OPENING ADDRESS FOR TOWN HALL SESSION
WITH MEDICAL DEVICE INDUSTRY
BY DR AMY KHOR, MINISTER OF STATE (HEALTH)
AT SPRING AUDITORIUM
20 APRIL 2012 (FRI), 2.30PM

Good afternoon

Mr George Huang, President of the Singapore Manufacturers' Federation;

Associate Professor John Lim, Chief Executive Officer, Health Sciences Authority;

Distinguished Guests;

Members of the Medical Device Industry.

Introduction

1. I am pleased to participate in this Town Hall session for a discussion on the medical device regulatory landscape in Singapore with all of you.

2. I would like to thank the Singapore Manufacturers' Federation for organising and hosting this Town Hall. This session is an important platform to facilitate interaction between industry and the regulators, to share the latest initiatives in response to feedback, and also to gather ideas for moving forward.

3. 1 January 2012 was a key milestone when the regulation for all risk classes of medical devices was fully rolled out. Four months into the New Year is therefore an opportune time to take stock on the phased

implementation of the medical device regulations that started with the introduction of the Health Products Act in 2007.

Why Regulation?

4. Health products regulation is important to ensure public health and patient safety. This is the cornerstone of HSA's mission, and forms the fundamental tenet of our medical device regulatory framework. The framework adopts a risk-stratified approach and is based on the internationally benchmarked principles of the Global Harmonisation Regulatory Taskforce (or GHTF). The GHTF is a regulator-industry partnership founded by the EU, US, Canada, Australia and Japan to harmonise national medical device regulatory systems. Singapore's HSA has observer status at the GHTF, participating in discussions as a representative of both ASEAN and the Asian Harmonisation Working Party.

5. It is vital that Singapore has a robust risk-stratified regulatory framework in place to assure patient safety, all the more given the pervasive use and rapid technological advances of medical devices at all levels of health care delivery.

6. You will be aware of major recalls of medical devices in other countries in recent years. These have included heart defibrillators, artificial hips and breast implants. This underscores the importance of a sound, rigorous regulatory framework to ensure that only medical devices of good quality, safety and meeting required performance standards are allowed into the market. For example, a patient who receives a cardiac pacemaker implant would want the

device to perform reliably for the years that it remains in the body. Failure of such devices can have life-threatening consequences. Even simple medical devices, such as contact lenses, if not properly made or used, could lead to lifelong disability and blindness with huge public health impact if product penetration to the population is extensive.

7. HSA has faced a number of challenges in being the first country in ASEAN to roll out a medical device framework. Medical devices cover a wide range of products, and their classification and regulation can be complex and not always intuitive. This also comes at a time when regulatory systems in major markets such as the United States and Europe are under pressure to tighten medical device regulation, after highly publicised device recalls. Many "FDA-approved" devices go through an expedited process instead of more thorough evaluation. This has come under criticism by independent bodies because it allows manufacturers to cite devices already in the market for the same use, but this per se does not always give an accurate picture of safety or effectiveness.

8. On the other side of the Atlantic, the European system has been criticised for the wide variation in standards amongst commercial certification bodies in different EU countries and the lack of public access to pre- or post-market data. In view of these issues, HSA has chosen, as a starting point, to adopt a more cautious regulatory approach when adapting best practices from developed countries. The aim has been to leverage on the regulatory decisions of reference agencies to avoid duplication of review, while maintaining

appropriate independence of regulatory decisions if there are potential safety concerns.

9. In implementing the framework, HSA has drawn upon the experience of regulating western medicines over the past twenty years. It appreciates the potential teething issues that all stakeholders - importers, wholesalers, manufacturers, doctors and the regulator itself - experience when moving from a non-regulated environment to a regulated system of dealer licensing, product registration and post-market surveillance. This was the reason for a phased approach introducing controls in stages over the past 4 years. The system has also provided a Transition List and Special Authorisation Routes to ensure that access to devices is not impeded while evaluation is ongoing. HSA also puts industry engagement as a priority in its device regulatory regime.

10. Since 2007 when the first phase of medical device regulation started, HSA has held more than 60 communication sessions to help guide and explain to stakeholders details about the roll out of the regulations. Over the past 6 months, in response to industry feedback, HSA has intensified its engagement with more focus groups and dialogues with industry, medical device associations, doctors, dentists, academia and hospital purchasing departments. This has been helpful to gather feedback for a holistic review of the regulations after full implementation, and allow more fine-tuning and enhancement of the framework.

11. I am assured that HSA will be flexible and respond to feedback, while not compromising its commitment to safeguard public health and patient safety. No regulatory framework can be cast in stone, especially in a complex area like medical devices. It will continue to require constant refinement and tweaking even after introduction of the full regulatory framework earlier this year.

