Eastern Mediterranean Region Countries Workshop on medication errors	
13 October 2019	
09h00-09h15	**Pr Rachida Soulaymani** welcomed everyone on behalf of the Moroccan Poison and Pharmacovigilance Center. She introduced representatives from the Eastern Mediterranean Region countries. She looks forward to meeting annually.
09h15-09h45	**Introduction of the International Medication Safety Network** **Michael Cohen**, Chairperson, IMSN (read the slides) Michael Cohen welcomed everyone to the meeting. He gave a brief background of the history of International Medication Safety Network (IMSN) from the first meeting in Salamanca, Spain to the 14th meeting in Rabat, Morocco. Within that background, he highlighted the FDA-IMSN Summit with International Drug Regulators, which took place June 19-20th, 2018 in White Oak, Maryland, USA and the draft white paper focused on harmonization. He spoke about the leadership structure and website as a means for communication. Overall, Cohen asks that all pharmacovigilance centers and IMSN members collaborate to promote the Global Targeted Medication Safety Best Practices (G-TMSBPs). He also called for increasing error reporting efforts and providing recommendations in lieu of errors with medication labels. He hopes IMSN will continue to grow through potential partnerships with the International Society of Pharmacovigilance (ISOP), Uppsala Monitoring Center (UMC) and the World Health Organization (WHO) to name a few.
09h45-10h00	**IMSN Strategic Plan 2019-2021** **David U**, IMSN General Secretary (read the slides) David U spoke about the need for a strategic plan and a workplan. He hopes to build momentum and engage stakeholders. The goals are to: • Expand the network's drug safety mission • Improve reporting, learning, and transparency • Enhance uptake of safe medication practices globally • Make IMSN a legal entity • Engage industry for the purpose of enhancing efforts to make products safer Discussion: Pakistan expressed interest in joining IMSN. Several attendees commented that IMSN is relatively unknown and it would be helpful to market and promote IMSN efforts. Alem Zekarias from UMC suggests incorporating IMSN information into the UMC bulletin.
10h00-10h30	**Coffee break**

10h30-11h30	**How MEs occur with drug container labeling and packaging** Moderators: Pr Rachida Soulaymani / David Cousins
10h30-11h10	**Working Together to Address Global Drug Safety Issues with Packaging and Labeling** **Michael Cohen**, President, Institute for Safe Medication Practices & Chairperson, IMSN **Lubna Merchant**, Deputy Director, Office of Medication Error Prevention and Risk Management, United States Food and Drug Administration (read the slides) Michael Cohen discussed important labeling and packaging problems including dangerous abbreviations, look-alike labeling, inconsistent and unclear expression of strength, cluttered labeling, poor visibility of information, highly stylized label graphics, overemphasis on company name and logos, lack of contrast on glass ampules, and inadequate prominence of reminders and warnings. The discussion prone purchasing for safety instead of looking for the cheapest product. Lubna Merchant discussed global harmonization of labeling and packaging, reviewed 10 key labeling recommendations discussed at the FDA/IMSN summit, and discussed the status of the IMSN white paper.
11h10-11h30	**Prescrire's approach to labelling, packaging and naming related errors** **Étienne Schmitt**, Prescrire (read the slides) Etienne Schmitt presented Prescrire's approach to choosing medicines based on efficacy, adverse reactions, and convenience of use. He discussed packaging-related errors highligted by Prescrire including errors related to high-strength insulins, tramadol oral solution, and colchicine. Prescrire's analysis of packaging was described as a two-step approach: systematic assessment of packaging by the Prescrire editors from the 'New Products' section and systematic assessment of packaging by Prescrire's packaging working group. He also mentioned the Prescrire Packaging Awards that highlight both good and bad medicines packaging and reviewed findings from Prescrire's packaging analysis for the above products.

