DAY 1 - MONDAY, OCTOBER 29, 2018

Global Meeting on Drug Product Labelling and Packaging Safety: implementing the recommendations of the 2018 IMSN / FDA Summit

Session chaired by Michael Cohen,
Chair, IMSN - President, ISMP

9:00-9:10

Welcome by Paulo Tavares de Almeida on behalf of the Portuguese Association of Hospital Pharmacists (APFH - Associação Portuguesa de Farmacêuticos Hospitalares)

- brief overview of the history of Cascais (read the slides)

9:10-9:30

Introduction address by Michael Cohen, Chair of IMSN

Background information and goal of the meeting

- Brief background of the International Medication Safety Network (IMSN) with mention of the IMSN website
- The goal is to create Global Standards for medication safety based on the objective of the IMSN Salamanca Declaration :
  "*Updating of manufacturing regulations to ensure that pre-market safety testing of product design features becomes mandatory. Manufacturers should be required to subject their products to human factors assessment and user testing, and a complete safety review of the packaging, labelling and product nomenclature, prior to product approval.*"
- Brief summary of the June 2018 US Food and Drug Administration (FDA)/IMSN summit with international drug regulators (read on): How to implement the recommendations? What should be done at the regulatory level? How to harmonize at the international level?
  with reference to the US FDA Commissioner Scott Gottlieb's declaration on generic drugs of October 18, 2018 (read on)
- Emphasizing the need for all stakeholders to work together in reducing medication errors (MEs): opening the discussion with pharmaceutical companies and pharmacovigilance centers.

9:30-10:00

Introduction of the participants

IMSN members:

- **ISMP USA**
  Michael Cohen, President
  Barbrakaryne Fobi, ISMP International Fellow
  Michelle Mandrack, Director Consulting Services
  Christina Michalek, Medication Safety Coord.
- **ISMP Canada**
  Carolyn Hoffman, President & CEO
  Sylvia Hyland, Vice President & COO
  David U, Advisor
- **ISMP Brasil**
  Mario Borges Rosa, Director
- **ISMP-Spain**
  María José Otero, Director
- **Hong Kong Hospital Authority**
  Benjamin Kwong, Senior Pharmacist
- **New Zealand Quality and Safety Commission (HQSC):** William Allan
- **Portuguese Association of Hospital Pharmacists** (APFH - Associação Portuguesa de Farmacêuticos Hospitalares)
  Paulo Almeida
- **Prescrire - France**
  Étienne Schmitt, Head Programme Éviter l'Évitable (Preventing the Preventable)
  Marie-France Gonzalvez, Coordinator
- **Safe Medication Practices - England**
  David Cousins, Consultant
- **United Arab Emirates**
  Rabih Dabliz, Cleveland Clinic Abu Dhabi
  Manager, Quality & Medication Safety Services

