WHO GLOBAL BENCHMARKING TOOL (GBT) FOR EVALUATION OF NATIONAL REGULATORY SYSTEM OF MEDICAL PRODUCTS

MARKET SURVEILLANCE AND CONTROL (MC): INDICATORS AND FACT SHEETS

Revision VI version 1
November 2018
## Function:
### 04- MARKET SURVEILLANCE AND CONTROL (MC)

**Description:**

Market surveillance and control function plays a crucial role in assuring medical products consumer safety since its objective is to ensure compliance of the products placed on the market with pre-set criteria for quality, safety and efficacy (i.e., verify compliance with marketing authorization and good practices guidelines). Market surveillance and control function activities are primarily concerned with four themes: (1) control of import activities, (2) prevention and detection of and response to substandard and falsified medical products, (3) market surveillance program for monitoring the quality of medical products throughout the supply chain, and (4) control of promotional, marketing and advertising activities. The aforementioned activities may or may not be undertaken by a single entity (e.g., organization, division, or department).

A general limitation to one of the market surveillance and control function activities exists in countries where advertisement is not allowed or is restricted to specific medical products (e.g. over-the-counter medical products). However, in all cases, control of marketing and promotional materials (i.e., in its wider meaning that includes promotion to healthcare professionals) will always apply.

**Indicator:**

MC01 Legal provisions, regulations and guidelines required to define regulatory framework of market surveillance and control activities.

**Objective:**

The objective of this indicator is to ensure that market surveillance and control activities are backed up by a comprehensive set of legal provisions, regulations and guidelines that provide the necessary mandate to implement all activities related to this regulatory function.

**Category:**

01. Legal provisions, regulations and guidelines

**Sub Indicator:**

MC01.01: Legal provisions and regulations are in place with respect to import activities including permanent regulatory intervention at designated entry and exit ports where medical products are being moved.
<table>
<thead>
<tr>
<th>Maturity Level:</th>
<th>1</th>
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<tbody>
<tr>
<td><strong>Description:</strong></td>
<td>The assessor should verify that the medical products importation activities should be conducted in conformity with the mandate promulgated under the relevant legal provisions, regulations and guidelines as implemented and enforced by the National Regulatory Authority (NRA). These activities may be conducted in collaboration with other relevant authorities, e.g. customs. These mandates should require that transactions relating to importation of consignments of medical products be conducted by licensed entities and that good storage and distribution practices be followed. In exceptional cases (e.g., emergency situations for the public health interest), the NRA may retain the discretionary power to waive some licensing or authorization requirements for some medical product consignments. Such waivers should be properly justified and should not compromise patient safety or the risk-benefit balance of the medical products. Importation of medical products should be channeled exclusively through designated air, sea, or land ports. These designated entry and exit ports (i.e., air, sea, or land) should have permanent capacity for the regulatory intervention that is essential to ensure compliance with and enforcement of the relevant mandates. When justified by the workload, either full-time or part-time inspectors may be stationed at one or more of these designated ports.</td>
</tr>
<tr>
<td><strong>Objective:</strong></td>
<td>The objective of this sub-indicator is to ensure that the NRA has the necessary mandate, supported by the appropriate legal provisions and regulations, to control import activities of medical products. This control will, in turn, contribute to a positive public health impact. In the interest of public health, import activities related to medical products, unlike that of ordinary commodities, need to be controlled and under the proper oversight of the NRA. Hence, the NRA needs to be supported with the mandate needed to assume this responsibility. Import activities should then comply with this mandate, including the relevant legal provisions, regulations and guidelines. The activities should be supported by a regulatory presence at the entry and exit ports to enforce these mandates.</td>
</tr>
<tr>
<td><strong>Requirement:</strong></td>
<td>Legal provisions and regulations relevant to import activities of all medical products to or from the country.</td>
</tr>
</tbody>
</table>
| **Evidence to review:** | The assessor should ask for and review:  
1. Legal provisions relevant to medical products import activities.  
2. Regulations relevant to medical products import and.  
3. Guidelines relevant to medical products import activities including good storage and good distribution practices.  
4. Evidence of permanent regulatory intervention at the entry and exit ports. |
| **References:** | 1. Guidelines on import procedures for pharmaceutical products, World Health Organization (WHO) (22) |
### Framework:
Structure/Foundation/Input.

### Rating Scale:
- **NOT IMPLEMENTED (NI):** There are no legal provisions or regulations to satisfy the requirement of the sub-indicator.  
- **ONGOING IMPLEMENTATION (OI):** The NRA is taking steps towards establishment of legal provisions and regulations to satisfy the requirement of this sub-indicator; however no results exist so far.  
- **PARTIALLY IMPLEMENTED (PI):** Legal provisions and regulations to satisfy the requirement of this sub-indicator were recently established, and are in an early implementation phase, so no documented results exist so far.  
- **IMPLEMENTED (I):** There are legal provisions and regulations which satisfy the requirement of the sub-indicator and which are actually implemented and enforced.

### Limitations and remarks:
Permanent regulatory intervention at the entry and exit ports may or may not entail physical presence of regulators at these ports. Other acceptable alternatives include, but are not limited to, close cooperation between regulators and custom authorities with proper documentation and authorization controls or electronic systems. 

Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

### Sub Indicator:
**MC01.02:** Legal provisions and regulations authorize market surveillance and control activities which include product sampling from different points of the supply chain.

### Maturity Level:
1

### Description:
The assessor should verify the existence and implementation of legal provisions and regulations which establish a market surveillance program. Such market surveillance should normally include sampling of different medical products from different points across the supply chain, from the manufacturer, through the distributors and wholesalers, and up to the last point of sale or dispensing. In addition, the assessor should ensure that market control activities extend to the internet sales of medical products. It should be noted that testing is not limited to laboratory testing, but is extended to all types of testing including innovative technologies.

### Objective:
The objective of this sub-indicator is to ensure the quality, safety and efficacy of medical products placed on the market. The ultimate goal of the overall medical products regulatory system is to ensure public accessibility and affordability of safe, effective and high quality products. Hence, a market surveillance program, combined with market control activities, is necessary to regularly check the quality of medical products available on the market and to take any necessary regulatory actions. Market surveillance
and control activities should be based on and supported by an appropriate legal mandate.

<table>
<thead>
<tr>
<th>Requirement:</th>
<th>Legal provisions, regulations and guidelines relevant to market surveillance and control activities of all medical products.</th>
</tr>
</thead>
</table>
| Evidence to review: | The assessor should ask for and review:  
1. Legal provisions relevant to surveillance program which includes sampling and testing of samples of medical products.  
2. Regulations relevant to surveillance program which includes sampling and testing of samples of medical products.  
3. Guidelines relevant to surveillance program which includes sampling and testing of samples of medical products.  
4. Legal provisions, regulations or guidelines relevant to market control of internet sales of medical products. |
2. WHO guidelines for sampling of pharmaceutical products and related materials, World Health Organization (WHO) (31) ([http://digicollection.org/whoqapharm/p/about](http://digicollection.org/whoqapharm/p/about) and [http://apps.who.int/medicinedocs/en](http://apps.who.int/medicinedocs/en)) |
| Framework: | Structure/Foundation/Input. |
| Rating Scale: | NOT IMPLEMENTED (NI): There are no legal provisions or regulations to satisfy the requirement of the sub-indicator.  
ONGOING IMPLEMENTATION (OI): The NRA is taking steps towards establishment of legal provisions and regulations to satisfy the requirement of this sub-indicator; however no results exist so far.  
PARTIALLY IMPLEMENTED (PI): Legal provisions and regulations to satisfy the requirement of this sub-indicator were recently established, and are in an early implementation phase, so no documented results yet exist.  
IMPLEMENTED (I): There are legal provisions and regulations which satisfy the requirement of the sub-indicator and which are actually implemented and enforced. |
| Limitations and remarks: | Internet sales might be prohibited in some countries. In this case, the sub-indicator would not apply to internet sales provided that some legal provisions or regulations are in place to prohibit internet sales.  
Sampling activities at manufacturers, distributers and points of sale or dispensing might be undertaken during a regulatory inspection programme.  
Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs). |
<p>| Sub Indicator: | MC01.03: Legal provisions and regulations address the role of NRA in dealing with substandard or falsified (SF) |</p>
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<th><strong>Maturity Level:</strong></th>
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<tr>
<td><strong>Description:</strong></td>
<td>The assessor should verify that legal provisions, regulations and guidelines that address the role of the NRA in dealing with SF medical products are available and enacted. Examples of possible actions to be taken include: suspension of a drug’s marketing authorization, recall of certain batches, a warning in national drug bulletins, or a separate warning sent out to a list of institutions and key persons that deal with or prescribe pharmaceutical products. The legislation should provide for adequate and proportional sanctions, penalties and prosecutions for violations of the applicable legislation. The assessor should review the guidance published for all categories of stakeholders and find out if the guidance covers the scope of the applicable legislation and regulations. Consistency with World Health Organization (WHO) guidance should be checked as well and any differences should be identified.</td>
</tr>
<tr>
<td><strong>Objective:</strong></td>
<td>The objective of this sub-indicator is to ensure that the NRA is empowered with the proper legal provisions and regulations to work on prevention, detection and response to SF medical products.</td>
</tr>
<tr>
<td><strong>Requirement:</strong></td>
<td>Legal provisions, regulations and guidelines addressing products and personnel involved in SF medical products.</td>
</tr>
</tbody>
</table>
| **Evidence to review:** | The assessor should ask for and review:  
1. Legal provisions relevant to the role of the NRA in dealing with SF medical products;  
2. Regulations relevant to the role of the NRA in dealing with SF medical products;  
3. Guidelines relevant to the role of the NRA in dealing with SF medical products. |
2. SF- Frequently asked questions. Scope, scale and harm. How big is the problem of SF medical products? (87) (https://www.who.int/medicines/regulation/ssffc/faq-ssffc_1-10/en/)  
5. WHO Member State Mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products, A70/23,


