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FROM THE ISoP

Global Perspective on the Evolution and Future of Pharmacovigilance: Deliverables from the 24th Annual Meeting of the International Society of Pharmacovigilance Celebrating 25 Years of Excellence

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1 Introduction

1.1 Foreword

The International Society of Pharmacovigilance (ISoP) is a global, scientific, non-profit organization dedicated to advancing pharmacovigilance (PV) and promoting the safe and appropriate use of medicines and devices [1]. The society brings together professionals from diverse sectors, including academia, regulatory authorities, the pharmaceutical and medical device industries, healthcare institutions, clinical research organizations, independent researchers, and patient advocacy groups. Through scientific exchange, professional training, and international collaboration, ISoP provides an important forum for discussion and advancement in all areas related to the safety of medicines, medical devices, and other therapeutic and health products, including biologics, biosimilars, vaccines, and natural or herbal products.

ISoP was originally established in the early 1990s as the European Society of Pharmacovigilance (ESOP). As PV rapidly expanded beyond Europe and the society's membership became increasingly international, ESOP became the International Society of Pharmacovigilance in 2000 [2]. Since then, the organization has evolved into a leading global platform for advancing the science and practice of PV while maintaining a strong focus on protecting patients from harms associated with medicinal products across healthcare systems. As of April 2026, the society includes more than 1500 members from diverse organizations and disciplines across 118 countries. ISoP also supports a global network of 13 national and regional chapters (e.g., China and Europe) and 16 Special Interest Groups (SIGs), which constitute key components of the ISoP operational strategy, addressing areas such as artificial intelligence in PV and real-world evidence (RWE) and big data, and promoting collaboration and knowledge exchange in emerging fields of PV [3, 4]. In addition, ISoP facilitates member engagement through dedicated ISoP communities (e.g., Students, Fellows, Industry), which provide platforms for professional interaction, capacity building, and collaboration across different career stages and sectors [5].

1.2 Preface

The 24th Annual Meeting of the ISoP was held during 24–27 October 2025 in Cairo, Egypt, and was co-hosted by the Egyptian Chapter of ISoP [6]. The event brought together over 500 participants from more than 80 countries across North America, Europe, Africa, Asia, Latin America (LATAM), and Oceania [7].

The meeting was hosted by the Egypt Chapter, with support from a Local Organizing Committee comprising selected members from the ISoP Egypt Chapter. The scientific programme was developed by the ISoP Scientific Committee, chaired by Brian Edwards (United Kingdom) with Hadir Rostom (Egypt) serving as Co-Chair. Committee

In Memory of Siti Asfijah Abdoellah: The ISoP dedicates this article to the late Siti Asfijah Abdoellah in recognition of her outstanding efforts to promote pharmacovigilance worldwide.

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members included Mayada Alkhakany (Iraq), Mohamed A. Elhawary (Egypt), Jimmy Jose (Oman), Jayesh Pandit (Kenya), Viola Macolic Sarinic (Netherlands), Santiago Schiaffino (Spain), Eugene van Puijenbroek (Netherlands), and Alem Zekarias (Sweden). Christina Saad (Egypt) served as the Committee Rapporteur.

The meeting brought together PV professionals and stakeholders from around the world to share scientific advances, discuss emerging challenges, and strengthen international collaboration in medicine safety. The conference theme, "Pharmacovigilance: Back to the Future," invited participants to reflect on how the historical foundations of PV continue to shape its future [8]. From foundational documents such as the reports of the Council for International Organizations of Medical Sciences (CIOMS) to the adoption of innovative digital tools and data-driven approaches, the field continues to evolve by building upon established knowledge while embracing new technologies. Cairo, an ancient city that bridges the millennia of civilization with a dynamic modern society, provided a fitting backdrop for this reflection on continuity, progress, and innovation.

In addition to its scientific programme, the 2025 meeting marked a significant milestone—the 25th anniversary of ISoP as an international society. The anniversary celebration provided an opportunity to reflect on ISoP's achievements, its global impact on PV, and its enduring mission to protect patients from medicine-related harm. Reflecting on this milestone, Ivor Ralph Edwards, First President of the ISoP (2000–2002), delivered opening remarks at the Society's 25th Anniversary Celebration, as follows:

> "*Looking back over the past twenty-five years since I served as ISoP's first president, it is remarkable to see how the Society has grown into a truly international community. Hearing the reflections of the current leaders was particularly inspiring, reaffirming our shared commitment to supporting those harmed by medicines and to preventing such harm in the future. The meeting in Cairo brought together colleagues from many countries to exchange ideas and advance PV. It was a truly splendid gathering. My best wishes to all in ISoP for the future, which I hope will be more peaceful. Amor vincit omnia* (love conquers all), as expressed by Chaucer in *The Canterbury Tales*."

