KEYNOTE ADDRESS BY DR JOHN LIM
CHIEF EXECUTIVE OFFICER, HEALTH SCIENCES AUTHORITY
AT THE OPENING CEREMONY OF
THE 25TH MEETING OF THE ASEAN WORKING GROUP ON PHARMACEUTICALS DEVELOPMENT (AWGPD)
TUESDAY, 3RD NOVEMBER 2009, 10 AM
AT MERITUS MANDARIN HOTEL, SINGAPORE

Distinguished ASEAN Delegates and Participants;

Dr Bounpheng Philavong, ASEAN Secretariat;

Ladies and Gentlemen;

Good Morning.

It is a great pleasure for Singapore to host the 25th Meeting of the ASEAN Working Group on Pharmaceuticals Development (AWGPD). On behalf of Singapore's Ministry of Health and the Health Sciences Authority, I warmly welcome all of you to our garden city. I think it is a tremendous achievement that this gathering has been meeting for the past three decades to foster understanding and collaboration on technical issues in drug regulation across our region.

2. When I used to be Director of what was previously HSA's Centre for Drug Administration, I attended a number of ASEAN meetings, including the AWGPD Meeting, and I still hold fond memories of the warmth and hospitality of the different host countries around ASEAN. I hope your stay in Singapore over the next three days will be similarly fruitful and enjoyable.

ASEAN's Commitment to Regional Cooperation and Integration

3. When ASEAN was founded in 1967, the original founding members defined the shared vision to form a regional grouping that would represent "the collective will of the nations of Southeast Asia to bind themselves together in friendship and cooperation and, through joint efforts and sacrifices, secure for their peoples and for posterity the blessings of peace, freedom and prosperity". This is a noble and inspiring sentiment that continues to form the basis for all we do as a regional grouping.

4. ASEAN has since grown not only in terms of the number of member states but also the commitment to deepen regional cooperation and integration. The signing of the ASEAN Charter by the ASEAN leaders in November 2007 was the beginning of a new phase to develop a more integrated community. The goal of the ASEAN Charter represents the commitment for our region to "unite under One Vision, One Identity and One Caring and Sharing Community". This was reaffirmed at the 15th ASEAN Summit recently held in Thailand on 23 Oct 2009.

5. Your gathering together today from nine of our ASEAN member countries will allow for diverse views to be heard and make the discussions and interaction rich and meaningful.

Perspectives from HSA

6. In my capacity as Chief Executive Officer of Singapore's Health Sciences Authority (HSA), I thought it would be useful for me to give you a brief overview of my organisation and in that context, share a few perspectives of the key challenges faced by drug regulatory agencies in the globalized world. Many of these critical challenges can be more effectively overcome when countries work together to achieve the common goal.

7. 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 organizer 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.

8. Over the last three 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

9. While globalization 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 API supply chain which is now seeing an increasing throughput of harmful, adulterated products and counterfeits. While the problem of counterfeit products has been around for a long time, it is no longer confined to developing countries but is now also posing problems in developed countries with robust regulatory systems.

10. WHO has spearheaded a critical initiative through IMPACT, or the International Medical Products Anti-Counterfeiting Taskforce, of which Singapore is currently the co-chair. As you are aware, this Taskforce, created in 2006, has been active in forging international collaboration to seek global solutions to the global challenge of counterfeits and raising awareness of the dangers of these products. Regulatory systems, legal frameworks, and the interactions amongst and across key national and international agencies need to be better strengthened to more effectively deal with the growing problem of sub-standard, adulterated and counterfeit products. While public health protection agencies aim for innovation, criminal networks can be even more innovative because of the high monetary rewards. We need stronger regulatory networks to find solutions that can better tackle these problems and more effectively safeguard our populations. I am happy to note that the AWGPD has already initiated a project on “Counterfeits”, and I hope that the meeting will have a productive time discussing and sharing information on strategies that can be used to combat this serious public health issue.

11. Another challenge relates to advances in information technology. We all know that while technology can have strong multiplier effects in tackling public health problems and improving our healthcare systems, technology can also be abused. The prime example and problem is of course the supply of prescription drugs and controlled substances over the Internet.

12. We are all facing the problem of increased personal purchases of medical products of dubious origin from Internet websites. HSA has issued a number of public advisories to educate the public on the risk of purchasing drugs from overseas websites as the quality and safety of the products cannot be ascertained. But this needs to be an ongoing effort as Internet websites can also be extremely attractive and convincing in their web content to unsuspecting or naïve visitors. Here again, collaboration amongst relevant agencies within countries and across regions is one critical way forward to deal with this challenge, especially when it comes to tackling the source of such websites, since these are often sited outside our national jurisdictions.

13. A third major challenge we all face is that of resources and capacity. This is where enhanced cooperation and collaboration across our member states in terms of better and more effective information sharing can help to deal with resource constraints. Our agencies have always been very active in supporting one another through assistance and sharing of good practices, and we should continue to leverage on the regulatory decisions and findings of one another. A critical area of cooperation is in pharmacovigilance, since enhancing our post-market information sharing is an effective way to address our resource constraints that limit our ability to carry out in-depth pre-marketing assessments that large agencies like the US FDA do. Adopting a risk-based approach and focusing on health products and issues with highest risk is clearly the way to move ahead, supported and strengthened by proactive and up-to-date sharing of adverse event information we detect in our different countries.

14. In the context of this Working group, Singapore will be coordinating the pharmacovigilance development programme and is in discussion with WHO and the Uppsala Monitoring Centre on the organization of group training for ASEAN in 2010. I am happy that we will be able to share the experiences gained and lessons learnt with our friends in ASEAN.

15. There are, of course, a variety of other challenges we face, for example, in better and more effective ways of communicating an understanding of the risk-benefit profiles of health products to our populations. But I would like to highlight that perhaps what is most important for all of us as drug regulatory authorities, is to ensure that we are always individually and collectively looking for ways to improve and enhance our systems. Sometimes, we think that all the innovations can only come from large and developed regulatory authorities such as the US FDA. While we certainly can learn much from others, we should not underestimate how we can also find new solutions to old and emerging challenges as we pool our thinking on operational and strategic issues. Through meetings like this, we can draw on our collective wisdom to find innovative and effective ways to overcome the challenges that we face.

Conclusion

16. In closing, I would like to inform you that in collaboration with WHO, HSA will be hosting the next International Conference of Drug Regulatory Agencies (ICDRA) in Singapore in the first week of December 2010. This will be the fourteenth meeting of ICDRA and will mark the thirtieth anniversary since WHO first started this important gathering. I have personally found ICDRA to be a very useful regulatory forum where key officers of drug regulatory agencies from all over the world are able to meet one another and discuss current and topical issues of global concern. I hope all ASEAN member countries will be able to participate in the next ICDRA and I would like to extend my personal invitation to your agencies to visit Singapore for this meeting next December.

17. On that note, I would like to thank the ASEAN Secretariat for facilitating the meeting and once again, I wish all of you success in your deliberations and a most enjoyable stay in Singapore.

Thank you.