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<td>Rating Scale:</td>
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<td>Limitations and remarks:</td>
<td>Formal guidelines might not exist, however relevant guidance may be provided in other types of documentation (e.g., regulations). Scoring this sub-indicator as &quot;not applicable NA&quot; is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).</td>
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<tr>
<td>Sub Indicator:</td>
<td>MC01.04: Legal provisions and regulations exist for the control of promotion, marketing and advertising of medical products to avoid communication of false or misleading information.</td>
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<td>Maturity Level:</td>
<td>2</td>
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<tr>
<td>Description:</td>
<td>The assessor should verify the availability of legal provisions, regulations and guidelines which set the rules for control of promotional, marketing and advertising activities of medical products. These rules should ensure that communication of false or misleading information to health professionals, the public, or any other stakeholders is avoided.</td>
</tr>
</tbody>
</table>
### Objective:
The objective of this sub-indicator is to ensure that medical professionals and the public have access to accurate data about the medical products through different promotional, marketing and advertising activities. Inappropriate promotion and advertisement of medicines may contribute to the irrational or incorrect use of medicinal products. The impact of accurate and science-based promotional activities is related to the existence of trustworthy and accessible information sources and the level of medical knowledge of the population. Hence, the control of promotion and advertisement of medical products is necessary and should be sustained by a legal and regulatory framework.

### Requirement:
Legal provisions, regulations and guidelines for the control of promotion, marketing and advertising of medical products.

### Evidence to review:
The assessor should ask for and review:
1. Legal provisions relevant to control of promotion, marketing and advertising of medical products.
2. Regulations relevant to control of promotion, marketing and advertising of medical products.
3. Guidelines relevant to control of promotion, marketing and advertising of medical products.

### References:
5. Drug Promotion - What We Know, What We Have Yet to Learn - Reviews of Materials in the WHO/HAI Database on Drug Promotion, World Health Organization (WHO) (89) (http://apps.who.int/medicinedocs/pdf/s8109e/s8109e.pdf)
6. Cross-border Advertising, Promotion and Sale of Medical Products Using the Internet. WHA Resolution; Fifty-First World Health Assembly, WHA51.9 (93) (http://apps.who.int/medicinedocs/documents/s21471en/s21471en.pdf)
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| Rating Scale: | NOT IMPLEMENTED (NI): There are no legal provisions or regulations to satisfy the requirement of the sub-indicator.  
ONGOING IMPLEMENTATION (OI): The NRA is taking steps towards establishment of legal provisions and regulations to satisfy the requirement of this sub-indicator; however no results exist so far.  
PARTIALLY IMPLEMENTED (PI): Legal provisions and regulations to satisfy the requirement of this sub-indicator were recently established, and are in early implementation phase so no documented results yet exist.  
IMPLEMENTED (I): There are legal provisions and regulations which satisfy the requirement of the sub-indicator and which are actually implemented and enforced. |
| Limitations and remarks: | Formal guidelines might not exist, however relevant guidance may be provided in other types of documentation (e.g., 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: | MC01.05: Legal provisions and regulations exist for placement of a product's unique identification number on its outer packaging. |
| Maturity Level: | 4 |
| Description: | The assessor should verify the availability of legal provisions and regulations setting the rules for placement of a unique identification number on the outer package of each medical product. Legal provisions and regulations should indicate that an identification number is assigned to each product that receives marketing authorization. |
| Objective: | The objective of this sub-indicator is to ensure the placement of a unique identification number on each outer packaging in order to facilitate tracking and tracing activities of medical products throughout the supply chain. These activities, in turn, support the detection and response activities related to SF medical products. |
| Requirement: | Legal provisions, regulation and guidelines for the placement of product’s unique identification number on outer packaging. |
| Evidence to review: | The assessor should ask for and review:  
1. Legal provisions relevant to placement of unique identification number on outer packaging of medical products.  
2. Regulations relevant to placement of unique identification number on outer packaging of medical products.  
### References:

### Framework:
Structure/Foundation/Input.

### Rating Scale:
- **NOT IMPLEMENTED (NI):** There are no legal provisions or regulations to satisfy the requirement of the sub-indicator.
- **ONGOING IMPLEMENTATION (OI):** The NRA is taking steps towards establishment of legal provisions and regulations to satisfy the requirement of this sub-indicator; however no results exist so far.
- **PARTIALLY IMPLEMENTED (PI):** Legal provisions and regulations to satisfy the requirement of the sub-indicator were recently established and are in early implementation phase so no documented results yet exist.
- **IMPLEMENTED (I):** There are legal provisions and regulations which satisfy the requirement of the sub-indicator and which are actually implemented 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:
**MC01.06: Guidelines exist for importers that specify the format and content of the relevant applications and procedures to receive the necessary authorizations or permissions.**

### Maturity Level:
2

### Description:
The assessor should verify the existence and implementation of guidelines for importers that specify the format and content of the relevant applications and procedures to receive the necessary authorizations or permissions.

### Objective:
The objective of this sub-indicator is to ensure the existence of guidelines for import activities as a tool for ensuring the quality and effectiveness of NRA’s actions of surveillance and market control. The guidelines are necessary to establish clearly the rules that
importers have to follow to obtain the necessary authorizations or permissions from the NRA.

**Requirement:** Guidelines for the format and content of import authorizations or permissions.

**Evidence to review:** The assessor should ask for and review:
1. Guidelines for applicants on the format and content of import authorizations or permissions

**References:**

**Framework:** Structure/Foundation/Input.

**Rating Scale:**
- NOT IMPLEMENTED (NI): There are no guidelines to satisfy the requirement of the sub-indicator.
- ONGOING IMPLEMENTATION (OI): The NRA is taking steps towards establishment of guidelines to satisfy the requirement of this sub-indicator; however no results exist so far.
- PARTIALLY IMPLEMENTED (PI): Guidelines to satisfy the requirement of the sub-indicator were recently established and are in early implementation phase so no documented results yet exist.
- IMPLEMENTED (I): There are guidelines which satisfy the requirement of the sub-indicator and which are actually implemented and enforced.

**Limitations and remarks:**
Formal guidelines might not exist, however relevant guidance may be provided in other types of documentation (e.g., 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:** **MC01.07: Guidelines exist on the recall, storage and disposal of SF medical products.**

**Maturity Level:** 2

**Description:** The assessor should verify the existence of national guidelines for relevant entities on the best practices for effective recall of SF medical products. The guidelines should cover recalls throughout the supply chain up to the desired point (e.g. distributor, wholesaler, or point of sale or use) so that the detected SF medical products are removed from the supply chain. In addition, the assessor should check if a guideline on the best practices for handling recalled SF medical products includes provisions for safe storage and disposal that provide a high degree of assurance that the detected SF medical products will not be re-introduced to the supply chain. Furthermore, the guidelines should ideally provide guidance on the ways by which recall effectiveness is
measured in terms of time, recalled units and other relevant aspects.

**Objective:**
The objective of this sub-indicator is to ensure the existence of guidelines for recall, storage and disposal of SF medical products. These guidelines should ideally reflect the NRA thinking and provide guidance to the responsible entity about effective actions that prevent re-introduction of detected SF medical products into the market.

**Requirement:**
Guidelines for recall, storage and disposal of SF medical products.

**Evidence to review:**
The assessor should ask for and review:
1. Guidelines relevant to recall and safe disposal of SF medical products.

