WELCOME REMARKS BY A/PROF JOHN LIM,
CEO, HEALTH SCIENCES AUTHORITY
AT THE OPENING SESSION OF THE
HPRG HEALTH PRODUCTS REGULATORY CONFERENCE
ON 9 SEPTEMBER 2013 AT 9.00 AM
AT GRAND COPTHORNE WATERFRONT, GRAND BALLROOM, LEVEL 4

Good morning,

Professor Hubert Leufkens, Chairman of the Dutch Medicines Evaluation Board,

Professor Stephen Evans, Professor of Pharmacoepidemiology, London School of Hygiene and Tropical Medicine,

and all our Industry Speakers and Participants

1. On behalf of HSA's Health Products Regulation Group (HPRG), I would like to welcome you to HPRG's annual Health Products Regulatory Conference. It is heartening to see more than 500 of our industry stakeholders joining us at this year's forum.

Objectives and Scope of Conference

2. The key objective of this annual forum is to provide a structured platform for regulators to share information and provide the latest updates on local health products regulatory requirements. This year, we have taken further steps to strengthen this objective with an enhanced event programme. We are privileged to have distinguished international speakers from external regulatory authorities, academia, local partner agencies and industry players to share updates on global regulatory developments, industry best practices, as well as collaborative initiatives between regulators and stakeholders. This is part of HPRG's move to be "stakeholder inclusive", in line with its aim to be a trusted, informed and engaged regulator protecting and advancing public health.

3. We are honoured to have our close colleague, Professor Hubert Leufkens from the Dutch Medicines Evaluation Board deliver the first day's keynote lecture on global developments in regulatory science for ensuring public health and stimulating innovation. We are also delighted that Professor Stephen Evans from the London School of Hygiene and Tropical Medicine will enlighten us tomorrow on the opportunities, challenges and success stories of pharmacoepidemiology as a risk management tool in health product regulations. Mr Mark Paxton from the US FDA is not able to be physically with us, but has kindly pre-recorded his presentation on global developments in supply chain integrity and security.

4. We are also happy to have Mr Kevin Lai from the Singapore Economic Development Board to update us on the developments in Singapore's biomedical science industry. In addition, we look forward to hearing from respected leaders representing the life sciences and medical technology industry associations. They will share collaborative regulator-industry initiatives to enhance understanding of our health products regulations, facilitate Singaporeans' access to health products and treatments, and promote innovations to boost industry competitiveness.

5. On the regional front, HPRG and our industry partners are actively involved in regional collaborative platforms such as the Medical Device Product Working Group (MDPWG) and the Pharmaceutical Product Working Group (PPWG), both of which function under the ASEAN Consultative Committee on Standards and Quality (ACCSQ). Working closely with our ASEAN regulatory partners to harmonise technical regulatory requirements is part of the overarching government objective to facilitate trade and market penetration of locally-grown enterprises in ASEAN. Updates in these areas will be provided at this conference.

Engaging and Enabling Industry Stakeholders

6. We live in interesting and exciting times. The world is getting increasingly interconnected and the health products landscape is fast expanding in diversity and complexity. Innovative drugs and new medical technologies continue to blur the lines between product categories, posing challenges to traditional regulatory frameworks.

7. Added to that are higher expectations from the industry, healthcare professionals and patients. The expectation is for shorter time-to-market and quicker access to new and innovative therapies. This has to be balanced with the need to support efforts to manage healthcare costs, and to deal with the realities of doing business in a small market like Singapore that is nonetheless significantly plugged into wider regional and international markets.

8. HSA's mandate is to protect and advance national health and safety. But to effectively respond to the environment we operate in, and to ensure that our regulatory expertise is both top notch and relevant, HSA - and HPRG in particular - must continue to engage our stakeholders to strengthen and streamline our frameworks and policies.

9. This explains the choice of this year's conference theme - ***'Enhancing Scientific and Regulatory Collaboration in Safeguarding Public Health'***.

Review of the Past Year

10. In the past year, HPRG has been working hard at strengthening communication and collaborations. With feedback from various forums and conferences, several new initiatives were reviewed and introduced to communicate better, facilitate faster access of health products, and lower regulatory costs while safeguarding public health and safety.