<table>
<tr><td></td><td>Medicine Agencies:
Food & Drug Administration USA
Lubna Merchant, Deputy Director, Office of Medication Error Prevention and Risk Management (OMEPRM)
Brazil National Health Surveillance Agency (ANVISA Brasil)
Douglas Simoes Costa Souto
Medicines and Health products Regulatory Agency (MHRA) United Kingdom
Helena Bird, Vigilance and Risk Management of Medicines
Norway Medicine Agency (NOMA)
Sigurd Hortemo, MD
Nina Malvik</td><td>Pharmacovigilance Centers:
French Network of Pharmacovigilance Centers
Marie-Blanche Valnet Rabier
German Medical Association Drug Commission
Ursula Köberle
Thomas Stammschulte
Morocco Pharmacovigilance & Poison Centre
Ghita Benabdallah
New Zealand Pharmacovigilance Centre - Michael Tatley
Unidade de Farmacovigilância Setúbal e Santarém: Paula Barao, Rita Alves</td></tr>
<tr><td></td><td>Pharmaceutical companies
Abbvie – USA: James Duhig
Baxter – Portugal: Diogo Lima
BMS – USA: Alpa Bhattacharyya, Yusuf Oni
Eli Lilly – UK: Ralph Tahchi
Hikma – USA: Constance Long
Janssen, J&J – Netherlands: Esther van der Linde
Novartis – USA:
Dorothy Linvill-Neal, Phuong Nguyen
Pfizer – USA: Mary Baker
UCB – USA: Chidi Maduka</td><td>Others:
WHO Phamacovigilance Programme
Shanthi Pal, Group Lead, Medicines Safety, Safety & Vigilance (joined via videoconference on day 1)
Brand Institute - UK
Ioannis Balamotis
Med-ERRS - USA
Kristine Needleman
Organización de Farmacéuticos Ibero-Latinoamericanos (OFIL) – Uruguay
Estela Sarries</td></tr>
<tr><td>10:06-10:35</td><td colspan="2">Update on WHO Global Challenge on Medication Safety - Medication Without Harm
Shanthi Pal, WHO Phamacovigilance Programme Coordinator (read the slides)
Dr. Shanthi Pal summarized the history of the World Health Organization’s (WHO) pharmacovigilance (PV) program, its members, reporting databases, report types (adverse drug reaction [ADR] and medication errors [ME]), reporting countries, top medical dictionary for regulatory activities (MedDRA) terms related to MEs, published ME signals, and patient empowerment in reporting MEs.
The ME signals are based on information derived from Individual Case Safety Reports (ICSRs) available in the WHO Global ICSR database, VigiBase, and published in the column 'Signal' of the WHO Pharmaceuticals Newsletter.
With the funding from the Research Directorate of the European Union under its 7th Framework Programme, the WHO published a guidance entitled "Reporting and learning systems for medication errors: the role of pharmacovigilance centres" in October 2014 (publication details), intended to strengthen the capacity of national pharmacovigilance centres (PVCs) to identify, analyse and issue guidance to prevent or minimize medication errors (MEs) that harm patients.
This guidance is intended to assist pharmacovigilance centres ((PVCs) and patient safety organizations (PSOs) to begin using the same philosophy, terminology and processes. The success of ADR and ME reporting programs depends on just culture and information sharing.
Regarding the 3rd WHO Global Patient Safety Challenge on tackling medication-related harm, medication as products are the 2nd domain of the medication safety to be addressed, in particular naming for which WHO is considering the Identification of Medicinal Products (IDMP), offering a global source of validated, unique PhPIDs.
Discussion: Participants discussed the overlap between ME captured by national error reporting programs and PV centers; availability of aggregated ME reports submitted to Uppsala Monitoring Center (UMC); and access to Vigibase, eventually using Vigilyze.</td></tr>
<tr><td>Break</td><td colspan="2"></td></tr>
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	Drug Product Labelling and Packaging Safety: implementing the recommendations of the 2018 IMSN / FDA Summit (continued)
10:45-11:10	**Summary of ME concerns raised during the 2018 FDA/IMSN summit** Barbrakaryne Fobi, ISMP International Fellow (read the slides) Dr. Barbrakaryne Fobi gave an overview of labeling-related ME concerns leading to recommendations, including: • expression of strengths (quantity per mL versus quantity per container, ratios, percentages and trailing zeros) • error-prone abbreviations and dose designation • cautionary statements (vinca alkaloids, concentrated potassium chloride [KCL], and neuromuscular blocking agents [NMBs]) • use of contrasting background and label position for ampules • two component medications
11:10–11:35	**Strategies for Reducing Medication Errors Related to Labeling: the list of labeling recommendations discussed at the FDA/IMSN summit** Lubna Merchant, Deputy Director OMEPRM , FDA (read the slides) • Dr. Lubna Merchant gave an overview of the participants during the June 2018 summit and discussed factors to consider when designing a label, how information crowding and visual clutter on labels can be addressed, how important information can be displayed on the Principal Display Panel (PDP). • Comparing labeling requirements for FDA, European Medicine Agency (EMA), and Health Canada, she presented the 6 first proposed labeling recommendations, focusing on small volume parenteral products: ○ expression of strength in metric units; ○ consistent unit of measure across all elements of labels and labeling; ○ elimination of the use of non-standardized abbreviations, symbols, and dose designation; ○ prominent display of cautionary statements; ○ use of contrasting label backgrounds and label orientation on ampules; ○ physical linking or integrating special diluents with respective dry powder drugs; • Finally, she introduced the next steps for discussion with several questions, in particular: ○ To what extent has the issuance of regulatory guidance related to best practice with labels and product design impacted the safe use of medications? ○ What impact of drug shortages-importation of foreign products-on global best practices? ○ What opportunities for global implementation of best practices for labeling and what barriers?
11:35-11:40	**Feedback of the European Medicines Agency on the labeling recommendations** Alexios Skarlatos, Head of Labeling Review & Standards, European Medicines Agency (read the slides) • M. Cohen presented Alexios Skarlatos's perspective on the proposed labeling best practice recommendations. • EMA feedback was supportive of the expression of strength and special warnings with reference to EMA's guidance documents; expressed difficulties in completely banning abbreviations from EMA labels; mention the routine assessment of contrast and label position on ampules by internal packaging specialist reviewers. Some topics are out of the EMA's regulatory remit: linking or integrating special diluents with their powder component; barcodes on packages under the national responsibility of each EU Member State.