The anniversary celebration and scientific sessions together highlighted the continued relevance of PV in an evolving patient safety landscape. The meeting featured 84 speakers, panellists, and chairpersons across 5 plenary sessions and 25 parallel sessions, along with over 400 abstracts submitted, with the accepted abstracts now published in the journal *Drug Safety* [9, 10]. Among the key programme components was the joint session between ISoP and the World Health Organization (WHO), which focused on the WHO Global Smart Pharmacovigilance Strategy. This session explored how smarter, risk-based approaches to PV can be operationalized across diverse regulatory contexts, emphasizing lessons learned, regulatory reliance, and the strengthening of PV systems worldwide. The meeting also included the ISoP General Assembly 2025, during which the new ISoP Advisory Board (2025–2028) was officially announced [11, 12].

2 Multidisciplinary Pre-conference Training Courses: Designed for the Diverse Pharmacovigilance Community

The pre-conference programme included five advanced multidisciplinary training courses delivered by international experts in PV on the day preceding the main conference. These courses addressed specialized and emerging areas of PV practice and were designed for professionals working across regulatory authorities, healthcare systems, academia, and the pharmaceutical industry.

The courses included "PV in the Community & Healthcare," "Advanced PV for the Industry: Mastering Inspections, Data Quality & Risk Management in the Digital Age," "PV in Vaccines," "Introduction to Pharmacoepidemiology," and "Benefit–Risk Assessment for Medicinal Products." These sessions provided practical insights and methodological perspectives that complemented the scientific programme and set the stage for further discussions during the main conference on evolving approaches to medicines' safety monitoring and evaluation.

3 Global Landscape of Pharmacovigilance: Evolution and Future Prospects

High-level panel discussions constituted a central component of the conference programme, bringing together leaders from key global PV stakeholders, including the WHO, European Medicines Agency (EMA), Uppsala Monitoring Centre (UMC), CIOMS, Drug Safety Research Unit (DSRU), African Union Development Agency—New Partnership for Africa's Development (AUDA-NEPAD), United States Pharmacopeia (USP), Coalition for Epidemic Preparedness Innovations (CEPI), Medical Dictionary for Regulatory Activities Maintenance and Support Services Organization (MedDRA MSSO), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), Medicines and Healthcare Products Regulatory Agency (MHRA), Saudi Food and Drug Authority (SFDA), Egyptian Drug Authority (EDA), European Training Programme in PV and Pharmacoepidemiology (EU2P), and the Rabat Collaborating Center (RCC),

alongside representatives from the pharmaceutical industry (e.g., Pfizer and Roche).

The discussions opened with the plenary panel "Driving the Future of PV: Global Strategies and Perspectives," which set the tone for subsequent panel sessions across the parallel programme. Collectively, these sessions explored the evolving global PV landscape, highlighting emerging scientific, regulatory, and collaborative approaches to medicine safety monitoring.

A major theme throughout the conference was the growing role of real-world data (RWD), including electronic healthcare records, insurance claims databases, and large-scale data networks, as complementary sources of evidence alongside spontaneous reporting systems and clinical trials [13, 14]. The increasing importance of RWE—generated from such data—was emphasized in the context of evolving regulatory frameworks and the expanding use of accelerated authorization pathways by agencies such as the US Food and Drug Administration (FDA) and the EMA [15]. These pathways facilitate earlier patient access to promising therapies but simultaneously reinforce the need for robust post-marketing safety surveillance capable of detecting and evaluating risks throughout the product lifecycle. Similar considerations apply to early access programmes, where post-authorization evidence generation plays an important role in monitoring safety and effectiveness in real-world settings [16].

Beyond safety signal detection, the potential applications of RWD extend to broader aspects of healthcare decision making. These include estimating anticipated uptake of new medicines, characterizing the demographic and clinical profile of target populations in routine care, and evaluating the effectiveness of risk-minimization strategies. Consequently, discussions highlighted the importance of defining, in advance, how emerging RWD will be incorporated into integrated evidence-generation strategies supporting both regulatory decision making and clinical practice [17].

Large-scale RWD networks were also recognized as a major advancement in PV capability [13]. However, panel discussions acknowledged that such networks are not without limitations. Challenges include incomplete data capture, delays in data availability, and potential information loss when heterogeneous datasets are standardized using common data models for large-scale analysis. Emerging developments in generative artificial intelligence (AI) were discussed as a potential means to overcome some of these constraints by enabling more flexible and rapid analyses across diverse data structures [18]. Further research and methodological development in this area were encouraged.

Another key topic addressed the differing perspectives and information needs of PV stakeholders. Regulatory authorities focus primarily on population-level benefit–risk evaluation, where rare but serious adverse drug reactions (ADRs) can alter the overall safety profile of a medicine. An example discussed was the signal linking the glucagon-like peptide-1 receptor agonist semaglutide with non-arteritic anterior ischaemic optic neuropathy (NAION), a rare but potentially vision-threatening condition [19]. Although the incidence is estimated to be approximately 1 in 10,000 patients, the severity of the outcome has prompted updates to product information advising patients to seek medical attention in the event of sudden visual changes and to discontinue treatment if NAION is confirmed [20]. Such signals raise important clinical considerations regarding treatment continuation, therapeutic alternatives, and the consequences of untreated underlying disease.