11. Let me share a few here.

Improving Communications

12. HPRG has stepped up engagement with healthcare professionals, academic institutions and the industry through regular forums and dialogue sessions. These include roadshows on adverse event reporting of medical devices and Traditional Chinese Medicine (TCM) to healthcare professionals, TCM physicians, herbalists and TCM students.

13. A Hospital Liaison Officers (HLO) programme was also set up. This is a new initiative to address issues on medical device access and encourage adverse event reporting. These face-to-face engagements have enhanced our stakeholders' understanding of health products regulations, and at the same time, allowed HPRG to hear and better appreciate their concerns.

14. In addition, the inaugural issue of NEX2US, the newsletter to connect with our partners, was launched in May 2012 to keep industry partners abreast of the latest regulatory developments, updates and events. This will be produced three times a year. We hope that you have been enjoying this newsletter and have found it informative and useful.

Enhancing Processes and lowering costs

15. We are mindful that any regulatory requirements will have implications on product cost and accessibility. Without compromising public health and safety, HSA aims to constantly streamline and simplify our processes. We have taken steps to further enhance the regulation of medical devices by reducing the time required for the review process and lowering regulatory fees. Importers and wholesalers dealing solely with low risk Class A medical devices no longer need require a Good Distribution Practice for Medical Devices in Singapore (GDPMDS) certification issued by an accredited third party body. This means 30% less documentation and lower costs for these dealers. In addition, applicants of minor variations applications (MIV-2s) no longer need to wait for 40 working days after submission before they can implement the proposed changes. All these initiatives have been implemented following engagement and communication with industry associations

Enhancing international collaboration

16. Our collaborative work extends beyond Singapore. HSA continues to strengthen our global network with strategic partnerships that leverage and focus collective resources in a more effective, coordinated and sustainable manner. To be better aligned with the latest regional and international developments of regulatory science, HSA has signed Memoranda of Understanding with Malaysia's National Pharmaceutical Control Bureau (NPCB) and the Dutch Medicines Evaluation Board (MEB) in the past year. These add to our extensive network of partners and facilitate mutual exchange of information and co-operation in the areas of strengthening regulatory science and work-sharing.

Going Forward into the Future

17. In spite of these new and ongoing initiatives, we would still like to do more. From next year, we will be intensifying engagements through a series of "**HPRG Dialogues**" to better review and refine our regulatory policies and

frameworks for health products with all of you. I am hopeful that with these collaborative dialogues and engagements, we can collectively enhance our health products regulatory landscape, streamline our systems, and better advance our public health goals to the benefit of our patients.

18. My regulatory colleagues aim to be more proactive in engaging with industry and healthcare institutions to better understand and review practices on the ground. They would also like to keep abreast of the latest scientific developments that can improve the evaluation of latest health products submitted for product evaluation and registration in Singapore. Please give your time and support to my regulatory colleagues as they visit you so that we can develop and refine policies that better reflect the concerns that you face.

19. In the year to come, we will also further involve industry in **advisory committees**, to leverage on your expertise in co-creating solutions that reflect real and relevant perspectives and needs. Such strategic engagement is especially important in the dynamic environment we work in today.

20. One of the successful examples of such collaboration was seen in the review of the sale of Chinese Proprietary Medicines (CPM) containing berberine in Singapore. Following close collaboration and consultation with our expert committee that comprised TCMP practitioners, medical and pharmaceutical expertise, HSA worked with the Ministry of Health to lift the ban on such medicines through a phased approach from 1 Jan this year. At the same time, an active post-market monitoring programme was also instituted with sufficient safeguards in place to address underlying risk issues.

Conclusion

21. In HSA, we believe that when we improve the quality of our working relationships, this invariably strengthens the quality of our collective thinking, enhances the effectiveness of our follow through actions, and significantly increases the impact and quality of the results.

22. However, relationships are built on trust and this requires open communication and transparency in sharing information with each other. This is the rationale for all I have shared with you on HPRG's approach to open and consultative engagement with our stakeholders. Through the various interactive platforms, we hope you will also share with us your honest opinions and constructive feedback to yield win-win solutions in a collegial and collaborative eco-system.

23. We would now like to screen a video clip of HPRG's past initiatives. These reflect a pro-enterprise stance embody HSA's Core Values of serving the nation, being passionate about excellence, developing our people, inspiring trust, and living innovation, exemplified through the new channels of stakeholder partnership.

24. On that note, I wish you a fruitful and productive conference.

25. Thank you.