11:40–12:40	**Panel discussion** – moderated by Michael Cohen, Chair of IMSN **Further input from industry into understanding the challenges or barriers in implementing best practices. What opportunities do you see for global implementation of best practices for labeling?** Panelists: Chidi Maduka (UCB), Diogo Lima (Baxter), Dorothy Linvill-Neal (Novartis), Ralph Tahchi (Eli Lilly) • The panelists discussed industries' focus on regulators rather than patients; limited information from national PV centers; the need for industry to be more proactive; differences between information needed by patients versus practitioners; use of human factors studies; variability in the use of color; European Union's (EU) purchasing process variability; time restrictions related to the needs of patients; reduction in the time spent on reviewing medications; the need for a top down approach or legalization of these best practices/ recommendations; inclusion of practice regulators like accrediting agencies; and the review process for the best practice guidance document. • Further discussions centered around industry's process of investigating medication errors related to their products and the need for industry stakeholders to come together to work on harmonizing some of their practices.
12:40–12:50	**Package Design Affects Accuracy Recognition for Medications** Sigurd Hortemo, MD, Norway Medicine Agency (NOMA) (read the slides) • Dr. Sigurd Hortemo presented on the Norwegian generic substitution regulations and how it leads to duplicate therapy errors. In an interview study of 174 Norwegian hypertensive patients, 5% of the patients used more than one equivalent generic product at the same time (Håkonsen H et al. Generic substitution: additional challenge for adherence in hypertensive patients? *Curr Med Res Opin*. 2009 Oct;25(10):2515-21.) • He gave an overview of a study that compared the original packaging of drugs with their modified package (varied placement of the name, dose, and background of active substance), indicating a reduction in duplicate therapy errors for modified packages with prominent placement of the international non-proprietary name (INN) and dose using a high-contrast color. (Endestad T, Wortinger LA, Madsen S, Hortemo S. "Package Design Affects Accuracy Recognition for Medications" *Hum Factors* 2016; 58 (8):1206-1216.) • Another study showed that prominent placement of the active substance(s) name(s) and strength(s) in the front of the medication package may reduce time for nurses when preparing medications, without increasing medication errors. (Garcia BH, Elenjord R, Bjornstad C, Halvorsen KH, Hortemo S, Madsen S. "Safety and efficiency of a new generic package labelling: a before and after study in a simulated setting" *BMJ Qual Saf*. 2017; 26(10):817-823.)
Lunch	
13:50-14:10	**Medication error concerns observed with the use of ampules: positioning of labels and use of a contrasting ceramic or paper background** Mario Borges Rosa President, ISMP Brasil (read the slides) • Mr. Mario Rosa presented on MEs related to the use of ampules highlighting the role of labeling, environment, and practice. • He presented examples of error-prone ampules including inadvertent vaccination of 76 patients with insulin due to color similarities (free drugs supplied by Brazilian Health systems are predominantly green in color). ANVISA and ISMP Brasil are collaborating to improve drug packaging.
14:10-14:30	**Medication error concerns due to the limited availability of ready-to-use packaging** Rabih Dabliz, Cleveland Clinic Abu Dhabi (read the slides) • Dr. Rabih Dabliz gave an overview of the challenges faced by the United Arab Emirates (UAE) related to ready-to-use (RTU) products including minimal availability, lack of barcoding, and inability to outsource sterile compounding; leading to the implementation of error-prone practices like batching premixed solutions and application of auxiliary labels. • EMA's perspective on the proposed packaging best practices included the potential reflection of RTU/ready-to-administer drug products in EMA guidance; current evaluation of methotrexate labeling and packaging; and the limited scope of EMA related to the inclusion of a barcode on drug packages. • R. Dabliz later showed "**Just and Fair Culture**", a training video illustrating the need for a just culture: (play the video)

