

**KEYNOTE ADDRESS BY DR JOHN LIM, CEO HSA  
AT OPENING CEREMONY OF THE 18<sup>TH</sup> MEETING OF THE  
ASEAN CONSULTATIVE COMMITTEE ON STANDARDS AND  
QUALITY (ACCSQ) – PHARMACEUTICAL PRODUCT WORKING  
GROUP (PPWG),  
GRAND COPTHORNE WATERFRONT HOTEL, SINGAPORE, 9 JUNE  
2011**

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Dato' Eisah Abdul Rahman, Chair, PPWG  
Dr Yuppadee Javroongrit, Co-Chair, PPWG  
Mr Isagani Erna, Senior Officer, ASEAN Secretariat  
Distinguished ASEAN Delegates and Participants;  
Ladies and Gentlemen;

Singapore is honoured to host the ACCSQ PPWG meeting for the second time. On behalf of Singapore's Ministry of Health and the Health Sciences Authority, it is my great pleasure to extend a very warm welcome to all of you to the 18<sup>th</sup> ACCSQ PPWG Meeting. As ever, I am delighted to see many friends from around the region in our midst today, and would like to express my personal appreciation for your being here, and for the collegiality that we have shared in ASEAN harmonisation efforts over the years.

2. The initiatives and effort undertaken by the PPWG over the last decade have been remarkable. The working group is one of the longest standing in the region since its formation in 1998. It has covered much ground and made significant achievements to bring about the integration of the pharmaceutical sector through the harmonisation of technical requirements for pharmaceutical products in the ASEAN region. These efforts have resulted in the signing of the ASEAN Sectoral Mutual Recognition Arrangement (MRA) for Good Manufacturing Practice Inspection of Manufacturers of Medicinal Products in 2009, as well as the successful implementation of the ASEAN Common Technical Dossier (ACTD) and the on-going development of common technical guidelines for medicinal products.

3. The PPWG was established under the ACCSQ with the main objective of facilitating economic integration initiatives for pharmaceutical products without compromising their quality, safety and efficacy. This original objective has been augmented to enhance standards and quality of pharmaceutical products in ASEAN by the alignment of technical requirements to internationally recognised criteria and standards. The PPWG has therefore not only made headway in minimising technical barriers to trade, but the harmonisation initiatives have also enabled the strengthening of public health protection through ensuring better quality pharmaceutical products in the region.

4. With the tremendous milestones achieved so far, it is reassuring to note that ASEAN's drug regulatory authorities continue to work in very close partnership with one another and with the pharmaceutical industry to ensure the smooth functioning of implemented initiatives. I am also glad to note that the PPWG is exploring new areas for collaboration and harmonisation, and that a new technical working group will be established for biologic products. This is very important, given the emerging trend of biosimilar and biotechnology products. The timely establishment of this new technical working group, which is expected to bring together experts from the regulatory authorities and industry, signifies another major step in advancing the integration of the ASEAN pharmaceutical sector.

### **Perspectives from HSA**

5. In my capacity as Chief Executive Officer of Singapore's Health Sciences Authority (HSA), I am happy to share with you that this year (2011) marks an especially exciting year for HSA as we are celebrating our 10<sup>th</sup> year as a regulatory and scientific authority protecting and advancing national health and safety. Over the past decade, HSA has undergone significant transformation – strengthening professional expertise, putting in place organizational systems, growing significantly in international standing and fostering closer industry linkages. In this context, I would like to share a few perspectives of the key challenges faced by drug regulatory agencies in the globalised world. Many of these critical challenges can be more effectively overcome when countries work together to achieve the common goal.

6. HSA was established as a statutory board under our Ministry of Health in April 2001. It is a unique organisation that comprises three key professional areas. The Health Products Regulation Group (HPRG) is Singapore's national drug and devices regulatory agency, and is the organiser of this meeting. HSA also includes an Applied Sciences Group, which provides analytical chemistry and forensic science laboratory services and forensic medicine expertise. Certain laboratories support HPRG but the other CSI-type functions provide critical support for our law enforcement agencies and the courts. The third major area of HSA is the Blood Services Group which operates our national blood bank and is also involved in cell processing to develop therapeutic products. This unusual combination of expertise allows us to explore new scientific synergies and innovation across our professional groups. This will be spearheaded by our HSA Academy which has been established not so much to provide training as to promote discussions and symposia looking at new frontiers across HSA's areas of responsibilities. One project we are involved in with MIT is looking at whether the drug development paradigm can be approached in a new way.

7. Over the last four years, HSA has been on an intensive transformation journey to make us a stronger and more effective organization. We have been undertaking major human resource and business process re-engineering reviews across the whole of HSA. We have also injected additional resources into HPRG to enhance our ability to evaluate and regulate innovative products, in particular advanced therapeutic agents such as cell and tissue therapy. We have strengthened post-market activities such as pharmacovigilance, compliance monitoring and enforcement to enhance HSA's ability to detect potential problems and respond effectively to minimize the risks to public health. The strengthening of HSA is crucial in view of the many challenges faced by drug regulatory agencies such as ours today. Let me highlight a few of these challenges.

### **Challenges for Drug Regulatory Agencies**

8. While globalisation and the rapid advances in information technology have brought about many benefits and improved living standards of people in many countries, including ASEAN Member States, they have also brought about new challenges to public health and drug regulatory agencies. One key challenge is the increased complexity of the pharmaceutical and active pharmaceutical ingredients supply chain which is now seeing an increasing throughput of harmful, adulterated products and counterfeits. We need stronger regulatory networks to find solutions that can better tackle these problems and I am happy to note that the ASEAN Post-Market Alert System (PMAS) has extended its radar to capture counterfeit and adulterated products. This will enable timely sharing of alerts on such products among the ASEAN Member States.

9. Drug regulators must also keep up with research and innovation in medical technology. As an example, the traditional regulatory frameworks for chemical drugs are no longer adequate for new technologies. Regulators will always have to look into new areas of collaboration, taking into account safety, quality and efficacy, as well as ethics and conformance to global best practices. In this respect, the PPWG is in a strategic position to drive the development of regulatory standards for emerging pharmaceutical products in the region, through active discussion and collaborative efforts in establishing the necessary technical requirements and guidelines.

10. A third major challenge we all face is that of resources and capacity. This is where enhanced cooperation and collaboration across ASEAN Member States in terms of capacity building and more effective information sharing, can be fostered. Under the auspices of the PPWG, one of the areas of cooperation is in GMP inspection for manufacturers of medicinal products. The implementation of this MRA means that ASEAN Member States can leverage on the inspection performed by a Listed Inspection Service, thereby minimising duplication of effort by other Member States. This represents an effective way to address both resource constraints as well as the provision of technical assistance to level up the capacity in ASEAN Member States.

11. There are, of course, a variety of other challenges we face. However it is through meetings like this that we can draw on our collective wisdom to find innovative and effective ways to overcome the challenges that we face.

## **Conclusion**

12. In closing, I would like to thank the 18<sup>th</sup> ACCSQ PPWG Meeting Organising Committee for its commendable efforts in organising this Meeting, and wish all of you a very fruitful and productive meeting. To our ASEAN friends, I wish you a most enjoyable stay, and for those who enjoy shopping, do take advantage of the fact that we are now in the midst of the annual Great Singapore Sale!

13. Ladies and Gentlemen, I now have great pleasure in declaring the 18<sup>th</sup> ACCSQ PPWG Meeting officially open.

14. Thank you.