WELCOME ADDRESS BY A/PROF JOHN LIM
CEO, HEALTH SCIENCES AUTHORITY, SINGAPORE
AT THE OPENING CEREMONY OF THE
4th PIC/S API EXPERT CIRCLE MEETING ON
"SUPPLY CHAIN MANAGEMENT OF
HEALTH PRODUCTS AND APIs"
12 OCT 2011, 9.30AM,
SWISSOTEL MERCHANT COURT, SINGAPORE

PIC/S API Expert Circle Steering Committee Members:

- Mr Doug Fenwick;
- Mr Chris Cullen;
- Mr Victor Garvin;
- Mr Cormac Dalton;
- Mr Lionel Viornery; and
- Mr Michel Keller;

Distinguished Speakers, Facilitators & Participants;

Ladies and Gentlemen.

Good morning and a very warm welcome to all of you.

Introduction

Singapore is honored to host the 4th PIC/S Expert Circle Meeting on Active Pharmaceutical Ingredients. This is the first time and also a historic milestone for a major PIC/S event to be jointly organized by two regulatory authorities - the Therapeutic Goods Administration (TGA) of Australia and the Health Sciences Authority (HSA) of Singapore.

2 Just as HSA is celebrating its 10th anniversary this year, I also understand that 2011 marks the 40th anniversary of PIC/S. Since it was set up in 1971, PIC/S has demonstrated leadership in promoting co-operation amongst member states to share quality standards for pharmaceutical manufacturing facilities. It is also notable that the US FDA joined PIC/S from the beginning of this year, and member states now have access to a greater body of inspection data of manufacturing facilities, including in the US.

3 The choice of topic for this fourth API Expert Circle meeting is highly-relevant for drug regulatory authorities in the current global environment. A product is as safe as its ingredients. This simple principle underscores the importance of API quality for the safety of medicinal products. There are no safe medications without safe ingredients. It is therefore a good trend that more regulatory authorities are recognizing the need for greater regulatory oversight over APIs.

Globalization and the Borderless World

4 Many leading global pharmaceutical companies have chosen Singapore as their global manufacturing base, operating multi-purpose plants with the capability to manufacture a wide range of active pharmaceutical ingredients and biologics.

5 As a global city state committed to free markets, Singapore appreciates the many economic and associated trade benefits associated with globalization and trade liberalization. At the same time, we are all aware that a more borderless world is also associated with new health challenges. In the first few years of the 21st century we have already encountered the emergence and threat of new infectious diseases such as SARS, H1N1 and Avian Flu, tainted dairy and food products, and – of particular significance to this gathering - adulterated, counterfeit and substandard health products and APIs.

6 As was noted by Dr Margaret Hamburg, US FDA Commissioner during her keynote speech at the PIC/S 40th Anniversary celebration in Geneva, “there is no longer such a thing as an American drug supply (chain)” but rather “global drug supply”. She highlighted that a “stunning” 80% of APIs used in US drug products originate from outside the US.

7 Coupled with this, the supply chain from manufacturers to consumers now comprises complex global distribution channels, both real and virtual. These involve multiple players, such as re-packagers, re-distributors, logistics providers, brokers and middlemen, as well as cyber pharmacies and online suppliers. This is further compounded by the challenges posed by differences in climatic zones, transportation modes, customs clearance and regulatory compliance – to name a few. As a consequence, health products are now more exposed to conditions that can adversely affect their quality, safety and efficacy. These include inappropriate transportation and storage conditions, and improper handling of products which can lead to mix-ups, cold chain breaks as well as

infiltration of substandard or counterfeit products into the legitimate supply chain. All these factors have made regulatory oversight highly challenging.

8 In Singapore, we are now developing a specific regulatory framework for the manufacturing, importation, supply, transport, possession and storage of active ingredients. This will enhance the distribution chain control of active ingredients to tackle the rising concerns of sub-standard ingredients, diversion and counterfeit.

9 It is therefore very timely and relevant that this meeting will be discussing the issues of counterfeit and falsified products, impurities and contaminants, and supply chain management of health products and APIs.

Falsification and Counterfeits

10 Related to the issue of falsification and counterfeits, HSA signed a Co-operation Agreement with INTERPOL in June this year. The follow through is targeted to coincide with the opening of INTERPOL's Global Complex in Singapore in 2014. Under this Agreement, HSA will work with INTERPOL to strengthen training in the investigation and testing of counterfeit medical products for law enforcement officers, as well as greater anti-counterfeit awareness, capabilities and skills sets for regulatory personnel from different authorities around the world.

11 In Singapore, we have recently detected an increase in counterfeit health products, including counterfeit contact lenses and internet sales of birth control pills devoid of the labeled hormones after testing in HSA's analytical laboratories. It is important for us to enhance and share intelligence on new trends of falsified or counterfeit APIs, so that authorities can tackle these early and holistically in order to protect public health and safety in our various jurisdictions.

