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HSA
Health Sciences Authority

FEBRUARY 2013

A Year *in* Focus
A Better Year Ahead

2013

HAPPY
CHINESE
NEW YEAR

3



A NEWSLETTER *for our* HEALTH PRODUCTS INDUSTRY & COMMUNITY

From the Editor-in-Chief

Dear Readers,

February is a month of fun, feast and celebrations when we bid farewell to the Dragon Year and usher in the Year of the Snake. Being the sixth sign of the Chinese Zodiac, the Snake displays the characteristic of being the enigmatic, intuitive, introspective, refined and collected animal among the Animals Signs.

Ancient Chinese wisdom says a snake in the house is a good omen because it means that your family will not starve.

To celebrate this festive occasion with our stakeholders, we are happy to share with you this special Chinese New Year edition of the NEX2US newsletter. In this edition, our CEO, Associate Professor John Lim, together with some of our Health Products Regulation Group (HPRG) staff would like to extend their Chinese New Year wishes and share their thoughts on service excellence. At the same time, we would like to share some quick facts & figures on Chinese Proprietary Medicines (CPM), one of the regulated health products in HPRG. In line with our Chinese New Year theme, it will feature the number "8", which is traditionally believed to be an auspicious number (page 16).

Along this same theme, we have also dedicated two other articles pertaining to CPM on the lifting of the ban on berberine (page 4) and HPRG's outreach programmes to Traditional Chinese Medicine (TCM) institutions on adverse event reporting (page 15).

We would also like to recognise individuals from HPRG who have delivered quality service and exemplified service excellence behaviour. As such, I would like to cordially invite you to nominate the Service Icons of HPRG and share with us your feedback on how we can improve the delivery of our service to you as our valued regulatory partners.

As we usher in the Year of the Snake, I would like to take this opportunity to wish everyone peace, prosperity, happiness and great health for the entire year.

花开富贵喜临门
迎春接福庆丰年!

Yours sincerely,

Raymond



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A YEAR IN REVIEW

Top 10 HPRG stories in 2012

Refinement of screening checklists and Good Manufacturing Practice (GMP) certificate validity requirements to facilitate new and generic drug application submissions

February / March 2012

Announcement of a series of enhancements to the medical device regulatory framework

March - December 2012

Participation in Operation Pangea V by INTERPOL to target illegal online sale of unregistered, counterfeit and adulterated health products

September / October 2012

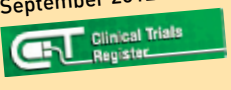
Hosting of the 19th PIC/S Expert Circle Meeting on Human Blood, Tissues and Cells – a first in Asia; Membership into the Steering Committee of the Expert Circle

October 2012



Launch of the HSA Clinical Trials Register

September 2012



Signing of Memorandum of Understanding with the National Pharmaceutical Control Bureau (NPCB), Ministry of Health, Malaysia and with the NUS Saw Swee Hock School of Public Health

March / October 2012

Outreach to Traditional Chinese Medicine Practitioners on regulations and adverse event reporting of Chinese Proprietary Medicines

May / November 2012

Launch of "NEX2US", HPRG's stakeholder engagement campaign focusing on the 5C's – Communication, Consistency, Collaboration, Collectivity, Collegiality

February 2012



Announcement on allowing the sale of berberine-containing Chinese Proprietary Medicines from 1 January 2013

September 2012

S'pore-KL drug regulation pact



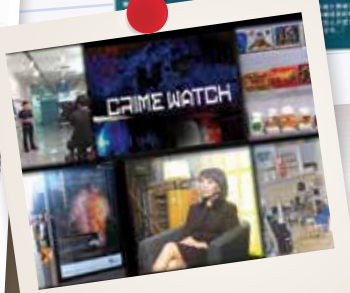
Mr Gan (third from right) and Dato Sri Lim (third from left) witnessing the signing of the MOU by Prof Lim (second from right) and Dato Ehsah A. Rahman (second from left). Senior Director of the Pharmaceutical Services Division, Malaysia. ST PHOTO: DESMOND WEE



Stepping up public education efforts –

- (i) Broadcasting of specially-commissioned episode of Crime Watch on the dangers of illegal sexual enhancement products and
- (ii) Launch of new public education campaign on the dangers of buying medicines from dubious sources

May / June and November 2012



Use of Naturally-Occurring Berberine in Chinese Proprietary Medicines

Industry players from the Traditional Chinese Medicine (TCM) community can now look forward to the re-introduction of naturally-occurring berberine to the existing commercial range of Chinese Proprietary Medicines (CPM) in Singapore.



With effect from 1 January 2013, the Health Sciences Authority (HSA) has allowed the sales of CPM containing berberine (小檗碱). Berberine is an alkaloid present naturally in herbs such as Rhizoma coptidis (黄连) and Cortex phellodendri (黄柏) that are commonly used in TCM, owing to their "heat-clearing" and "dampness-drying" (清热燥湿) properties in the body.

The prohibition of the use of berberine, as controlled under the Poisons Act, was first implemented by the Ministry of Health (MOH) in 1978, arising from local safety concerns that berberine could cause kernicterus, severe jaundice and brain damage in glucose-6-phosphate dehydrogenase (G6PD) deficient babies. Adverse effects such as nausea, vomiting and rashes have also been reported with the use of berberine.

Over the years, HSA had been working closely with its established panel of expert committees and MOH in monitoring the local situation and conducting ongoing scientific reviews on the safety profile of berberine. This included extensive literature review of scientific publications on the safety of berberine and its related adverse reactions as documented in other countries. Based on the recommendations of the Berberine Expert Panel and taking into consideration the sufficient regulatory safeguards over the years, such as the pre-market approval of CPM products and the mandatory registration of TCM practitioners, HSA decided to adopt a phased approach in lifting the prohibition of berberine use in Singapore.

