

43rd Annual Meeting of the Members of the WHO Programme for International Drug Monitoring

**“Leaving no one behind:
pharmacovigilance in women of
childbearing potential and children”**

27 – 29 October 2025

Cairo, Egypt

InterContinental Cairo Semiramis

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The Pharmacovigilance Team (PVG) within the Regulation and Safety Unit of the Department of Regulation and Prequalification, the World Health Organization (WHO), will organize the 43rd Annual Meeting of the Members of the WHO Programme for International Drug Monitoring (PIDM). This meeting will be held under the overall coordination of the WHO PVG team, the WHO Regional and Country Offices, with local hosting support from the Egyptian Drug Authority (EDA). The meeting will focus on pharmacovigilance in women of childbearing potential and children, and the operationalization of the WHO Global Smart Pharmacovigilance Strategy¹.

Background

The WHO Programme for International Drug Monitoring (PIDM) was established by the World Health Organization (WHO) in 1968 to ensure the safety of medicinal products (i.e., medicines and vaccines). It aims to enhance the detection, assessment, understanding, and prevention of adverse reactions related to medicinal products. As of January 2025, the WHO PIDM Members consist of over 180 WHO Member States, territories and areas. The WHO PIDM facilitates collaboration among the Members by providing a platform for sharing pharmacovigilance data, learning and expertise, and also organizes the annual meeting of the PIDM representatives to foster discussions on the safety of medicinal products and emerging issues.

Pharmacovigilance in women of childbearing potential and children plays an important role due to their unique physiological and pharmacokinetic characteristics that can significantly affect the safety of medicinal products.

Despite their unique physiological and pharmacokinetic characteristics, these populations are frequently underrepresented in clinical trials resulting in a lack of robust safety data for medicinal products in these groups. Pharmacovigilance plays a critical role in providing the required real-world data and evidence

¹ WHO Regulation and Prequalification Update. Dec 2024. <https://createsend.com/t/d-20A0DBC4FCE03A202540EF23F30FEDED>

that inform the benefit-risk assessment of medicinal products in these populations, improving their access to safe medicines and vaccines.

The WHO Global Smart Pharmacovigilance Strategy, referred to as the Strategy hereafter, is proposed as an approach that can help establish robust, proactive, product-focused monitoring and risk management systems that leverage existing infrastructure but consider the specific constraints and requirements of the healthcare settings in which the products are, or will be used.

The WHO Global Smart Pharmacovigilance Strategy was presented at the WHO Pharmacovigilance Partners' Meeting in October 2024 in India, on the margins of the International Conference of Drug Regulatory Authorities (ICDRA). Four key principles which underpin the Strategy were discussed at the Partners' Meeting: 1) Previous pharmacovigilance efforts and lessons learnt²; 2) Risk-based approach and prioritization; 3) Work-sharing and Reliance; 4) Pharmacovigilance as part of stepwise regulatory system strengthening efforts.

The Strategy can be applied to advance pharmacovigilance activities for subpopulations including women of childbearing potential and children in multiple key areas, such as:

- Harmonization of adverse events terminologies, case definitions and data standards
- Improvement of data sources, data management and data sharing
- Development of tailored study protocols, risk management plans (RMP) and strategies, including implementation of risk minimization measures for old products
- Establishment of background rates of adverse events of special interest (AESI)
- Studying and documenting the specificities and needs of subpopulations in low- and middle-income countries (LMICs)
- Application of artificial intelligence such as machine learning in safety signal detection and analysis.

WHO has been working to operationalize this Strategy for the pharmacovigilance in pregnant and breastfeeding women, and in neonates³. The resources and learnings from these efforts will be discussed more broadly at the PIDM meeting, to develop a guidance for countries in the pharmacovigilance in women of childbearing potential and children.

The WHO PIDM Meeting will begin with a joint session between the WHO and the International Society of Pharmacovigilance (ISoP) on the afternoon of 27 October 2025, to discuss the implementation of the WHO Strategy (Session theme - Operationalizing the WHO Global Smart Pharmacovigilance Strategy). The ISoP is a member of the WHO Coalition of Interested Parties (CIP)⁴ which is referred as one of the implementation frameworks in the Strategy.

² This refers to human resources, as well as tools and methods available to conduct pharmacovigilance activities.