14:10-15:15	**Panel discussion** – moderated by Dr. Mary Baker (Pfizer, USP) **The barriers that limit greater access to prefilled syringes, premixed solutions, ready-to-use and ready-to-administer products: how can we address this?** Panelists: Constance Long (Hikma), Diogo Lima (Baxter) and Ralph Tahchi (Eli Lilly) Was discussed: • value and cost of prefilled products; • importance of market size (purchasing power); • hang time for ready-to-use (RTU) products; • need for new cost-benefit analysis; • production and distribution of products; • compounding standards for pharmacy versus nursing; • cost and bulkiness of compounding robots; • and drug shortages.
Break	
15:30-17:30	**Panel discussion** – moderated by David Cousins, Consultant, Safe Medication Practices (read the slides) **on producing IMSN guidance on safer labelling and packaging of medicines** • Participants discussed the variability in different guidance documents, audience (e.g., drug regulators, industry, practice regulators), and meeting objectives. • Participants agreed on the following best practices: 1. Include both the per mL and the per container quantity, not the per mL quantity alone, when presenting the concentration for injectable; with prominence given to total content per container 2. Use metric units for products and eliminate ratio expressions 3. Eliminate potentially error-prone abbreviations and dose designations on labels, such as U for units, IU for international units, and trailing zeros (e.g., 1.0) to express strength 4. Prominently display cautionary statements on the carton and immediate container labels of NMBs, KCL concentrate injection, methotrexate, and other selected error-prone medications 5. Use contrasting label backgrounds for printing on glass ampules and recommended font size and label orientation to improve readability 6. Physically link or integrate "special" diluents for "specific drugs" with their powder component 7. Increase the adoption of RTU/ready-to-administer syringes, premixed IV solutions, unit-dose packaging, and other more efficient, safer packaging, while considering the overall cost of implementation 8. Develop product-specific world safety standards; for example, standard packaging for non-oncologic methotrexate to prevent accidental daily use and overdose 9. Include barcodes on primary packages so they can be scanned at the bedside or other locations where medications are dispensed and administered by healthcare practitioners 10. Mention prominently international non-proprietary names (INN) on labels • **Discussion:** Participants discussed the following; ○ the 10th best practice may be problematic for multi-ingredient products, such as antivirals ○ transition period with dual expression of strength during the removal of ratio and percent strength expression; ○ identification of a single language for drugs in countries with multiple languages; ○ including a mention "This is the diluent for…" on the label of diluents ○ rewording of best practice number 7 to include “when commercially available...”; combining recommendations on methotrexate; packaging of other high alert medications; ○ enforcing practitioner use of barcode; ○ product differentiation; color differentiation; design identity; ○ critical information (in same field of view); standardization of it position on the outer packaging; ○ readability (font size, crowding); and secondary packaging. • **Follow-up**: Participants agreed that an IMSN Guidance targeting International best practice for safe labelling and packaging of prescription medicines should be drafted, reviewed by stakeholders, and submitted to International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

