



ISoP MENA Chapter: Strategic Development and Future Directions Following a Decade of Strengthening Pharmacovigilance in the Middle East and North Africa

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Received: 16 August 2026 / Accepted: 20 August 2026 / Published online: 2 September 2026
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1 Introduction

Pharmacovigilance (PV) in the Middle East and North Africa (MENA) region has advanced substantially over the past decade, driven by diverse surveillance methodologies, expanded pharmacological knowledge and innovative approaches, including artificial intelligence (AI) and real-world data and real-world evidence, to enhance medicine safety and prevent patient harm [1].

Many national PV centres across the MENA region joined the World Health Organization (WHO) Programme for International Drug Monitoring during the 1990s and early 2000s and subsequently established national PV systems [2]. However, considerable heterogeneity remains across the region, with PV systems that range from well-established programmes to initiatives that are still in the early stages of development [3].

Ensuring the safe and effective monitoring of medicines in routine clinical practice remains challenging and requires collaboration among a broad range of stakeholders, including medicines regulatory authorities, pharmaceutical

companies, academic institutions, healthcare professionals, policymakers and patient organisations [4]. Recognising the need to strengthen regional collaboration, build capacity and promote stakeholder engagement in PV, the International Society of Pharmacovigilance (ISoP), with the support of its Executive Committee (2012–16), launched the Middle East Chapter during its Annual Meeting in Prague, Czech Republic, in October 2015 [5].

Building on this initiative, and despite the challenges posed by the coronavirus disease 2019 (COVID-19) pandemic, the ISoP Egypt Chapter was officially launched during the virtual ISoP General Assembly on 14 October, 2020, with the support and guidance of the ISoP Executive Committee (2019–22) [6]. The Chapter was established to advance PV practice, education, research and stakeholder engagement in Egypt and to support the growing PV community within the country.

Over the subsequent years, both the ISoP Middle East Chapter and the ISoP Egypt Chapter contributed significantly to advancing PV through scientific meetings, educational initiatives, networking opportunities and collaborative activities involving regulators, academia, healthcare professionals, industry representatives and patients. Their achievements demonstrated the value of regional cooperation and

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highlighted opportunities to further strengthen collaboration across the broader Arab region.

The 24th ISoP Annual Meeting, held in Cairo, Egypt, from 24 to 27 October 2025, provided an important opportunity for PV professionals from around the world to exchange experiences, strengthen collaborations and celebrate the 25th anniversary of ISoP [7]. During the meeting, discussions among leaders and members of both chapters underscored the potential benefits of a unified regional structure capable of supporting a wider network of PV stakeholders across the Arab world.

Consequently, with the support of the ISoP Executive Committee (2025–28), the ISoP MENA Chapter was established through the merger of the ISoP Middle East Chapter and the ISoP Egypt Chapter [8, 9]. The new Chapter combines the experience, expertise, networks and achievements of its predecessor chapters while expanding participation to PV professionals and stakeholders from Arab countries throughout the MENA region.

2 Strengthening Pharmacovigilance (PV) in the Region: A Decade of Progress (2015–25)

2.1 Trainings and Workshops

Following its establishment in 2015, the ISoP Middle East Chapter undertook a range of activities to strengthen PV capacity, foster regional collaboration and support PV system development across Arab countries. Adopting a multidisciplinary approach, the Chapter engaged stakeholders from academia, regulatory authorities, the pharmaceutical industry, healthcare institutions and patient organisations.

The Chapter's first meeting, held in Dubai, United Arab Emirates, in 2016, initiated strategic planning for regional educational and scientific activities. This led to a series of training programmes and workshops addressing key PV topics, including individual case safety reports, signal detection, risk management, safety communication, medication errors, post-authorisation safety studies, pharmacoepidemiology, and clinical trial safety. The first Middle East PV Training Workshop was held in Dubai in 2017, followed by additional programmes in Iraq and the United Arab Emirates in 2018. In 2019, collaboration with the Medical Dictionary for Regulatory Activities Maintenance and Support Services Organization expanded training to include Medical Dictionary for Regulatory Activities coding, signal management, biologics and biosimilars, and safety data analysis.

