Overview of Pharmacovigilance Requirements in Brazil
Definitions

- **Instructions for use:** manuals, brochures and other documents accompanying a health product that contain technical information about the product.

- **Notification:** the act of informing health authorities, or other organizations, about the occurrence of adverse events or malfunctions involving health products, by the registration holder.

- **Health product:** a product falling into one of the following two categories:
  
  - **Medical product** – a product, such as equipment, device, material, article or system having a use or application that is medical or dental or for laboratory use, that is intended to prevent, diagnose, treat, rehabilitate, or for contraception, and that does not rely on pharmaceutical, immunological, or metabolic means to achieve its primary function in humans, but may however be assisted by such means.
  
  - **In-vitro diagnostic product:** reagents, standards, calibrators, controls, materials, articles and instruments along with their instructions for use, used to perform a qualitative, quantitative, or semi-quantitative determination on a sample derived from the human body and is not intended to perform an anatomical, physical, or therapeutic function, nor to be ingested, injected or inoculated into humans, but is to be solely used to provide information about a sample derived from a human.
Definitions

- **Alert**: written communication directed at health professionals, patients, users, the regulatory sector, and general communications, having for objective to inform with respect to the risk of occurrence of adverse events in relation to a health product;

- **Field action**: action performed by the manufacturer or holder of a health product registration, having for objective to reduce the risk of occurrence of adverse events related to the use of a marketed health product;

- **Adverse event**: any undesirable effect to humans resulting from the use of products subject to health surveillance; serious adverse event: an adverse event that meets at least one of the following:
  - Leads to death;
  - Causes a disability or permanent damage in a structure of the body;
  - Requires medical or surgical intervention to prevent permanent harm to a function or structure of the body;
  - Requires hospitalization of a patient or a prolongation of hospitalization;
  - Leads to a disturbance or risk to a fetus, fetal death, or a congenital anomaly.

- **Non serious adverse event**: any other adverse event not included in the definition of a serious adverse event;

- **Risk management**: systemic application of policies, procedures and practices with the objective to analyze, assess and control risks;
Definitions

- **Malfunction**: notification of suspected adulteration or irregularity of a product or company in relation to technical or legal aspects, and that could, or not, cause harm to individual and collective health;

- **Traceability**: the ability to describe the history, application, processes and the location of a product, in a particular organization, by means of records and identification;

- **Risk**: the combination of the probability of occurrence of harm and the severity of the harm; serious threat to public health: any type of occurrence that results in an imminent risk of death, serious lesions or serious disease, that requires rapid corrective measures;

- **National System of Health Surveillance (SNVS)**: constituted of the Ministry of Health, the National Health Surveillance Agency (ANVISA), and the Health Surveillance Centers of the States, Territories, and the Federal District.

- **MedDRA** is a standardized medical terminology with the aim of facilitating the international sharing of information is the terminology adopted in the VigiMed system.
The national pharmacovigilance centre in Brazil is the Pharmacovigilance Management Unit (GFARM) of the Brazilian health regulatory agency (Anvisa), which coordinates the pharmacovigilance system, undertaking the surveillance of adverse events related to medicines at a national level, and formulating and implementing technical and operational guidelines, regulations, and standards.

GFARM adopted International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the incorporation of ICH guidelines became mandatory, especially those for pharmacovigilance (namely E2B, E2D, and M1).

GFARM uses VigiMed that is the same system than VigiFlow.

All ICSRs are reported and sent to Anvisa database VigiBase.
Anvisa Pharmacovigilance Spontaneous Notification System
Brazil National Pharmacovigilance Structure

- Visas (State)
- Anvisa (SNFV Coordinator)
- Notifiers
- Ministry of Health (MS)
- Visas (municipality)

- Anvisa / GFARM Coordinator of the National Pharmacovigilance System
What is VigiMed?

- VigiMed is the system adopted in 2019 provided by Anvisa for monitoring adverse events related to medications and vaccines.

- VigiMed is the name given in Brazil to the VigiFlow system, which is provided to the national pharmacovigilance centers of the countries of the International Drug Monitoring Program by the Uppsala Monitoring Centre (UMC), a WHO collaborating center that operates the Program.
PV Managers or designee should send an e-mail to vigimed@anvisa.gov.br to request the registration and account creation.
Information to be reported in VigiMed

1. Notification information
   • Initial date of receipt
   • Notification type
   • Date of receipt of additional information
   • Qualification of notification

2. Patient
   • Initials of the patient
   • Sex
   • Date of birth
   • Age at the beginning of the reaction or Age group
   • If the notification is Parent Child
     • Gestational age at the onset of the reaction (if fetus)
     • Gestational age at exposure (if fetus) (in the Medicine)

3. Drug product
   Name of medication
Information to be reported in VigiMed

3. Medicine
   Indicate at least one suspicious medicinal product or two medicinal products in interaction
   Name of the medicine (WHO Drug) or
   Name of the medicinal product reported by the initial notifier

4. Reaction
   Reaction/event event as reported by the initial notifier or
   Reaction/Event (MedDRA)

However, a more complete notification will lead to better analysis of the data. One should enter as many fields as possible.
<table>
<thead>
<tr>
<th>Reaction/ Event</th>
<th>Timeline</th>
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| after becoming aware of:  
  • serious adverse events not involving death;  
  • non-serious adverse events, the re-occurrence of which has the potential to cause a serious adverse event to a patient, user, or other person. | 10 (ten) days |
| malfunction within the national territory and associated with a health product registered in its name, that could lead to a serious adverse event in a patient, user, or other person, provided that one of the following conditions applies:  
  • the possibility of re-occurrence of the malfunction is not remote;  
  • an event of the same type has caused or contributed to a death or serious harm to health in the last three years;  
  • the registration holder of the product needs, or needed, to perform an action to prevent danger to health;  
  • the possibility that an error was caused by deficient design, labelling, or instructions. | 30 (thirty) days |
## Reporting Timelines

<table>
<thead>
<tr>
<th>Type of event</th>
<th>Reporting Timelines</th>
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<tbody>
<tr>
<td>Fatal or life-threatening, unexpected ADRs occurring in clinical investigations</td>
<td>7 days for reporting followed by, followed by a complete report within 8 additional calendar days.</td>
</tr>
<tr>
<td>Serious, unexpected reactions (ADRs) that are not fatal or life-threatening</td>
<td>15 days</td>
</tr>
</tbody>
</table>
References


- RESOLUTION- RDC no. 4, 10/Feb/09: Good Pharmacovigilance Practices and Inspection (GPPI) for MAHs


- Mr. MedDRA. Available in www.meddra.org/ https://


- Agência Nacional de Vigilância Sanitária – Anvisa-farmacovigilancia@anvisa.gov.br