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HSA SINGAPORE HOSTS INTERNATIONAL HEALTH PRODUCTS REGULATORY CONFERENCE FOR THE FIRST TIME

MOU signed between Singapore and Dutch regulators to enhance patient access to safe and effective medicines

On 28 January 2013, the Asia Regulatory Conference 2013, a major conference in the fields of medical product development and regulations, was hosted by the Health Sciences Authority (HSA) in Singapore for the first time. Themed "Regulatory Convergence and Cooperation to Improve Access and Quality", the conference brings together over 300 experts from health authorities, pharmaceutical companies and academia across almost 30 countries in the Americas, Asia and Europe to exchange views and identify specific areas to enhance patient access to new and improved medicines. The three-day conference is co-organised by HSA, the Drug Information Association (DIA) and the International Federation of Pharmaceutical Manufacturers Association (IFPMA).

2 Among the key topics being covered at the conference are issues of global significance, including how regulators and industry can work together to enable faster patient access to safe and better medicine, ensuring viability of global supply chains, the importance of post-market and active surveillance, and combating the problem of counterfeit health products.

Collaboration is key to safeguarding and enhancing public health

3 In recent years, the Asian region has experienced very fast growth in global drug development activities, encouraged by various initiatives and incentives from countries in this region. Many multi-national pharmaceutical corporations and global contract research organisations are now operating in Asia, and drug development is undergoing constant growth and advancement. The diversity of the region and the spectrum of different demographic and socio-economic settings allow for medicines to be developed for disease conditions in developed and developing countries.

4 Over the last few decades, the world has also seen a significant change in disease demographics, and some communicable diseases like tuberculosis have re-emerged with strains that are resistant to conventional treatments. Other emerging diseases like H1N1 and SARS have also posed increasing challenges to our healthcare systems.

5 “Countries like Japan, Korea and Singapore face the increasing challenge of appropriately managing the healthcare needs of a rapidly ageing population and the rising incidence of chronic diseases. It is therefore important to look at more public-private partnerships to ensure better utilisation of resources to meet national healthcare needs, as well as to create the right environment for ongoing life science innovation. Greater collaboration among industry players and regulators will not only ensure more effective and efficient drug development, provide early access to safe and high quality products to markets, but will also ensure more effective surveillance of medicines already in the market,” said Dr Amy Khor, Minister of State for Health and Manpower, Singapore at the Opening Ceremony.

Post-market and active surveillance are critical to ensuring drug safety

6 Post-market surveillance, a growing discipline among regulators, industry and healthcare professionals, is a key area being discussed at the conference. Recent high profile cases relating to drug safety and withdrawal of blockbuster drugs, for example, Vioxx and Avandia, has led to extensive discussion over placing greater emphasis in this area.

7 “Globally, more emphasis is being placed on post-market surveillance. This is not only due to the strain on expertise and resources to keep on building up pre-market assessment capability, but more significantly, because not every major adverse event can be averted by pre-market studies and information. To strengthen post market surveillance, regulators and industry should harness the power of technology to further enhance active monitoring of drug safety. In this respect, Singapore’s small population size and the presence of robust health IT systems have proven advantageous,” said Associate Professor John Lim, Chief Executive Officer of HSA.

8 Singapore is now ranked number one by the World Health Organisation (WHO)-Uppsala Monitoring Centre in terms of the number of reported adverse events per million inhabitants. This illustrates the effectiveness of Singapore’s reporting system which allows HSA to pick up adverse drug reaction reports directly from healthcare professionals, analyse and address any drug safety issues expeditiously.

Combating cyber crime and counterfeiting

9 The increasing threat to public health contributed by cyber crimes and counterfeit medicines will be another key area for discussion at this conference. Having collaborated with INTERPOL on the training of law enforcement officers to combat cyber pharmaceutical crimes and counterfeit medicines, HSA will join experts and officials from INTERPOL and the pharmaceutical industry to share their best practices in dealing with this major public health issue.

10 Counterfeiting is greatest in regions where regulatory and enforcement systems for medicines are weakest, and the problem is complicated by the growth in international trade of pharmaceutical ingredients and medicines, according to the WHO[1]. In a recent global operation spanning 100 countries aimed at disrupting the organised crime networks behind the illicit online sale of medicines, some 80 arrests and the seizure of 3.75 million units of potentially life-threatening medicines worth USD $10.5 million (about SGD $12.9 million) were made worldwide[2]. In Singapore, HSA seized about SGD $18,000 worth of illegal health products and investigated 10 individuals for the sale of those products, as a partner in the international operation led by INTERPOL in 2012.

11 Dr Ling Su, President, DIA Board of Directors, said, "This three-day conference offers a unique opportunity for key stakeholders from health authorities, local and multinational pharmaceutical companies, and clinical research to meet and exchange views, discuss topics of interest and identify focus areas for ongoing efforts to increase patient access to new and improved medicines. We are honoured to have Dr Amy Khor, Minister of State for Health and Manpower in Singapore, speaking at the event as well as speakers from top-level regulatory authorities in several Asian countries and leading experts in the International Conference of Harmonisation process."

12 The Asia Regulatory Conference will be held at the Raffles City Convention Centre from 28 to 30 January and is the second that follows the first such meeting in Seoul, Korea in 2011.

Singapore and Dutch regulators sign MOU to shore up collaboration in health products regulation

13 To further enhance access to safe and effective medicines, and advance the services relating to public health in order to meet the needs of the populations**,** HSA signed a Memorandum of Understanding (MOU) with the Medicines Evaluation Board (MEB) of the Netherlands on the sidelines of the conference. This MOU aims to shore up collaboration between the two agencies through the following areas**:**

a. Strengthen regulatory science as a discipline fostering evidence based and harmonised decision making on medicinal products;
b. Share pharmacovigilance and risk management strategies;
c. Collaborate on the improvement and harmonisation of methods on decision making in the area of benefit-risk assessment of medicinal products;
d. Exchange information on pharmacogenomics and personalised medicine; and
e. Stimulate joint education and training of regulatory experts, Master and PhD students.

[1] Source: WHO, http://www.who.int/mediacentre/factsheets/fs275/en/
[2] Source: INTERPOL, http://www.interpol.int/News-and-media/News-media-releases/2012/PR077

14 Signed by Associate Professor John Lim, Chief Executive Officer of HSA and Professor Hubert Leufkens, Chairman of MEB, and witnessed by Dr Amy Khor, Minister of State for Health and Manpower, Singapore, the MOU will advance collaboration between the two regulatory agencies.

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- **About the Health Sciences Authority (HSA)**

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit http://www.hsa.gov.sg/.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

- **About HSA's Health Products Regulation Group**

The Health Products Regulation Group (HPRG) of HSA ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.