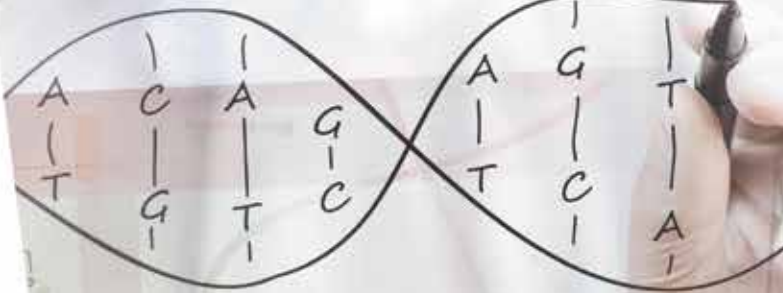


NEXUS



CONNECTING WITH
OUR PARTNERS

FEBRUARY 2015



MODERNISING REGULATION IN THE NEXT DECADE



A NEWSLETTER for our HEALTH PRODUCTS INDUSTRY & COMMUNITY

FROM THE EDITOR-IN-CHIEF

Dear Readers,

It has been a busy and fruitful year for us in the Health Products Regulation Group (HPRG) and I hope it has been likewise for you and your business. At this point, I will like to thank you for being so engaging and forthcoming in sharing with us your views, opinion and input to improve the regulatory system and policies over the past 1 year.

As we bid farewell to the Horse and usher in the year of the Goat, we can look forward to another year of exciting initiatives that we have planned to engage and collaborate with our different stakeholders in the industry and healthcare institutions to further enhance the regulatory approaches of the various health products. We are aware of the lightning speed at which science and medical technology are advancing, bringing with it increasingly sophisticated medical devices and new treatment options, such as cell and tissue-based therapies. Besides, with an ageing population and increasing connectivity, we will also expect to see more innovative devices targeted at patients for better and more cost-effective healthcare, such as mobile health applications and telehealth devices with the potential for tele-monitoring and tele-consultation. There is therefore a need to better understand such products and the technology behind them. While these new developments bring immense opportunities, so too are the possibilities of new and never encountered before risks. As such, HPRG will need to continually engage the different stakeholders to ensure better understanding of the scientific developments, business modalities and facilitate the access of these new and innovative products into Singapore to meet the medical needs of our patients and consumers, whilst safeguarding public health.

We will continue our stakeholder consultation to seek feedback regarding the transfer of the regulatory controls of pharmaceutical products under the existing laws to the Health Products Act. In addition, there will be a move to further refine our regulatory controls and policies, such as the timelines and transparency in the submission of drug applications, as well as the Change Notification process and Field Safety Corrective Actions for medical devices. To ensure that our regulatory framework and policies are kept up-to-date, HPRG will also keep an eye on regional and global regulatory developments to ensure alignment and synergism. And that's why we conduct regular forums and seminars with our overseas regulators and experts each year, to increase the regulatory awareness of our industry stakeholders and also to enhance the competency of our regulators. You can look forward to more of these focus group discussions and initiatives in 2015!

With all these in mind, we have aptly titled the theme of this first issue in 2015 as "Modernising Regulation in the Next Decade" as we "future-proof" our regulatory framework and policies to allow us to be nimble and adaptable to take on the new and emerging health products coming up in the near term horizon. And we cannot be embarking on this journey ourselves, without all of you as our partners and collaborators! And to do so effectively and efficiently, we are willing to try out different innovative approaches of engagement and feedback-gathering mechanisms so that we can better understand the ground and cope with the fast-changing environment.

And since the Goat is the 8th sign in Chinese astrology and the number "8" is considered to be a very lucky and auspicious number, symbolising wisdom, fortune and prosperity, on behalf of HPRG and HSA, I would like to wish our readers a happy, prosperous and healthy Lunar New Year of the Goat!

Yours Sincerely,
Raymond

Asst Prof Raymond Chua
Group Director, HPRG, HSA

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editorial team

Editor-in-Chief

Asst Prof Raymond Chua

Executive Editor

Angie Tan

Assistant Editors

Choong Chih Tzer, Diana Koh, Valerie Wee

Contributing Authors

Ananda Padmanabhan Muthalagu, Choong Chih Tzer, Dr Lakshmidivi Balakrishnan, Dr Srinivasan Kellathur, Evelyn Lee, Kenneth Low, Mae Mah, Natalie Low, Neo Cherg Yeu, Patricia Ng, Sia Chong Hock, Sumitra Sachidanandan, Valerie Wee, Wong Woei Juang

Corporate Content

Contributors

Sophus Chong, Wang Yunshi

Advisors

Lee Hui Keng, Suvarin Chaturapit

A YEAR IN REVIEW

TOP HPRG STORIES IN 2014!