In contrast, patients typically assess medicines through an individual perspective based on their lived disease and treatment experiences, and their healthcare professionals (HCPs) take benefit–risk decisions on therapeutic options based on the patient's individual factors. Tolerance for ADRs is influenced by perceived therapeutic benefit, the severity and duration of adverse effects, and their impact on daily functioning and quality of life. Consequently, patients and HCPs require PV information that extends beyond the type and frequency of ADRs to include characteristics such as onset, duration, reversibility, and strategies for prevention or management [21]. Information about whether ADRs are transient or persistent, mild, or severe, and how they affect daily life can be critical in supporting shared decision making and treatment adherence.

Current product information often provides limited contextual detail beyond ADR frequency categories. However, in some cases—such as with semaglutide—additional evidence suggests that the most common adverse events are typically mild to moderate and transient, information that may reassure patients and support continued therapy when clinically appropriate. Where risk factors and preventive measures for ADRs are established, they are described in the warning section of the product information. These discussions highlighted the need for PV systems to generate and communicate safety information that addresses both regulatory benefit–risk assessments and the practical information needs of patients and HCPs.

Looking ahead, the future of PV was framed in terms of resilience, regional leadership, and strengthened global cooperation. As healthcare systems and regulatory environments become increasingly complex, sustainable PV networks that are digitally enabled and patient-centred will be essential. In this context, the development of strong regional systems capable of supporting local populations while contributing to the global safety ecosystem was emphasized.

An illustrative example is the development of PV capacity in Africa through the African Union Smart Safety Surveillance (AU-3S) programme, supported by the Gates Foundation [22]. This initiative has strengthened regulatory

collaboration, supported technical PV infrastructure, and aligned regional systems with international standards. Programme assets—including governance structures, trained personnel, and the first continental safety data repository—are now transitioning into the PV framework of the African Medicines Agency (AMA), embedding PV within an emerging continent-wide regulatory architecture.

Within this evolving landscape, ISoP was highlighted as playing a key role in advancing the field. As a neutral global professional network, ISoP facilitates collaboration across regions, disciplines, and sectors, supporting education, training, and capacity building. Initiatives such as regionally relevant curricula, training-of-trainers programmes, and professional community development were identified as mechanisms through which society can contribute to strengthening PV systems worldwide. Strengthened regional PV capacity will be particularly important as new health technologies are introduced, ensuring effective post-marketing surveillance and maintaining public trust in medicines and vaccines.

4 Main Conference: Key Outputs and Scientific Deliverables

The Scientific Committee ensured comprehensive representation across the full spectrum of PV, while also integrating key interdisciplinary topics that interface with and contribute to PV practice. The key outputs and deliverables of this approach are summarized under the following domains.

4.1 Core Domains of Pharmacovigilance

4.1.1 Regional Updates in Pharmacovigilance Practice: Initiatives and Systems

Recent presentations highlighted continued progress in PV systems across regions through concrete regulatory and operational developments.

In Africa, the establishment of the AMA in 2025 marked an important step toward regulatory harmonization [23]. National advances included the establishment of a pharmacovigilance centre within the Agence Marocaine du Médicament et des Produits de Santé (AMMPS), reflecting the transfer of PV responsibilities from the Centre Anti Poison et de Pharmacovigilance du Maroc to the national regulatory authority (NRA), thereby strengthening regulatory oversight and system integration [24]. In parallel, capacity at the Pharmacy and Poisons Board of Kenya was further strengthened through engagement in the AU-3S Programme [25]. In South Africa, the South African Health Products Regulatory Authority (SAHPRA) is advancing frameworks to support safety monitoring in the context of expanded medical cannabis use.

In the European Union (EU), important developments included the continued integration of RWD integration through the DARWIN EU network, updates to EU-GVP, adoption of the ICH E2D (R1) guideline, and post-authorization vaccine safety activities under the SAFETY-VAC initiative [26, 27].

In the Middle East, the EDA strengthened collaboration with scientific societies to support safety data collection, while the Lebanese National Pharmacovigilance Program (LNPVP) launched national GVP guidelines in 2025, and the SFDA reported updates to its GVP framework [28].

Across LATAM and Asia, national updates including revisions to GVP guidelines in India, Sri Lanka, and Bangladesh reflected continued regulatory alignment. In Lima, Peru, initiatives by the Sociedad Peruana de Farmacovigilancia supported national PV system strengthening. In addition, the initiative of the Pan American Network for Drug Regulatory Harmonization (PANDRH) has established platforms for technical collaboration that enable the identification of priority issues and opportunities to advance harmonization and regulatory convergence [29].