DAY 2 - TUESDAY, OCTOBER 30, 2018

	Drug Product Labelling and Packaging Safety: implementing the recommendations of the 2018 IMSN / FDA Summit (continued)
	Session chaired by David U *IMSN Executive Committee Advisor, ISMP Canada*
9:00-9:30	**Discussion on bar codes on product labels** Moderated by Michael Cohen, Chair, IMSN • Starting from Christina Michalek's presentation on the use of technology to reduce errors (read the slides), Mike Cohen elaborated on the global utilization of barcodes indicating that it drives verification technologies used during medication dispensing and administration. He gave a brief history of the adoption of barcode scanning in the US, highlighting the need for the healthcare community and practice regulators to enforce its use. He started the discussion with the following questions: What systems are now utilized globally to identify specific drugs and dosage forms (DIN, NDC, etc.)? Possible to have a universal bar code? • **Discussion**: Participants discussed the cost of implementation, the need of evidence to convince health system managers to use barcode in the medication use process and the necessity for a barcode readiness assessment to identify barriers and similarities across countries, eventually with a survey to be launched by the IMSN. During the previous day's discussions, it was deplored that Datamatrix codes had been made mandatory in Europe only on external packaging to fight against counterfeit medicines and to ensure the traceability of authorized medicines. Pharmaceutical companies oppose applying Datamatrix codes on the primary packaging (unit dose) because the European Directive do not oblige them. The only way out of this scandalous situation is to promote the systematic use of existing codes during dispensing control in ambulatory/community pharmacy as well as various stages of the medication use process in hospital settings, and to encourage manufacturers to affix it on unit doses. An IMSN Position Statement on barcoding could then be developed. IMSN can work with groups like International Pharmaceutical Federation (FIP), and at the European level: EMA's Committee for Medicinal Products for Human Use (CMPH), Heads of Medicine Agencies (HMA), European Association of Hospital Pharmacist (EAHP), European Federation of Nurses Association (EFN), etc.
	Panel Discussion on Medication Error in Pharmacovigilance Programs
	Moderator Michael Tatley, Director, Pharmacovigilance Centre, New Zealand
9:30-9:35	Welcome of Pharmacovigilance (PV) center representatives by David U on behalf of the IMSN • David U introduced the questions that need to be considered by a simple observation regarding Canadian pharmacovigilance: in the context of ISMP Canada's collaboration with Health Canada, a review of 115 serious preventable adverse drug reactions (ADRs) found exploitable elements for error analysis in only 25 cases. • He concluded his brief overview of the similarities between MEs and ADRs emphasizing that they are two sides of the same coin: drug safety.

9:35-9:40	**Introduction** by Michael Tatley, Director, Pharmacovigilance Centre, New Zealand • The close association of pharmacists who were already involved in the ISMP/IMSN, and who were also often key members of pharmacovigilance programs, was recognised as preamble to the session. This alignment in some centres had led to their increasing focus on medication error monitoring being seen as within the spectrum of pharmacovigilance and a potential factor in accounting for some reports of harm or Adverse Drug Reactions. Earlier in the decade-to-date, some countries such as Morocco and New Zealand had as progressed to integrating medication error into their pharmacovigilance programs. • As part of a project funded by the European Union (FP7-HEALTH: Optimizing Drug Safety Monitoring to Enhance Patient Safety and Achieve Better Health Outcomes, 2009-2013), a workshop in Rabat, Morocco, in 2011, led by the National Patient Safety Agency in the United Kingdom (UK NPSA), ISMP Canada, the WHO Uppsala Monitoring Centre (UMC) and WHO, was organised to advocate and encourage pharmacovigilance centres to become more involved in medication error reporting and analysis.
9:35-9:40	**Introduction of the participants** • The panel discussion provided an opportunity to identify the current (2018) state of the interface between medication error and pharmacovigilance programs. The nine countries that presented were: New Zealand, Morocco, United Kingdom, Canada, USA, France, Portugal, Germany and Norway.
9:40-10:00	**Medication Error Reporting Programme: strengthening pharmacovigilance in New Zealand** Michael Tatley, Director, Pharmacovigilance Centre, New Zealand (read the slides) • Michael Tatley gave an overview of New Zealand's PV center highlighting the strength of their ME reporting program. • In New Zealand, no official mandate existed to underpin support for taking on medication error analysis within pharmacovigilance; and the NZ PV Centre lost the corresponding funding from the Ministry of Health for this reason in June 2017. Since then, there is no one national agency in NZ with medication error mandate.
10:00-10:20	**Management of Medication Errors within Pharmacovigilance centres** Ghita Benabdallah, Morocco Pharmacovigilance & Poison Centre, WHO Collaborating Centre Rabat for Strengthening Pharmacovigilance Practices (read the slides) • Dr. Ghita Benabdallah gave an overview of the WHO collaboration center for strengthening PV practices with reference to the WHO Guidance "Reporting and learning systems for Medication Errors: detecting, analyzing and preventing within Pharmacovigilance centres" October 2014 ; 110 pages (read on). • She presented on the history of ME reporting within the PV centers; challenges and successes of Moroccan PV center; PV process; ME classification; and risk minimization strategies (regulatory actions, communication of risk, and implementation of health strategies).
10:20-10:40	**Medication errors - The French experience** Dr Marie-Blanche Valnet Rabier, French Network of Pharmacovigilance Centers (read the slides) • Dr. Marie-Blanche Valnet Rabier gave an overview of the French network of Regional PV Centers (RCPV) highlighting the chronology of ME reporting, complexity of ME reporting and analysis whose organization is compared to an octopus, need for confidentiality and just culture; identification and reporting of MEs in hospitals versus primary care, and actions taken to reduce MEs.
Break	
10:55-11:10	**MHRA and NHSI's National Medication Safety Network Improves Patient Safety** Helena Bird, Vigilance and Risk Management of Medicines, MHRA (read the slides) • Ms. Helena Bird gave an overview of vigilance and risk management of medicines within the Medicines and Healthcare Products Regulatory Agency (MHRA), highlighting activities (e.g., MEs and device incident reporting, national medication safety network, medication safety officer steering groups) that strengthen the reporting governance in the National Health Service (NHS); collaboration between NHS improvement and MHRA; methods of communication (e.g., publications, alerts, WebEx, forum). • Examples of safety signal identification leading to regulatory actions were presented: Braltus Zonda° inhaler choking risk; Incorrect storage of dabigatran in medication dosette boxes leading to degradation of capsules and increased risk of stroke; cobicistat, ritonavir and co-administration with a steroid;