November 2014
 Collaborated with Ministry of Health and Health Promotion Board (HPB) to carry out engagement sessions with tobacco retailers on Point-of-Sale Display ban of tobacco products

September 2014
 Led the 1st ASEAN Panel of Experts to assess the Thai FDA for equivalency to the PIC/S framework and for inclusion in the List of Accepted ASEAN Inspection Services



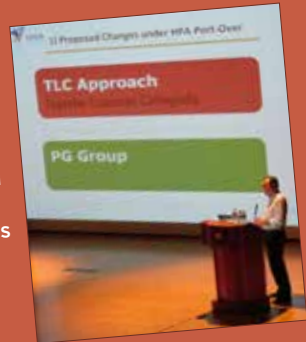
November 2014
 Signed the ASEAN Medical Device Directive Agreement on convergence of regulatory controls for medical devices with ASEAN regulatory authorities

April 2014
 Enhanced the Change Notification process for Registered Medical Devices



January - December 2014
 Enhanced public education efforts by partnering HPB to distribute HSA's consumer booklets on the dangers of buying illegal health products and to carry HSA's messages at HPB's Community Functional Screening & Lose To Win events respectively

October - November 2014
 Conducted public consultation on the review and transfer of the legislative controls for medical advertisement and retail pharmacy licensing of pharmaceutical products under Medicines Act and Poisons Act to the Health Products Act



December 2014 - January 2015
 Conducted public consultation on proposed ASEAN Agreement on Traditional Medicines and ASEAN Agreement on Health Supplements



March - November 2014

- 7th International Generic Drug Regulators Pilot Meeting
- 7th ACSS Consortium Generics Working Group Meeting
- 12th Standing Committee Meeting and 5th International Symposium of the Western Pacific Regional Forum for the Harmonisation of Herbal Medicines
- 2014 APEC Harmonisation Centre-Health Sciences Authority Cell- and Tissue-based Therapeutic Products Workshop
- First-in-world pilot training programme on Multi-Regional Clinical Trials



August - November 2014

Enforcement Operations	Quantity Uncovered	Date
Operation White Rabbit	60,634 units of sexual enhancement products worth \$151,585	November 2013 - September 2014
Operation Cactus	30,491 units of sexual enhancement products worth \$76,227	August 2014

HOT OFF-THE-PRESS

CRP-CRCS Forum

HSA co-organised the combined Clinical Research Professionals (CRP) - Clinical Research Coordinator Society (CRCS) Forum held at the National University of Singapore on 12 December 2014.

The CRP Forum and the CRCS Forum were set up in 2003 and 2006 respectively to provide a platform for clinical research professionals from pharmaceutical companies, contract research organisations and institutions to network and keep abreast of the latest developments in the clinical research industry.

Apart from the fora organised by each group, combined fora are also organised on a bi-annual basis to encourage networking between industry and institution stakeholders. Both groups organised a total of 4 fora in 2014. HSA had the privilege to co-organise the combined CRP-CRCS Forum with the National Healthcare Group (NHG) on 12 December 2014. The theme of the combined CRP-CRCS Forum was 'Quality by Design'. Speakers from the Health Products Regulation Group (HPRG) of HSA shared their thoughts about how quality of clinical trials can be improved by applying quality assurance upstream of clinical trials as compared to the traditional downstream approach whereby quality improvements are made only after quality lapses occur.

Forum Highlights

The forum started off with Ms Angie Sim (Founder, CRP Forum) and Ms Lim Boon Hwee (Vice Chairperson, CRCS) welcoming the speakers and participants.



Left: Participants at the Forum



Asst Prof Raymond Chua, Group Director of HPRG and Principal Director of HSA Academy, delivered the keynote lecture. Asst Prof Chua emphasised the importance of robust regulations and governance to safeguard the interests of trial participants and instil trust in the safety and quality of the research framework. The way forward is to ensure that quality assurance is involved at the most early stages to build quality into the initial design and conduct of clinical trials, rather than to use monitoring or audits to address subsequent quality concerns.

“Deficiencies could be minimised if Quality Assurance had been involved right from the set-up of the trial or at the design stage.”

Asst Prof Raymond Chua

He explained that sponsors should adopt a risk-based approach in their quality management plan. Such an approach should be used to facilitate proportionate use of resources by all parties, by focusing on activities critical to ensuring human subject protection and reliability of trial results.



Ms Angie Sim (left) and Ms Lim Boon Hwee (above) jointly delivered the opening address





Ms Sumitra Sachidanandan, Good Clinical Practice (GCP) Inspection Consultant from the Clinical Trials Branch of HSA, spoke on Common GCP Inspection Findings for 2014.



Left: Ms Sumitra Sachidanandan used case studies to illustrate common GCP inspection findings in 2014

Ms Sachidanandan shared that a total of 66 GCP Site Inspections had been conducted since its inception in 2009, and presented case studies on the common GCP Inspection Findings for 2014.



The forum noted that informed consent and investigational product (IP) management remained the most common major GCP Inspection Findings. In addition to conducting GCP Inspections, quality improvement initiatives have been implemented by HSA upstream (e.g. upstream consultation on IP management, template forms repository etc.) of clinical trials to improve the quality of clinical trials.

We would like to extend our appreciation to all participants for their active participation and support.

We certainly look forward to more enriching and engaging sessions with our stakeholders in 2015!