11h30-13h00	**Addressing three significant high alert medications** Moderated by Ghita Benabdallah and Etienne Schmitt
11h30-12h00	**A Spotlight on Oral Methotrexate** (read the slides) **Allison Hanson**, 2019-2021 ISMP International Medication Safety Management Fellow Allison Hanson presented a brief history of medication error reporting in the United States, highlighting the contribution of ISMP. Her presentation focused on the error reporting of a high-alert medication, oral methotrexate. Hanson reviewed cases to highlight how errors in daily vs. weekly use of methotrexate can lead to a fatal outcome. She presented the goal and recommendations provided by the IMSN Global Targeted Medication Safety Best Practice: "Prevent inadvertent daily dosing of oral methotrexate for non-oncologic conditions". Lastly, she reviewed the European Medicines Agency recommendations regarding methotrexate including to restrict who can prescribe these medicines, make warnings on the packaging more prominent and provide educational materials for patients and healthcare professionals.
12h00-12h30	**Medication Safe Practice Review of Anticoagulant Therapy** (read the slides) **David Cousins**, Safe Medication Practice Consultant - England David Cousins presented the different types of errors and their root causes for the anticoagulant therapies such as warfarin, unfractionated heparin, low molecular weight heparin and novel oral anticoagulants (NOACs). Cousins reviewed the guidance document by the World Health Organization (WHO) which highlights anticoagulants as one of the high-risk situation medicines. He expressed the need to have a reliable follow-up system in primary care to ensure that patients on anti-coagulants are reviewed regularly and not lost to follow up. Cousins highlighted a study that concluded human factor being a leading cause of medication errors before and after the publication of the guidelines on integrated antithrombic care, suggesting that only publishing recommendations without improving follow-up has no effect on patient safety. He provided safety indicators and resources that can be utilized to ensure patient safety for the patients on oral anticoagulants. Lastly, he suggested some quality/safety improvement collaboration that can be undertaken at an institution or primary care level that can help implement some safety guards. The session was concluded with some discussion points to help guide the implementation.
12h30-13h00	**Canadian Initiatives to Support Safe Use of Acetaminophen (Paracetamol)** (read the slides) **Sylvia Hyland**, ISMP Canada Sylvia Hyland presented on Canadian initiatives to support safe use of acetaminophen (paracetamol). She reviewed the Canadian context including the fact that many Canadians are hospitalized annually for overdose, most overdoses are intentional, and there are 500 acetaminophen containing products marked in Canada. Hyland discussed risk mitigation strategies including a Health Canada labelling standard with clear instructions, enhanced display information stating “contains acetaminophen”, a drug facts table mandatory in 2021, and a calibrated dosing device provided in the package. Lastly, she discussed how ISMP Canada has increased public awareness through key messages and media engagement

14h00-15h30	**Moroccan case studies** Moderated by Houda Sefiani and Thamer El Shammari
	Fatal outcome due to Rocuronium (read the slides) **Loubna Alj**, Morocco Poison Control and Pharmacovigilance Centre (CAPM), Rabat Loubna Alj spoke about a serious medication error in Morocco. Six newborns were given rocuronium instead of the hepatitis B vaccine. The newborns were treated with sugammadex. Five newborns recovered, one with sequelae, and one died. The vaccination programme was suspended in the corresponding maternity unit. An investigation was launched by the Ministry of Health and involved the Moroccan Poison and Pharmacovigilance Center as well as other organizations. The root cause analysis confirmed look-alike packaging between rocuronium (produced by SAHAM Pharma) and hepatitis B vaccine (Euvax, produced by LG Life Sciences) and a variety of other contributing factors involving working conditions, education and training, equipment and resources, storage, processes and communication. Discussion: It was confirmed by Alj that the CAPM contacted the regulatory authorities to draw their attention to the resemblance of the packaging and to ask them that the laboratories which market the neuromuscular blocker add a red mention "Warning: paralyzing agent — causes respiratory arrest".
	Medication errors occuring in hospital: experience of Ibn Sina Hospital (read the slides) **Dr. Casimir Adade Adade & Pr. Ait El Cadi Mina**, University Hospital Ibn Sina Avicenne, Rabat Casimir Adade Adade spoke about a retrospective review of the drug errors in his pharmacy between January and September 2019. He found the majority of detected errors occurred in dispensing areas, were the wrong dose, and occurred on the internal medicine floor. Antiinfectives and LWMH were the most common drug class involved.
	Intercepted serious medication error: intrathecal use of Vincristine (read the slides) **Dr. Hajar Daoudi & Pr. Ait El Cadi Mina**, University Hospital Ibn Sina Avicenne, Rabat Hajar Daoudi's presentation focused on a "near miss" medication error with vincristine in his hospital. Two of five oncology medications were prepared in syringes for a patient: vincristine and methotrexate. The hematologist almost gave vincristine intrathecally instead of the methotrexate. The error was intercepted by the pharmacist. The pharmacist contacted the physician and prevented the error. Daoudi identified several causes for the error including handwritten labels, rushing, staff fatigue, workload and lack of an independent double check. In response, the hospital made changes to the label, changed the size of the vincristine syringe to 20mL and instituted independent double checks. Michael Cohen reminded that a better prevention would be the use of minibag, as stated in the IMSN G-TSMP "Prepare and dispense vinca alkaloids in a minibag, never in a syringe"

Medication errors with methylergometrine (Methergin°) in newborn (read the slides)
Fouad Chafik, Morocco Poison Control and Pharmacovigilance Centre (CAPM), Rabat

Fouad Chafik presentation focused on methylergometrin administration errors in neonates in Morocco. Five errors involving methylergometrine intended to be administered to the mother were reported to the Moroccan Poison and Pharmacovigilance Center in 2002 and 2003. Historically, the prescriptions for the mother and infant were written on the same piece of paper and often contained abbreviations such as "gttes" for "drops". This created confusion as to whether the methylergometrine suspension was intended for the mother or the infant. To counteract these errors, the Health ministry sent out an alert to health professionals and banned the use of the pre-printed prescription form with the mother and infant on the same for. Methylergometrin drops were removed from the market.