**References:**
1. WHO good manufacturing practices for pharmaceutical products: main principles (51) ([http://digicollection.org/whoqapharm/p/about](http://digicollection.org/whoqapharm/p/about) and [http://apps.who.int/medicinedocs/en](http://apps.who.int/medicinedocs/en))
2. WHO good distribution practices for pharmaceutical products, World Health Organization (WHO) (27) ([http://digicollection.org/whoqapharm/p/about](http://digicollection.org/whoqapharm/p/about) and [http://apps.who.int/medicinedocs/en](http://apps.who.int/medicinedocs/en))
3. Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies (97) ([http://apps.who.int/medicinedocs/pdf/whozip51e/whozip51e.pdf](http://apps.who.int/medicinedocs/pdf/whozip51e/whozip51e.pdf))

**Framework:**
Structure/Foundation/Input.

**Rating Scale:**
- **NOT IMPLEMENTED (NI):** There are no guidelines to satisfy the requirement of the sub-indicator.
- **ONGOING IMPLEMENTATION (OI):** The NRA is taking steps towards establishment of guidelines to satisfy the requirement of the sub-indicator however no results are yet exist.
- **PARTIALLY IMPLEMENTED (PI):** Guidelines to satisfy the requirement of the sub-indicator were recently established and are in early implementation phase so no documented results yet exist.
- **IMPLEMENTED (I):** There are guidelines which satisfy the requirement of the sub-indicator and which are actually implemented and enforced.

**Limitations and remarks:**
Formal guidelines might not exist, however relevant guidance may be provided in other types of documentation (e.g., regulations).
Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

**Indicator:**
**MC02 Arrangement for effective organization and good governance.**
Objective: The objective of this indicator is to ensure the implementation of effective organization and good governance practices at the organizational structures in charge of establishment licensing activities, which in turn contributes to effective and efficient functioning of the market surveillance and control activities.

Category: 02. Organization and governance

Sub Indicator: MC02.01: There is a defined structure, with clear responsibilities, to conduct market surveillance and control activities.

Maturity Level: 2

Description: The assessor should identify the organization with responsibility to establish, implement and maintain the market surveillance and control regulatory function, including the specific organizational structures assigned the different relevant activities. Responsibilities, duties and roles of these structures should be clearly defined and documented. If more than one organizational structure is involved, the assessor should check the ways and approaches by which coordination among these structures takes place.

Objective: The objective of this sub-indicator is to ensure effective organization and good governance of market surveillance and control activities and that these activities are taken over by defined organizational structures with clear roles and responsibilities.

Requirement: Roles and responsibilities of the structures in charge of market surveillance and control activities.

Evidence to review: The assessor should ask for and review:
1. Organization chart of the institution responsible for the implementation of market surveillance and control activities. The chart and related information should identify the particular structures responsible for implementing the function.
2. Documentation clarifying roles and responsibilities of the structures implementing market surveillance and control activities. These may include administrative decrees, terms of reference, or other relevant documentation.
3. Documentation identifying and establishing mechanisms of coordination (e.g., committees, internal work-sharing and workflow) among the structures, if any, that take part in market surveillance and control activities.

<table>
<thead>
<tr>
<th>Framework:</th>
<th>Structure/Foundation/Input.</th>
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</table>
| Rating Scale: | NOT IMPLEMENTED (NI): There is no defined structure in charge of market surveillance and control activities.  
ONGOING IMPLEMENTATION (OI): A mandate to establish a structure in charge of market surveillance and control activities is available; however the structure itself is not established yet.  
PARTIALLY IMPLEMENTED (PI): A structure in charge of market surveillance and control activities is newly established and mandated; however the regular work and practice of this structure is not consolidated yet.  
IMPLEMENTED (I): There is a defined structure in charge of market surveillance and control activities with clear and well documented roles and responsibilities. |
| 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: | MC02.02: Documented procedures or mechanisms are implemented to ensure the involvement and communication among all stakeholders relevant to market surveillance and control activities. |
| Maturity Level: | 3 |
| Description: | The assessor should verify that the different stakeholders relevant to market surveillance and control regulatory function are identified. These stakeholders may include not only different organizational structures (e.g., organizations, institutions, or departments) that implement the function, but also other entities such as: other governmental agencies (e.g., laboratories, police departments, and customs and judicial authorities), regional and international organizations (e.g. WHO), non-governmental organizations, professional associations, customer representative associations, and industry representatives (e.g., manufacturers, distributors, and wholesalers). In addition, the assessor should verify the availability and implementation of agreements, memoranda of understanding (MOUs) and other documented procedures that ensure the involvement, communication and collaboration among the identified stakeholders relevant to market surveillance and control activities. |
| Objective: | The objective of this sub-indicator is to ensure that documented procedures or other mechanisms are implemented to ensure the involvement and communication among different organizations, institutions, and departments, as well as the appropriate organization and good governance of the function. |
| Requirement: | Agreements, MOUs and procedures for collaboration among stakeholders relevant to market surveillance and control regulatory function. |
Evidence to review:
The assessor should ask for and review:
1. List of stakeholders relevant to market surveillance and control.
2. Agreements, MOUs or standard operating procedures (SOPs) that describe the procedures for communication and collaboration among the identified stakeholders.
3. Example records of communications and collaborations that demonstrate implementation of the above mentioned procedures.
4. Guidelines or SOPs that cover external and internal communications.
5. Evidence that demonstrates that there are regular formal meetings or official communications among the above-mentioned key players. These are important to verify that it is a systematic and well established process.
6. Documentation of paths of communication and reporting.
7. Documentation of platforms for information sharing and exchange.

References:

Framework:
Structure/Foundation/Input.

Rating Scale:
NOT IMPLEMENTED (NI): There are no information exchange procedures or mechanisms among different stakeholders of the market surveillance and control function or between the central authority and the decentralized entities.
ONGOING IMPLEMENTATION (OI): The NRA is developing an information exchange mechanism, but it is not ready yet or exchanges are being conducted without an established methodology.
PARTIALLY IMPLEMENTED (PI): The NRA recently established an information exchange procedure or mechanism and it is at the implementation stage, so this practice is not consolidated yet.
IMPLEMENTED (I): There are established, implemented and maintained information exchange procedures or mechanisms among different stakeholders of the market surveillance and control function and between the central authority and the decentralized entities.

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:
MC03 Human resources to perform market surveillance and control activities.
**Objective:**
The objective of this indicator is to ensure that all entities within a National Regulatory Authority (NRA) are adequately resourced with a trained, experienced and skilled workforce that is empowered to fully perform the market surveillance and control function. This will ensure that market surveillance and control processes and activities are performed in accordance with international best practices.

The objective of this indicator is to evaluate the human resource capacity of the entities with respect to the number of personnel, the skills and experience of the personnel, and the overall composition the workforce, with the goal of evaluating whether the workforce possesses the specific expertise required to perform the market surveillance and control function.

<table>
<thead>
<tr>
<th>Category:</th>
<th>06. Resources (HR, FR, infrastructure and equipment)</th>
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<tr>
<td>Sub Indicator:</td>
<td><strong>MC03.01: Sufficient competent staff (i.e., education, training, skills and experience) are assigned to perform market surveillance and control activities.</strong></td>
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<tr>
<td>Maturity Level:</td>
<td>3</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify that the human resources assigned to perform market surveillance and control activities should be sufficient with respect to numbers and competent with respect to the requisite skills, education, experience and training. There should be technical documents and SOPs that provide guidance on the required background for market surveillance and control activities and that consider the requirements for educational background, competencies, skills, experience, and training. The assessor should verify that the NRA estimated the number of staff required to effectively and efficiently perform market surveillance and control function and that the NRA actually recruited that number. In addition, the assessor should verify that these competency requirements are well-established and maintained by the NRA. Metrics and statistics on the different activities performed as well as performance indicators can be used for estimating the adequacy of the number of the assigned staff. The assessor should also verify that the competency of the assigned staff is built, maintained and improved through recruitment as well as continuous on-the-job training.</td>
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</table>

**Objective:**
The objective of this sub-indicator is to ensure the existing human resources for market surveillance and control are sufficient, in terms of numbers, experience, and specific competencies, to perform all the activities along the entire market surveillance and control chain.

**Requirement:**
Sufficient number of competent human resources in charge of market surveillance and control activities.
Evidence to review:
The assessor should ask for and review:
1. Evidence that the number of staff members involved in each of the documented activities along the entire market surveillance and control process flow is adequate.
2. Evidence that the systems and structures are in place to ensure appropriate placement of staff with respect to competence and skills.
3. Evidence that the system and structures have been implemented. The documentation should include the records to verify that the staff competence is appropriate for the job requirements.
4. Evidence that the professional profiles of the human resources engaged in market surveillance and control activities are appropriate with respect to education, skills, and expertise, to perform a particular function along the market surveillance and control chain. Documentation should include a list of the requisite skills and training for each position.
5. Recruitment plan.