Ms Poh Cuiqin sharing requirements for notification of serious breaches

Ms Poh Cuiqin, GCP Compliance Inspector from the Clinical Trials Branch of HSA, spoke about notification of serious breaches. Ms Poh explained that a serious breach is a deviation that is likely to affect to a significant degree the safety, physical or mental integrity of any subject in a clinical trial, or the scientific value of the clinical trial.

As notification of serious breaches will be a requirement under the revised clinical trial regulations, HSA will be developing a Guidance on Notification of Serious Breaches in early 2015 to provide ample time and enable a seamless transition for stakeholders to comply with the revised regulations.



Left: Ms Jeannie Cho, Lilly-NUS Centre for Clinical Pharmacology, posing a question

Below: Speakers & Participants of the Combined CRP-CRCS Forum. Front row: (from left) Ms Lim Boon Hwee, Ms Angie Sim, Mr Foo Yang Tong, Asst Prof Raymond Chua, Ms Sumitra Sachidanandan, Ms Poh Cuiqin



Participants

The response was overwhelming with close to 300 participants attending the forum. The audience enthusiastically volunteered answers for the case studies presented during the forum and actively participated during the 'Question and Answer' session.



SPECIAL FEATURE



Quality and Supply Chain Integrity of Pharmaceutical Excipients: Opportunities for International Regulatory-Industry Collaboration

Pharmaceutical excipients are defined as substances other than the active pharmaceutical ingredients (APIs) which are included in a dosage form to aid in processing during its manufacture, or to enhance stability, bioavailability or patient acceptability of the finished dosage form during storage and use.

The API and finished dosage form are also referred to as drug and finished product (FP) respectively. Pharmaceutical excipients include diluents, disintegrants, lubricants, solvents, anti-oxidants, flavouring agents and anti-microbial preservatives. Common examples are starch, cellulose, croscarmellose, magnesium stearate, polyvinylpyrrolidone, polyethylene glycol, parabens, glycerin, silicone dioxide and water. Historically, excipients were viewed as inert ingredients contributing generally to the stability of the FP.

However, in recent years, the interest in specialised drug delivery systems and modified-release FP has led to the development of novel and more sophisticated excipients to fulfil specific functions which include optimising the pharmacokinetics of the FP, increasing its efficacy and improving patient's compliance. In view of their specific roles, these novel pharmaceutical excipients may no longer be considered "inactive or inert" ingredients.

Globalisation and Adulteration of Pharmaceutical Excipients

Globalisation of the pharmaceutical industry has resulted in an increasingly complex supply chain of FPs, APIs



“ Globalisation of the pharmaceutical industry has resulted in an increasingly complex supply chain of FPs, APIs and excipients, which in turn created opportunities for substandard and falsified excipients to enter the supply chain. ”