In North America, developments in Canada focused on regulatory modernization, including risk-based approaches, streamlined processes, enhanced international alignment, and the federal Red Tape Reduction initiative, alongside prioritization of medication safety in older populations [30].

Overall, these updates reflect converging global priorities, including regulatory agility, strengthened collaboration, and the integration of RWE and advanced analytical approaches in PV systems.

4.1.2 Stepping Back into the Future of Signal Detection

The session opened with an acknowledgement of Ronald Meyboom, recognizing his substantial contributions to the development of signal detection in PV [31]. Disproportionality analysis was highlighted as a key quantitative approach for signal detection, enabling hypothesis generation from large spontaneous reporting databases, but with important methodological limitations [32]. These include susceptibility to confounding, masking, effect modification, and reporting biases, as well as sensitivity to analytical choices, which may lead to misinterpretation if results are considered in isolation. Accordingly, its use, and indeed spontaneous reports more broadly, should remain focused on signal detection, supported by complementary robust methods and data sources [13]. In this context, an analysis of the WHO global database (VigiBase) identified potential safety signals linking proton pump inhibitors to sexual dysfunctions, including erectile dysfunction, decreased libido, hypogonadism, and genital discomfort. While biologically plausible mechanisms

were proposed, the findings remain hypothesis-generating given the limitations of spontaneous reporting data and require confirmation through well-designed observational studies.

4.1.3 Safe Use of Vaccines and Pandemic Planning

The session on Safe Use of Vaccines and Pandemic Planning highlighted diverse approaches to vaccine safety surveillance in both preparedness and response settings, drawing on experiences from high and low-middle-income countries (LMICs). A central theme was that effective vaccine safety monitoring can be achieved through contextually tailored objectives, outcomes, and methodologies.

The keynote presentation described vaccine safety surveillance during a public health emergency, using the 2023 mpox outbreak as a case example [33]. It outlined operational lessons from implementing a large cohort event monitoring (CEM) study alongside an immunization campaign, demonstrating a collaborative framework that integrates local leadership with support from regional and international partners. Ongoing efforts to establish background incidence rates for key safety outcomes were also highlighted to support interpretation of safety data in both emergency and routine settings.

Subsequent presentations addressed methodological advances in vaccine safety monitoring, including identification of core elements for active mpox vaccine surveillance, use of national healthcare databases to evaluate adverse events following COVID-19 vaccination through self-controlled risk interval designs, and post-marketing safety characterization of an influenza vaccine produced in a public-sector manufacturing setting.

4.1.4 Medical Device and Combination Products Safety

This session highlighted the growing importance of medical device vigilance and the safety of combination products in an increasingly complex healthcare environment. The oral presentations illustrated the diversity of challenges across settings and product types. Examples from Algeria, Uganda, and the United States showed that device-related safety issues may arise from technical failures, inadequate surveillance systems, and broader social determinants of health affecting the safe use of combination products. Common themes included under-reporting, limited user training, insufficient post-marketing surveillance, and the need to better understand how patient context influences safety outcomes.

The panel discussion placed these issues in a broader international perspective through contributions from representatives of the EDA, SFDA, UMC, and Boston University School of Medicine. The discussion emphasized that the boundaries between medicines, devices, and digital technologies are increasingly blurred, requiring vigilance systems that go beyond traditional PV approaches [34]. The EDA perspective highlighted ongoing efforts to strengthen post-marketing surveillance for medical devices and combination products and to align Egyptian requirements with international standards. The SFDA perspective focused on the potential of digital reporting systems and AI to support more proactive signal detection and risk management. UMC addressed the methodological challenges of integrating device-related data into existing global signal detection systems, including the need for new approaches capable of combining device and medicine safety information [35]. Finally, the academic perspective from Boston University stressed the need for further research, education, and training to address emerging risks associated with increasingly sophisticated devices and combination products.

Overall, the session concluded that effective medical device vigilance requires stronger international collaboration, multidisciplinary expertise, improved data sharing, and greater investment in regulatory and scientific capacity building [36].

4.1.5 Global Regulatory Convergence and Reliance for Strengthening Pharmacovigilance Systems

Presenters on Identification of Medicinal Products (IDMP) highlighted key deliverables to support standardized product identification and improved signal detection in global PV [37]. These included the development of a global IDMP framework and business rules, supported by a multistakeholder working group and informed by pilot testing using RWD. A central output was the implementation of the Pharmaceutical Product Identifier (PhPID), enabling product-level identification based on substance, strength, and dose form, alongside the introduction of a standardized global dose form attributes model with demonstrated high applicability. The initiative also identified persistent data quality gaps in individual case safety reports, underscoring the need for improved data completeness and granularity. Collectively, these efforts support a transition toward more precise, product-level signal detection and strengthened PV systems.