References:

Framework:
Structure/Foundation/Input.

Rating Scale:
NOT IMPLEMENTED (NI): The NRA does not have enough competent staff (i.e., education, training, skills and experience) to perform market surveillance and control activities
ONGOING IMPLEMENTATION (OI): The NRA has recently developed a plan to recruit adequate competent staff; however, the plan has not been implemented.
PARTIALLY IMPLEMENTED (PI): The NRA has initiated the implementation of the human resources development plan; however, there is need to complete the competency profile.
IMPLEMENTED (I): The NRA has a sustained number of competent staff (i.e., education, training, skills and experience) assigned to perform market surveillance and control activities.

Limitations and remarks:
Assessment of the adequacy and appropriateness of the number of staff members is quite subjective and should be linked to some process or output indicators. When estimating staff adequacy, the assessor should consider the workload, backlog, and delays in delivery based on established timeframes.

In some countries, internal staff might not be sufficient; however external staff (e.g., fellows or interns) may be involved in the performance of the work.
### Sub Indicator: MC03.02: Duties, functions, and responsibilities of the staff in charge of market surveillance and control activities are established and updated in the respective job descriptions

#### Maturity Level: 3

#### Description:
The assessor should verify that procedures are in place to maintain a current and updated structure for managing job descriptions for personnel participating in market surveillance and control activities. In addition, job descriptions should address current staff duties, responsibilities and the requisite competencies. A job description with this format and content should be established and implemented for all staff. The management of job descriptions should be supported by a guidance document that provides direction on when and how to update the information, and where the information should be kept for easy access. The guidance document should present the appropriate duties and responsibilities that are assigned to each member of the organization involved in market surveillance and control activities. Thus, the professional profiles of staff are reflected in their respective roles and responsibilities within the NRA. There should be procedures to guide responsible persons to document that duties, functions and responsibilities are revised and kept up to date. In addition, procedures should be available to guide the keeping and documenting of up to date work schedules and enforcing the implementation of the documented guidelines and procedures.

#### Objective:
The objective of this sub-indicator is to ensure that duties and responsibilities of the staff are clear and well defined, that job descriptions are kept up to date with current duties, functions and responsibilities, and that these activities are adequately documented.

#### Requirement:
Duties, roles and responsibilities of the staff relevant to market surveillance and control activities.

#### Evidence to review:
The assessor should ask for and review:
1. Procedures and guidelines that guide placement of staff members within the NRA;
2. The professional profiles of staff (i.e., job descriptions) and documentation that they are related to their current roles and duties;
3. The professional profiles of the external experts and documentation that the profiles provide a composition that is complete and consistent with that prescribed in the legal provisions;
4. Procedures to guide the documentation of up to date duties and work schedules, and to enforce the implementation of the documented guidelines and procedures;
5. Job descriptions for designated staff.
### References:


### Framework:

Structure/Foundation/Input.

### Rating Scale:

- **NOT IMPLEMENTED (NI):** There is no evidence of defined or established duties, functions, responsibilities, respective job descriptions and necessary required competencies.
- **ONGOING IMPLEMENTATION (OI):** The NRA has recently drafted or developed the role and responsibilities document but it has not yet been implemented.
- **PARTIALLY IMPLEMENTED (PI):** The NRA has initiated implementation of this requirement but it has not been defined or followed for all staff or the roles and responsibilities documents, including staff job descriptions, are not up to date.
- **IMPLEMENTED (I):** The NRA has defined and established all required duties, functions, and responsibilities, and respective job descriptions are up-to-date.

### 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:

**MC03.03: Training plan developed, implemented and updated at least once a year for staff in charge of market surveillance and control activities.**

### Maturity Level:

3

### Description:

The assessor should verify that training plans are developed, implemented and updated at least once every year to reflect the current situation by considering education and experience of the staff. The training plan should be complemented with guidelines or similar documents that guide the development and implementation of training plans. The assessor should ensure that induction training for new staff as well as continued on-the-job for staff is planned and implemented. There should be procedures to
approve the training plan and the budget allocated for implementing and updating the training plan. The plans should present clearly defined training goals, and should include training in certain topics and skills to address identified deficiencies. Learning objectives, training methods and activities, evidence of learning, and evaluation and assessment of training should be documented. This documentation should confirm that the learning objectives were achieved and were designed to address weaknesses within the entities. Procedures should be in place to ensure that a training plan is developed, implemented and updated at least once every year. The assessor should verify that there is a system in place for monitoring the implementation and effectiveness of the training plan and for documenting the skills acquired in training activities for internal and external experts.

### Objective:

The objective of this sub-indicator is to ensure that a training plan for staff exists, and that it is implemented and updated annually. Through the training plan, NRA can be sure that competency of staff in charge of market surveillance and control activities is maintained and enhanced.

### Requirement:

Implementation of training plan

### Evidence to review:

The assessor should ask for and review:

1. Guidelines for development, implementation and annual update (i.e., at least once per year) of the training plan. Guidelines should also provide for a mechanism to measure effectiveness of training.
2. Documentation for the system or structures used to approve the training plan and to evaluate the adequacy of the budget allocated to the training activities.
3. The current or existing staff training plan (or matrix) for staff. The assessor should assess this in relation to the respective individual job descriptions.
4. SOP for developing and maintaining the training plan.
5. Evidence that the NRA has investigated and identified training needs.
6. List of trainings performed.
7. Example records for training activities.

### References:

### Framework:
Process

### Rating Scale:
- **NOT IMPLEMENTED (NI):** There is no systematic training program including training plan (or matrix).
- **ONGOING IMPLEMENTATION (OI):** The NRA has recently drafted or developed the training plan but there is no evidence of implementation.
- **PARTIALLY IMPLEMENTED (PI):** The NRA has developed and initiated the training plan implementation. However, the NRA has not fulfilled all required planned training or has been applying the plan for less than two years.
- **IMPLEMENTED (I):** The NRA has an updated training plan developed that is supported by adequate records to demonstrate effective plan implementation, including induction training for new staff and routine on-the-job training for recruited staff.

### Limitations and remarks:
- Training plans must be updated regularly; ideally on an annual basis, but not less frequently that once every two years.
- Some regulatory functions may include many training activities that are not incorporated in the institutional training programme. Such training normally is offered by invitation. In this case, the assessor should recognize reports from non-routine market surveillance and control-relevant training not included in the NRA training plan.
- Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

### Sub Indicator:
**MC03.04:** The NRA generates and maintains records of staff training activities and training effectiveness verification.

### Maturity Level:
3

### Description:
The assessor should verify that records of staff training that is performed or organized by the NRA are generated, maintained, regularly updated. This activity should be supported by guidelines that direct the NRA to generate and maintain records of staff training activities. Procedures should be in place to document and propose staff training needs and to allocate a budget for continuous staff capacity building and development. The assessor should check that there is an evaluation or assessment mechanism to verify the quality of learning, and to confirm that learning objectives are achieved. Documentation should include an inventory (i.e., soft and/or hard) system that records all impactful and non-impactful trainings, and identifies all staff members who participated. A system to measure or estimate impact of trainings should be established.
### Objective:
The objective of this sub-indicator is to ensure that training organized by the NRA or responsible regulatory authority is adequately documented and that the training records are adequately maintained and kept. Staff training records are considered an integral part of staff file and are a tool for measuring and tracking staff competency, development and adequacy.

### Requirement:
Training records

### Evidence to review:
The assessor should ask for and review:
1. Guidelines or similar documents that guide the NRA to generate and maintain records of staff training activities;
2. Evaluations of training effectiveness;
3. The training inventory, and procedures for completing the inventory;
4. Examples of archived records of staff training, and procedures for the archiving system

### References:

### Framework:
Output

### Rating Scale:
- **NOT IMPLEMENTED (NI):** There is no evidence that the NRA generates and maintains records of staff training activities.
- **ONGOING IMPLEMENTATION (OI):** The NRA has recently initiated plans to generate, document and keep records of staff training activities, however they are not yet followed.
- **PARTIALLY IMPLEMENTED (PI):** The NRA has recently initiated plans to generate, document and keep records of staff training activities but they are not fully followed for all training activities or they have been established for less than two years.
- **IMPLEMENTED (I):** The NRA generates and maintains records of staff training activities.
| Limitations and remarks: | The assessor should note that some NRAs out-source training including staff capacity development activities. In this case the assessor should request the identity of the provider, as well as evaluations of the provider. The assessor may request the professional profiles of tutors or resource persons used to offer training. The assessor may also request records covering the archiving systems in place.

Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs). |
|-------------------------|--------------------------------------------------------------------------------------------------------|

<table>
<thead>
<tr>
<th>Indicator:</th>
<th><strong>MC04 Procedures established and implemented to perform market surveillance and control</strong></th>
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<tr>
<th>Objective:</th>
<th>The objective of this indicator is to ensure that different activities of the market surveillance and control programme are implemented through standard procedures and work instructions in order to ensure consistency, effectiveness, efficiency, impartiality and proportionality of the programme.</th>
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<tr>
<th>Category:</th>
<th>07. Regulatory process</th>
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<tr>
<th>Sub Indicator:</th>
<th><strong>MC04.01: Documented and implemented procedures exist to grant the necessary authorizations or permissions for import activities.</strong></th>
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<th>Maturity Level:</th>
<th>3</th>
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<tr>
<th>Description:</th>
<th>The assessor should verify the availability of documented standard procedures within the NRA to receive, review and make a decision on import applications of medical products. The assessor should also verify proper implementation of the procedures through review of the relevant records and documentation. The records for an application should include documentation of receipt, screening, review, regulatory decision-making, (i.e., approval or denial), and notification of the applicant. Regulatory decisions should be scientifically justifiable.</th>
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<tr>
<th>Objective:</th>
<th>The objective of this sub-indicator is to ensure that the control of import activities of medical products are an integral part of the overall market surveillance and control regulatory function. Therefore, procedures to handle and decide on (i.e., approve or deny) applications relevant to these activities are essential to ensure the consistency and effectiveness of these regulatory activities.</th>
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<tr>
<th>Requirement:</th>
<th>Procedures along with their relevant records for regulatory decisions on import activities</th>
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<tr>
<th>Evidence to review:</th>
<th>The assessor should ask for and review:</th>
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</table>
1. SOPs that guide the handling of applications for medical products import activities.
2. List of import applications over a wide range of time (e.g., 6 months or 1 year).
3. Example records and documentation of receiving, processing and decision-making for medical products import applications.

**References:**

**Framework:**
Process

**Rating Scale:**
- **NOT IMPLEMENTED (NI):** There are no documented procedures in the NRA for the prevention of unauthorized import activities, and no procedures to grant the necessary authorizations or permissions for import activities.
- **ONGOING IMPLEMENTATION (OI):** The NRA has taken some steps to establish procedures to grant the necessary authorizations or permissions for import activities; however, no results exist so far.
- **PARTIALLY IMPLEMENTED (PI):** Documented procedures to grant the necessary authorizations or permissions for import activities were recently established; however, the procedures are recently implemented and no results associated with this sub-indicator are documented yet.
- **IMPLEMENTED (I):** There are documented procedures to grant the necessary authorizations or permissions for import activities, and these procedures are actually 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:**
MC04.02: Documented and implemented procedures exist for regulation of promotion and advertisement of medical products

**Maturity Level:**
3

**Description:**
The assessor should verify the availability of documented standard procedures within the NRA to receive, review and make a decision on promotion, marketing and advertisement applications. Assessor should also verify proper implementation of the procedures through review of the relevant records and documentation. The records for an application should include...
documentation of receipt, screening, review and regulatory decision-making, (i.e., approval or denial), and notification of the applicant. Regulatory decisions should be scientifically justifiable.

**Objective:**
The objective of this sub-indicator is to ensure that the control of promotion and advertisement of medical products is an integral part of the overall market surveillance and control regulatory function. Therefore, procedures to regulate the information that reaches health professionals, as well as the general public, are an important component to promote the rational use of these products.

**Requirement:**
Procedures along with the relevant records for engagement of regulatory entities in the regulation of promotion and advertisement of medical products.

**Evidence to review:**
The assessor should ask for and review:
1. SOPs that guide the handling of applications for promotion and advertisement activities.
2. List of promotion, marketing and advertisement applications received and reviewed over a wide range of time (e.g., 6 months or 1 year).
3. Example records and documentation of regulatory decisions on promotion and advertisement applications.

**References:**
3. Cross-border Advertising, Promotion and Sale of Medical Products Using the Internet. WHA Resolution; Fifty-First World Health Assembly, WHA51.9 (93) (http://apps.who.int/medicinedocs/documents/s21471en/s21471en.pdf)
5. Ethical Criteria for Medicinal Drug Promotion, World Health Organization, 1988 (13) (http://apps.who.int/medicinedocs/documents/whozip08e/whozip08e.pdf)
8. Drug Promotion - What We Know, What We Have Yet to Learn - Reviews of Materials in the WHO/HAI Database on Drug
<table>
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<tr>
<th>Framework:</th>
<th>Process</th>
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| Rating Scale: | NOT IMPLEMENTED (NI): There are no documented procedures in the NRA for regulation of promotion and advertisement of medical products.  
ONGOING IMPLEMENTATION (OI): The NRA has taken some steps to establish procedures for regulation of promotion and advertisement of medical products; however no results exist so far.  
PARTIALLY IMPLEMENTED (PI): Documented procedures in the NRA for regulation of promotion and advertisement of medical products were recently established; however the procedures are recently implemented and no results associated with this sub-indicator are documented yet.  
IMPLEMENTED (I): There are documented procedures in the NRA for regulation of promotion and advertisement of medical products, and these procedures are actually implemented. |
| Limitations and remarks: | Procedures and documentation relating to the approval of promotion and advertisement applications might not exist if the NRA does not have the mandate to pre-approve such applications. In case no pre-approval system is in place the assessor should verify the existence of an alternative approach (e.g., active surveillance of promotional materials, rather than proactive approval) which satisfies the adequate control of promotion and advertisement activities.  
Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs). |
| Sub Indicator: | MC04.03: Documented and implemented procedures for active monitoring of the promotion and advertisement of medical products |
| Maturity Level: | 4 |
| Description: | The assessor should verify the availability of documented standard procedures within the NRA to actively monitor promotion and advertisement of medical products. These procedures should include screening mechanisms to identify false or misleading information contained in promotions and advertisements of medical products in the market. The monitoring and screening should include promotional materials on the internet. The assessor should also verify proper implementation of the procedures through checking of the relevant records and documentation. The records should include documentation of data collected, screening, review and regulatory decision-making, if any. Regulatory decisions should be scientifically justifiable. |
### Objective:
The objective of this sub-indicator is to ensure that the control of promotion and advertisement of medical products is an integral part of the overall market surveillance and control regulatory function. NRAs must have mechanisms in place to actively monitor these activities and take the necessary regulatory measures in case of misconduct.

### Requirement:
Procedures along with the relevant records of regulatory decisions for monitoring the promotion and advertisement of medical products.

### Evidence to review:
The assessor should ask for and review:
1. SOPs that guide the active monitoring of the promotion and advertisement of medical products.
2. List of data collected from the market regarding the promotion and advertisement of medical products received over a wide range of time (e.g., 6 months or 1 year)
3. Example records and documentation of regulatory decisions, if any.

### References:
3. Cross-border Advertising, Promotion and Sale of Medical Products Using the Internet. WHA Resolution; Fifty-First World Health Assembly, WHA51.9 (93) (http://apps.who.int/medicinedocs/documents/s21471en/s21471en.pdf)
5. Ethical Criteria for Medicinal Drug Promotion, World Health Organization, 1988 (13) (http://apps.who.int/medicinedocs/documents/whozip08e/whozip08e.pdf)
8. Drug Promotion - What We Know, What We Have Yet to Learn - Reviews of Materials in the WHO/HAI Database on Drug Promotion, World Health Organization (WHO) (89) (http://apps.who.int/medicinedocs/pdf/s8109e/s8109e.pdf)
### Rating Scale:

<table>
<thead>
<tr>
<th>NOT IMPLEMENTED (NI):</th>
<th>There are no documented procedures in the NRA for active monitoring of the promotion and advertisement of medical products.</th>
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<tbody>
<tr>
<td>ONGOING IMPLEMENTATION (OI):</td>
<td>The NRA has taken some steps to establish procedures for active monitoring of the promotion and advertisement of medical products; however no results exist so far.</td>
</tr>
<tr>
<td>PARTIALLY IMPLEMENTED (PI):</td>
<td>Documented procedures in the NRA for active monitoring of the promotion and advertisement of medical products were recently established; however the procedures are recently implemented and no results associated with this sub-indicator are documented yet.</td>
</tr>
<tr>
<td>IMPLEMENTED (I):</td>
<td>There are documented procedures in the NRA for active monitoring of the promotion and advertisement of medical products and these procedures are actually implemented.</td>
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</tbody>
</table>

### 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:

**MC04.04**: Documented and implemented procedures exist for risk-based sampling of medical products from different points of the supply chain.

