

**SPEECH BY A/P JOHN LIM, CEO, HEALTH SCIENCES AUTHORITY
OPENING CEREMONY OF WHO-HSA
INTER-REGIONAL PHARMACOVIGILANCE TRAINING COURSE
WEDNESDAY, 10 OCTOBER 2012**

Professor Hubert Leufkens, *Professor of Pharmacoepidemiology,
Utrecht Institute of Pharmaceutical Sciences and Chairman of the Dutch
Medicines Evaluation Board*

Dr Ruth Savage, *Senior Medical Assessor at the Centre for Adverse
Reactions Monitoring (CARM), New Zealand Pharmacovigilance Centre
and Senior Lecturer at Christchurch School of Medicine, University of
Otago, New Zealand*

Ms Jeanette Johansson, *Team manager of Uppsala Monitoring Centre's
Analysis Team*

Mr Daisuke Koga, *Technical Officer, World Health Organisation*

Distinguished friends and colleagues

Good Morning

1 I would like to extend a very warm welcome to all of you to the WHO-HSA Inter-regional Pharmacovigilance Training Course in Singapore.

2 We are honoured and privileged to host this training with the participation of WHO and the Uppsala Monitoring Centre, and to have with us renowned experts in the areas of pharmacoepidemiology and data mining. We would like to thank Professor Leufkens, Dr Savage and Ms Johansson for making available their time to conduct this training course. I am certain that all of you will gain valuable insights from their extensive experience and the knowledge that they are going to share over the next three days.

NEW TECHNOLOGICAL OPPORTUNITIES IN DRUG SAFETY

3 Advancements in technology have allowed large amounts of health data to be stored and collected in electronic formats. This presents an opportunity to further enhance the monitoring of drug safety in the postmarket environment that reflects real-world use of drugs, and holds

tremendous potential for detecting, quantifying, and characterizing drug safety alerts. There is therefore a need for quantitative data mining tools and pharmaco-epidemiology capabilities to properly harness the benefits of using electronic health data for enhanced signal detection.

4 The traditional paradigm of using spontaneous adverse drug reaction reports from healthcare professionals to identify the potential unknown risks of medicines after a medicine is brought to market remains important. However, these may be inadequate to detect more subtle risks and those adverse drug reactions (ADRs) that may have a longer latency to onset. Drug regulators are increasingly looking at data mining and statistical tools to further analyse adverse drug reaction data, to identify such rare and subtle drug-adverse event relationships in order to pick up potential safety signals

TECHNOLOGICAL DEVELOPMENTS IN SINGAPORE

5 In Singapore, the Vigilance Branch at HSA has over the years strengthened its pharmacovigilance processes by leveraging on technology to amplify local signals for post marketing surveillance. The Electronic Medical Record Exchange (EMRx) system was implemented

by Singapore's Ministry of Health in 2006 to enable secure health information exchange amongst public sector clinicians. As part of the EMRx initiative, the Critical Medication Information Store (CMIS) was developed to serve as an electronic data repository for structured medical alert, drug allergy and adverse drug reactions. This shared electronic repository of medical information is linked to all the public hospitals in Singapore.

6 Through the introduction of the CMIS, the Vigilance Branch has been receiving AE reports directly from the electronic databases in healthcare institutions. Over the past 11 years, the number of adverse event (AE) reports for marketed pharmaceuticals, herbal medicines, health supplements and cosmetics received by HSA has risen almost 40-fold from 627 in 2001 to almost 24,000 in 2011. In addition, Singapore has taken the world lead in terms of the number of valid reports per million inhabitants submitted to the WHO global database.

7 Recently, HSA was one of the first regulators in Asia to detect serious cutaneous reactions suspected to be associated with the osteoporosis drug, strontium ranelate. HSA released early interim alerts

to healthcare professionals in August 2011. A full benefit-risk assessment of the drug was performed and presented to HSA's Product Vigilance Advisory Committee. If you are interested in finding out more, the follow through and systems are described in this month's issue of the Regulatory Affairs Journal, in the article "*Pharmacovigilance in Singapore – harnessing IT and genomics to detect safety signals.*"

PHARMACOVIGILANCE INITIATIVES

8 In 2007, HSA embarked on a pharmacogenetics-based approach to pharmacovigilance, to identify possible genetic associations that could potentially impact drug safety in Singapore's resident population. In collaboration with the Saw Swee Hock School of Public Health at the National University of Singapore, the team is developing a user-friendly web-based portal to guide regulators, healthcare professionals and researchers on possible differences in drug responses, efficacy and safety based on genetic differences in the populations. This project will be further developed under the scope of a memorandum of understanding which was signed between HSA and the School of Public Health last week on 1 Oct. This MOU seeks to encourage knowledge exchange, enhance academic and professional competencies and

develop scientific leadership to promote the protection of public health and the advancement of public health science.

9 Moving forward, the Pharmacogenomics team at HSA will continue to apply pharmacogenetic research findings to the local clinical setting. An area that we will be working on is the validation of the association between HLA-B*5801 and allopurinol-induced serious skin reactions in the local population, followed by the development of appropriate genotyping guidelines for new allopurinol patients. We will also be furthering our efforts to investigate pharmacogenomic associations with drug-induced liver injury.

10 Despite many advances on the pharmacovigilance front, there is still room for further enhancements, and we continue to press on with other initiatives in the interests of patient safety. We are implementing closer post-market surveillance for medical devices, including working on establishing a national registry system for medical devices to complement mandatory pre-market regulatory controls.

11 Over time, complementary health products have proven to be of higher extrinsic risk of being adulterated and marketed with unsubstantiated therapeutic claims. More proactive post-market activities are therefore targeted at this group, especially on the highest risk sub-group of lifestyle products related to slimming or sexual performance.

12 Moving forward, as we seek to further reach out to engage the public, we plan to produce consumer articles for drug safety alerts, building on those which are only currently available for healthcare professionals. We would also like to explore developing mobile applications for reporting of ADRs. Global developments in pharmacovigilance such as the new EU Pharmacovigilance legislation are of significant interest to us, and the Vigilance team will be closely monitoring developments in these areas.

13 Pharmacovigilance today is a sophisticated combination of science and technology. It is crucial that we continue developing and expanding our capacity in this rapidly evolving and dynamic discipline. With the unique opportunity of having such an assembly of experienced and

knowledgeable experts with us this week, I hope all of you who are participating in this training course will be able to use this opportunity to learn from them and also from your fellow colleagues from around the Asia Pacific region.

14 Once again, I would like to thank our speakers and all of you for taking the time to participate in this event. I wish you a fruitful time ahead and that this training session will be both rewarding and memorable. I also hope you will find time to explore and discover the exciting attractions and delights Singapore has to offer so that your vigilance skills will extend beyond the purely scientific, and will take in many other cultural and social signals as well.

Thank You.