For a start, the use of berberine containing CPM, e.g. finished dosage forms such as capsules, oral liquid preparations, powders and granules used by TCM practitioners, will be allowed.

In the absence of major safety issues, HSA will review the possible further lifting of the prohibition on Chinese herbs containing berberine by Year 2015.

With this phased approach in lifting the berberine prohibition, HSA will continue to monitor the situation closely for any occurrence of adverse reactions relating to the use of berberine.

HSA strongly encourages all stakeholders to highlight to their patients or customers that berberine should be avoided at all times in infants, G6PD deficient individuals of all ages, pregnant and breastfeeding women.

“Over the years, HSA had been working closely with its established panel of expert committees and MOH in monitoring the local situation and conducting ongoing scientific reviews on the safety profile of berberine.”

The Service ICONs of Health Products Regulation Group

HSA is committed to providing you with the best service possible. The Service ICONs of Health Products Regulation Group (HPRG) is a new initiative by HSA to recognise individuals from HPRG who have delivered quality service and exemplified service excellence behaviour.

If you have received exemplary service from any of our officers, please let us know so that they can be acknowledged and recognised as HPRG's Service ICONs.



Event Highlights

Medical Device Adverse Event Reporting Road Show to Healthcare Professionals

HSA rolls out continuing educational road shows to update healthcare professionals in health product regulations and safety issues. HSA also strongly encourages reporting of medical device adverse events from healthcare professionals.

Singapore is currently positioned as Number 1 in the submission of valid adverse drug reaction reports per million inhabitants to the World Health Organisation (WHO) global database from year 2007 to 2012 (WHO Uppsala Monitoring Centre Report October 2012). With this strong culture of safety reporting among healthcare professionals for adverse drug reactions, HSA urges healthcare professionals to extend a similar vigilance stance towards adverse event reporting for medical services.



Left to right: Beverly Liew (HSA), Lakshmi Devi Balakrishnan (HSA), Ho Swee Juan (HSA), Valerie Wee (HSA), Rayner Lee (Fortis Healthcare), Jocelyn Yen (HSA), Tan Wei Chuen (HSA), Dr Dorothy Toh (HSA)

Recognising that the approach to medical device risk detection and management is unfamiliar to most healthcare professionals and being significantly different from that of drugs, HSA seeks to reach out to healthcare professionals on medical device regulations and safety reporting. To achieve this, HSA will be conducting a series of continuing educational road shows to healthcare professionals. During the inaugural continuing education road show to Fortis Healthcare, HSA strongly encouraged healthcare professionals to report medical device adverse event to further enhance safety surveillance of medical devices.

“We would like to take this opportunity to welcome interested stakeholders to contact us and work out an engagement model to update your team of professionals on the medical device regulatory framework and share the mechanisms of medical device adverse event reporting by healthcare professionals. For more information on Medical Device Adverse Event reporting, please visit our weblink [here](#) .”


The continuing education road show was kicked-start by HSA’s Medical Device Branch which shared the basis and need for a medical device regulatory framework. HSA’s Compliance Branch then elaborated on the importance of reporting adverse events of medical devices and brought home the message that healthcare professionals play an important role in detecting medical device safety issues. The session was wrapped up by the Vigilance Branch which shared on the framework in place to manage medical device safety issues and how the Vigilance Branch had successfully managed the adverse drug reactions reports submitted to HSA through this existing spontaneous reporting framework.


Participants were given copies of Medical Device Adverse Event Reporting Forms, the Adverse Drug Reaction Bulletin and the NEX2US publication to enhance their understanding on health products regulatory and safety matters.

The session was well received with a good turnout of healthcare professionals from diverse backgrounds including bio-engineering, nursing and pharmacy. We received positive feedback and requests for HSA to share more on other aspects of our work.

The team found it rewarding to share on regulatory and safety knowledge to assist our stakeholders and partners in their work. We look forward to similar partnerships with other stakeholders as well.

You may submit your feedback through three ways:

Website portal  ¹ to access the Customer Service Feedback webpage

Download HSA’s ‘Customer Service Feedback Form’ via this  ² and email to HSA_HPRG_NEX2US@hsa.gov.sg

or mail the form to the following address:

Service ICONs of Health Products Regulation Group (HPRG)
NEX2US Newsletter, Health Products Regulation Group
11, Biopolis Way, #11-01 Helios,
Singapore 138667

Thank you.

Yours sincerely,
Dr Raymond Chua

Group Director
Health Products Regulation Group
Health Sciences Authority





Event Highlights

WHO-HSA Inter-regional Pharmacovigilance Training Course

The month of October marked a milestone event when over 40 participants, including more than 20 overseas delegates from ASEAN and the Asia-Pacific region (Brunei, Cambodia, Hong Kong, Korea, Indonesia, Malaysia, New Zealand, Sri Lanka, Thailand and Vietnam) gathered in Singapore to attend the WHO-HSA Inter-regional Pharmacovigilance Training Course held from 10 to 12 October 2012.



The Vigilance Branch with invited speakers Prof Hubert Leufkens (Utrecht Institute of Pharmaceutical Sciences & Chairman of the Dutch Medicines Evaluation Board), Dr Ruth Savage (Centre for Adverse Reactions Monitoring, New Zealand), Ms Jeanette Johanssen (Uppsala Monitoring Centre) at the WHO-HSA Inter-regional Pharmacovigilance Training Course

This training was jointly organised by the World Health Organisation (WHO) and the Health Sciences Authority (HSA), with participation from the Uppsala Monitoring Centre (UMC). Covering a series of advanced topics, it is a follow-up to the WHO-UMC-HSA Basic Pharmacovigilance (PV) Training which was conducted in 2010. The course aimed to equip participants with the necessary skills to further strengthen PV capabilities in the region, with particular focus on pharmacoepidemiology and data mining. These objectives were well aligned with WHO's and UMC's continual drive to communicate the importance of drug safety and PV among countries.

