⇒ ONGOING IMPLEMENTATION (OI): The NRA does not have a website but demonstrable steps have been taken towards this. ⇒ PARTIALLY IMPLEMENTED (PI): The NRA has started to use its website but the information posted is not up to date. ⇒ IMPLEMENTED (I): The NRA has a website with timely information that gives public access to related legal provisions, guidelines and decisions.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS09.10 An opportunity for interaction between the NRA and stakeholders is given**
Maturity Level:	3
Scope:	1. Blood Products (whole blood, blood components and PDMPs) 2. Blood Product Associated Substances and Devices including In Vitro Diagnostics 3. Medical devices including in vitro diagnostics
Description:	The assessor should request documents that define the pathways through which stakeholders are informed of opportunities to communicate with the NRA. Different pathways may be provided for specified stakeholders that are directly affected by blood/medical devices regulation (e.g., meetings for manufacturers, distributors and other sponsors) and for other interested parties (e.g., policy documents posted for written comments or periodic open public hearings on societally-impactful matters).

Objective:	The interests of transparency, accountability and communication of the NRA are best served by providing avenues for stakeholders to provide input and to obtain feedback regarding the policies and decisions of the NRA. Such opportunities strengthen the acceptance of the NRA and work to assure that the NRA will be fully aware of the consequences of its actions and will be in the best position to balance conflicting interests.
Requirement:	Opportunities for stakeholders to communicate with the NRA
Evidence to review:	The assessor should request for and review: 1. sections of statutes and regulations containing information on opportunity for interaction between the NRA and stakeholders 2. guidance documents containing information on opportunity for interaction between the NRA and stakeholders
References:	1. WHO Guideline on Management of Blood Components as Essential Medicines, TRS 1004 (2017), Annex 3 Aide Memoire: Good Policy Process for Blood Safety and Availability (2008) 2. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 3. WHO Guidance on post-market and market surveillance of medical devices, including IVDs https://apps.who.int/iris/handle/10665/337551
Framework:	"Process"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): Opportunities for stakeholders to interact with the NRA are not specified in statutes, regulations or guidance documents ⇒ ONGOING IMPLEMENTATION (OI): Procedures to provide opportunities for stakeholders to communicate with the NRA are in development or are established only for a narrow scope of stakeholders (e.g., only for product sponsors) ⇒ PARTIALLY IMPLEMENTED (PI): Procedures exist through which a broad range of stakeholders are informed of opportunities to communicate with the NRA, but the specific opportunities are limited or cumbersome to use ⇒ IMPLEMENTED (I): Procedures are in place that provide flexible and robust opportunities for stakeholders to communicate routinely with the NRA
Limitations and remarks:	The NRA needs to structure its interactions with stakeholders in a manner that avoids biases and maintains internal efficiency. For example, policy documents can be posted widely for public comments while the number of meetings allowed to a sponsor during a product review can be limited.

Sub Indicator:	**RS09.11 Written procedures exist for meetings with manufacturers, distributors and other sponsors**
Maturity Level:	4
Scope:	1. Blood Products (whole blood, blood Components and PDMPs) 2. Blood Product Associated Substances and Devices including In Vitro Diagnostics 3. Medical devices including in vitro diagnostics
Description:	The assessor should request documents that define the scope, objectives, timelines and methods to document the outcomes of meetings between the NRA and specified stakeholders that are directly affected by blood and medical devices regulation (e.g., manufacturers, distributors and other sponsors)
Objective:	Interactions between the NRA and stakeholders that are directly affected by blood and medical devices regulation are sensitive at many levels (e.g., implications for costs and scale of validation requirements, or public perceptions of responsibility and in case of medical devices e.g., classification, reclassification, post market surveillance, market surveillance, nomenclature, regulatory fees) and warrant good mutual communication. A structured process for meetings with the NRA promotes good communications by defining the scope, objectives and timelines for such meetings and the methods to document their outcomes.
Requirement:	Written procedures for meetings with blood/medical devices establishments, manufacturers, distributors and other sponsors exist in guidance, regulation or statute
Evidence to review:	The assessor should request for and review: 1. Applicable sections of statutes and regulations 2. Applicable guidance documents
References:	1. WHO Guideline on Management of Blood Components as Essential Medicines, TRS 1004 (2017), Annex 3 2. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1 3. WHO Guidance on post-market and market surveillance of medical devices, including IVDs https://apps.who.int/iris/handle/10665/337551
Framework:	"Process"