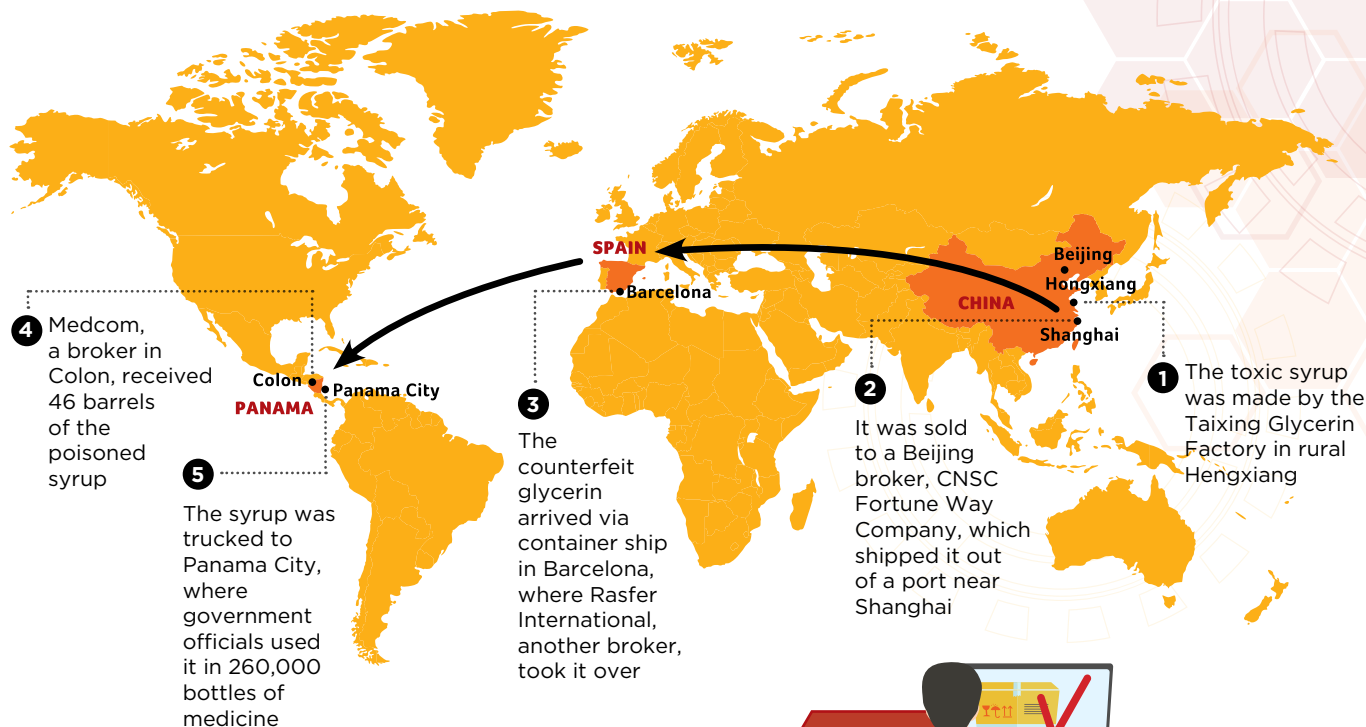


and excipients, which in turn created opportunities for substandard and falsified excipients to enter the supply chain. In 2006, 115 individuals in Panama died after receiving cough syrup containing glycerin - an excipient that was adulterated with toxic diethylene glycol (DEG).

The adulterated glycerin was traced to a chemical manufacturer in China which was not approved to manufacture pharmaceutical excipients, and which falsely attested to the purity of the glycerin in the certificate of analysis.

The adulterated glycerin passed through several brokers located across 3 continents, who resold it without specifying the previous owners or performing any purity tests. Similar cases of adulterated glycerin also surfaced in Haiti (1995-1996), Nigeria (1990 and 2008) and India (1986).





National and International Controls of Pharmaceutical Excipients

Currently, most national drug regulatory authorities, including HSA, place the onus on FP manufacturers to procure excipients which they have assessed for safety and quality. For example, FP manufacturers will need to:



The growing global supply chain, as well as differing pharmacopoeial and regulatory requirements have made it more challenging for regulatory authorities and the industry to control quality and manage supply chain integrity. Arising from this, the excipient and pharmaceutical industries have come together to form the International Pharmaceutical Excipients Councils (IPEC) Federation, with regional entities such as IPEC-Americas, IPEC-Europe, IPEC-Japan (JPEC) and IPEC-China.

The key objectives of IPEC are the development and harmonisation of international excipient standards, promotion of supply chain security, development of third-party certification, bearing in mind the applicable laws and regulations of the respective regions. IPEC publishes guidelines on various aspects of excipient control, and updates the industry and authorities through workshops and seminars.

Source: "A Review of the Regulations and International Developments on Quality and Supply Chain Integrity of Pharmaceutical Excipients", *Pharmaceutical Engineering*, Nov/Dec 2014 Issue, co-authored by Sia Chong Hock (HSA), Vimal Sachdeva (WHO) and Sean Lee and Chan Lai Wah (NUS).

The Paper Trail

The certificates falsely stated that the shipment of glycerin was 99.5% pure. Each broker put its own name on the certificates, obscuring the original source of the syrup.



Conclusion

With the growing, globalised pharmaceutical excipient market and the emergence of more sophisticated excipients, the regulation of excipients is expected to become more challenging. Currently, reported cases of adulterated excipients appear to be limited to DEG-laced glycerin and propylene glycol.

However, as the excipient industry becomes more sophisticated and lucrative, temptations to profit unethically may increase, and other types of economically-motivated adulterated excipients may manifest. The initiatives from IPEC are a good start. IPEC could expand its reach to more countries and collaborate with regulators with a view to integrate some of its guidelines into legislations.

CNY GREETINGS FROM US AT HSA!

2015



On behalf of HSA, I would like to wish all of our stakeholders and partners a very happy and fulfilling 2015. I would also like to take this opportunity to extend our warmest Lunar New Year greetings to everyone for a successful year ahead. We look forward to working with and engaging our stakeholders and partners to further enhance our health products regulatory framework and service standards.

Dr Mimi Choong
Chief Executive Officer
Health Sciences Authority



祝贺大家
新年快乐，
喜气洋洋，
万事胜意，
步步高升，
生意兴隆，
财源滚滚来！

Asst Prof Raymond Chua
Group Director,
Health Products Regulation
Group



Wishing our stakeholders and partners a happy and prosperous Lunar New Year!

A/Prof Chan Cheng Leng
Deputy Group Director,
Health Products Regulation
Group



I would like to wish all HPRG stakeholders a prosperous and successful lunar New Year of the Goat! May this New Year bring our collaborative partnership in safeguarding public health and safety to greater heights!

Ms Lee Hui Keng
Assistant Group Director,
Health Products Regulation Group



NEX2US Editorial Team

NEX2US has progressed significantly for the past two years and nine months. With seven issues bringing us through various regulatory updates, we are glad that it is still going strong! The Editorial team will continue to deliver more updates to you, our valued readers, wherever you are. Our deepest wish: We will always be next to you, and hope you will be next to us too!

Angie Tan
Executive Editor, NEX2US newsletter



HSA wishes you good health, lasting prosperity and great success in all your endeavours in the coming Chinese New Year.