International and Local Panel of Speakers

Renowned experts in the areas of pharmacoepidemiology and data mining chaired the training sessions. These included i. Professor Hubert Leufkens, Professor of Pharmacoepidemiology Utrecht Institute of Pharmaceutical Sciences and Chairman of the Dutch Medicines Evaluation Board; ii. Dr Ruth Savage, Senior Medical Assessor at the Centre

for Adverse Reactions Monitoring (CARM), New Zealand PV Centre and Senior Lecturer at Christchurch School of Medicine, University of Otago, New Zealand; and iii. Ms Jeanette Johansson, Team Manager of UMC's Analysis Team. Dr Dorothy Toh, Director of Vigilance Branch, HSA, presented on HSA's PV and pharmacogenetics initiatives. The occasion was also graced by the attendance of Mr Daisuke Koga from the WHO.

Key Topics Covered

As technological advancements continue to facilitate the collection of large amounts of health data, regulators are turning to data mining tools and pharmacoepidemiology capabilities to analyse adverse drug reaction databases. Participants gained valuable insights on various aspects of data mining, including its application in signal detection, methodology, as well as interpretation of results. These were further illustrated with examples of actual signals picked up through data mining encountered by the speakers in the course of their work. Participants also had a hands-on session using

VigiMine™, a powerful data mining tool which analyses Individual Case Safety Reports (ICSR) from WHO.

Apart from these, the training covered pharmacoepidemiological principles, methods and applications. Participants were provided an opportunity to apply this knowledge as they worked on case studies and engaged in group discussions to formulate their own study designs. This was followed by a lively presentation session as participants critically reviewed each other's work.

Participants of the course were also introduced to pharmacogenomics, an area which is receiving increasing attention. Participants learned about how pharmacogenomics research is currently applied in PV work, the great potential that pharmacogenomics holds, and how this could be harnessed in the ongoing pursuit for patient safety.

Moving Forward

The training was well-received by participants and provided a unique opportunity for delegates across the region to interact and share their experience in PV work. As Associate Professor John Lim, CEO of HSA, shared in his opening speech, PV is a rapidly evolving and dynamic discipline, and it is crucial that we continue to develop and expand our capabilities. It is hoped that, armed with new knowledge and perspectives, participants would be empowered to enhance PV capabilities in their countries, and improve drug safety in the region. This sentiment was shared by the participants, who found the course well-organised and informative, and looked forward to applying the concepts gleaned from the lectures and breakout sessions in their respective areas of work.

19th Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) Expert Circle Meeting on Human Blood, Tissues and Cells

The Health Sciences Authority (HSA) successfully hosted the 19th PIC/S Expert Circle Meeting on Human Blood, Tissues and Cells at the Swissotel Merchant Court from 15 -19 October 2012. This was the first time this expert circle meeting was held in Singapore and in Asia.



Left to right: Professor James Isbister, University of Sydney, Australia; Dr Yoshiaki Maruyama, Pharmaceuticals and Medical Devices Agency, Japan; Dr Kellathur N. Srinivasan, Health Sciences Authority

In total, 66 participants and speakers, mostly from PIC/S participating authorities and other interested national drug regulatory authorities, attended this meeting. The aim of this expert circle meeting was to facilitate discussion and exchange of information among the regulators and inspectors, to develop and harmonise technical guidance documents and to provide training in the area of inspections of cell and tissue therapy facilities. In addition, this meeting also assisted in the building of mutual confidence through networking and workshop discussions amongst the participants.

In line with the theme “Advancing The Science & Regulations In Human Blood, Tissues & Cells”, the presentations in this meeting covered updates on:

- a. Scientific development in the area of stem cells and other emerging cellular therapies; and
- b. Regulatory development on the regulations and inspections of cellular therapies, including the regulatory framework for cell and tissue-based therapeutic products to be implemented in Singapore.

The three workshops at the expert circle meeting provided opportunities for participants to calibrate their understanding of the regulatory expectations of different countries and to share essential inspection experience and issues.

The workshop also provided a platform for participants to actively discuss and provide valuable inputs during the review of the draft PIC/S Aide Memoire for Inspection of Cells and Tissues, which was later compiled in a finalised aide memoire for submission to the PIC/S Secretariat.

The overall comments for this meeting gathered via the feedback forms ranged from very good to excellent. This greatly encouraged the organising committee. In addition, HSA accepted the invitation to join as a member of the PIC/S Steering Committee for the expert circle. Moving forward, the Steering Committee will continue to work towards the improvement and harmonisation of technical standards in the inspection of establishments involving blood, tissues and cells.



Left to right: Goh Choon Wee, HSA; Diane Maloney, US FDA; Alice van Sliedregt, Inspectorate of Healthcare Netherland; Gita Nayeri, Health Canada; Jessica Teo, HSA; Susanne Douglas, TGA; Dr Kellathur N. Srinivasan, HSA; Sivani Gopalan, HSA; Dr Ong Kang Teng, HSA; Diyanah, HSA; Sherilyn Zamani, HSA

Below: 19th PIC/S Expert Circle Meeting on Human Blood, Tissues and Cells, 15-19 Oct '12



Wishing Everyone Great Health, Prosperity & Longevity in the Year of the Snake

Associate Professor
Chan Cheng Leng
Deputy
Group Director
HPRG, HSA



"Wishing our stakeholders and partners in health products regulation a blessed new year. We will continue to strengthen our engagement with members of the industry and healthcare professionals."

