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**HEALTH SCIENCES AUTHORITY
PRESS RELEASE**

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HSA HOSTS INAUGURAL WHO-UMC-HSA BASIC PHARMACOVIGILANCE TRAINING FOR ASEAN HEALTH PRODUCTS REGULATORS

The Health Sciences Authority (HSA) welcomes members from ASEAN to the inaugural WHO-UMC-HSA Basic Pharmacovigilance Training from 31 May to 4 June 2010. This event marks the first tailored training on pharmacovigilance developed for ASEAN health products regulators, and HSA is proud to partner the World Health Organisation (WHO) and the Uppsala Monitoring Centre¹ (UMC) to jointly organise this regional event.

2 Participants² from the ASEAN countries could expect to build up their capabilities and knowledge on pharmacovigilance, learning from the insights and experiences of internationally-renowned experts, local clinical experts and HSA's pharmacovigilance trainers. Topics selected for the training reflect not only the current issues of today, but trends and developments that will shape the practice of pharmacovigilance in the future.

Why Pharmacovigilance?

"Not all hazards of a drug can be known before it is marketed"

- *Report for 1969-70 by the UK Committee on the Safety of Drugs*

3 As pharmacological agents, all medicines have benefits and risks. It may take several years after a drug has been marketed to know its full safety profile. Hence pharmacovigilance, which involves the detection, assessment, understanding and prevention of adverse drug reactions, is a key tool for drug regulatory authorities to continually keep a watchful look on the safety of drugs in the market.

4 Through analysis of adverse reaction reports received, health regulatory authorities could take prompt action to reduce the risks if a certain drug is deemed to have its risks exceeding its benefits. The actions could range from drug withdrawals, product insert amendments to update the risks, communication to doctors and/or public.

Tailored-Training for ASEAN

5 During the 24th meeting of the ASEAN Working Group for Pharmaceutical Development (AWGPD)³, ASEAN Member States identified the need to build their capabilities in pharmacovigilance. According to a survey conducted by HSA, ASEAN Member States recognised the importance for a robust pharmacovigilance system in their respective countries, with many expressing a need to be trained in this area.

6 Participants of this WHO-UMC-HSA Basic Pharmacovigilance Training would familiarise themselves with theories and best practices on PV activities, involving know-how to attract reporting, manage safety reports, and communicate safety information. Unique to the region, the course curriculum also includes topics such as safety monitoring of traditional medicines and challenges in tracking product quality, as well as the fight against counterfeit and adulterated complementary health products.

7 “The forthcoming training is well aligned with WHO's ambition to exploit regional expertise for regional development in pharmacovigilance. The course will adapt the PV training package of WHO and UMC, to address current needs and priorities in the safety monitoring of medicines in ASEAN countries. Singapore joined the WHO Programme for International Drug Monitoring in 1993 and has an impressive track record in pharmacovigilance in the region. The HSA is thus the ideal host for what we hope is the first of a recurrent and regular training event in pharmacovigilance for ASEAN countries”, said Dr Shanti Pal, Acting Programme Manager (Pharmacovigilance), WHO.

Enhancing Drug Safety in the Region

8 Most ASEAN Member States have unique and relatively small regulatory set-ups, compared to large regulatory agencies in Europe and America. Pharmacovigilance activities were previously ranked lower in priority as compared to other activities such as drug registration and quality audits, largely fuelled by the lack of resources to run these activities. In the recent decades, with greater recognition of drug safety issues (and their impact on public health) and higher expectations from the public, ASEAN regulatory authorities have also advanced in the area of pharmacovigilance and see the need to enhance training for their new recruits to cope with the expanded pharmacovigilance activities in each country.

9 Said Dr John Lim, CEO of HSA, “Beyond developing and strengthening regional capabilities in pharmacovigilance activities such as adverse drug reaction monitoring, Singapore hopes to take this chance to provide a forum for ASEAN delegates to network and share their experiences or problems encountered in the area of drug safety monitoring. This inaugural training course will potentially serve as a springboard for future collaborations in the area of pharmacovigilance among ASEAN member countries to enhance drug safety in the region.”

¹**Uppsala Monitoring Centre (UMC)** is the WHO Collaborating Centre for International Drug Monitoring and is responsible for the management of WHO Programme for International Drug Monitoring. To date, there are a total of 98 member countries in this WHO Programme.

²Participants are from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Thailand, Vietnam and Singapore.

³The AWGPD started off as a project originally called the ASEAN Technical Cooperation Project in pharmaceuticals involving ASEAN member states which serve to promote mutual development with each member of ASEAN contributing expertise in some areas and acquiring skills in others. The primary objective of the AWGPD is to strengthen the pharmaceutical sectors in all ASEAN countries to ensure the sufficient and regular supplies of effective and safe essential drugs of acceptable quality.

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

The Health Sciences Authority (HSA) is a multidisciplinary agency that applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services, Applied Sciences, to protect and advance national health and safety. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. It operates the national blood bank, Bloodbank@HSA, securing the nation's blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit www.hsa.gov.sg.

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

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