### Maturity Level:

3

### Description:

The assessor should verify the availability within the NRA of a structured programme, with documented standard procedures, to carry out a medical products sampling and quality surveillance programme. The programme should be risk based with consideration of different risk factors (e.g. nature and category of products, location within the territory, manufacturer, product quality history, previous complaints, vigilance data, and any other relevant information). The quality surveillance programme should be extended to cover all points across the supply chain with emphasis on the terminal point and last stages of the chain (e.g., points of sale, handling or administration). The programme should include laboratory testing of the quality of the medical products. The assessor should also verify that procedures specify any follow up and regulatory actions to be undertaken in the event that SF medical products (i.e., products failing the quality surveillance) are detected. Ideally, the follow-up actions should include regulatory inspection when necessary.

### Objective:

The objective of this sub-indicator is to ensure that risk based sampling and quality surveillance of medical products are implemented as a means for confirming quality of medical products in the market and throughout the supply chain. Additionally, a surveillance program may significantly contribute to detection of SF medical products.

### Requirement:

Procedure along with relevant records for risk-based sampling of medical products on the market.
| Evidence to review: | The assessor should ask for and review:  
| | 1. SOPs that guide medical product sampling and quality surveillance across the supply chain.  
| | 2. Examples of relevant records and documentation of surveillance activities, including product sampling, requests for testing, and testing results.  
| | 3. Examples of relevant records and documentation for any follow up or regulatory actions taken in the event that medical product failures are detected during the quality surveillance.  
| Framework: | Process  
| Rating Scale: | NOT IMPLEMENTED (NI): There are no documented procedures for risk-based sampling of medical products from different points of the supply chain.  
| | ONGOING IMPLEMENTATION (OI): The NRA has taken some steps to establish procedures for risk-based sampling of medical products from different points of the supply chain; however no results exist so far.  
| | PARTIALLY IMPLEMENTED (PI): Documented procedures for risk-based sampling of medical products from different points of the supply chain were recently established; however the procedures are recently implemented and no results associated with this sub-indicator are documented yet.  
| | IMPLEMENTED (I): There are documented procedures for risk-based sampling of medical products from different points of the supply chain, and these procedures are actually 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: | MC04.05: Documented and implemented procedures exist to enable the public to report suspected SF medical products.  
| Maturity Level: | 3  
| Description: | The assessor should verify the availability and implementation of documented procedures for enabling the public to report medical products suspected to be SF. Ideally the reporting procedures should be simple, effective, easy to use and accessible to a
majority of the people. The reporting should be two-way, enabling public reporting to the NRA as well as regulatory feedback to the informants about the outcome of the relevant investigation. When appropriate, a wider group may be targeted for the feedback (e.g., media, professional associations, and customer representatives).

**Objective:**
The objective of this sub-indicator is to ensure that the public is involved in the reporting of suspected SF medical products as an essential approach for detection and prevention of this problem. In addition, these activities contribute to building the public confidence and trust in the regulatory system.

**Requirement:**
Procedures along with their relevant records to enable the public to report SF medical products

**Evidence to review:**
The assessor should ask for and review:
1. SOPs for enabling the public to report suspected SF medical products.
2. Examples of relevant records and documentation, including reporting forms, referral procedures, and reports of actions taken or regulatory decisions made, if any.
3. Examples of feedback to the informants.

**References:**
1. SF- Frequently asked questions. Scope, scale and harm. How big is the problem of SF medical products? (87) (https://www.who.int/medicines/regulation/ssffc/faq-ssffc_1-10/en/)
4. Recommendations for health authorities to detect and deal with actions, activities and behaviors that result in substandard/spurious/falsely-labelled/falsified/counterfeit medical products, A68/33, annex 1 (129) (http://apps.who.int/ebwha/pdf_files/WHA68/A68_33-en.pdf)

**Framework:**
Process

**Rating Scale:**
NOT IMPLEMENTED (NI): There are no documented procedures to enable the public to report suspected SF medical products.
<table>
<thead>
<tr>
<th><strong>Sub Indicator:</strong></th>
<th>MC04.06: Documented and implemented procedures exist in the NRA to review any complaints or market reports received.</th>
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<tbody>
<tr>
<td><strong>Maturity Level:</strong></td>
<td>3</td>
</tr>
<tr>
<td><strong>Description:</strong></td>
<td>The assessor should verify the availability of documented procedures within the NRA to receive, review and respond to any complaints or reports related to medical products. These may include complaints and reports related to: (1) quality, safety or efficacy of medical products, (2) suspected cases of SF medical products, and (3) misconduct in promotion or advertising, including via the internet. Complaints and reports could be related to any medical product or company. The assessor should verify actual and proper implementation of the procedures through review of the relevant records and documentations. The records should include documentation of investigations of complaints and any subsequent regulatory decisions. Complaints and reports may come from consumers, health professionals, health institutions, and participants in the supply chain.</td>
</tr>
<tr>
<td><strong>Objective:</strong></td>
<td>The objective of this sub-indicator is to ensure that complaints and reports, as a major feedback mechanism about market control activities, are properly received and handled following well-established procedures in order to ensure consistency and effectiveness in the responses to these cases.</td>
</tr>
<tr>
<td><strong>Requirement:</strong></td>
<td>Procedures along with relevant records of regulatory decisions on complaints and reports received.</td>
</tr>
</tbody>
</table>
| **Evidence to review:** | The assessor should ask for and review:  
1. SOPs that guide the handling of complaints and reports.  
2. List of market complaints and reports over a wide range of time (e.g., 6 months or 1 year).  
3. Examples of market complaints and reports along with associated records (e.g., reports of case investigations and any |
### References:
1. WHO good manufacturing practices for pharmaceutical products: main principles (51)
   (http://digicollection.org/whoqapharm/p/about and http://apps.who.int/medicinedocs/en)

### Framework:
Process

### Rating Scale:
- **NOT IMPLEMENTED (NI):** There are no documented procedures in the NRA to review and respond to any complaints or market reports received.
- **ONGOING IMPLEMENTATION (OI):** The NRA has taken some steps to establish procedures to review and respond to any complaints or market reports received; however no results exist so far.
- **PARTIALLY IMPLEMENTED (PI):** Documented procedures in the NRA to review and respond to any complaints or market reports received were recently established; however such procedures are recently implemented and no results associated with this sub-indicator are documented yet.
- **IMPLEMENTED (I):** There are documented procedures in the NRA to review and respond to any complaints or market reports received, and these procedures are actually 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:
**MC04.07: Documented and implemented procedures and mechanisms exist to prevent, detect and respond to SF medical products.**

### Maturity Level:
3

### Description:
The assessor should verify the availability of documented standard procedures and mechanisms within the NRA to prevent, detect and respond to SF products in the market, including products being distributed via the internet. These procedures and mechanisms should include various approaches. Examples of approaches for detection of SF medical products might include routine inspections, targeted risk-based surveys, or investigations of reports of complaints, suspicious observations, unexpected adverse events, or whistle-blower concerns. Similarly measures for prevention of SF medical products might include public education and awareness campaigns, as well as other measures to ensure access to and affordability of quality medical product. Actions for response to SF medical products might include rapid alerts, prosecutions, and recalls, quarantines, or withdrawals of affected products.

The assessor should verify actual and proper implementation of the procedures through checking of the relevant records and subsequent regulatory decisions.
documentation. The records should include relevant databases, evidence collected, investigation reports (including descriptions of any field procedures, inspections and intelligence activities that might have been carried out jointly or with the support of national and international stakeholders) and any follow-up regulatory decisions.

**Objective:**

The objective of this sub-indicator is to ensure that well established procedures or mechanisms are implemented for the prevention, detection, and response to SF medical products.

**Requirement:**

Procedures along with the relevant records for prevention, detection and response to SF medical products

**Evidence to review:**

The assessor should ask for and review:
1. SOPs and other mechanisms to prevent, detect and respond to SF medical products.
2. Example records and documentation of prevention, detection and response to SF medical products.

**References:**


**Framework:**

Process

**Rating Scale:**

NOT IMPLEMENTED (NI): There are no documented procedures or mechanisms, in the NRA, for prevention, detection and response to SF medical products.
**Sub Indicator:**

**MC04.08: Documented and implemented procedures exist to ensure safe storage and disposal of detected SF medical products.**

**Maturity Level:** 3

**Description:**
The assessor should verify the availability of documented standard procedures within the NRA for safe storage and disposal of detected SF medical products. Safe storage and disposal provides assurance that detected SF medical products are not re-introduced to the market and that the best practices were employed to avoid or minimize adverse effects of this disposal on the people and environment. The assessor should also verify actual and proper implementation of the procedures through review of the relevant records and documentation. The records should include proof of storage and disposal along with documentation for the reconciliation between the recovered quantities versus the disposed ones.