Key Concerns and Proposed Solutions

12. Through its recent engagement sessions, HSA has informed me that it has noted several key concerns. These include:
    a) Uncertainty of the market viability of a medical device after investing in product registration, primarily due to Singapore's small market size;
    b) Longer-than-expected approval timelines, which could pose obstacles to the introduction of innovative devices in order for Singapore to remain at the forefront of healthcare technology;
    c) Relatively high registration costs for certain niche devices in relation to their annual turnover, due to the lack of a more refined regulatory cost structure;
    d) Why the need to "re-invent the wheel" when registering devices already approved by reputable agencies such as US FDA and EU; and
    e) A high rate of obsolescence within a short timeframe due to the relatively short product life cycle of medical devices, compared to drugs.

13. I want to assure participants and all stakeholders in the healthcare industry that HSA acknowledges these as valid concerns. More

details will be shared in the later presentation but essentially, HSA is introducing further stratified clearance and initiatives to address these concerns. This is still based on a sound risk management approach so that within each risk class of devices, there can be further streamlining of clearance, whilst ensuring the safety of existing and new devices to meet the clinical needs of our patients. The initiatives seek to simplify the regulatory process to reduce cost and processing time and facilitate access to medical devices without compromising on patient safety.

14. Firstly, with effect from 1 May 2012, HSA will exempt all the lowest risk Class A devices except for sterile devices. This will cover about 2,700 Class A product types, in addition to the 2000 products types exempted earlier. The net effect is that 80% of Class A device types will be exempted. In addition, sterile devices with the CE mark will be cleared faster.

15. Secondly, as cost issues have been a key concern to industry, HSA will continue to review its fee framework to better stratify the regulatory fee structure for devices. The first step will be to review the fees for low cost, low volume devices that are brought in through the Special Authorisation Routes. These allow products yet to be registered to be brought in for patient use under the responsibility of a doctor. The lower tiered fee for low cost, low volume devices under special authorisation is targeted for implementation on 1 August 2012.

16. Thirdly, judicious referencing of reputable agencies will be used to expedite clearance for Class B devices, as the processing time to

register such devices has been identified as a major hurdle for bringing in moderate risk products. Taking into account the tightening of medical device regulations in agencies like the US FDA and EU, HSA has assessed that a good way forward is to reference approvals given by reputable independent agencies and market history of safety for these products to further expedite clearance. The reference agencies for this purpose would be the US FDA, EU, the Australian TGA, Health Canada and Japan.

17. Two additional faster access routes with lower fees will thus be introduced for moderate risk Class B devices from 1 Sep 2012. The first is an immediate registration route for products approved by two of HSA's reference agencies and marketed without safety concerns for at least three years. The second is an expedited registration route for Class B devices that *either* have been approved in two of the reference agencies, *or* in one of those agencies and marketed in that jurisdiction or Singapore without safety concerns for at least three years.

18. The combined enhancements for Class B device clearance will impact more than 3,500 applications or about 85% of current Class B applications received. HSA will also continue to study potential extension of this approach using reference agencies and history of safety to the higher risk Class C and D devices in an appropriate way at a later date.

19. As no health product is 100% safe, these refinements will mean that more emphasis must be placed on post-market surveillance of devices to ensure that products remain reasonably safe for continued

use in Singapore. This is the same approach adopted in our medicines regulatory system.

20. Consumer education will also be stepped up significantly to educate the public on the medical device regulations and enlist their support to report any safety and performance issues to their doctors or to HSA directly. This is especially critical as Singapore moves into the next era of innovative healthcare for personalised medicine, genetic testing and home care where more consumer medical devices will be introduced to the market.

Working Together

21. As Singapore transits to a fully regulated environment for medical devices, it is inevitable that adjustments will need to be made by the various stakeholders. These regulatory transitions might involve adjustments to the way products are brought in. For example, dealers may need to change their business practices to check with more purchasers first before grouping their devices together under one application for more cost savings on the dealers' end. Also, non-institutional doctors could potentially band together to purchase a larger quantity of consumable devices.

22. HSA will also be working with the Singapore Manufacturers' Federation (SMa) to work out a possible "concierge service". This aims to provide companies with a range of services from pre-submission consultation, training to consultancy services, which will again help the companies with their pre- and post-marketing needs.

23. Going forward, HSA had initiated a stakeholder engagement campaign, with the slogan '*NEX^{2}US – Connecting with Our Partners'* to represent its commitment to collaborate and connect with its stakeholders. This will also be shared later on.

Conclusion

24. Let me conclude. I would like to thank you once again for your participation in this Town Hall event. I encourage you to provide your feedback so that HSA can work closely with you to further fine-tune its regulatory systems and processes leveraging on greater post-marketing surveillance, while ensuring that patients in Singapore continue to have access to safe, effective and good quality devices.

25. Thank you and I look forward to a most productive Town Hall.