Dr Raymond Chua
Group Director
HPRG, HSA



"Many thanks for all the collegiality and collaboration for the past year! Looking forward to a stronger engagement in 2013!"

Wishing all of you a very prosperous and successful Year of the Snake, filled with joy, wealth & health!

祝你们在新的蛇年生意兴隆，财源广进，龙马精神，万事胜意，好事连连，笑口常开！

Associate Professor
John Lim
Chief Executive Officer
HSA



"On behalf of HSA, I would like to wish all our stakeholders and partners in health products regulation a happy and fulfilling 2013!"

May I also take this opportunity to extend our Lunar New Year greetings for a harmonious and fruitful year ahead: 贺佳节平安如意，迎新年富贵吉祥！

We look forward to forging stronger ties with members of the industry and healthcare professionals through deepening our engagements, as we strive collectively to bring our regulatory framework and service standards to greater heights."

Dr Christina Lim
Senior Director
International Relations
HPRG, HSA



"To all our Partners, Friends and Colleagues in Singapore and Globally.... Wishing You a Wonderful Year of the Water Snake. May 2013 bring all of you better times, goodwill and success!"

NEX2US
Advisors



"I wish all a happy new year!"

In the new year, I look forward to continuing working closely with our stakeholders, in enhancing the robustness and transparency of the health products regulations and in our communications.

In working towards our goals of protecting and advancing public health, I wish all of us can continue to enjoy good health and harmony, and have a great year ahead."

Ms Lee Hui Keng
Advisor, NEX2US

HPRG Management & Advisors



"To build a true bond with our customers, service should be intrinsic and be displayed just the way we treat our friends and family.

New Year is a time when we reflect on what we had done, should have done and could have done. As we embrace the Year of the Snake with anticipation and appreciation, the Editorial Team is proud to share important regulatory information in this NEX2US publication and we hope all our stakeholders will be able to benefit greatly from it."

Ms Angie Tan
Executive Editor of NEX2US

"I would like to wish our HPRG stakeholders a Happy & Prosperous New Year 2013, filled with good health, abundant wealth and prosperity. May your business flourish with success, your home overflows with happiness, your mind filled with wisdom and a heart filled with peace!"

As HPRG embarks on another new year of health product regulation, we endeavour to continue engaging our stakeholders and strive to improve our service levels."

Ms Valerie Wee
Assistant Director
Service Management
& Industry Development Office
HPRG, HSA

HPRG Connects Centre staff



"Wishing everyone a Happy and Prosperous Chinese New Year in the Year of the Snake. With the arrival of a brand new year, I wish to be able to contribute to the HSA team in bringing up our Service Standards to a higher level. Our aim will be to provide high quality service to our Customers at all times!"

恭祝大家新年快乐，蛇年行大运。随着新的一年的到来，我希望能与卫生科学局全体同仁一起努力，提高我们的服务水平。我们的标准是提供高品质的服务！

Ms Ng Ling Ling
HPRG Client Liaison Officer

HPRG Client Liaison staff



NEX2US Editorial Team



In Conversation with Ms Ellen Woo

Our Partners in Regulation

HPRG's stakeholders span different segments of the health products industry. In this edition of our NEX2US newsletter, we feature the thoughts and insights of entrepreneurs and leaders of the clinical research, medical device and traditional medicine community.



Ms Ellen Woo, Director,
Global Monitoring
Operations, Parexel
International Pte Ltd and
Sumitra Sachidanandan,
Compliance Inspector,
Clinical Trials Branch,
HPRG, HSA

Ms Ellen Woo is a Director of Global Monitoring Operations at PAREXEL International Pte Ltd. She is responsible for overseeing the management of Phase I to IV clinical trials conducted in Singapore, Malaysia, Indonesia and Hong Kong.

Please share with us the challenges that you face when conducting clinical trials.

The conduct of clinical trials can be challenging given the complexity involved. Singapore benefits from a favourable ethics and regulatory environment with highly responsive agencies which significantly helps considerably in navigating through the complexities. However, as with many other locations, patient enrolment can be a challenge.

You have been dealing with HSA's Health Products Regulation Group over the last few years and witnessed many changes in processes and regulatory requirements in response to industry feedback. In which areas do you think HSA has done well, and where can we do better?

The Clinical Trials Branch (CTB) of the Health Products Regulation Group has performed well in engaging their stakeholders by being approachable and transparent.

Having had the opportunity to undergo Good Clinical Practice (GCP) inspections, I found the experience to be rewarding for the individuals involved and the company since the process actively helps stakeholders to continuously improve processes and achieve a high standard of quality.

The Pharmaceutical Regulatory Information System (PRISM), HSA's electronic module for all regulatory activities including license applications, has been used by the industry for almost 10 years during which time there has been significant change. It would be beneficial to see this evolve. For example, one improvement could be for HSA to incorporate access by third party service providers contracted by *Sponsors in PRISM given the rising trend in outsourcing of clinical trial activities.

**An individual, company, institution, or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial.*

How do you think you can help HSA as a stakeholder to maintain a good working relationship and foster reciprocal trusting regulator-stakeholder relationship that would serve as a platform for effective collaboration with mutually positive outcomes for both parties?

The regular communications from HSA in the Clinical Research Professional Forum are very informative. It would be beneficial to increase the frequency of stakeholder consultations conducted by HSA.

With the government's initiative to engage the public and stakeholders more in co-creating regulations and government policies, how do you think HPRG can best engage and solicit feedback from the industry?