**Objective:**
The objective of this sub-indicator is to ensure the control of detected SF medical products. Therefore, a national policy and strategy, combined with procedures to ensure safe storage and disposal of detected SF medical products, are essential to avoid re-introduction of these products to the market.

**Requirement:**
Procedures along with their relevant records for safe storage and disposal of SF medical products

**Evidence to review:**
The assessor should ask for and review:
1. SOPs for storage and disposal of SF medical products.
2. Example records and documentation of SF medical products storage and disposal including reconciliation of quantities (i.e., quantities detected, recovered, or recalled vs. quantities disposed).
### References:

1. Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies (97)  
   [http://apps.who.int/medicinedocs/pdf/whozip51e/whozip51e.pdf](http://apps.who.int/medicinedocs/pdf/whozip51e/whozip51e.pdf)
2. WHO good manufacturing practices for pharmaceutical products: main principles (51)  

### Framework:

Process

### Rating Scale:

- **NOT IMPLEMENTED (NI):** There are no documented procedures, in the NRA, to ensure safe storage and disposal of detected SF medical products.
- **ONGOING IMPLEMENTATION (OI):** The NRA has taken some steps to establish procedures to ensure safe storage and disposal of detected SF medical products; however no results exist so far.
- **PARTIALLY IMPLEMENTED (PI):** Documented procedures to ensure safe storage and disposal of detected SF medical products were recently established; however such procedures are recently implemented and no results associated with this sub-indicator are documented yet.
- **IMPLEMENTED (I):** There are documented procedures to ensure safe storage and disposal of detected SF medical products, and these procedures are actually 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).

### Indicator:

**MC05 Mechanism in place to monitor regulatory performance and output.**

### Objective:

The objective of this indicator is to ensure that mechanisms are in place to track regulatory effectiveness of the market surveillance and control activities, to measure relevant progress in the programme, and to establish, implement and regularly verify performance indicators.

### Category:

09. Monitoring progress and assessing outcomes & impact

### Sub Indicator:

**MC05.01: Database exists of approved and refused promotional and advertising materials along with the supporting documentation.**

### Maturity Level:

4
| Description: | The assessor should verify the establishment of a database of approved as well as refused marketing, promotional and advertising materials, along with documentation that supports the decisions taken. The database should not be limited to listing of approved and rejected materials. Instead, the database should also include the applications, the supporting documentation submitted by applicants, and records of the regulatory review, assessment, and final decision-making for these applications. |
| Objective: | The objective of this sub-indicator is to ensure that a database of applications for marketing, promotional and advertising materials is established for storing, consolidating and analyzing relevant information. The database also serves as a basis for further follow up and enforcement actions. Thus tracing relevant regulatory activities and decisions for the sake of institutional memory is ensured. Furthermore, analyses of the data would contribute to optimization of the performance of the regulatory program. |
| Requirement: | Database of promotional, marketing and advertising materials applications, documentations and regulatory decisions |
| Evidence to review: | The assessor should ask for and review:  
1. Database of applications and supporting documentation of marketing, promotional and advertising materials.  
2. Database of regulatory reviews and assessments of marketing, promotional and advertising materials. |
| References: |  |
| Framework: | Output |
| Rating Scale: | NOT IMPLEMENTED (NI): There is no database for approved and refused promotional materials along with their supporting documentation.  
ONGOING IMPLEMENTATION (OI): The NRA is preparing to establish a database, but there is no evidence of results from such activities.  
PARTIALLY IMPLEMENTED (PI): There is evidence that the NRA has the elements (i.e., procedures, documentation, management systems, and related information,) and the capacity to perform the processes mentioned in the indicator; however it has only limited experience or a limited number of documented events.  
IMPLEMENTED (I): There is a database for approved and refused promotional materials along with their supporting documentation. |
| Limitations and remarks: | This sub-indicator is applicable only to the countries where there are pre-approval activities related to medical products promotion and advertising. In case there is no NRA pre-approval system is in place, the assessor should verify the existence of an
alternative approach which provides adequate control of promotional, marketing and advertising activities.

<table>
<thead>
<tr>
<th>Sub Indicator:</th>
<th>MC05.02: Database for product batches that have undergone surveillance along with their relevant testing results and regulatory actions is established and periodically reviewed.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maturity Level:</td>
<td>4</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify the establishment and maintenance of a database of product batches that have been included in the market surveillance program (i.e., batches that have been sampled or tested). The database should include relevant findings, test results, and regulatory decisions. Importantly, this database should include information about SF medical products. The database should not only include a listing of the relevant information, but also provide data analyses designed to optimize the surveillance program, identify repeated violations and trends, and guide regulatory measures to prevent, detect and respond to SF medical products. Also, such database makes it possible to compile the information needed for similar actions at the global and international level.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure the establishment of a database of product batches that have been included in the surveillance program. The database should store, consolidate and analyze information from the market surveillance program. Thus tracing relevant regulatory activities and decisions for the sake of institutional memory is ensured. Furthermore, analyses of the data would contribute to optimization of the performance of the regulatory program.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Database of product batches that have been included in the market surveillance program, their relevant testing results and regulatory decisions or actions, if any</td>
</tr>
</tbody>
</table>
| Evidence to review: | The assessor should ask for and review:  
1. Database of product batches that have been included in the market surveillance program along with their results and regulatory actions, if any.  
2. Updated analyses of the data along with consequent optimization, if any. |
| References:    | |
| Framework:     | Output |
| Rating Scale:  | NOT IMPLEMENTED (NI): There is no database within for NRA for product batches that have undergone surveillance along with |
their regulatory actions.

ONGOING IMPLEMENTATION (OI): The NRA is preparing to establish a database, but there is no evidence of results from such activities.

PARTIALLY IMPLEMENTED (PI): There is evidence that the NRA has the elements (i.e., procedures, documentation, management systems, and related information) and the capacity to perform the processes mentioned in the indicator; however it has only limited experience or a limited number of documented events.

IMPLEMENTED (I): There is a database within the NRA for product batches that have undergone surveillance along with their regulatory actions. Also, this database is regularly 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: **MC05.03: Performance indicators for market surveillance and control activities are established and implemented**

Maturity Level: 4

Description: The assessor should verify the existence and implementation of performance indicators for different activities included under the market surveillance and control functions. Specifically, the system should define key performance indicators (KPIs) along the entire market surveillance and control activity chain and all indicators should be adequately justified. For the purpose of clarity and consistency, established KPIs should be supported with guidelines for monitoring and maintenance of the KPIs. The guidelines in turn should be supported by SOPs and tools that define the procedures to be used for monitoring and evaluating the performance indicators and that define procedures and timelines for reviewing and revising the indicators.

For market surveillance and control activities, the performance indicators should cover the four themes: (1) control of import activities, (2) preventing, detecting and responding to SF medical products, (3) market surveillance program for monitoring the quality of medical products, and (4) control of promotional, marketing and advertising activities. Examples of indicators include, but are not limited to: number of product batches sampled as part of market surveillance program, number of approvals and refusals of promotional materials, and number of detected SF medical products (with sub-category).

Established KPIs might be qualitative, quantitative or combination of both. In general, quantitative indicators are preferred to avoid bias or misinterpretation. However, qualitative indicators are also accepted. Qualitative indicators may or may not include scoring or scaling to render them semi-quantitative and thus more informative. The assessor should ensure that indicators are measured on a regular basis to monitor progress and advancement.

In addition, the assessor should verify measured indicators are analyzed to identify trends or abnormalities. Justifications for any
identified abnormalities should be provided; when necessary, process optimizations should be introduced to avoid recurrence.

**Objective:**

The objective of this sub-indicator is to ensure that a system, mechanism, or procedure exists to require the NRA to establish performance indicators along the entire market surveillance and control chain. Additionally, the objective is to ensure that KPIs are actually contributing to monitoring of regulatory performance, to measuring effectiveness of market surveillance and control regulatory activities, and to making any necessary adjustments or optimizations.