Mr Aw Ann Beng, Client Liaison Officer

Here's toasting to bundles of joy, happiness and good luck in this Year of the Goat to you, from all of us at HSA Connects Centre!

Kenny and Natalie, Customer Service Officers, HSA Connects Centre

HPRG Management and Advisors Team



In this year of the Goat, we would like to wish all our stakeholders and customers a peaceful, joyous, successful and wonderful New Year! May the new year bring forth more partnerships and collaborations with our stakeholders to protect and safeguard public health.

Valerie Wee
Deputy Director,
Service Management and Industry
Development Office

How HPRG Excellent Service Award (EXSA) Winners Maintain Excellent Customer Service Standards

To respect and always give more than what they expect to get.

Ms Christine Ho
Senior Regulatory Specialist,
Vigilance and Compliance Branch

Greetings to you! Empathy will be the key element. When dealing with stakeholders, I often ask myself the questions "Do I want to be treated this way? Is there other areas that I would need help on?".

Mr Ashton Quek
Senior Regulatory Executive,
Group Director's Office

Always treat others the way we want to be treated. Follow-up on what we have promised to do and ensure that regular updates are provided. It is important to always evaluate the way we communicate with others.

Ms Mae Mah
Assistant Director, Service Management
and Industry Development Office

I believe what it takes is to have a sincere attitude towards your stakeholders, be courteous and polite and have the willingness to listen with compassion and going the extra mile to assist them. It is also important to keep them posted on the latest updates of their requests so that they will feel assured and being valued.

Ms Saw Hui Ping
Regulatory Executive, Vigilance and Compliance Branch

I try to put myself in the customers' shoes and reply to their queries in the same way that I would like to be answered.

Ms Sally Soh
Senior Regulatory Specialist,
Vigilance and Compliance Branch

Be patient, have empathy, and provide alternatives wherever possible.

Ms Stella Ee
Regulatory Manager,
Vigilance and Compliance Branch

Being genuine, sincere and being able to put myself in the stakeholders' shoes bridged some of the differences between the regulator and the stakeholder. Understanding their issues and being able to help them navigate the regulatory processes without compromising our core values is a necessary art and with that I was able to gain a bit of experience in this to achieve this service award.

Dr Yow Soh Zeom
Senior Regulatory Specialist, Medical Device Branch

Always put yourself into the shoes of the customer. Imagine how you, as a person, would like to be treated, and apply that your best desired treatment in your interaction with the customer. This has always proven effective in maintaining high service standards in my context.

Mr Ng Wei Hiong
Senior Regulatory Inspector, Tobacco Regulation Branch



EVENT HIGHLIGHTS

Towards Enhanced Integration of the Medical Device Sector within ASEAN



The ASEAN Consultative Committee for Standards and Quality (ACCSQ) was formed by the ASEAN Economic Ministers in 1992 with the aim of removing technical barriers to trade. With this aim, the formation of the Medical Device Product Working Group (MDPWG) was proposed during the 24th ACCSQ meeting held in August 2004.

Upon the establishment of the MDPWG in 2005, there had been intensive discussions to develop an ASEAN Medical Device Directive (AMDD) to enhance cooperation amongst Member States in ensuring the safety, quality and claimed benefits of medical devices marketed within ASEAN. The Directive also aims to eliminate restrictions to trade medical devices amongst Member States through the harmonisation of technical requirements. The AMDD was finalised in October 2013 in Singapore.



Mr Zamane Abdul Rahman (far left), Chairman of the ACCSQ-MDPWG Meeting, addressing the delegates

On 7 - 8 May 2014, the 18th ACCSQ-MDPWG Meeting was held in Singapore, at the Shangri-La Hotel. It was well attended by delegates from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Thailand, Vietnam and Singapore. During this meeting, the synergistic cooperation amongst Member States culminated in the adoption of the Report of the 18th Medical Device Product Working Group. This paved the way for enhanced integration of the medical device sector for ASEAN Member States.

In August 2014, Brunei Darussalam, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Vietnam and Singapore signed the AMDD at the sidelines of the 46th ASEAN Economic Minister's meeting held in Myanmar. Subsequently, Cambodia and Thailand completed the signing of the AMDD in November 2014 in the sidelines of the 25th ASEAN Summit in Thailand.

EVENT HIGHLIGHTS

12th FHH Standing Committee Meeting and 5th FHH International Symposium

As part of the Health Sciences Authority (HSA)'s international collaboration efforts, its Complementary Health Products Branch hosted the 12th Standing Committee Meeting of the Western Pacific Regional Forum for the Harmonisation of Herbal Medicines (FHH) on 25 to 26 November 2014 at the Peninsula Excelsior Hotel and the 5th FHH International Symposium on 27 November 2014 at the HSA Auditorium.

Supported by the World Health Organisation (WHO), the FHH was formed in 2002 with the objective of establishing common technical standards for herbal medicines in the Western Pacific region to improve their quality, safety and efficacy. Singapore is among the founding members, together with Australia, China, Hong Kong, Japan, Korea and Vietnam. There are also three sub-committees under the FHH, namely, Sub-committee I: Nomenclature & Standardisation, Sub-committee II: Quality Assurance & Information, and Sub-committee III: Adverse Drug Reactions.