HSA has successfully engaged industry stakeholders through forums. These interactions are very useful, providing ample time for stakeholders to digest new regulations and policies, raise feedback to HSA and initiate applicable changes within their companies in order to conform with new regulations.

How do you envisage the Pharmaceutical / Contract Research Organisation Industry will be like in the next 5 years, taking into consideration a better and trusted relationship between regulators and industry?

With the positive working relationship between HSA and its stakeholders along with a favourable Ethics and Regulatory environment, Singapore will continue to be a prime location for conducting clinical trials.

In Conversation with Mr Henry Tan

Mr Henry Tan is the founder and Group Managing Director of Alpha-Health Asia, a healthcare company that markets and distributes medical devices and aesthetic products in Singapore and the region. Henry is also the founder and current President of the Association of Medical Device Industry (AMDI).

Please share with us the challenges in running a small and medium enterprise (SME).

Regionalisation and staying competitive are critical to the success of an SME. While Singapore is generally considered to be a strong platform environment from which SMEs can spin off businesses into the region, challenges in navigating the local regulatory environment usually have negative ramifications on regional trade.

You have had many interactions with HSA and witnessed many changes over the last few years. In which areas do you think HSA has done well, and where can we do better?

In the past, the sentiment was that HSA lacked understanding of the industry. As a result, the regulations imposed were not industry-friendly and resulted in less-than-optimal consumption of resources.

In recent years, however, HSA has made tremendous effort to be more receptive to feedback, and adopted a more consultative approach when developing new policies. A positive example was the new approach to regulation of Class A medical devices.

Moving forward, I would suggest that HSA consider taking on a stronger thought leadership role e.g., in developing policies and standards, while looking to industry associations to enforce those standards. Such a collaborative regulatory approach is likely to garner more industry buy-in and promote “co-ownership” of the commitment to public safety and quality. This will, over the long term, be more effective in achieving the objectives of regulation.

How do you think you can help to foster a good regulator-stakeholder working relationship that would serve as a platform for effective collaboration with mutually positive outcomes?

Relationships are based on trust, which needs time to cultivate. It is my belief that with more dialogue and interaction, AMDI and HSA will eventually reach a mutual understanding of each organisation’s commitment to public health. On our part, AMDI has initiated discussions with SPRING to obtain support for regulatory capability and capacity building. This will equip us to better understand the standards expected by regulatory bodies, and assist our member companies attain those standards. We hope that by building a credible platform and standing, doors will open in future to trusted, win-win collaborative partnerships between AMDI and HSA for the good of the Singapore public.



Mr Henry Tan, President, Association of Medical Device Industry, and HSA interviewers Valerie Wee, Assistant Director, Service Management & Industry Development Office, HPRG (left) and Diana Koh, Regulatory Consultant, Clinical Trials Branch, HPRG (right)

With the government’s initiative to engage the public and stakeholders more in co-creating regulations and government policies, how do you think HPRG can best engage and solicit feedback from industry?

HSA’s regular focus group sessions, dialogue sessions, workshops, briefings, etc. are useful feedback and communication channels with industry. I would suggest, however, that HSA find ways to broaden outreach to the general trade, some of which may be dealing with medical devices but are unaware of regulations, or who have never been consulted about new initiatives. The trade associations may be able to assist with this outreach.

How do you envisage the Medical Device Industry will be like in the next 5 years?

Singapore-based SMEs will expand in ability to meet the high expectations and quality standards resulting from regional harmonisation. The assurance of quality will create opportunities for a greater presence of SMEs in the region and outside of Asia.

I also foresee more resources being invested in research and development by SMEs. This will spearhead further growth of the local medical device industry as companies are transformed from being mere traders of medical devices to innovators of medical devices.

In Conversation with Mr Cheong Wing Kiat

Left to right: Dr Raymond Chua, Group Director, HPRG, HSA;
Valerie Wee, Assistant Director, Service Management & Industry
Development Office, HPRG, HSA; Lee Li Lim, Senior Regulatory
Specialist, Complementary Health Products Branch, HPRG, HSA;
Mr Cheong Wing Kiat, Executive Director, Business Concept Pte. Ltd.



Mr Cheong Wing Kiat is a business owner, angel investor and executive of a portfolio of companies dealing with the development of a variety of health products, mainly Over-The-Counter medicinal products, Traditional Chinese Medicines (TCMs) or Chinese Proprietary Medicines (CPM), Traditional Medicines (TM), Health Supplements (HS) and Functional Foods. His products are sold through different supply channels, such as healthcare institutions, retail pharmacies, hypermarkets, medical halls and provision shops in Singapore and in over 20 other countries worldwide.

Please share with us the challenges that you face running a portfolio of SMEs.

There are many challenges in my job. Sustaining a profitable business and managing the different types of companies amidst the buoyancy of our economy and the complexity of our regulatory landscape are some of the challenges I face.

With regards to health product regulations in Singapore, I will say that the major challenges I face would largely be on matters pertaining to the classification, registration and obtaining Free Sale Certificates. In addition, CPM and TM products face stiff competition from other non-CPM and non-TM products such as Health Supplements and functional foods.

You have been dealing with HSA's Health Products Regulation Group over the many years and witnessed many changes in processes and regulatory requirements in response to industry feedback. In which areas do you think HSA has done well, and where can we do better?

I have been transacting with HSA, even during its time when it was known as National Pharmaceutical Administration (NPA), for over 17 years. It has been a long relationship with HSA. It had been challenging, especially during the early period. Communications between regulator and industry could have been better. Nonetheless, I would say HSA has made some improvements in the recent times.