**Requirement:**

KPIs for market surveillance and control activities

**Evidence to review:**

The assessor should ask for and review:

1. Documents supporting the system, mechanism, or procedure compelling the NRA to establish and implement performance indicators along the entire market surveillance and control activity chain.
2. Evidence that the performance indicators have been established and implemented, and that the members of staff involved in the market surveillance and control function are aware of the indicators and the guidelines and SOPs used for monitoring and evaluating their performance.
3. The current performance indicators for market surveillance and control activities. KPIs should cover the four themes listed in Description column.
4. Analyses of the measured indicators along with the investigations done to identify trends or abnormalities.
5. Documentation for follow-up of any observed abnormalities, including justifications for any identified abnormalities as well as any process optimizations introduced to avoid recurrence.

**References:**


**Framework:**

Output
### Rating Scale:
- **NOT IMPLEMENTED (NI):** There are no KPIs for market surveillance and control activities.
- **ONGOING IMPLEMENTATION (OI):** The NRA has recently drafted KPIs for market surveillance and control activities but they have not yet been reported.
- **PARTIALLY IMPLEMENTED (PI):** The NRA has developed KPIs for market surveillance and control activities and has been applying them for less than two years or they have not covered all critical steps.
- **IMPLEMENTED (I):** The NRA has established and implemented KPIs for market surveillance and control activities. The indicators are reviewed regularly, and appropriate actions are taken and decisions made.

### Limitations and remarks:
When they refer to outcomes, indicators may be ambiguous and difficult to interpret, as outcomes are the result of many factors that are difficult to disentangle. When they refer to processes, indicators are often too specific, as they may focus on a particular intervention or condition or they may quickly become outdated as business models develop.

Different methodologies are used to measure the NRAs performance on market surveillance and control activities. In this case, the assessor should verify that adequate supporting documents are available. The assessor should consider that developed performance indicators should be Specific, Measurable, Achievable, Realistic, and Time-bound (i.e., “SMART”).

Scoring this sub-indicator as "not applicable NA" is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).

### Indicator: MC06 Mechanism exists to promote transparency, accountability and communication.

### Objective:
The objective of this indicator is to ensure that mechanisms are in place that promote effective communication of market surveillance and control activities and related information within the NRA, that promote transparency and outreach to the public, and that establish milestones that encourage accountability of the NRA to its mandate. Additionally these activities contribute to mutual understanding and involvement of all stakeholders relevant to market surveillance and control activities. Consequently, confidence in the regulatory system is raised.

### Category: 08. Transparency, accountability and communication

### Sub Indicator: MC06.01: Market surveillance and control activities are appropriately communicated within the NRA.

### Maturity Level:
3

### Description:
The assessor should verify that market surveillance and control activities are properly communicated among different institutions,
departments, and entities of the NRA (e.g. laboratory, inspection and enforcement departments). These internal communications should be guided by appropriate policies or procedures and supported by mechanisms for implementation.

**Objective:**
The objective of this sub-indicator is to ensure that communication of market surveillance and control activities within the NRA is well established as a best practice to promote regulatory effectiveness. In addition, such communication increases awareness and encourages internal understanding and cooperation among all relevant entities and departments within the NRA.

**Requirement:**
Communication within the NRA of the market surveillance and control activities

**Evidence to review:**
The assessor should ask for and review:
1. Documentation of guidelines, policies, procedures or mechanisms for communicating market surveillance and control activities within the NRA.
2. Records of communication (i.e., paper based or electronic) proving communication of information within the NRA.

**References:**

**Framework:**
Output

**Rating Scale:**
- NOT IMPLEMENTED (NI): Market surveillance and control activities are not communicated within the NRA.
- ONGOING IMPLEMENTATION (OI): The NRA is preparing to establish mechanisms for communication of market surveillance and control activities, but there is no evidence of results from such activities.
- PARTIALLY IMPLEMENTED (PI): There is evidence that the NRA has the elements (i.e., procedures, documentation, management systems, and relevant information) and the capacity to perform the processes mentioned in the indicator; however it has only limited experience or a limited number of documented events.
**IMPLEMENTED (I):** Market surveillance and control activities are appropriately communicated within the NRA, and documentation is available to support that communication within the NRA is well-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:** MC06.02: Findings and regulatory decisions of market surveillance and control activities are appropriately communicated to all national stakeholders including the general public.

**Maturity Level:** 3

**Description:** The assessor should verify that market surveillance and control activities are properly communicated to all relevant national stakeholders. For this activity, the intended stakeholders include, but are not limited to, governmental agencies (e.g., police and judicial authorities), non-governmental organizations, professional associations, customer representative associations, and the public community.

**Objective:** The objective of this sub-indicator is to ensure that market surveillance and control activities are actively communicated among all relevant stakeholders. These communications, in turn, ensure regulatory effectiveness through involvement of these key players. In addition, such communication increases awareness, encourages mutual understanding and cooperation, and builds confidence and trust among all stakeholders, including public trust in the regulatory system.

**Requirement:** Communication to different stakeholders including the community of market surveillance and control activities.

**Evidence to review:** The assessor should ask for and review:
1. Records of communication (i.e., paper based or electronic) proving communication of market surveillance and control activities with other relevant stakeholders.

**References:**
2. Recommendations for health authorities to detect and deal with actions, activities and behaviors that result in substandard/spurious/falsely-labelled/falsified/counterfeit medical products, A68/33, annex 1 (129) (http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_33-en.pdf)
3. Guidance on developing a national plan for preventing, detecting and responding to actions, activities and behaviors that result in SF medical products. WHO (document A70/23) (130) (https://www.who.int/medicines/regulation/ssffcmechanism/A70_23-
<table>
<thead>
<tr>
<th>Framework:</th>
<th>Output</th>
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</thead>
<tbody>
<tr>
<td>Rating Scale:</td>
<td>NOT IMPLEMENTED (NI): Market surveillance and control activities are not communicated to national stakeholders or the public. ONGOING IMPLEMENTATION (OI): The NRA is preparing to establish mechanisms for communication of market surveillance and control activities to national stakeholders and the public, but there is no evidence of results from such activities. PARTIALLY IMPLEMENTED (PI): There is evidence that the NRA has the elements (i.e., procedures, documentation, management systems, and other relevant information) and the capacity to perform the processes mentioned in the indicator; however, it has only limited experience or a limited number of documented events. IMPLEMENTED (I): Market surveillance and control activities are communicated to national stakeholders and the public.</td>
</tr>
<tr>
<td>Limitations and remarks:</td>
<td>Scoring this sub-indicator as &quot;not applicable NA&quot; is excluded (i.e. this sub-indicator will always apply for all benchmarked NRAs).</td>
</tr>
<tr>
<td>Sub Indicator:</td>
<td>MC06.03: Findings and regulatory decisions of market surveillance and control activities of common interest are appropriately communicated and shared with other countries and regional and international organizations.</td>
</tr>
<tr>
<td>Maturity Level:</td>
<td>3</td>
</tr>
<tr>
<td>Description:</td>
<td>The assessor should verify that findings and regulatory decisions of market surveillance and control programme of common interest are shared with other countries, regional networks and international organizations (e.g. Rapid Alert Notifications and WHO Global Surveillance and Monitoring System for SF medical products). The assessor should verify that the relevant information is shared with external partners in a timely manner so that the information remains valuable and has the potential to minimize adverse events in locations outside the country.</td>
</tr>
<tr>
<td>Objective:</td>
<td>The objective of this sub-indicator is to ensure that those findings and regulatory decisions that are related to the market surveillance and control programme and that are of common interest, are shared with other countries, regional networks and international organizations. Sharing of market surveillance and control information, including decisions, is essential for ensuring coordinated global efforts for access to medical products of reliable quality.</td>
</tr>
<tr>
<td>Requirement:</td>
<td>Sharing of market surveillance and control information of interest with other countries and regional and international organizations.</td>
</tr>
</tbody>
</table>
### Evidence to review:

The assessor should ask for and review:

1. Agreements, MOUs and other documentation reflecting cooperation between the NRA and other foreign entities for the purpose of sharing findings, data and decisions of market surveillance and control programme.
2. Examples of communication with foreign entities for the purpose of sharing findings, data and decisions of market surveillance and control programme.

### References:


### Framework:

Output

### Rating Scale:

- **NOT IMPLEMENTED (NI):** Market surveillance and control activities are not communicated or shared with other countries or regional or international organizations.
- **ONGOING IMPLEMENTATION (OI):** The NRA is preparing to establish mechanisms for communication of market surveillance and control activities with other countries and regional and international organizations, but there is no evidence of results from such activities.
- **PARTIALLY IMPLEMENTED (PI):** There is evidence that the NRA has the elements (i.e., procedures, documentation, management systems, and other related information) and the capacity to perform the processes mentioned in the indicator; however, it has only limited experience or a limited number of documented events.
- **IMPLEMENTED (I):** Market surveillance and control activities are communicated and shared with other countries and regional and international organizations.

### 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).