At this year's meeting, the member states were joined by Canada as a special member and also observers from the United States Pharmacopoeial Convention (USP), China and Switzerland's CAMAG Laboratory. The meeting shared updates about the regulation of herbal medicines in their countries, as well as research related to the standardisation of herbal materials.

The Standing Committee Meeting was followed by the 5th FHH International Symposium which served as a platform for local and overseas speakers, as well as participants, to exchange their views and share developments in research on herbal medicines.

Below: Overseas delegates and speakers of the 5th FHH International Symposium

5th International Symposium of the Western Pacific Regional Forum for the Harmonization of Herbal Medicines (FHH)
27 Nov 2014 • HSA Outram Auditorium • Singapore



Above: Participants of the 5th FHH International Symposium

The theme for the Symposium was 'Synergy for Harmony'. Besides the FHH member states and overseas observers, representatives from the Singapore Traditional Chinese Medicine Organisations Committee, Nanyang Technological University, National University of Singapore, Nanyang Polytechnic, Ngee Ann Polytechnic, Republic Polytechnic, Singapore Polytechnic and Temasek Polytechnic were also invited to attend the Symposium.

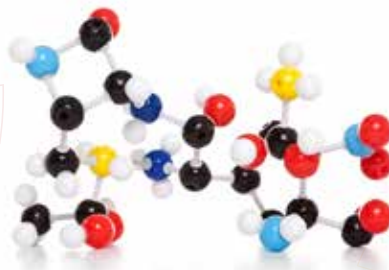
The Symposium discussed topics including: pharmacovigilance and challenges of herbal medicines, quality control of herbal medicines and developments in regulation, as well as developments in analysis of herbal medicines. The participants had an enriching learning experience from the lively discussions and also gained valuable insights from the speakers' wealth of experience and expertise.



Above: Participants of the 12th FHH Standing Committee Meeting



INTERNATIONAL ENGAGEMENT



Bringing Together International Experts - 2014 APEC Harmonisation Centre-Health Sciences Authority Cell- and Tissue-Based Therapeutic Products Workshop

Cell- and Tissue-based Therapeutic (CTT) products (stem cells, gene modified cells or tissue engineered) are an emerging group of products used in regenerative medicine and in the treatment of several debilitating diseases and conditions.

Regulation of CTT remains at nascent stage in many countries and globally, only few products have received marketing authorisation. The Regulatory Harmonisation Steering Committee (RHSC) of the Asia Pacific Economic Cooperation Life Sciences Innovation Forum (APEC LSIF) works to achieve its mandate of increasing the level of convergence of regulatory requirements for medical products throughout the APEC region. Taking advantage



“ to achieve its mandate of increasing the level of convergence of regulatory requirements for medical products throughout the APEC region... ”



115 participants, including regulators from 11 APEC economies (Canada, China, Chinese Taipei, Hong Kong, Japan, Korea, Peru, Philippines, Singapore, Thailand, United States of America), 4 non-APEC economies (Finland, India, Italy and Switzerland), representatives from the local and overseas cell therapy industry, as well as scientists from local research institutes and healthcare establishments participated in the workshop.

of APEC LSIF's unique role as an 'enabler of harmonisation', RHSC endorsed the CTT roadmap in July 2013 to promote prospective harmonisation dialogue in the area of advanced therapies.

As part of the CTT roadmap, APEC Harmonisation Center (AHC) and Health Sciences Authority hosted an international workshop on CTT Products in Singapore from 1 to 3 July 2014. The workshop objectives were to facilitate understanding of the current regulatory landscape and to provide a platform for sharing challenges in CTT product manufacturing and manufacturing facility from regulators and product developers.

Most CTT products are in the early phase of development, largely being developed in academia, hospitals or SMEs. Being an emerging area, regulators shared that considerable challenges are observed in areas related to product manufacturing, preclinical and clinical requirements, and manufacturing establishments. Hence, an early dialogue with regulators was encouraged to clarify regulatory requirements.

It was also mentioned that unlike traditional drugs or biologics, good manufacturing practice standards for CTT is not a "one size fits all" model, as there are unique challenges in CTT product manufacturing such as lack of reference standard, short shelf-life, and low production batch.

More information can be obtained from here!

REGULATORY UPDATES

Dialogue Sessions with Our Industry Stakeholders 2014

As part of our regular stakeholder engagement initiatives, HSA held a series of high-level industry dialogue sessions with the following associations:

- Singapore Association of Pharmaceutical Industries (SAPI) on 17 September 2014.
- Singapore Pharmaceutical Manufacturer's Council (SPMC) and Singapore Pharmaceutical Trade Organisation (SPTO) on 18 September 2014.
- Association of Medical Device Industry (AMDI) on 15 October 2014.
- Singapore Manufacturing Federation (SMF) - Medical Technology Industry Group (MTIG) on 28 November 2014.