12 When falsified APIs are not detected promptly, adverse outcomes can be significant within and across jurisdictions. One well known example is the heparin contamination incident in 2008 when around 150 deaths occurred after the manufacturer substituted oversulfated chondroitin sulfate for raw heparin. This contaminant was traced to 12 other different companies and found in heparin batches shipped to more than 10 countries. While the contaminant was first identified in the US, the recall of affected products was international in scope. This incident reinforces the critical need, amongst regulatory agencies around the world, to tighten GMP inspection programs, especially in APIs.

13 In addition, it is important that manufacturers ensure that their supply chains, both pre- and post-manufacturing, are reliable and trustworthy. A concerted effort is needed by all stakeholders involved in manufacturing and distribution channels to play their respective roles in assuring the quality and safety of products throughout the entire supply chain, with regulators maintaining close vigilance.

14 But how do we maintain close vigilance, especially when there are so many products in the market manufactured in so many different countries?

The Need for Closer Global Regulatory Collaboration

15 Ensuring GMP of APIs is the key to assuring the quality of APIs and therefore drug safety. PIC/S plays a pivotal role, by being an “aggregator” to ensure the quality of drugs and APIs through a high-functioning, co-operative arrangement among regulatory authority member states globally. By bringing member states together, opportunities are created to share ideas and information, and to exchange a wide variety of critical data, including inspection reports, recall alerts and reinforcing the vision of global drug quality. It also provides the platform to discuss science, brainstorm smart approaches for protecting our populations from falsified and potentially deadly products, and dealing with common challenges such as adequacy of resources. Coordinated global vigilance by all member states is clearly the way to advance global health and safety.

16 One good initiative in this regard is the successful pilot API collaboration involving the US FDA, TGA, EMA and EDQM (the European Directorate for Quality of Medicines), reported in August this year. Over the course of this 24-month pilot project, the participating agencies exchanged nearly 100 inspection reports and conducted 9 joint inspections of sites common to the 3 regions. This pilot project is an important stepping stone towards further global regulatory collaboration. Going forward, we look forward to such initiatives including PIC/S members in Asia – Singapore’s HSA Singapore and Malaysia’s National Pharmaceutical Control Bureau.

17 I am also sure that increasingly, more countries see the benefits of their regulatory authorities attaining membership of PIC/S. These benefits include reduced duplication of inspections, operational cost savings, and enhanced market access to more safe and high quality drugs.

Towards Quality Health Products and Supply Chain "Pedigree"

18 These beneficial outcomes are also significant for the wider healthcare systems in our respective countries. A continuous, uninterrupted supply of safe, efficacious and high quality health products contributes to good quality patient care and more effective disease treatment.

19 A robust and sound supply chain is associated with higher standards of healthcare, characterized by greater affordability of health products and less wastage. Achieving this requires each and every player in the supply chain striving to assure and maintain the quality of products from point-of-origin to point-of-use.

20 However, the pharmaceutical and health product industry faces considerable challenges in providing consumers with a timely and constant supply of high quality, yet affordable health products. With the widespread sourcing of materials and products from various geographical locations around the world, it is important that supply chain systems are able to ensure that only products from known origins and sourced from reliable suppliers and vendors reach patients and consumers. In line with this, there is a need for regulators to adopt a robust approach in assessing the impurity profiles of APIs. Purchases and business deals should not be driven by price alone, but also by the integrity and reliability of quality assurance in the supply chain. The global health products industry should enhance its capabilities to build up robust supply chain management systems.

21 In addition, through PIC/S, the adoption, strict enforcement and compliance of internationally harmonized GMP and GDP quality system standards by regulators can help to assure the preservation of medicinal product quality along secure supply chains after manufacture. Combining IT and technology, such as radiofrequency identification or RFID, together with current best practice, the pharmaceutical and healthcare industry can reap enormous benefits in the form of timely and uninterrupted supply of safe, high quality health products to patients and consumers. At the same time, the penetration of substandard, adulterated, falsified and counterfeit products into the supply chain can be prevented, and product recalls facilitated promptly, when the need arises. This will be a win-win-win outcome for industry, regulators and consumers.

Conclusion

22 In conclusion, because patient health and safety are at stake, we cannot afford to let up on our determination and efforts to enhance the integrity and robustness of the supply chain. You are all here today with the common objective to improve and strengthen the management of the global health product and API supply chain. Your ultimate objective is to assure the timely delivery of safe and high quality health products to patients and consumers around the world. With such a strong line-up of knowledgeable and experienced speakers and experts, I am confident that the networking, sharing of knowledge and exchange of ideas during this meeting will benefit regulators, the legitimate pharmaceutical industry, and of course, our ultimate target beneficiaries – patients and the general public.

23 Our HSA 10th Anniversary theme has been “Science Saves Life”. In that same spirit, I trust that the science undergirding your discussions over the next few days will generate fresh ideas, knowledge and skills to assure a safe supply chain that will save many lives in the years ahead.

24 On that note, and on behalf of TGA and HSA, I wish you all a fruitful and enriching API Expert Circle Meeting. It has been a pleasure collaborating with the TGA in this historic partnership to co-organize the 4th PIC/S API Expert Circle Meeting. May it set a trend for the future.

Thank you.