During the COVID-19 pandemic, the Chapter adapted its activities to virtual formats, delivering programmes on PV business continuity, medication safety and COVID-19

vaccine safety surveillance. Educational activities subsequently expanded through specialised pre-conference training associated with ISoP Annual Meetings in the region. These included courses on pharmacoepidemiology, signal management, periodic benefit–risk evaluation reports, vaccine PV, digital-era PV and benefit–risk assessment. Collectively, these initiatives contributed to strengthening PV expertise, promoting regional networking and knowledge exchange, and supporting the development of a growing community of PV professionals across the MENA region.

2.2 Sharing Global Experience

A significant milestone in the development of the ISoP Middle East and Egypt Chapters was their hosting of two ISoP Annual Meetings in the region, reflecting the growing maturity of regional PV systems and their increasing contribution to the global PV community. In 2021, the ISoP Middle East Chapter hosted the 20th Annual Meeting of ISoP in Muscat, Oman, under the theme “Integrated Pharmacovigilance for Safer Patients”. Despite the challenges posed by the COVID-19 pandemic, the meeting brought together international experts and regional stakeholders to address key issues in PV, including vaccine safety, benefit–risk assessment, regulatory frameworks, patient engagement, signal detection, PV reliance and ecopharmacovigilance. The meeting also provided an important platform for regional perspectives and international collaboration.

In 2025, the ISoP Egypt Chapter hosted the 24th Annual Meeting of ISoP in Cairo, Egypt, under the theme “Pharmacovigilance: Back to the Future”, coinciding with ISoP's 25th anniversary. The meeting brought together a diverse international PV community and addressed emerging and established areas, including signal detection, vaccine safety, regulatory convergence, risk management, AI, digital health, active surveillance, patient engagement and workforce development. Together, these meetings enhanced the visibility of the MENA region within the global PV community and demonstrated the capacity of regional ISoP Chapters to foster scientific exchange, international collaboration and advances in medicine safety.

2.3 International Society of Pharmacovigilance (ISoP)–World Health Organization (WHO) Joint Collaboration

Collaboration with international organisations has been a key component of the activities undertaken by both the ISoP Middle East and ISoP Egypt Chapters. Through partnerships with the WHO and its regional offices, the chapters have contributed to knowledge sharing, capacity building and the advancement of global PV priorities within the MENA region.

During the COVID-19 pandemic, the rapid development and deployment of vaccines created an urgent need for reliable information on vaccine safety and effective PV systems. In response, the ISoP Middle East Chapter, in collaboration with the WHO and the WHO Regional Office for the Eastern Mediterranean, organised the webinar “COVID-19 Vaccines from All Angles: Focusing on Safety Information” in 2021. The webinar brought together international experts in immunisation and vaccine safety to discuss safety considerations associated with the introduction of COVID-19 vaccines, including different vaccine platforms, their safety profiles and approaches to post-marketing safety surveillance. The programme also highlighted the roles and responsibilities of key stakeholders in vaccine safety monitoring and explored methods for identifying, assessing and responding to adverse events following immunisation.

The ISoP Egypt Chapter hosted the ISoP–WHO Joint Session: Operationalizing the WHO Global Smart PV Strategy during the 24th ISoP Annual Meeting in Cairo in 2025. The session focused on the implementation of the WHO Global Smart PV Strategy and explored how risk-based and resource-efficient PV approaches can be operationalised across diverse regulatory settings. Discussions emphasised lessons learned from national and international experiences, the importance of regulatory reliance and work sharing, and opportunities to strengthen PV systems through integration with broader regulatory system strengthening initiatives. The WHO subsequently finalised this strategy in 2025, consolidating global guidance on risk-based prioritisation and regulatory reliance for PV systems worldwide.