The respective teams were led by: Dr Mimi Choong, CEO of HSA, Ms Neo Kah Yean, President of SAPI, Dr Stuart Koe, Chairman of SPMC, Mr Adam Hamid, Chairman of SPTO, Mr Henry Tan, President of AMDI, and Mr Albert Lee, Chairman of MTIG respectively.

The main objective of the dialogue sessions was to provide a platform for sharing and networking between HSA and our industry stakeholders. It was also an opportunity for both parties to discuss and better understand the issues and challenges faced collectively, as well as to explore potential solutions collaboratively.

During the dialogue sessions, some issues that were discussed included the proposed changes and timelines of the Health Products Act Portover for Therapeutic Products, Turn-Around-Time (TAT) for Change Notification and Field Safety Corrective Actions (FSCA), and capability-building for the medical device industry.



Above: HSA and Medical Technology Industry Group (MTIG)



Left: Discussion with Association of Medical Device Industry (AMDI)



Above: SMF - Medical Technology Industry Group (MTIG)



Above: Discussion with Association of Medical Device Industry (AMDI)

The outcome of these discussions were fruitful and led to a few post-dialogue initiatives which included the formation of a few working groups between HSA and the different industry associations to co-create solutions to the issues and challenges faced by both parties.

We will also aim to engage our stakeholders early in our policies and initiatives during the regulatory policy and development phase so that stakeholders' feedback can be incorporated where possible.

Moving forward, we are committed to continue similar dialogue sessions with our industry stakeholders on a regular basis.




REGULATORY UPDATES

Faster Correction of Existing Medical Devices in The Market Following Field Safety Corrective Actions

On the 4 and 5 September 2014, HSA's Vigilance and Compliance Branch (VCB) conducted an industry briefing on refinements to the Change Notification (CN) process for Field Safety Corrective Actions (FSCA) which are aimed to enhance the compliance to the postmarket regulatory requirements for medical device. The intent of an FSCA is to address the risks posed by defective devices when administered to patients by users such as healthcare professionals.

With the refinements to the FSCA-CN process, faster corrections or rectifications can be implemented to the affected devices that are already in use locally in less than 20 days. Prior to these refinements, any FSCA-related change, made to a registered medical device that impacts its safety, quality or efficacy required approval from HSA via the CN route before it can be implemented including for devices that are already in use.

The refined 2 stage process will enable timely implementation of corrections to the units of the affected medical devices that are already in use on patients locally.

This is facilitated through the FSCA notification process which is the first stage. At the second stage, the changes to the registered medical devices are reviewed in the CN application that will be submitted via the MEDICS² system to ensure the safety, quality and efficacy of the device units that will be supplied in future to users locally. 

These refinements are part of the initiatives aimed at enhancing the compliance to regulations involving medical devices. The refinements to the CN process for FSCAs were implemented on 1 October 2014 after targeted consultation sessions with industry members.

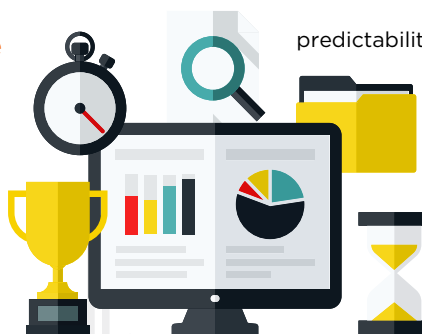
“These refinements are part of the initiatives aimed at enhancing the compliance to regulations involving medical devices.”

Participants who attended the briefing reacted positively to the announced refinements as it provided a clear communication of timelines for corrections to their customers. Participants also expressed interest to further cooperate with HSA as patient safety was a priority for both HSA and industry.



Improving Timelines and Transparency of Drug Applications

As part of ongoing efforts to enhance regulatory processes and improve timelines and transparency, HSA's Therapeutic Products Branch (TPB) has identified several priority areas for improvement, one of which is to establish a target processing timeline or turnaround time (TAT) for screening of drug applications.




predictability to help both HSA and the industry better manage overall timelines for drug applications.

Several initiatives to the MIV application process were implemented from 2 December 2014, to facilitate timely processing of MIV applications. Some of the enhancements made to PRISM, HSA's electronic regulatory transaction system, was the replacement

From October 2014, TPB embarked on a pilot project to gather data from all drug applications screened, in order to formulate a feasible overall screening TAT for better predictability of overall timelines. The pilot project will run over the course of one year (from 1 October 2014 to 30 September 2015) for new drug applications (NDA), generic drug applications (GDA), and major variation applications (MAV), and six months (from 2 December 2014 to 31 May 2015) for minor variation applications (MIV-1). Following completion of the pilot project, the overall screening TAT will be announced to the industry, to provide better

free-text format in Section 0.4 'Amendment Details' to a drop-down listing of applicable MIV checklist titles. This had been done to allow better categorising of MIV applications and facilitate the tracking of non-consequential changes. In addition, the number of MIV-1 applications that can be submitted in PRISM at any one time has been increased from 3 to 5, based on feedback from the industry, to facilitate timely submission of MIV updates.