Complementing these developments, the Medicines for All (M4All) initiative provides a structured European pathway to facilitate access to new medicines in LMICs through scientific opinions issued by the EMA [38]. A key deliverable is a reliance-based framework—a regulatory approach where an NRA gives significant weight to assessments or decisions of trusted authorities to inform its own decisions—enabling NRA to leverage these opinions to accelerate local decision making [39]. The pathway is aligned with the WHO, including integration into the WHO Prequalification

programme and involvement of WHO experts in assessments, while maintaining EU-equivalent standards for quality, non-clinical, clinical, and safety evaluation. Lifecycle oversight, including post-authorization safety monitoring and studies, ensures continuous benefit–risk evaluation. Together, these elements contribute to regulatory convergence, more efficient use of resources, strengthened PV, and improved access to quality-assured medicines.

4.1.6 Safety Monitoring of Herbal, Traditional Medicines, and Cosmetics

The evolution of phytovigilance in the Middle East and Africa reflects increasing recognition of the safety risks associated with herbal and traditional medicines (HTMs) and the need for structured monitoring systems [40]. Regional assessments in Egypt, the UAE, and Saudi Arabia revealed incomplete integration of HTMs into national PV frameworks, underreporting of adverse events, and gaps in awareness among HCPs and the public. Major safety concerns—including ADRs, herb–drug interactions, and quality issues—alongside high reliance on HTMs, have driven initiatives to strengthen regulatory frameworks, reporting mechanisms, and signal detection. Updates from the National Programme for the Promotion of Traditional Medicine (PNPMT) in Côte d'Ivoire provided valuable insights for capacity-building and standardized PV practices. The Ministry of Health and Prevention in UAE issued GVP guidelines requiring marketing authorization holders to maintain a Pharmacovigilance System Master File (PSMF), including detailed procedures for reporting ADRs, encompassing those associated with HTMs, to support comprehensive safety monitoring.

4.1.7 The Importance of Communication in Pharmacovigilance

Communicating about risks and safe use is essential for increasing patient safety [41]. For communication and risk minimization materials to be effective, their tailoring to the information needs and media preferences of patients and HCPs is crucial, as is issuing them well designed, in the local languages, and for general comprehension.

As these needs and preferences are subject to changing common knowledge, public debates and media technology, the understanding of target populations must be kept up to date. Therefore, a formative approach using mixed methods and stakeholder participation was introduced at this session [42, 43]. This approach—well established in education, communication, and implementation sciences—is still new and innovative in PV [44].

With about 7000 languages spoken in the world, providing materials even in the most frequently spoken languages only is a challenge [45]. Hence, generative AI is promising to help. Inspired by the US Food and Drug Administration's concept of patient medication information [46], the session presented positive results from research into using generative AI for extracting essential messages from regulatory source documents and translating them into a large array of languages in a standardized format and with little need for content editing [47]. Moreover, materials must be well designed to avoid errors, confusion, and harm. With this aim, human factors, visualization, and user participation can ensure clearer, more actionable safety information [48, 49]. The session showcased this with examples, including a multi-lingual patient-targeted warfarin education animation and handbook, and improvements in computerized prescribing and dispensing systems [50]. Overall, the session took a real-life behavioural perspective on communication in PV, to be pursued further.

4.1.8 Shaping the Future Workforce: Curricula and Qualification in Pharmacovigilance

Updating the ISoP–WHO Pharmacovigilance Curriculum, originally published in Drug Safety in 2014, represents a major ongoing initiative of ISoP in collaboration with WHO [51]. The revision reflects substantial scientific and regulatory advances over the past decade, including developments in monoclonal antibodies, mRNA vaccines, antimicrobial resistance, and opioid misuse, alongside increased global engagement in PV. The updated curriculum, developed through a collaborative effort involving 82 experts across 62 working groups, retains its three-level structure but has been expanded to 26 chapters with integrated practical exercises and extensive references. Designed as a flexible framework rather than a prescriptive course, it supports adaptation to diverse educational needs while ensuring comprehensive coverage. By October 2025, content development had been completed, with ongoing harmonization and clarification. Publication is anticipated in Drug Safety in 2026, with supplementary materials provided electronically.

The session also provided the latest updates on the Global Pharmacovigilance Professional Certification (GPPC) [52].

4.1.9 Risk Management and the Measurement of Risk Minimization Measure Effectiveness

The session brought together regulatory, academic, and industry perspectives to examine current challenges and emerging practices in the design, implementation, and evaluation of risk minimization measures (RMMs) across diverse healthcare settings. Regulatory insights highlighted the importance of aligning effectiveness evaluation with real-world clinical practice and available data sources.