Particular attention was given to the four pillars of the WHO Global Smart PV Strategy: consolidating previous global PV efforts, applying risk-based prioritisation, promoting work-sharing and regulatory reliance, and integrating PV within broader regulatory strengthening frameworks, including the WHO Global Benchmarking Tool and Institutional Development Plans. The session highlighted the potential of these approaches to reduce safety surveillance gaps, improve preparedness for public health emergencies, and strengthen equitable access to effective PV systems worldwide. These collaborations demonstrate the commitment of the ISoP Chapters in the region to aligning local and regional PV activities with global priorities and to fostering partnerships that support the continuous strengthening of medicine safety systems.

2.4 Promoting Research and Scientific Exchange

The ISoP Middle East and Egypt Chapters have contributed to PV research and scientific exchange across the MENA region through sustained participation in ISoP Annual Meetings. Since 2015, researchers and practitioners from across the region have presented research findings, case

studies, regulatory experiences and capacity-building initiatives, reflecting the progressive development of regional PV systems. Chapter leaders have also supervised research theses and dissertations within the European Programme in Pharmacovigilance and Pharmacoepidemiology (Eu2P), supporting research capacity and the training of future PV professionals.

Regional contributions evolved considerably over successive annual meetings. Early participation focused primarily on foundational PV activities, including spontaneous reporting, adverse drug reactions, medication errors, PV centre functions, traditional medicine safety and the development of national PV systems. Contributions subsequently expanded to pharmacoepidemiology, signal detection, risk management, regulatory activities, medication safety and vaccine surveillance.

During the COVID-19 pandemic, research priorities increasingly addressed COVID-19 vaccine safety, active PV, immunisation errors, vaccine hesitancy, risk communication and digital approaches to PV. More recent meetings have demonstrated further diversification and methodological advancement, with increasing contributions on AI, real-world data, machine learning, risk minimisation, PV inspections, teratovigilance, environmental PV, maternal and child safety, and patient-centred approaches. The 24th Annual Meeting in Cairo in 2025 particularly demonstrated the breadth and maturity of regional PV research, with contributions spanning AI, vaccine safety, real-world data, risk minimisation, oncology PV, teratovigilance, materiovigilance, medication safety, regulatory PV, and substandard and falsified medicines.

Collectively, these contributions illustrate the evolution of PV research in the MENA region from foundational system development and spontaneous reporting toward advanced, data-driven and patient-centred approaches. Sustained scientific engagement through ISoP Annual Meetings has strengthened regional collaboration, research capacity, knowledge exchange and the contribution of MENA researchers to the global PV community.

2.5 Networking within ISoP and with Other International Organisations

The ISoP Egypt and Middle East Chapters established collaborations with several ISoP Special Interest Groups (SIGs), regional chapters, and international organisations to support PV and medication safety activities in the region. Since its establishment in 2020, the ISoP Egypt Chapter has coordinated MedSafetyWeek activities in collaboration with the Uppsala Monitoring Centre, the WHO Collaborating Centre for International Drug Monitoring, supporting regional medicine safety awareness campaigns and promoting adverse event reporting [10].

In 2021, the ISoP Egypt Chapter, in collaboration with the ISoP Medication Errors SIG and the International Committee of the Red Cross, implemented a medication safety project in the clinical settings of the Palestine Red Crescent Society aimed at improving medication safety for Palestinian refugees [11]. In 2023, the ISoP Middle East Chapter, together with the ISoP Patient Engagement SIG, delivered the on-site training course *Art of PV: Regulations, Digitalization, and Leadership* in Muscat, Oman. In the same year, the ISoP Egypt Chapter collaborated with the ISoP Middle East, Africa and Latin America (LATAM) Chapters in a scientific session highlighting the role of ISoP in supporting PV activities in low- and middle-income countries [12].