I see that there are positive changes in the organisational direction and leadership in the Health Products Regulation Group (HPRG), HSA. It is now attempting to nurture 'T-shaped' professionals, who are able to engage both horizontally and vertically. These are people who not only understand the rules and regulations in the health product industry, but also have industry ethics, knowledge and experience. This is especially important when they become leaders who can be role models and exemplify a consultative communication approach with stakeholders. This is evident through the initiatives of the NEX2US newsletter which features face-to-face interviews with different industry players who provide both positive and negative feedback. This is definitely very critical in the 'new norm' where having frank conversations with stakeholders in an open manner is essential. I would say that there are positive shifts within HPRG towards being more pro-enterprise and customer-focused. This will result in even faster turnaround time for regulatory approvals.

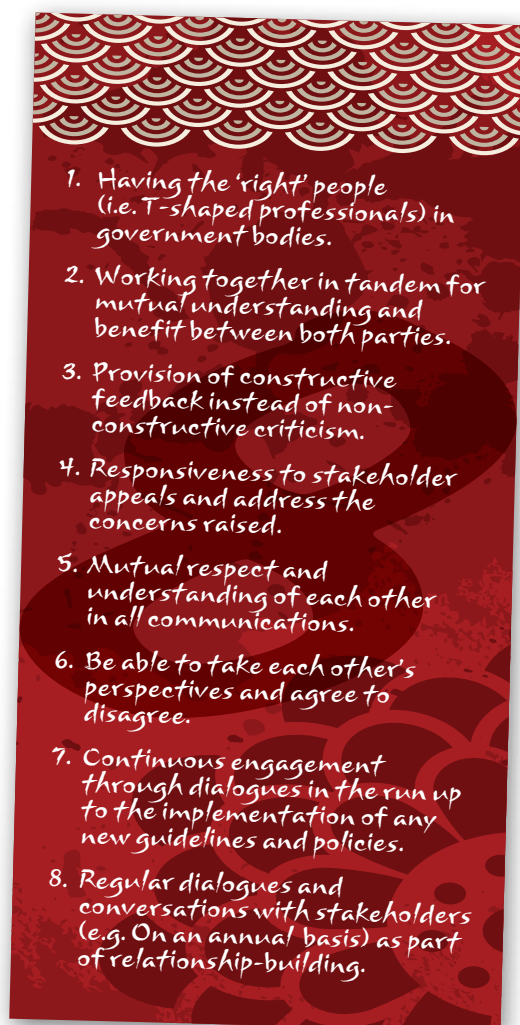
How do you think you can help HSA as a stakeholder to maintain a good working relationship and foster reciprocal trusting regulator-stakeholder relationship that would serve as a platform for effective collaboration with mutually positive outcomes for both parties?

There is a saying 'One needs to build good relationship, before one can maintain it'.

Building a good regulator-stakeholder relationship takes time and effort from both parties. Hence, it means that mutual respect is required to withstand possible strains that may occur. For example, implementation of new regulations and changes to regulatory guidelines may be

difficult for industry to adapt at times and it is natural for industry to complain and be unhappy with the additional regulatory costs and requirements before a product can be sold in Singapore. Hence, it is important for the regulator to gather feedback prior to and upon implementation of these new regulations in order to understand the issues faced on the ground and re-calibrate the regulations if need be.

I would like to suggest eight points in building and maintaining a good regulator-stakeholder relationship:

- 
1. *Having the 'right' people (i.e. T-shaped professionals) in government bodies.*
 2. *Working together in tandem for mutual understanding and benefit between both parties.*
 3. *Provision of constructive feedback instead of non-constructive criticism.*
 4. *Responsiveness to stakeholder appeals and address the concerns raised.*
 5. *Mutual respect and understanding of each other in all communications.*
 6. *Be able to take each other's perspectives and agree to disagree.*
 7. *Continuous engagement through dialogues in the run up to the implementation of any new guidelines and policies.*
 8. *Regular dialogues and conversations with stakeholders (e.g. On an annual basis) as part of relationship-building.*

I am glad that with my regular communications with the regulators, they had been open to listening to my feedback on the regulations for TCM, CPM, TM and Health Supplements.

With the government's initiative to engage the public and stakeholders more in co-creating regulations and government policies, how do you think HPRG can best engage and solicit feedback from the industry?

There are 2 main points which I would like to share on ensuring optimal engagement and soliciting feedback.

Having the Right People:

It is important for HSA to have the 'right' people both in leadership positions as well as on the ground. It is also equally important for the 'right' people to be in leadership positions in the health product industry. These would include board members of industry associations who would be in the position to represent industry players within this field comprising of suppliers and wholesalers of health products, retailers of health products as well as marketing and advertising agencies. Engagement is optimum when there is effective 2-way communication.

I strongly propose that for every company in the health product industry, depending on its size, to have at least one Certified Health Industry Manager (CHIM) approved by the association. CHIM can be a board member (i.e. director) or a staff working in the company. The CHIM of each company could be an industry association board or committee member and adhere to a set of ethical standards and practice endorsed by HSA, just like how SAPI (Singapore Association of Pharmaceutical Industries) has theirs too.

Having the Right Communication:

Having the 'right' form of communication is also important. Some of the ways that this can be done would be to conduct annual forum for CHIMs of health product industry on regulatory guidelines, changes and industry ethics. Holding public forums to educate consumers on health product safety, efficacy, limitations, and broad regulatory guidelines would also be something I am sure the public welcome.

As technology advances, we should evaluate, embrace and add new media platforms to communicate with CHIMs, industry stakeholders and the public if it allows better and more effective dissemination of information. Nonetheless, we should also be cognizant of the segment of the industry that are not internet-savvy and hence continue to ensure that this segment of stakeholders is not left behind.