A key theme was the increasing role of digitalization in strengthening RMM implementation. Contributions explored the feasibility of deploying digital RMM control tools across multiple countries, emphasizing challenges related to stakeholder engagement and regulatory heterogeneity, while demonstrating their potential to improve consistency, monitoring, and timely assessment of RMM performance. Practical implementation at the national level was illustrated through the phased integration of additional RMMs into hospital information systems, showing how embedding measures within clinical workflows can enhance adherence and enable continuous effectiveness evaluation at scale. Finally, a longitudinal perspective on US Risk Evaluation and Mitigation Strategies (REMS) with Elements to Assure Safe Use highlighted the need for iterative adaptation, ongoing measurement, and regulatory flexibility to ensure that risk minimization remains proportionate and effective throughout the product lifecycle.

4.1.10 MedSafetyWeek: A Global Pharmacovigilance Campaign

At the 10th anniversary of MedSafetyWeek, it was highlighted that fewer than 10% of ADRs are reported globally [53]. Coordinated by the UMC, the campaign aims to enhance awareness and encourage reporting of suspected side effects among patients and HCPs through coordinated global activities and social media outreach.

Global experiences demonstrated effective implementation models. In Iraq, strong engagement of regional PV centres supported the campaign through multilingual materials (Arabic, Kurdish, Turkmen, and English), expanded outreach beyond hospital settings, shared content platforms, and structured reporting and evaluation mechanisms.

In Egypt, the ISoP Egypt Chapter, in collaboration with the UMC, implemented a hybrid model combining online and field activities [54]. This approach facilitated broader stakeholder engagement, including healthcare institutions, academia, community pharmacies, and individual HCPs, contributing to strengthened PV awareness and ADR reporting culture.

A dedicated workshop focused on developing effective communication strategies to promote PV and adverse event reporting. Participants addressed three case-based challenges, each targeting key elements of communication campaign design.

4.1.11 Active Surveillance in a Rapidly Evolving Therapeutic Landscape

The session highlighted active surveillance as an increasingly important operational component of modern PV, particularly in settings where passive reporting alone is insufficient for timely risk identification [13]. Presentations focused on practical surveillance approaches, including CEM, registries, electronic health records, digital tools, and large-scale data networks such as Sentinel and DARWIN-EU [55]. These methods were presented as useful for earlier signal detection, improved risk quantification, and the generation of RWE, especially for innovative therapies and vaccines. CEM was discussed as a practical and adaptable method, with examples from vaccine safety activities in Europe and antimalarial programmes in Africa [56]. These experiences illustrated how active surveillance can be implemented across different settings and resources levels when objectives, data sources, and follow-up methods are clearly defined.

Operational challenges remain important, including data quality, interoperability, standardization, infrastructure, and workforce capacity.

Overall, the session underscores that active surveillance is not a substitute for spontaneous reporting, but a necessary component that strengthens PV systems and supports timelier and more informed regulatory and public health action.

4.1.12 Medicines in Women: Addressing Sex-Specific Safety and Efficacy

Updated EU guidance in GVP Module XVI Addendum I introduced strengthened risk minimization measures for embryo–foetal risks, including enhanced counselling, clearer pregnancy prevention programme criteria, and a patient-centred approach balancing precaution with clinical need [57]. In parallel, the newly developed EU-GVP P.III guidance established, for the first time, comprehensive and harmonized PV guidance for pregnancy and breastfeeding, covering structured follow-up, improved surveillance, and strengthened data analysis and reporting requirements [58]. The guideline came into effect on 9 February 2026.

RWE highlighted a high prevalence of preventable medication-related problems among women in correctional facilities, particularly related to inappropriate drug selection and polypharmacy.

Finally, emerging data on paternal exposure showed no increased risk of neurodevelopmental disorders with paternal valproate use, alongside methodological advances in surveillance using tree-based scan statistics. These data related to a safety concern for which more data are awaited, while some jurisdictions currently advise caution in this respect.

Overall, the session underscored regulatory progress, methodological innovation, and remaining evidence gaps in reproductive PV.

4.2 Interdisciplinary Contributions to Pharmacovigilance

4.2.1 Pharmacogenomics: Transforming Drug Safety

PV is increasingly integrating pharmacogenomics to elucidate the mechanistic basis of ADRs, thereby improving the identification of at-risk populations, and supporting safer drug development. In this context, a genome-wide association study of venous thromboembolism (VTE) following SARS-CoV-2 vaccination, based on spontaneous reports submitted to the Swedish Medical Products Agency within the Swedegene project, identified no genome-wide significant signals [59].

The session also highlighted methodological advances spanning the continuum from signal detection to product labelling, alongside the application of biosimulation and large-scale real-world polypharmacy data to enable more proactive, data-driven PV.

