The WHO Safety and Vigilance Team

Who are we and what is our goal?

The Safety and Vigilance (SAV) team is part of the Regulation of Health Technologies unit. Its overall goal is to provide evidence-based support to countries to ensure safe use of health technologies (devices, medicines, vaccines, procedures and systems) in patients.

Who are our partners?

The SAV team works in close collaboration with the three other teams of Medical Products unit (Norms and Standards team, Prequalification team, and Regulatory Systems Strengthening team), with WHO public health programmes, with the National Regulatory Authorities, the national Vigilance Centres, Uppsala Monitoring Centre (UMC) and other relevant WHO Collaborating Centres (in Oslo, Ghana, Morocco, the Netherlands), UN procurement agencies, Advisory Committees, professional associations such as the International Society of Pharmacovigilance (ISoP), groups representing industry (International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Council for International Organizations of Medical Sciences (CIOMS)), control laboratories, and manufacturers as well as other internal and external stakeholders.

What are our key achievements in the last five years?

The WHO Programme for International Drug Monitoring and more recently, the Global Vaccines Safety Initiative have expanded rapidly. A strategic approach has been to use various priority diseases as pathfinders, to introduce active surveillance of priority health products (in HIV, TB and malaria treatment programmes or new vaccines), leading to robust safety data for these products in the short-term, and resulting in sustainable pharmacovigilance (PV) infrastructure in the long-term. Rapid response to safety signals is required to identify those rare instances where real adverse reactions occur so their impact can be minimized as they emerge. This is of particular importance for products that have recently become available for public use and for which only limited experience is available. WHO proposes the following stepwise approach to provide enhanced capacity for the monitoring of priority products:

1. Development of a product specific strategy validated by independent external experts. Implementation of the strategy relies on WHO’s unique network of regional and country offices that provide advice to national health authorities
2. Capacity-building that relies on a country-owned five step process (benchmarking, assessment, planning, technical support and evaluation)
3. Multi-country assessment through networks of clinical centres and pooling of data
4. Independent risk assessment through expert advisory body
5. Network of experts who provide geographically and culturally adapted support
6. Collaborative platforms, that allow synergies, alignment of efforts and coordinated resource mobilization from multiple partners - including information exchange with private sector – through a portfolio of activities maintained by the WHO secretariat.

Our targets:

In the short to medium-term

- **Advocacy**: Use the World Health Assembly (WHA), International Conference of Drug Regulatory Authorities (ICDRA) and annual meetings of national vigilance centres to engage with the Government at the highest level, and advocate a comprehensive PV strategy
- **Leverage**: Build on 5 decades of WHO experience, mandate and network to establish / strengthen national vigilance systems for priority medical products
- **Partnership**: Engage WHO Collaborating Centres and other partners, to build capacity for safety monitoring of priority products in key countries
- **Infrastructure**: Provide tools and systems (eg Vigiflow, Vigilyze, PV Toolkit) and support countries in safety reporting, data management, analysis and risk communication.
- **Active surveillance**: Develop methods for the proactive safety monitoring of selected priority products
- **Training**: Build capacity for proactive safety monitoring of selected priority products (e.g. Cohort Event Monitoring (CEM), Targeted Spontaneous Reporting (TSR) in selected national sentinel sites)
- **Combat SSFFC**: Develop effective monitoring tools and systems for SSFFC medical product detection
  - Improved reporting for Member States (smart phone app technology etc.), improved fast time drug alerts, development of awareness and advocacy material
  - Improved data analysis of SSFFC incidents, reporting on trends and vulnerabilities.

In the long-term

- **Strengthen** safety surveillance before and after introduction of priority health products; implement active surveillance of some of the high risk products
- Host advisory bodies on product safety, to evaluate the benefit risk data for new products
- Strengthen regulatory oversight for safety of new vaccines and medicines in particular, and all products in general
- Establish regional surveillance, reporting, alerting and laboratory capacities for better, focused and directed action at the local level on SSFFCs
- Develop data mining tools to better detect hidden signals of SSFFC medicines in the supply chains
- Improve directed market surveillance programmes through early dissemination of SSFFC products, improve reporting through pharmacovigilance networks in low and middle income countries