Rating Scale:	⇒ NOT IMPLEMENTED (NI): There is no evidence that written procedures exist for meetings with manufacturers, distributors or other sponsors ⇒ ONGOING IMPLEMENTATION (OI): Written procedures for meetings with manufacturers, distributors or other sponsors are under development, but are not yet available for use or are available only for a narrow scope of types of significant meetings ⇒ PARTIALLY IMPLEMENTED (PI): The NRA has established written procedures for most meetings with manufacturers, distributors or other sponsors, but gaps exist for some types of significant meetings ⇒ IMPLEMENTED (I): The NRA has established written procedures for all types of meetings with manufacturers, distributors or other sponsors
Limitations and remarks:	Provisions for meetings with applicants involved in clinical studies should be in place for the NRA to provide scientific advice (preclinical and clinical) on the design of clinical trials or on issues related to the submission of appropriate data
Indicator:	**RS10 Mechanism in place to monitor regulatory performance and output.**
Objective:	The objective of this indicator is to ensure monitoring of regulatory performance through the establishment of key performance indicators. Monitoring of regulatory performance plays an important role when taking the appropriate actions and when adjusting the process to ensure that the regulatory activity conforms to its specifications. In addition, the NRA should monitor and review the performance of the contracted entities (in the case of outsourced activities) including the implementation and effectiveness of any needed improvements.
Category:	09. Monitoring progress and assessing outcomes and impact
Sub Indicator:	**RS10.01: Requirements established to monitor, supervise and review the performance of the NRA and affiliated institutions using key performance indicators (KPIs).**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs) 4. Medical devices including in vitro diagnostics

Description:	The assessor should verify the existence and implementation of requirements and procedures for monitoring, supervising, and reviewing the performance of the NRA and affiliated institutions. Monitoring and evaluating NRA performance are essential components of a regulatory framework, and the provisions necessary to achieve this need to be included in the regulatory oversight of medical products. Key issues include: explicit government commitment to the principles of monitoring and evaluation; monitoring of the pharmaceutical sector through regular indicator-based surveys; and independent external evaluation of the impact of the regulatory oversight. The assessor should confirm the establishment of a set of KPIs for monitoring progress in meeting the objectives of the strategic plan (or equivalent) and the institutional development plan. The assessor should check whether the outcome of monitoring and measuring regulatory performance has resulted in corrective actions, preventive actions, and/or improvements in the regulatory activities.
Objective:	The objective of this sub-indicator is to ensure the NRA and affiliated institutions have established requirements to monitor, supervise and review its performance. Establishment of KPIs is a very effective approach for measuring and monitoring progress. A KPI is a measurable value that evaluates how effectively the NRA is achieving the strategic plan and the institutional development plan. Organizations use KPIs to evaluate their success at reaching targets. In the case of outsourced activities, the NRA should monitor and review the performance of the contract acceptor including the implementation of any needed improvements and the assessment of their effectiveness.
Requirement:	Monitor, supervise and review the key regulatory performance indicators used for monitoring performance
Evidence to review:	The assessor should request for and review: 1. Written documents that describe the monitoring, supervision and review of different regulatory activities; 2. Supporting records, including corrective actions and preventive actions, when applicable; 3. Documentation of KPIs; 4. Records of surveys conducted, and indicators reported; 5. KPI evaluation reports, including statistical data and trend analyses in regard to KPIs, where applicable.
References:	1. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 2. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf)