11:10-11:20	**Portuguese Pharmacovigilance system and management of medication error reports** Paula Barao, Rita Alves, Unidade de Farmacovigilância Setúbal e Santarém (read the slides) • Paula Barao gave an overview of the Portuguese PV system highlighting their successes (decentralized system, PV delegates, academic/hospital integration, and training) and challenges (app creation, webservice implementation, healthcare practitioner education, and population awareness) in receiving ADR reports. • Rita Alves presented their approach for receiving feedback and management of ME reports. Since 2012, the Portuguese Pharmacovigilance System only received 112 cases where medication errors were reported. 85 % of these were reported between 2012 and 2014.
11:20-11:35	**Drug Commission of the German Medical Association- Part of the German Pharmacovigilance System** Ursula Köberle and Thomas Stammschulte, AkdÄ (read the slides) • Dr. Thomas Stammschulte gave an overview of the Drug Commission of the German Medical Association (DCGMA), an ancillary to the German PV system, accentuating its members; handling of ADR reports; collaboration with the national authorities. Amongst publications in *Deutsches Ärzteblatt* (DÄB) related to medications errors: Vincristine accidental intrathecal application (DÄB, 22 June 2018); Vitamin D overdose (AkdÄ Drug Safety Mail, 30 November 2017);Fatal colchicine accidental overdose (DÄB, 20 January 2017); Drug name confusion between haloperidol and haloperidol decanoate (DÄB, 28 October 2016). • Dr Ursula Köberle presented the AkdÄ project of recording and assessing medication errors within the German spontaneous reporting system (read on in German).
11:35-11:50	**Overview of FDA's Pharmacovigilance and Medication Error Reporting Systems** Lubna Merchant, Acting Director, Medication Error Prevention and Analysis (DMEPA) (read the slides) • Dr. Lubna Merchant gave an overview of FDA's PV and ME reporting systems highlighting the different centers and reporting systems within FDA; the role of the division of medication error prevention and analysis (DMEPA); number of ME reports received per year; signal detection and analysis. • Amongst challenges and future considerations to enhance the ME/ADR reporting systems: exploring artificial intelligence techniques for medication error analysis; using Sentinel System for medication error analyses (i.e. Brilinta°-Brintellix° name confusion, methotrexate wrong frequency dosing errors). • She concluded on the need for harmonization, especially in the areas of: medication error reporting (to capture relevant information), product identification, medication error terminology and coding.
11:50-12:05	**Outreach, Education and Feedback – Mandatory Reporting of Serious Adverse Drug Reaction (ADR) and Medical Device Incident (MDI) by Health Care Institutions** Reviewed by: Health Canada, Presented by Sylvia Hyland, ISMP Canada (read the slides) • Dr. Sylvia Hyland gave an overview of Health Canada's PV activities highlighting the reporting landscape; Vanessa's Law (Bill C-17); approaches to improve reporting; regulatory process for mandatory reporting; partnerships (ISMP Canada, health standards organization [HSO], Canadian patient safety institute [CPSI]); key milestones; consistent themes; implementation plan; and need for outreach and communication.
12:05-12:15	**Risk communication - Use of Direct Healthcare Professional Communications in Norway** Sigurd Hortemo, MD, Norway Medicine Agency (NOMA) (read the slides) • Dr. Sigurd Hortemo presented on risk communication and the use of direct healthcare professional communications (DHPCs) in Norway, emphasizing the transition from a passive approach of risk communication (post, snail mail) to an active approach (media, press release, journal publications, point of care alerts [general practitioners via electronic prescription system, patients via medicine app]).
Lunch	