4.2.2 Substandard and Falsified Medicines: Threats, Detection, and WHO's Role

Substandard and falsified (SF) medical products represent a significant global public health challenge, contributing to treatment failure, toxicity, antimicrobial resistance, and mortality. Substandard products arise from manufacturing or quality deficiencies, whereas falsified products deliberately misrepresent identity, composition, or source. Their persistence is driven by limited access to quality medicines, insufficient detection capacity, and regulatory weaknesses. The WHO addresses this threat through collaboration with NRA and the Global Surveillance and Monitoring System (GSMS), which validates reports, assesses risks, and supports public health action [60]. Timely reporting by healthcare professionals and patients remains critical for early detection and prevention of harm.

The session presentations highlighted the increasing role of PV in identifying SF products using VigiBase. Harmonized definitions and expanded MedDRA terminology, including product quality–related terms, have improved the capture of cases of suspected ADRs indicating possible quality defects and SF products. Analyses of VigiBase ADR reports demonstrated growing detection potential through evaluation of reporting trends, geographic distribution, and affected therapeutic classes, notably antidiabetics, analgesics, and ophthalmic products. However, challenges such as underreporting, limited data completeness, and the absence of standardized queries remain. Strengthening reporting practices, data quality, and integration with broader surveillance systems was emphasized as essential to enhance global monitoring and reduce patient harm associated with SF medical products.

4.2.3 Market Access: From Safety to Safe Availability

The presentations positioned PV as a core element of regulatory oversight for local manufacturing, essential to ensure product quality, safety, and efficacy across the lifecycle, with a stronger current focus on post-marketing activities.

They identified key capacity gaps, including limited integration of PV in pre-authorization stages, weak cross-functional collaboration, and underdeveloped safety data systems and data-sharing mechanisms. Priority actions included earlier integration of PV into product development, strengthening safety data management, and enhancing collaboration between manufacturers and regulators. Innovative initiatives, such as sandbox approaches, were highlighted to support regulatory flexibility and system strengthening.

Alignment with broader regulatory development was emphasized, alongside examples such as Medicines Supply Resilience (MedSuRe) Africa [61], which supports regional manufacturing and improved access to quality-assured medicines.

4.2.4 Ecopharmacovigilance and Antimicrobial Resistance: Environmental Dimensions of Medicines Safety

Pharmaceuticals and their metabolites can exert off-target effects in the environment, termed Environmentally Persistent Pharmaceutical Products (EPPPs), representing a form of adverse effects on wildlife and ecosystems. In the context of antimicrobials, distinguishing true ineffectiveness from resistance is critical; structured algorithms facilitate standardized data collection and reliable interpretation of antimicrobial resistance trends. Enhancing the quality of adverse reaction reports related to environmental exposure is essential for robust signal detection and validation. Overall, appropriate characterization, risk minimization, and integration of Ecopharmacovigilance into existing PV systems are pivotal to addressing these environmental safety challenges efficiently, which is why ISoP has a dedicated SIG on this topic.

4.2.5 Enhancing Medication Safety: Prevention and Management of Medication Errors

Medication errors are a major patient safety concern and an increasing focus of modern PV [62]. The session highlighted the evolving EU framework for managing these errors, where regulators use lifecycle PV supported by Good Practice Guides (GPG I & II) to standardize recording, coding, reporting, and assessment [63]. Implementation has improved capture and evaluation of cases in EudraVigilance, informing regulatory decisions and risk minimization, with outcomes including updated SmPCs and package leaflets, revised Risk Management Plans (RMPs), and EU-wide

safety communications, notably on methotrexate dosing errors. Additionally, the ISoP Hackathon 2025, a global innovation challenge to make medication use safer worldwide, was announced, reflecting a proactive, evidence-driven approach to preventing medication errors.

4.2.6 Artificial Intelligence in Pharmacovigilance: From Data to Safety Decisions

The session on AI and digitalization in PV highlighted the shift from manual, document-centric operations toward integrated, data-driven systems. AI adoption was framed as a gradual, stepwise evolution rather than a sudden disruption, relying on strong digital infrastructure, harmonized processes, and well-defined governance to ensure effective and responsible implementation. Presentations illustrated practical applications, including automation of safety documentation, executable workflows, improved audit readiness, enhanced data quality, and AI-assisted signal detection and causality assessment, where tools such as large language models support human assessors while maintaining expert oversight. Human–AI collaboration was underscored throughout, positioning AI as a decision-support enabler rather than a replacement for PV professionals, with transparency, explainability, and regulatory compliance as essential prerequisites [64, 65]. Context-specific implementation strategies were highlighted as critical to ensuring that digital transformation remains ethical, scalable, and aligned with patient safety objectives.

4.2.7 Bridging the Gap with Digital Healthcare

The session brought digital media-driven self-medication among youth as an emerging novel signal for drug safety monitoring, with unreported adverse drug reactions and unverified content posing key challenges [66]. Proactive tracking of AI-influenced health content and social media engagement is critical for timely intervention. Digitalization also offers opportunities to spread risk minimization measures, including targeted safety messaging, educational campaigns, and real-time monitoring of emerging trends. Engaging youth communities through these channels can promote safer medication practices and strengthen public health.