How do you envisage the Traditional Medicine and Health Supplement Industry will be like in the next 5 years, taking into consideration a better and trusted relationship between regulators and industry?

Singapore and the world economy for the next 5 years remain uncertain and slow. I expect that there might be a dip in the economy in the next two years and this will not fare well for the industry. Hence, I foresee that there might be growth for the Health Supplement sector, but possibly a contraction for the Traditional Medicine sector. The net growth for both TM and HS combined will be marginal, if any.

Pro-Enterprise Survey 2012

The Health Products Regulation Group (HPRG) of the Health Sciences Authority (HSA) has been a regular participant of the annual pro-enterprise ranking (PER) exercise coordinated by the Ministry of Trade and Industry since 2004, and has benefited from stakeholder feedback through this channel.

Review of Rules
How often does the agency review its rules and whether it adopts the public consultancy approach for these revisions

Compliance Costs
All costs associated with licensing, project-based fees, and general compliance

Transparency
Clarity in administering the rules and regulations in the decision-making process etc

Pro-Enterprise Orientation
How friendly are the policies of the agency in nurturing new business ideas

Customer Responsiveness
Agency's awareness and responsiveness towards customer preferences

The key objective of the PER exercise is to measure and improve the effectiveness of current government initiatives in building a pro-enterprise regulatory environment in Singapore. It also identifies key areas of improvement and provides a benchmark for the 26 participating agencies.

Five benchmarking components were surveyed and measured, namely compliance cost, review of rules, transparency, customer responsiveness and pro-enterprise orientation. HSA has been rated well for the components "Review of rules" and "Transparency". The results also reflect that the key areas for HSA's improvement include areas relating to compliance costs and pro-enterprise orientation.



Inaugural Pro-Enterprise Panel (PEP)-Singapore Business Federation (SBF) Pro Enterprise Awards Ceremony, held on 28 Nov 2012. Photo courtesy of the Ministry of Trade and Industry.

"Workshops are held often to address concerns and seek knowledge from other experts. All communication modes are continually improved with respect to response time and availability as well as usage of the different modes."

"All the HSA officers are very helpful; they do their best to serve customers."

"Over the years, HSA has improved gradually and is more flexible with rules and regulations. It has a better understanding of the industry."

We would like to extend our appreciation to the stakeholders who have responded to the survey for their time and support. We will take into consideration all the feedback and look forward to collaborate and forge partnerships with our stakeholders as part of our continuous efforts to meet the needs of the industry, while safeguarding public health.

"HSA is very systematic, helpful in providing feedback and is informative. When HSA provides assistance, it is very detailed and easy for us to follow."

"HSA proactively interacts with the industry and tries its best to help out with the issues that customers are facing. There has been significant improvement in customer service over the past two years."

Regulatory Updates

Outreach Lectures to Traditional Chinese Medicine Institutions – “Orient”-ating TCM Practitioners on Regulations and Adverse Events Reporting Programme

As part of HSA’s ongoing efforts to promote understanding of the regulation of Chinese Proprietary Medicines (CPM) and reporting of adverse events associated with this group of products, HPRG’s Complementary Health Products and Vigilance Branches jointly conducted three outreach lectures in 2012.



The first lecture in May 2012 was conducted in Mandarin to some 70 working adults attending evening classes of the Chinese Medicinal Materials Dispensers Training Course at the TCM College (Singapore) Pte Ltd. The audience consisted of those working in the related industry as well as attendees with a strong personal interest in the TCM healing paradigm. The Q&A time was lively and fruitful, and the HPRG officers were able to share more in depth on the areas of interest.

Two English lectures were also delivered in November 2012 to a group of more than 30 graduands of the NTU Double Degree in Biomedical Sciences and Chinese Medicine. These TCM practitioners-to-be had completed their TCM training in Beijing, and would be starting their practice in Singapore.

The sessions were well-received, and it was beneficial for these future practitioners to understand more on how CPM are regulated in Singapore, as well as the importance of adverse event reporting.

In consideration that industry members, TCM practitioners and other healthcare professionals are HSA’s key partners in supporting our objective to safeguard public health and safety, HPRG will continue to organise such outreach sharing sessions to the relevant stakeholders in the future.

HPRG’s WINning Pro-Enterprise Efforts - Minor Variation-2 (MIV-2) Notification

WIN, which stands for Work INnovation Team, is a mechanism used in HSA to promote team innovation. Work Innovation Teams are groups of staff who meet regularly to identify work areas that need improvement e.g enhancements to service delivery procedures, processes, resource management, work environment, etc.

The FUGU WIN (Work INnovation) team kicked off a project in early 2012 to implement the notification system to inform applicants of MIV-2 applications that the proposed changes (which HSA has no objection to) had been notified.

As stated in the current Drug Registration Guide, the procedure allows an applicant who has submitted an MIV-2 application to implement the proposed change(s) if HSA does not raise any objection within 40 working days after submission. Previously, applicants were required to regularly check PRISM online, call or email HSA to find out the status and outcome of their MIV-2 applications. At times, effort and time were spent to locate the HSA staff who had sent the input request query, resulting in extra time taken for HSA to respond to applicants’ queries. This was particularly evident when the query was done via the fax mode.