	Medication Error in Pharmacovigilance Programs (continued)

13:15-13:45	**Discussion on Medication Error in Pharmacovigilance Programs**
	Moderated by Michael Tatley, Director, Pharmacovigilance Centre, New Zealand
	• In wider discussion the meeting acknowledged the complementarity of pharmacovigilance centres and progress in medication error integration achieved to-date as exemplified by the presentations. The immense potential for IMSN working in closer collaboration with pharmacovigilance centres was recognized as an important mutual advantage, including :
	  ○ the update of the IMSN Position Paper on Pharmacovigilance and Medication Errors (read on);
	  ○ the IMSN membership for PV centers and regulators;
	  ○ the presentation of IMSN initiatives during the November 5, 2018 annual meeting with representatives of national PV centers in Geneva;
	• Further discussions included reduction of reporting steps; imbalance between industry versus practitioner reporting; information sharing; industry access to PV reports.
	• Discussion also identified that pharmacovigilance centres do receive reports identified as medication error that are coded with the MedDRA medication error hierarchy terms. These reports, like other ADR reports from national pharmacovigilance centres, are uploaded to the WHO Programme for International Drug Monitoring database at the Uppsala Monitoring Centre. Based on an earlier presentation by the WHO, currently this database holds over 900,000 reports in the MedDRA medication error hierarchy which have not been analysed for pattern. This potentially offers further opportunity to utilise IMSN expertise to explore this dataset with Vigilyze° and foster IMSN/Pharmacovigilance collaboration.
	• There was a consensus view that more attention should be focussed on promoting and extending greater involvement of more pharmacovigilance centres in medication error reporting and analysis and that the IMSN should become more active in participating and facilitating in this harmonisation.
	• Specific activities and projects aimed at strengthening the harmonisation, complementarity and integration of pharmacovigilance and medication error were identified and supported by consensus. These included the following:
	  ○ Inviting pharmacovigilance centres to join the IMSN as active members;
	  ○ Pharmacovigilance centre participation in presenting findings at IMSN meetings such as in a dedicated session;
	  ○ Potential IMSN role in strengthening pharmacovigilance centres ability and knowledge to increase medication error report identification and assessment: possibly through workshops similar to the 2011 example harnessing the IMSN member expertise.
	  ○ Analyse and review the Vigilyze° medication error hierarchy data as a collaboration of IMSN expertise with pharmacovigilance centre(s) access to this dataset.
	  ○ A joint/collective publication summarising the status of medication error in pharmacovigilance programs (based on the 9 country inputs). Discussion addressing topics such as challenges, opportunities in working in closer collaboration with the IMSN to strengthen, harmonise and integrate medication error in Pharmacovigilance, will be of great benefit to achieving the safer use of medicines.