³ WHO. Landscape analysis of pregnancy exposure registries in low- and middle-income countries. 2024. ([link](#)), WHO. Harmonized approaches for the vigilance of interventions during pregnancy. 2024 ([link](#))

⁴ WHO. Coalition of Interested Parties. <https://www.who.int/initiatives/coalition-of-interested-parties>

Meeting objectives

The objectives of the meeting are:

- to provide a forum for the WHO PIDM Members to meet and discuss pharmacovigilance for women of childbearing potential and children in the framework of the WHO Global Smart Pharmacovigilance Strategy
- to explain, promote and discuss latest developments, learnings, best practice and methodology of pharmacovigilance activities in women of childbearing potential and children
- to collect PIDM-member recommendations on future directions and priorities for the Programme
- to provide an opportunity for developing collaborations and synergies between PIDM members and ISoP for more effective pharmacovigilance worldwide (specific objective for the WHO-ISoP joint session)

Expected outcomes

- Agreement among PIDM members on key actions for implementing the Global Smart Pharmacovigilance Strategy worldwide, with a focus in women of childbearing potential and children
- Recommendations on future directions and priorities for the WHO PIDM in relation to the implementation of the Global Smart Pharmacovigilance Strategy.

Target participants

Safety focal points responsible for pharmacovigilance activities and representing the following entities joining the WHO PIDM are expected to attend this meeting:

- National Pharmacovigilance Centers (NPVCs)
- National Immunization Programmes (NIPs)
- WHO and WHO Collaborating Centres

Working language

English

Mode of participation

Given that nominees from different geographies and time zones are expected to attend, in-person participation of country nominees is strongly encouraged.

Only for the plenary sessions, a virtual link to join the meeting will be made available to those country nominees who are unable to join in person.

WHO-ISoP joint session
“Operationalizing the WHO Global Smart Pharmacovigilance Strategy”
27 October 2025

13:00 Lunch

Opening

14:00	Welcome address (3 mins) Introduction of the agenda (2 min)	Moderator: H. Sillo (WHO HQ) O.Aimer & A. Caro-Rojas (ISOP President)
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Plenary session 1 WHO Global Smart Pharmacovigilance Strategy

14:05	<p>Objective: To present and discuss the WHO Global Smart Pharmacovigilance Strategy focusing on its implementation and impact.</p> <p>Expected outcome: The audience will understand the principles of the WHO Global Smart Pharmacovigilance Strategy and identify opportunities for joint collaborations and implementation.</p> <p><i>Session plan</i></p> <ul style="list-style-type: none"> • Introduction (5 min) • Presentation on the WHO Global Smart Pharmacovigilance Strategy (15 min) • Discussion (15 min) 	Moderator: P. Hjelmström (UMC) P. Hjelmström (UMC) S. Pal (WHO HQ)
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Plenary session 2 WHO Global Benchmarking Tools and Institutional Development Plans

14:40	<p>Objective: To discuss how PV can be anchored in regulatory system-strengthening efforts using WHO benchmarking, to support resilience and sustainability using WHO Smart PV Strategy principles</p> <p>Expected outcome: Participants will gain insights from shared PV-GBT experiences and identify practical solutions for strengthening PV in their own regulatory settings using the Smart PV Strategy.</p> <p><i>Session plan</i></p> <ul style="list-style-type: none"> • WHO Global Benchmarking Tools and Institutional Development Plans – Current status and challenges (15 min) • Panel discussion on country experience with PV and GBT (25 min) • Discussion (10 min) 	Moderator: H. Rostom (ISOP Scientific Committee) H. Sillo (WHO HQ) <i>Panellists:</i> Y. Ragae (Egyptian Pharmacovigilance Centre EPVC) S. Abdoellah (Indonesia National Agency of Drug and Food Control) M. Abgrakhmanov (Kazakhstan NRA)
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15:30 Coffee break (15 min)

Plenary session 3 Coalition, regulatory reliance and work sharing

15:45	<p>Objectives:</p> <ul style="list-style-type: none"> To discuss the Coalition of Interested Parties (CIP), and highlight ISoP's contribution to pharmacovigilance as a CIP member To share country and regional experiences on regulatory reliance and work-sharing in pharmacovigilance in support of WHO's Smart PV strategy <p>Expected outcomes:</p> <ul style="list-style-type: none"> Participants understand the CIP and explore opportunities for collaboration. Participants gain insights into country practices and key considerations for implementing reliance and work-sharing principles. 	<p>Moderator: S.Pal (WHO HQ)</p>
<i>Session plan</i>		
Panel discussion		
<ul style="list-style-type: none"> Introduction (10 min) UMC role in PV system strengthening and contribution as a CIP member (10min) ISOP role in PV system strengthening and contribution as a CIP member (10 min) EUM4ALL and reliance (10 min) Regional /country experience (10min) Discussion (20 min) 	<p>H. Sillo (WHO HQ) P. Lundquist (UMC) B. Edwards (Chair of ISOP scientific committee) VM. Sarinic (ISOP Scientific Committee)</p>	<p><i>Panellists</i> South-East Asian Regulatory Network (SEARN) J. Prakash (National Coordination Centre for Pharmacovigilance Programme of India) W. Rungapiromnan (Thai Food and Drug Administration, Thailand)</p>
Update on WHO-ISOP PV Curriculum		
16.55	<p>Objective: To provide an update on the revised WHO-ISOP curriculum.</p> <p>Expected Outcomes: Participants will:</p> <ul style="list-style-type: none"> Be informed about the key revisions made to the WHO-ISoP curriculum. Be reminded how to access and use this resource effectively. 	<p>Moderator: H. Rostom (ISOP Scientific Committee)</p>
<i>Session plan</i>		
Updates to WHO-ISOP Curriculum		
17:15	Summary of the outcomes and closing (10 min)	<p>S. Pal (WHO HQ) O.Aimer & A. Caro-Rojas (ISOP President)</p>