	3. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 4. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116), (http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 5. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization, 2015 sub-clause 7., (4), (https://www.iso.org/iso-9001-quality-management.html)
Framework:	"Process"
Rating Scale:	⇒ NOT IMPLEMENTED (NI): There are no established requirements to monitor, supervise and review the performance of the NRA and affiliated institutions using KPIs. ⇒ ONGOING IMPLEMENTATION (OI): There are no established requirements to monitor, supervise and review the performance of the NRA and affiliated institutions using KPIs, but demonstrable steps have been taken towards this. ⇒ PARTIALLY IMPLEMENTED (PI): There are some established requirements to monitor, supervise and review the performance of the NRA and affiliated institutions but KPIs have not been established. ⇒ IMPLEMENTED (I): There are established requirements to monitor, supervise and review the performance of the NRA and affiliated institutions using KPIs.
Limitations and remarks:	▪ A regulatory impact analysis is a valuable tool for systematic assessment of the expected effects of regulatory proposals. It is aimed mainly at assisting decision makers in their consideration of the recommended proposal. ▪ Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).
Sub Indicator:	**RS10.02: Reports on the regulatory activities and on the progression and status of resources are available at regular intervals.**
Maturity Level:	4
Scope:	1. Medicines 2. Vaccines 3. Blood Products (whole blood, blood components and PDMPs)

	4. Medical devices including in vitro diagnostics
Description:	The assessor should verify that reviews are planned and carried out at regular intervals, and that these reviews take into consideration: 1. NRA performance and effectiveness of medical products regulatory oversight; 2. opportunities for improvement; 3. adequacy of resources.
Objective:	The objective of this sub-indicator is to ensure that top management reviews the NRA performance, the areas for improvement, and the status of resources at planned intervals. The purpose is to ensure continued effectiveness of medical products regulatory oversight and alignment with the organization's strategic direction (see also RS05). In addition, the review should evaluate whether required resources are available for conducting the regulatory activities .
Requirement:	Reports at regular intervals on the regulatory activities
Evidence to review:	The assessor should request for and review: 1. Management review procedures (i.e., SOPs or other written documents); 2. Records documenting the conduct of management reviews, including periodicity; 3. Annual reports of the NRA; 4. Documentation of the inputs to (e.g., audit results and customer satisfaction surveys) and outputs from (e.g., decisions, corrective actions, and preventive actions) these periodic reviews.
References:	1. Quality management systems — Requirements. International Standard ISO 9001:2015. International Organization for Standardization, 2015 sub-clause 5.1.1., (4), (https://www.iso.org/iso-9001-quality-management.html 2. National drug regulatory legislation: guiding principles for small drug regulatory authorities. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fifth report. Geneva: World Health Organization; 1999: Annex 8 (WHO Technical Report Series, No. 885) (1) (http://apps.who.int/medicinedocs/documents/s21964en/s21964en.pdf) 3. Guidelines for national authorities on quality assurance for biological products. In: WHO Expert Committee on Biological Standardization: forty-second report. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822), (2), (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf) 4. Regulation and licensing of biological products in countries with newly developing regulatory authorities. In: WHO Expert Committee on Biological Standardization: forty-fifth report. Geneva: World Health Organization; 1995: Annex 1 (WHO Technical Report Series, No. 858), (3), (http://www.who.int/bloodproducts/publications/WHO_TRS_858_A1.pdf) 5. How to develop and implement a national drug policy, Second edition. WHO, 2001., (116),

	(http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf) 6. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices. World Health Organization, 2017. https://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf?sequence=1
Framework:	"Output".
Rating Scale:	⇒ NOT IMPLEMENTED (NI): The NRA does not have reports at regular intervals on the NRA performance, areas for improvement and status of resources. ⇒ ONGOING IMPLEMENTATION (OI): The NRA does not have reports of such activities but demonstrable steps have been taken towards this. ⇒ PARTIALLY IMPLEMENTED (PI): The NRA has started to report on the NRA performance, areas for improvement and status of resources, but the activity is not conducted regularly. ⇒ IMPLEMENTED (I): Reports at regular intervals on the regulatory activities, progression and status of resources are available.
Limitations and remarks:	Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).