13:45-14:05	**Proposal for International Targeted Medication Safety Best Practices for Hospitals** Presented by Michael Cohen, Chair, IMSN (read the slides) • M. Cohen gave an overview of ISMP's Targeted Medication Safety Best Practices (TMSBPs) advocating the need for global TMSBPs. • Participants discussed the need for inclusion as IMSN members of accrediting bodies like The Joint Commission, Utilization Review Accreditation Commission (URAC), National Committee for Quality Assurance (NCQA), The French National Authority for Health (HAS: Haute Autorité de Santé), etc. Contacts and relationships should be developed in order to let them endorse IMSN proposals of International Targeted Medication Safety Best Practices for Hospitals. • It was concluded that a couple of global best practices will be drafted for review by participants, with vincristine as a good 1st candidate.

Business session

Session chaired by Michael Cohen, Chair, IMSN - President, ISMP

14:05-15:00	**Recruitment and membership** In order to be more efficient, IMSN should integrate more key stakeholders of medication safety as IMSN members. Participating pharmacovigilance centers and regulators were asked if they considered joining IMSN. Most participants are willing to benefit in sharing expertise on medication error analysis and prevention, and indicated that they will get back to IMSN about their interest in becoming members. The current member fee is 1 500 US dollars, voluntary contributions been needed to ensure the correct functioning of the organisation. This level of contribution caused a great deal of discussion, as in previous meetings. It was remarked that several members did not attend the meeting nor paid their membership fees, due to limited resources. Further discussions included: the revival of IMSN social media accounts; reconnecting with old IMSN members; other membership venues like FIP, regulatory affairs profession society (RAPS), drug information association (DIA), trade associations like PhRMA, EFPIA. IMSN will summarize the benefits of becoming a member (as a flyer or a dedicated webpage) emphasising more on shared expertise, mutual exchange and values of IMSN (independency and transparency); and will manage more proactively IMSN social media accounts.
	Financial report M. Cohen reviewed the financial standing of the organization. Most expenditure for the organization is on maintaining the website and paying for travel expenses. Currently some member countries have paid their dues but there are still outstanding dues for many members. The executive committee will develop a new registration fee system according to the World Bank classification of low, medium and high income countries and modify the constitution accordingly. On the basis of the annual report and the financial statements, the members approved the financial report for year 2017.
Break	
15:15-16:15	**Executive Committee** Participants agreed to make Dr. Lubna Merchant (FDA) an executive board member of IMSN
	Venue for the IMSN annual meeting 2019 Michael Tatley (New Zealand PV center) and Ghita Benabdallah (Morocco PV center) invited IMSN to their respective countries in 2019. Participants discussed the requirement of the hosting country, possibility of bi-annual meeting (two times a year), and early circulation of agenda (minimum 3 months). The executive committee will choose a venue for 2019

	Action Plan
	• Promoting IMSN membership
	  ○ Create a three-tier membership fee system based on the country's income
	  ○ IMSN webpage and/or flyer summarizing the benefits of becoming a member
	  ○ Contact previous members and other organizations to increase membership
	• Early announcement of the venue for the IMSN annual meeting 2019
	• Prepare an IMSN White Paper on Best Practices of Drug Product Labelling and Packaging
	  ○ Establish timeline
	  ○ Collect as many interesting references as possible (evidence of harm, safer practices, existing guidelines); call for contributions, editing draft (where we are, where we go, how we go)
	  ○ Send draft to participants for review
	  ○ Submit reviewed white paper to ICH
	• Update the IMSN Position Statement on pharmacovigilance and medication errors
	  ○ send to participating PV centers for review
	• Create barcode readiness assessment at international level and lobby for European Datamatrix code on unit doses
	• IMSN communication: establish effective management of social media

16:15-16:30	**'ASK' Medication & Patient Safety Video** Rabih Dabliz -Cleveland Clinic Abu Dhabi (play the video) • This short film, titled "ASK", highlights the importance of patients and family members asking questions about their medications on the basis of the "5 Questions to Ask About Your Medications" collaboratively developed in the Canada (read on).
16:30	David U and Mike Cohen thanked participants and adjourned the meeting

End of the 13th Annual IMSN Meeting

Notes taken by **Barbrakaryne Nchinda Fobi**, ISMP Fellow (**warm thanks to her!**);
review and final editing by **Étienne Schmitt**, Prescrire on behalf of the Executive Committee.