WHO PIDM meeting (28-29 October)

“Leaving no one behind: pharmacovigilance in women of childbearing potential and children”

28 October 2025

8:30	Arrival in the venue and morning coffee	
	Opening	
9:00	<ul style="list-style-type: none"> Welcome address (10min) Opening remarks (10min) 	Ministry of Health representative EDA Chairman RD for EMRO H.Sillo (WHO HQ)
	<ul style="list-style-type: none"> Reporting back on progress since the previous WHO PIDM Meeting (15 min) Objectives and expected outcomes, introduction of the agenda, brief report on the WHO-ISoP session (15min) 	N.Iessa (WHO HQ) S.Pal (WHO HQ)
10:00	Group photo	
10:15	Coffee break	
Plenary 1: Data harmonization for better safety monitoring of maternal and newborn health		
10:45	<p>Objective: To promote harmonization of PV data standards to monitor the safety of medicinal products in pregnant women and children</p> <p>Expected outcomes: Participants will be informed about the WHO Minimum Maternal and Newborn Health Data Set (mMNHDS) and its implementation and will identify opportunities to use it to improve data quality within their settings.</p> <p><i>Session plan</i></p> <ul style="list-style-type: none"> Unique challenges in PV of women of childbearing potential and children (10 min) WHO minimum Maternal and Newborn Health Data Sets (mMNHDS) (20 min) Lessons learnt from the pilot study (20 min) Discussions (25 min) 	<p>Moderator: M. Ansari (Drug Regulatory Authority of Pakistan)</p> <p>M. Ansari</p> <p>S.Lamprianou (WHO HQ)</p> <p>P.Zorto (WHO CO of Nigeria)</p>
12:00	Lunch (75 min)	
13:15	Vaccine Safety Net (VSN) Call for participation (15min)	S.Lamprianou (WHO HQ)
Plenary 2: Panel discussion- How can we measure our efforts and progress in pharmacovigilance?		

13:30	<p>Objective: To explore global and country-level indicators for measuring pharmacovigilance progress, including those for maternal and pediatric health</p> <p>Expected outcome: Participants will gain an understanding of key indicators and how to apply them effectively.</p> <p><i>Session plan</i></p> <ul style="list-style-type: none"> Existing global indicators and ongoing evolution (10 min) Regional adaption of the global indicators (10 min) Metrics used by countries– Inputs from panellists (30 min) Discussions (30 min) 	<p>Moderator: H.Langar (WHO EMRO)</p> <p>M. Balakrishnan (WHO HQ) A.Inoubli (WHO SEARO)</p> <p><i>Panellists:</i> R.Karam (Ministry of Public Health, Lebanon) M.Russom (National Medicines and Food Administration, Eritrea) J.Roldan (Anamed, Chile)</p>
14:50	Breakout Session Instructions and Transition (5 min)	M.Maarouf (WHO CO)
<p>Breakout group discussions There will be 4 breakout groups, with different topics, running in parallel.</p> <ul style="list-style-type: none"> Each group will have a country intervention presenting real-life challenges on the group topic, followed by group discussions and recommendations. Discussions in each breakout group will be led by a moderator and summarized by a session rapporteur. Allocation of participants into groups will be done randomly by the secretariat and communicated to participants beforehand. <p>Recommendations from the breakout groups will be presented to all participants in a plenary session.</p>		
14:55	Group 1 – Pharmacovigilance data for women of childbearing potential and children	Moderators: H.Ndagije (National Drug Authority, Uganda) and M.Ismail (WHO AFRO)
(including a 30-minute coffee break 16:00)	Group 2 – Signal detection and assessment in women of childbearing potential and children	Moderators: Q-Y Yue (UMC) and P.Tregunno (Medicines and Healthcare products Regulatory Agency, MHRA, UK)
	Group 3 – Risk Management Plans: awareness, feasibility and inclusion of pregnancy and pediatric risks	Moderators: T. Stammschulte (Swissmedic) and I.Gamal (Egyptian Drug Authority)
	Group 4 – Data and information sharing, and collaboration among stakeholders	Moderators: E.Diaz (COFEPRIS, Mexico) and G. Hill (WHO, WPRO)
17:20	Move to the main room (5 min)	M.Maarouf (WHO CO)
17:25	Recap and announcements for the next day (10 min)	M.Maarouf (WHO CO)
18:30	Dinner	