ME related to the preparation and administration of injectable medicines (read the slides)
Safaa El Marnissi, University Hospital Ibn Sina Avicenne, Rabat

Safaa El Marnissi spoke about medication errors related to the preparation and administration of injectable medicines. Her institution identified solutions to reduce errors including protocols, forms, and assessments. She showed examples of preparation sheets for antibiotics and emergency medications.

Discussion: The presenter mentioned her institution only had five pharmacists and 6 residents on staff in a 960-bed hospital due to costs.

Medication errors involving oral anticoagulants: vitamin K antagonists (read the slides)
Aicha Chaibi, University Hospital Ibn Sina Avicenne, Rabat

Aicha Chaibi's presentation focused on medication errors involving the only vitamin K antagonist (acenocoumarol) marketed in Morocco. A review of prescriptions by pharmacists in Chaibi's hospital identified that most medication errors regarding vitamin K antagonists result from drug-drug interactions, food interactions, and a lack of INR monitoring. In Morocco, pharmacies only dispense acenocoumarol 4mg tablets—no other tablet strength is available. Therefore, pharmacies and patients must cut tablets for other doses. For example, if a patient requires a dose of acenocoumarol 1mg daily, a patient must take ¼ of a 4mg tablet. Pharmacies and patients report difficulties in cutting the tablets because the tablets are so small. In response to these challenges, Chaibi's facility created a "monitoring medical sheet" which tracks the patient's INR. They also created an acenocoumarol protocol for resident doctors. Lastly, a free educational booklet was created for patients.

Securing high alert medication in newborns and mothers (read the slides)
Dr Siham Ziani, University Hospital of Marrakech

Siham Ziani, from Marrakech , spoke about a project regarding high-alert medications. Ziani and colleagues identified inappropriate storage of drugs in intensive care units. The group identified strategies to decrease errors associated with high-alert medications by standardizing the storage in red storage bins, labeling the storage bins, creating an identification label "Médicament à haut risque double vérification" and developing a bilingual logo in Arabic and French. Anaesthesia medications were also now labeled using colors.

	Discussion: One attendee asked if the Moroccan group has studied the impact of colors for anesthesia medications. Ziani responsed that Morocco has not studied the impact of this intervention. Lubna Merchant from US Food and Drug Administration (FDA) commented that US FDA does not recommend the use of color. Rachida Soulaymani from Morocco commented that color differenciation needs to be harmonized around the world.
15h30-16h00	**Coffee break**
16h00-16h30	**Discussion on what could be shared** Moderated by Rachida Soulaymani and Mike Cohen Rachida Soulaymani moderated the French language group Michael Cohen moderated the English language group

	English language group:
	Participants included IMSN, ISMP Canada, ISMP USA, Moroccan Poison and Pharmacovigilance Center, Uppsula Monitoring Center, US Food and Drug Administration and representatives from Egypt, Jordan, Lebanon, New Zealand, Oman, Pakistan, United Arab Emirates, United Kingdom. The English group discussed a need for:
	• Dialogue and engagement with the phamacovigilance community
	  ○ Engage with Uppsala Monitoring Center and the World Health Organization
	• Training of low- and middle- income countries to identify medication errors
	  ○ This training may include providing a tool to filter medication error reports and signals
	  ○ Providing clear responsibilities for different roles (e.g. pharmacovigilance staff, regulatory staff, clinical pharmacists, and medication safety officers), especially in countries with limited staff.
	• Fixing product issues to therefore decrease the downstream practice related issues
	  ○ Harmonize labelling and medication error reporting
	  ○ Stronger regulations for generics that match those of the innovator product
	• Increase medication error awareness and encourage reporting from healthcare providers
	  ○ Some countries are having difficulties encouraging physicians to submit error reports.
	  ○ Several countries mentioned most of their error reports come from the industry.
	
	The English language group also discussed updating the IMSN website, sending automated emails, integrating IMSN comment into the Uppsula Monitoring Center's bulletin.

	French language group: Participants included IMSN, ISMP USA, Moroccan Poison and Pharmacovigilance Center, and representatives from France and other French speaking nations. The French group discussed a need for: • Creation of a national Special Interest Group (SIG) for medication errors ○ including patient safety organizations • Importance of including medication safety at the university level and communicating the thesis on medication errors to the CAPM • Promoting electronic prescribing in primary care to improve community pharmacy safe practices • Communicating with industry regarding safety issues (e.g. labelling) • Implementation of a periodic meeting process or an annual meeting for the Eastern Mediterranean group • Prioritizing common issues (e.g. look-alikes medicines, high-alert medicines, never events)Encouraging development of policies based on presentations given earlier in the day (e.g. anticoagulant policies)
17h00-17h45	**Creation of a national Special Interest Group (SIG) for ME** Loubna Alj, Morocco Poison Control and Pharmacovigilance Centre (CAPM) • Issues regarding ME in Moroccan context • Strategic action plan 2020-2021
17h45-18h00	**Closing session: Wrap up** Pr Rachida Soulaymani