In 2024, the ISoP Egypt Chapter collaborated with the ISoP Herbal and Traditional Medicines SIG on the development of a framework to support the safety monitoring of herbal products [13]. In 2025, the ISoP Egypt Chapter collaborated with the ISoP PV in the Community SIG and the Egyptian Drug Authority to organise two scientific sessions focused on community-based PV [14]. These collaborations facilitated knowledge exchange and supported the implementation of PV and medication safety initiatives across the MENA region.

2.6 Contribution to Global Strategic Leadership in PV

Members of the ISoP Middle East and Egypt Chapters have contributed to global PV leadership and governance through roles within ISoP, WHO and other international initiatives, strengthening the region's visibility and facilitating knowledge exchange. Chapter members have served on the ISoP Advisory Board and Scientific Board, and chaired the ISoP Student Group and Patient Engagement SIG [15]. They have also contributed to global PV governance through WHO committees (e.g. WHO ACSoMP, WHO GACVS and WHO TAG-RSS), and represented ISoP on the Executive Committee of Council for International Organizations of Medical Sciences.

These roles have supported strategic decision making, scientific programme development, patient engagement and professional capacity building, while providing opportunities to strengthen collaboration and mentor emerging PV professionals. Collectively, the activities of the ISoP Middle East and Egypt Chapters established important platforms for PV education, professional development and stakeholder engagement across the Arab region, laying the foundation for the establishment of the ISoP MENA Chapter in 2025.

3 Future Directions for the ISoP MENA Chapter: Governance and Strategic Priorities

3.1 Governance and Coordination

The establishment of the ISoP MENA Chapter represents an important milestone in PV collaboration across the region. The new chapter builds upon the experience, professional networks and achievements of the former ISoP Middle East and ISoP Egypt Chapters, creating a broader platform for regional engagement and cooperation. As part of its establishment, elections will be conducted to form the chapter leadership through a transparent and democratic process.

The chapter is intended to strengthen collaboration among Arab countries, many of which utilise the Arab Guidelines on Good Pharmacovigilance Practices as a common framework for national PV activities [16]. Developed under the auspices of the League of Arab States, these guidelines provide a shared regional reference for the development and implementation of PV systems and activities [17]. Countries adopting or aligning with this framework include 22 Arab countries: Algeria, Bahrain, Comoros, Djibouti, Egypt, Iraq, Jordan, Kuwait, Lebanon, Libya, Mauritania, Morocco, Oman, Palestine, Qatar, Saudi Arabia, Somalia, Sudan, Syria, Tunisia, the United Arab Emirates and Yemen.

3.2 Strategic Priorities

The MENA region possesses several characteristics that can facilitate greater collaboration in medicine safety, including a shared Arabic language, similar cultural contexts and progressively harmonised regulatory approaches. Nevertheless, substantial heterogeneity exists in the maturity and capacity of PV systems across the region. While some countries have established regulatory frameworks, dedicated resources and advanced PV infrastructures, others remain at earlier stages of development and continue to strengthen their systems, workforce and technical capabilities. These observations are consistent with recent reviews of PV systems in low- and middle-income countries, which have documented persistent gaps in trained personnel, sustainable financing, data infrastructure and integration within broader health systems, even in countries that have formally adopted PV guidelines [18, 19].

These differences reflect diverse national contexts and priorities. Although several countries have developed robust institutional and regulatory capacities to support PV activities, others continue to face challenges related to limited resources, shortages of trained personnel, humanitarian crises, political instability or competing public health demands. Such disparities underscore the importance of regional collaboration, capacity building and the exchange of expertise to support sustainable development across the region.

