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National Strategy to stimulate reporting

# Background

Spontaneous reporting remains a key step to several regulatory activities which are key to ensuring the quality, safety and effectiveness/performance of medical products. These regulatory activities include vigilance, market surveillance (by NRAs for medical devices), post introduction surveillance by immunization programs, post-market surveillance (by manufacturers of medical devices), and market control (for substandard and falsified products).

The Council for International Organizations of Medical Sciences defines a spontaneous report as ‘an unsolicited communication by healthcare professionals or consumers to a company, regulatory authority or other organization that describes one or more suspected adverse drug reactions in a patient who was given one or more medicinal products’ (CIOMS 2021). However, spontaneous reporting concerns other situations which share the characteristic of being associated to a demonstrated or potential risk for patients or users, including adverse drug events (ADEs), adverse events following immunization (AEFI), feedback from medical devices users, quality defects, medication errors, etc. Further, WHO generally distinguishes the notification, when the health system (e.g. a healthcare professional) is informed about an event, and reporting, when the event is communicated (usually in pre-defined formats) to regulators, program managers, and manufacturers through paths defined at the national level for further analysis and, as required, to decide on risk minimisation measures (WHO n.d.).

While reporting contributes to building shared international knowledge which is used by the relevant actors, national reporting is also important to detect country-specific risks (e.g. products only marketed in the region, particular drug-drug interactions, regional specificities, programme errors etc.), quality issues, and to provide transparent and authoritative information to the public.

In general, and depending on national regulation and guidelines (e.g. program implementation guidelines), reports can be issued by different users, including healthcare professionals (e.g. medical doctors, pharmacists, midwives, nurses, etc.) patients, their caregivers, and manufacturers. These reports, once notified, are collected by manufacturers, program managers, and regulatory authorities to detect, analyse and minimize risks.

As evidenced in multiple works[[1]](#footnote-2), barriers to reporting are diverse, and addressing these to make a significant impact requires the collaboration of multiple stakeholders and the combination of multiple tools.

The development of national strategy to increase reporting is intended to develop such programme in a comprehensive manner, including monitoring its impact.

# Scope

This strategy addresses

* adverse drug events for medicines,
* adverse events following immunization,
* adverse events for traditional products,
* incidents with medical devices,
* and reporting substandard and falsified products.

*Note: it is recommended to address all to maximize synergies in using tools (e.g. communication campaign) and to consider the complexity of multiple reporting systems.*

# Responsible organizations

|  |  |  |
| --- | --- | --- |
| **Type of report** | **Responsible Organization(s)** | **Contact details** |
| Adverse Drug Events for Medicines |  |  |
| Adverse Events Following Immunization, |  |  |
| Adverse Events for Traditional Products |  |  |
| Incidents With Medical Devices |  |  |
| Substandard And Falsified Products |  |  |

# Description of the existing pathways for notification and reporting in [Name of the country]

## Adverse Drug Events for Medicines

## Adverse Events Following Immunization,

## Adverse Events for Traditional Products

## Incidents With Medical Devices

## Substandard And Falsified Products

# Review of barriers to reporting

The main barriers to reporting have been reviewed and discussed between the responsible organizations and the main stakeholders and were identified as follows:

*Note: check all which applies in the national context*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Main barriers identified | Medicines | Vaccines | Traditional products | Medical Devices | Substandard and falsified products |
| Lack of time |  |  |  |  |  |
| Governance and policy (legislation, guideline, Weak system/National PV center) |  |  |  |  |  |
| Language/literacy as a barrier |  |  |  |  |  |
| Complexity of reporting form |  |  |  |  |  |
| Complexity/lack of reporting system |  |  |  |  |  |
| Lack of knowledge/ training |  |  |  |  |  |
| Lack of motivation |  |  |  |  |  |
| Perception about products safety |  |  |  |  |  |
| Guilt/shame |  |  |  |  |  |
| Fear of consequences |  |  |  |  |  |
| Discouraging system |  |  |  |  |  |
| Lack of positive feedback to reporters |  |  |  |  |  |
| Uncertainties on what to report |  |  |  |  |  |
| Uncertainties on who should report |  |  |  |  |  |
| Preference for publication rather than PV report |  |  |  |  |  |

# Tools to address the main barriers identified in [Name of the country]

Considering the main barriers identified, the following tools have been identified:

*Note: Please delete the columns which are not relevant in your national context*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Tools** | **Lack of time** | **Legal framework, governance policy** | **Language/literacy** | **Complexity of reporting form** | **Complexity/lack of reporting system** | **Lack of knowledge/ awareness** | **Lack of motivation** | **Perception about products safety** | **Guilt/shame** | **Fear of consequences** | **Discouraging system** | **Lack of positive feedback** | **Uncertainties on what to report** | **Uncertainties on who should report** | **Preference for publication** |
| **Advocacy, engagement** with **stakeholders**, **communication campaign, Call for reporting in the product information template** | x |  | x |  |  | x | x | x | x | x | x |  | x | x | x |
| Inclusion of **reporting in the objectives/indicators** of programmes and facilities | x |  |  |  |  | x | x |  | x | x | x |  |  |  | x |
| **Adequate and timely feedback** +/- clinical advice, **appreciation** of efforts | x |  | x |  |  |  | x |  |  |  |  | x |  |  |  |
| **Functional reporting system** (test, feedback from users), **simplified/standard tools, integration** of vigilance | x |  | x | x | x |  | x |  |  |  | x | x | x | x |  |
| **Global benchmarking tool** and WHO guidelines |  | x |  |  | x |  |  |  |  |  |  |  |  |  |  |
| Clear and adequate public **national guidance,** reporting guide |  |  |  |  |  | x |  |  | x | x |  |  | x | x |  |
| **Training** |  |  | x |  |  | x | x | x | x | x |  |  | x | x | x |
| Vigilance and reporting included in healthcare **professionals curriculum** | x |  | x |  |  | x | x | x | x | x |  |  | x | x | x |
| **Adequate and timely feedback +/- clinical advice** | x |  |  |  |  |  | x |  | x |  | x | x | x | x |  |
| **Protective legal provisions for reporting** |  | x |  |  |  |  | x |  | x | x | x |  |  |  |  |
| Reporting system guaranteeing **anonymity** |  |  |  |  |  |  | x |  | x | x | x |  |  |  |  |

# National Strategy to increase reporting

## Overall strategy

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Action** | **Responsible Organization(s)** | **Key Stakeholders** | **Start date** | **End date** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

## Actions specific to Medicines

## Actions specific to vaccines

## Actions specific to Traditional Products

## Actions specific to Medical Devices

## Actions specific to Substandard and Falsified Products

# Monitoring and evaluation

The following indicators were identified to allow assessing the impact of the recommended strategy:

# References

* WHO. n.d. “Adverse Events Following Immunization (AEFI).” n.d. https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance/health-professionals-info/aefi.

1. South-East Asia Regulatory Network (SEARN), 2023. Action Point 10 - Strategy to Stimulate Reporting. https://searn-network.org/action-point-10-strategy-to-stimulate-reporting [↑](#footnote-ref-2)