Taking into consideration feedback received from applicants, the Generics and Biologics Branch (GBB) in HPRG

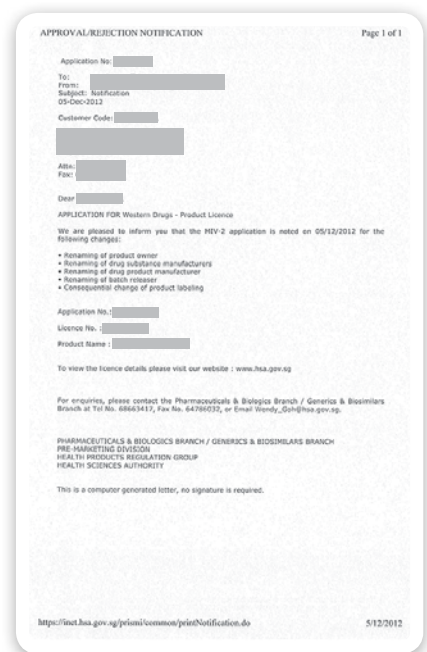
formed a WIN team to streamline this process and enhance the current notification system and input request templates. With the pro-enterprise efforts made, it led to a reduction in the number of enquiries on the status of MIV-2 applications. In addition, it also eliminated the need for applicants to track applications@PRISM and as a result, provides greater transparency of the screening and reviewing efforts.

The templates were customised to include contact details of the particular HSA screener concerned to facilitate contact and communication with the relevant party. The proposed changes were also copied from the PRISM online application form to the notification template to be sent to the applicants.

We hope that with this initiative, implemented on 1 October 2012, it is a step towards transparency in conveying regulatory outcomes to drug registration applicants.

Acknowledgement

The editorial team would like to thank our HPRG colleagues of the FUGU WIN Team Ms Wendy Goh, Mr Thomas Koh, Ms Chan Siang Yin, Ms Tan Xiao Hui, Ms Song Xueling, Mdm Tay Siew Ling and Ms Darani Ahmed Dari for their contribution to this project.



New & Revamped HSA Webpages!


Navigating the new Pre-marketing Division webpages

In the second phase of the minor HSA website revamp, we have updated the remaining four homepages of the Branches under HPRG's Pre-marketing Division to improve navigability, user-friendliness, as well as enhance their visual appeal. New sections include a 'Latest News' column, prominent banners for frequently used links, an updated contacts page and category icons for easy retrieval of information.

Western Medicines  4

Complementary Health Products  5

Cosmetic Products  6

Clinical Drug Trials  7

Look out for more changes on the way and happy surfing!

For feedback on improving our webpages, please click the weblink in each of the Branch pages stated above.



We welcome your feedback!

Please email the Editorial Team at HSA_HPRG_NEX2US@hsa.gov.sg or mail us at the following address:

NEX2US Newsletter, Health Products Regulation Group, 11 Biopolis Way, #11-01 Helios, Singapore 138667.

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
Behind the Scenes on Chinese Proprietary Medicines Regulations

Certain numbers, based on the meaning of the Chinese character that they sound similar to, are believed to be auspicious according to the Chinese tradition.

The number 8 sounds like "Prosper" or "fatt" in the Cantonese dialect, so while wishing you a most prosperous Chinese New Year, we would like to share with you 8 Things You Should Know About CPM:

1. There are about $[(88+88) \times (8 \times 8) - 880 - 880]$ listed CPM in Singapore.
2. HSA has issued more than $(88+88)$ CPM importer licences, $[(8+8+8) \times (8+8) \times 0.8 \times 0.8]$ CPM wholesale dealer licences and $(8+8+8+8+8)$ CPM manufacturer licences, of which 11 are ___ certified.
(a) GAP, (b) GDP, (c) ISO, (d) GMP
3. HSA receives more than $(8 \times 8 \times 8)$ advertising- related applications for CPM in a year.
4. A new CPM listing application has a processing timeline of ___ working days, starting at the point when the application is accepted for evaluation.

(a) 30, (b) 60, (c) 90, (d) 88

5. All new and amendment applications for CPM are currently _____.
(a) free of charge, (b) charged differently, (c) charged exorbitantly, (d) not done online
6. HSA conducts regular post-market sampling of CPM for _____, as well as compliance checking of CPM product labels.
(a) oranges, (b) prosperity, (c) testing, (d) snakes
7. There is an online search engine  8 on the HSA website for consumers to check if a CPM is listed with HSA.
8. Healthcare professionals and the CPM industry can report adverse events related to CPM using a bilingual reporting form  9 on the HSA website, and it can be submitted online, by fax or by post to HSA.

Fun Facts on Number 8

The word "eight" (八) sounds similar to the words which mean "prosper" or "wealth" (发 - short for "发财"). In the Cantonese dialect, it is pronounced as "faat", which also symbolises fortune.

Hurry up!

Send in your answers to these questions, together with your name, organisation, email address and mobile number to HSA_HPRG_NEX2US@hsa.gov.sg by 15 March 2013!

Winners will be notified by email and published in the next issue of NEX2US

URL Address Listings < 1 > http://www.hsa.gov.sg/publish/content/hsaportal/en/health_products_regulation/RateServiceIcons.html < 2 > http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/adverse_event_reporting.html#page=tab1 < 3 > http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/western_medicines.html < 4 > http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/complementary_medicines.html < 5 > http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/cosmetic_products.html < 6 > http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/clinical_trials.html < 7 > <http://www.hsa.gov.sg/prism/common/enquirepublic/SearchCPPProduct.do?action=load> < 8 > http://eservice.hsa.gov.sg/files_etc/medialib/hsa_library/health_products_regulation/safety_information/files_-_forms.Par.22696.File.dat/ADR_ENG_CHS_Yellow_240ct11.pdf < 9 > http://www.hsa.gov.sg/publish/etf/medialib/hsa_library/health_products_regulation/safety_information/files_-_forms.Par.22696.File.dat/ADR_ENG_CHS_Yellow_240ct11.pdf