To address these opportunities and challenges, the ISoP MENA Chapter has identified the following strategic priorities:

- Foster regional collaboration among PV stakeholders through networking, knowledge exchange and the sharing of best practices across MENA countries.
- Support the development, implementation, and progressive harmonisation of PV policies, guidelines and practices throughout the region.
- Strengthen national PV systems through sustainable capacity building tailored to country-specific needs.
- Advance risk management and medicine safety monitoring among regulatory authorities and marketing authorisation holders.
- Promote the integration of PV into public health programmes and healthcare systems.
- Increase awareness of PV and patient safety among healthcare professionals, patients and the public, while encouraging the reporting of ADRs and other medicine safety concerns.
- Advance PV education, professional development and workforce capacity through workshops, seminars, webinars and other capacity-building initiatives.
- Support the advancement of PV practices within the pharmaceutical industry.
- Strengthen partnerships with regional and international organisations to maximise collaboration and collective impact.
- Promote PV research, scientific exchange, and evidence generation to support medicine safety and regulatory decision making.
- Respond proactively to emerging PV challenges and evolving regional priorities.

Looking ahead, the ISoP MENA Chapter aims to serve as a regional platform that connects countries at different stages of PV development, fostering mutual learning, sustainable partnerships and coordinated action. Through continued collaboration, knowledge exchange and innovation, the Chapter seeks to strengthen PV systems and improve patient safety across the MENA region.

4 Conclusions

The establishment of the ISoP MENA Chapter represents the next stage in the development of regional PV collaboration. It brings together the experience and networks built through the former ISoP Middle East and Egypt Chapters within a broader structure serving professionals and stakeholders across the region.

The experience of both predecessor chapters demonstrates the value of sustained education, scientific exchange, multidisciplinary engagement and collaboration with international partners. It also shows that future progress will require broader participation, stronger multi-county research, more systematic evaluation of outcomes, and closer attention to the needs of under-represented and resource-limited settings.

The newly elected Executive Committee will determine the Chapter's strategic direction in accordance with ISoP governance and in consultation with its members. The Chapter's effectiveness should ultimately be judged not only by the number of activities delivered but by the relevance of those activities, the inclusiveness of participation, the quality of scientific collaboration and their contribution to improved PV practice. By providing a platform for regional dialogue, professional development and collaborative action, the ISoP MENA Chapter has the potential to strengthen medicine-safety practice while ensuring that regional experience contributes more consistently to the global PV community.

Acknowledgements The authors gratefully acknowledge Marco Tucori, Associate Professor of Pharmacology at the University of Verona, for sharing the governance model of the ISoP Europe Chapter and for his valuable contributions to the development of the ISoP MENA Chapter governance documents. The authors also thank Francesco Salvo, Vice-President of ISoP, for his contributions to stakeholder consultations and the development of the initiative. They further acknowledge Loubna Alj and Ghita Benabdallah for their engagement in discussions regarding the participation of North African (Arab Maghreb) countries in the new regional chapter. The authors are also grateful to Comfort Ogar, President of the ISoP Africa Chapter, and Jayesh Pandit, Treasurer of the ISoP Africa Chapter, for their valuable input during these discussions.

Funding No funding was received for the preparation of this article.

Declarations

Disclaimer The views expressed in this article are the authors' personal views and may not be understood or quoted as being made on behalf of or reflecting the position of the employing organisations unless explicitly stated.

Conflicts of Interest Hadir Rostom, Mohamed A. Elhawary, Mayada Alkhakany, Manal M. Younus, Thamir Alshammari, Felipe Villalobos, and Omar Aimer have no conflicts of interest that are directly relevant

to the content of this editorial. Manal M. Younus is an Editorial Board member of *Drug Safety* and was not involved in the selection of peer reviewers for the manuscript nor in any of the subsequent editorial decisions.

Ethical Approval Not applicable because this article does not contain any studies with human or animal subjects.

Consent to Participate Not applicable.

Consent for Publication Not applicable.

Availability of Data and Material Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

Code Availability Not applicable.

Author Contributions Conception: MAE and HR. Drafting, writing, reviewing and editing of the manuscript: HR, MAE and OA. Critical revision: FV and OA. All authors contributed to drafting the manuscript and read and approved the final version.

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