WHO Global Smart Pharmacovigilance Strategy: synopsis

Background

When faced with competing health priorities, countries will have to invest their limited resources judiciously, by focusing pharmacovigilance efforts on priority products and adopting approaches that are relevant to their settings, by relying on the work of other countries when possible and building national competence for those activities that cannot be delegated. This is Smart Pharmacovigilance.

A Global Smart Pharmacovigilance Strategy is proposed as an approach that can help establish robust, proactive, safety monitoring and risk management systems that leverage existing infrastructure but consider the specific constraints and requirements of the healthcare settings. The objective is to build on the learnings from the Smart Safety Surveillance (3S) pilot projects[1], the Global Vaccine Safety Blueprint (GVSB)[2] and the COVID-19 pandemic experiences[3], to develop a comprehensive and sustainable safety monitoring and risk management practice as an integral part of healthcare and regulatory system, enabling quick, adequate and sustainable responses to potential safety risks with priority medicinal products in all Member States. A key aspect of the 'Smart' approach lies in the fact that not all products would be monitored the same way, and not all countries would need to do everything. Instead, the focus would be on a development strategy that best serves the priority pharmacovigilance needs of the country while utilizing the information and leveraging the resources in other countries, to mutual benefit.

Four key principles underpin the strategy: 1) Previous pharmacovigilance efforts and lessons learnt; 2) risk-based (approach to prioritize) pharmacovigilance activities; 3) work-sharing and reliance in pharmacovigilance; 4) pharmacovigilance as part of stepwise regulatory system strengthening efforts.

1) **Previous pharmacovigilance efforts and lessons learnt**: Pharmacovigilance has come a long way since the establishment of the WHO Programme for International Drug Monitoring (PIDM) in 1968, and it is important to learn from and build on previous accomplishments. Successes can be observed at national, regional, and global levels. Tailored approaches are taken in different settings according to assessed needs and functionality.

2) **Risk-based approach and prioritization:** This consists of focusing PV efforts on priority products: 1) Products that are exclusive to their settings, introduced to address a disease of limited

[1] N. Iessa et al. Drug Saf. 2021 Oct;44(10):1085-1098. doi: 10.1007/s40264-021-01100-z. Epub 2021 Jul 31. Smart Safety Surveillance (3S): Multi-Country Experience of Implementing the 3S Concepts and Principles.
[2] WHO. Global vaccine safety blueprint 2.0 (GVSB2.0) 2021-2023. 2022 February 21. https://www.who.int/publications/i/item/9789240036963
[3] R Chandler et al. BMJ Glob Health. 2024 Mar 7;9(3):e014544. doi: 10.1136/bmjgh-2023-014544. Collaboration within the global vaccine safety surveillance ecosystem during the COVID-19 pandemic: lessons learnt and key recommendations from the COVAX Vaccine Safety Working Group

geographic prevalence, data for which will not be available or forthcoming from the rest of the world; 2) Products with limited clinical data, receiving accelerated approvals for several reasons and to be introduced simultaneously in high income- and low- and middle-income countries (LMICs), with little global experience that LMICs can rely-on.

3) **Work-sharing and Reliance:** The overarching vision for the WHO General Programme of Work (GPW14) is to promote, provide and protect the health and well-being of all people everywhere. This strategy recognizes variation in health systems, some with fragile health systems on one end of the spectrum and more mature health systems on the other end. It is proposed that the focus and prioritization of PV consider available resources and regulatory system capacity. The principles of work-sharing and reliance would be key considerations.

4) **Pharmacovigilance as part of stepwise regulatory system strengthening efforts:** Pharmacovigilance needs to be embedded into a regulatory framework for sustainability. Relevant legal frameworks empower regulatory agencies in the implementation and oversight of safety monitoring and related activities. The WHO Global Benchmarking Tool (GBT)[4] helps to benchmark and assess the maturity of an entire national regulatory system. It consists of a set of indicators categorized into nine regulatory functions, including PV. Following a benchmarking exercise, gaps or areas where the PV system can be improved are incorporated into an institutional development plan (IDP) providing a roadmap to stepwise system strengthening approach.

In view of some of the common processes and requirements between medicines and vaccines' safety surveillance, the strategy advocates the use of data tools and methods, and regulatory framework across the two product types. It promotes the use of existing networks and platforms such as the WHO Programme for International Drug Monitoring (PIDM), the African Medicines Regulatory Harmonization (AMRH), South East Asia Regulatory Network (SEARN), Association of South East Asian Nations (ASEAN), the Regional Pharmacovigilance Network of the Americas and Caribbean Sub-regional Network (VigiCarib) , the Western Pacific Regional Alliance of National Regulatory Authorities and the Coalition of Interested Parties (CIP), to name a few.

Medicine and vaccine safety communication is necessary throughout the life cycle of a product and is addressed as a cross-cutting component throughout the strategy. Methods to enhance communication are provided.

A few hypothetical scenarios of the introduction of medicines and vaccines in different settings and the application of the above concepts are also described, to help countries draft their own pharmacovigilance development strategies and plans.

The strategy's success can be measured by the number of countries adopting it and stakeholders contributing to its implementation. Several measures of impact are proposed, for example, changes in

[4] WHO Global Benchmarking Tools (GBT) for evaluation of national regulatory systems of Medical Products - Revision VI. 2021 May 10. https://www.who.int/publications/i/item/9789240020245

maturity of PV system measured by the Global Benchmarking tool, improvements in key performance indicators and others.