4.2.8 Patient Engagement: Elevating Patient Voices in Pharmacovigilance

The ISoP Patient Engagement (PatEG) SIG shared new strategies to integrate patient perspectives into PV, including knowledge exchange, capacity building, and policy alignment [67]. Patient advocates, regulators, academics, and regional PV experts explored how engagement strengthens medicine safety—improving reporting, understanding, adherence, risk communication, and trust. Presentations highlighted that preventable harm often arises from communication and access barriers rather than clinical risk alone, especially among older, low-income, and underserved populations. The session concluded that "meaningful" engagement should inform PV decisions, reconcile patient priorities with system imperatives, and ensure tailored, accessible approaches to reduce safety gaps.

5 ISoP–WHO Joint Session: Operationalizing the WHO Global Smart Pharmacovigilance Strategy

The collaboration between ISoP and WHO in joint sessions dates back to the 2nd Annual Meeting in 2002 in Amsterdam, The Netherlands, held alongside the 25th WHO National Pharmacovigilance Centres Meeting, marking the first coordinated joint sessions and reflecting a shared commitment to advancing PV and ensuring medication and patient safety worldwide [68].

Strengthening PV systems is essential to protect populations from preventable harm associated with medicines and vaccines and to sustain public confidence in health systems. While access to medicinal products has increased in LMICs, PV capacity has not kept pace [69]. Over 70% of WHO Member States are classified as LMICs, yet they contribute only a small proportion of global Individual Case Safety Reports (ICSRs) to VigiBase, reflecting ongoing gaps in reporting, data analysis, and signal detection which may impair regulatory decision-making in LMICs [70]. WHO benchmarking exercises indicate that many NRAs operate below Maturity Level 3, with common deficiencies including fragmented safety data sharing, limited analytical capacity, weak regulatory frameworks, insufficient oversight of RMPs, and inadequate investment in safety communication.

To address these challenges, WHO launched, on 7 November 2025, the Global Smart Pharmacovigilance Strategy, which promotes a stepwise, risk-based approach to strengthen PV systems worldwide [71]. The Strategy is built around four pillars: consolidating previous global efforts, applying risk-based prioritization, promoting work-sharing and reliance, and integrating PV into broader regulatory system strengthening through the Global Benchmarking Tool and Institutional Development Plans. By embedding PV within established regulatory frameworks, the Strategy aims to close safety surveillance gaps, enhance emergency preparedness, and ensure equitable protection for all populations. Initial calls for such a strategy were made during the 2018 International Conference of Drug Regulatory Authorities (ICDRA) in Dublin, with a mature version discussed at the ICDRA partners' meeting in New Delhi in 2024.

The WHO–ISoP joint session in Cairo focused on the implementation of the Strategy. As a member of the WHO Coalition of Interested Parties (CIP), ISoP contributed to discussions on operationalizing the Strategy and

- provided a forum for ISoP and WHO Programme for International Drug Monitoring (PIDM) members to discuss implementation approaches;
- explored recent developments, best practices, and methodologies in country-level PV activities;
- collected recommendations on future directions and priorities;
- facilitated collaborations and synergies between PIDM members and ISoP for more effective PV;
- agreed on key actions to advance the Global Smart Pharmacovigilance Strategy worldwide;
- raised recommendations for collaborative opportunities between WHO, PIDM members, and ISoP.

The session also highlighted persistent challenges in reporting by healthcare professionals and emphasized potential solutions, including integrating PV into continuing medical education, leveraging initiatives such as MedSafetyWeek, and promoting the WHO–ISoP PV curriculum as a structured approach to competency building.

6 Conclusion

The 24th Annual Meeting of ISoP, held in Cairo during the Society's 25th anniversary year, represented a significant milestone for PV and for ISoP as a global professional community. Under the theme "Pharmacovigilance: Back to the Future," the meeting convened an international audience and delivered a comprehensive scientific programme with both immediate and longer-term relevance.

Across sessions, the meeting highlighted the continued expansion of PV in scope, methodologies, and responsibilities. Discussions emphasized the need for systems capable of addressing increasingly complex medicinal products, integrating diverse data sources, and responding to evolving regulatory and public health contexts.

The importance of strengthening PV capacity globally was a consistent theme, with particular focus on collaboration, reliance models, education, and sustainable system development. In this context, ongoing initiatives involving ISoP, WHO, UMC, and international and regional regulatory stakeholders were recognized as key enablers of progress.

As ISoP enters its next 25 years, the Cairo meeting reaffirmed its role in advancing PV through both scientific exchange and practical initiatives supporting workforce development, system strengthening, and patient safety. Continued progress in PV will depend on maintaining scientific rigour while ensuring equitable implementation across settings, with patient safety remaining central.

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