Detailed information on the screening TAT project and initiatives on the MIV application process can be found on HSA's website³. 

HSA Facilitates Competency Building in Medical Device Regulatory Affairs



HSA endeavours to be a regulator which nurtures a strong regulatory environment while facilitating and enabling industry development in Singapore. As part of this objective, we are pleased to share with you some of HSA's collaborations with professional societies, educational institutions and industry on regulatory competency building for the medical device regulatory affairs professionals.

NUS-RAPS Graduate Certificate in Medical Device Regulatory Affairs Programme

The Graduate Certificate in Medical Devices Regulatory Affairs (MDRA) is a programme offered by the Department of Biomedical Engineering (BME), Faculty of Engineering and National University of Singapore, in partnership with the Regulatory Affairs Professionals Society (RAPS).


The programme draws on the multidisciplinary experience of the teaching and research faculty at BME which covers engineering, life sciences and medicine. RAPS is the largest global organisation of and for those involved with the regulation of healthcare and related products. This programme was developed with the support of the following Singapore Government Agencies: Agency for Science, Technology and Research (A*STAR), Health Sciences Authority (HSA), Economic Development Board (EDB), SPRING Singapore, and the Singapore Workforce Development Agency (WDA).

It targets industry professionals representing product developers, manufacturers, distributors, service providers, entrepreneurs, investors and regulators dealing with medical device products. It is open to those with a relevant bachelor's degree or its equivalent. Candidates with relevant qualifications and related working experience may also apply for the programme.



HSA was awarded the 'Special Partnership Recognition Award' by AMDI. From left to right: Ms Wong Woei Jiuang (HSA), Asst Prof Raymond Chua (HSA), Ms Valerie Wee (HSA)

The curriculum covers foundational knowledge and core competencies of regulatory professionals, fundamentals of global medical device regulation, device regulation in the US, EU, China, ASEAN and other Asia-Pacific countries, quality and compliance, application of regulatory knowledge, global regulatory pathways and submission process.

For more information, please visit 

Association of Medical Device Industry (AMDI) Medical Technology Industry Resource Centre - Regulatory Support Programme

In October 2014, the Association of Medical Device Industry (Singapore) [AMDI] officially launched its establishment of Medical Technology Industry Resource Centre (MTIRC) at its 2nd Annual Dinner, which was officiated by Dr Lam Pin Min, Minister of State for Health. The MTIRC is a culmination of AMDI, HSA and SPRING Singapore's collaborative partnership to elevate quality standards, enhance professional capabilities, and promote trade development of the medical technology (MedTech) industry.



Above, left to right: Dr Lam Pin Min (MOH), Mr Henry Tan (AMDI), Asst Prof Raymond Chua (HSA) and Mr Michael Pang (AMDI)

Set up with the support of SPRING Singapore, MTIRC is a one-stop centre offering business support, training and education as well as trade promotion services for the MedTech industry. It also serves to be a conduit to foster public and private collaborations for the professional and commercial developments of the industry. Recognising the importance and the need to uplift industry capabilities on regulatory affairs, AMDI is introducing a Regulatory Support Services (RSS) Programme through the MTIRC.



The RSS Programme aims to provide support for medical device companies in product registration and competency development in regulatory affairs. HSA is supporting this programme through working with AMDI to provide regulatory updates and sharing of regulatory knowledge. HSA was also awarded the 'Special Partnership Recognition Award' by AMDI for this collaboration. This collaborative partnership demonstrates the commitment by both organisations to enhance the professional development of the industry and achieve the goal of building Singapore as a leading biomedical hub.

REGULATORY UPDATES

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HSA Facilitates Competency Building in Medical Device Regulatory Affairs

Awareness Sessions with Singapore Manufacturing Federation – Medical Technology Industry Group (MTIG)

HSA facilitates competency building in medical device regulatory affairs by speaking at seminars on topics related to regulation of medical devices in Singapore. One of such seminars was the awareness session organised with Singapore Manufacturing Federation for its medical device industry members on 10 September 2014. The topics shared ranged from updates on medical device software, clinical evaluations of medical devices and in-vitro diagnostics medical devices to biocompatibility and animal studies aspects of medical device evaluations.



Regulatory Seminar for A*STAR Researchers and Innovators on Medical Device Regulations

The “Regulatory Framework on Medical Device Development 2014” Seminar was jointly organised by A*STAR, Diagnostics Development (DxD) Hub and HSA on 28 November 2014. It aims to address the questions and concerns from the scientific, clinical research start-ups and Small Medium Enterprise (SME) community regarding the medical device regulatory framework and requirements, especially in the Singapore context. It covered common regulatory challenges faced in the industry and possible ways to address them.



FUN LEARNING

Navigate The New Revamped HPRG Website

Having trouble finding the information you're looking for on health product regulations? Try out these quick links while you navigate about the new HSA website!



URL Address Listings < 1 > <http://www.nifds.go.kr/apec/contents/page.jsp?mcode=3021901> < 2 > http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/MEDICS_e-Services.html < 3 > http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Western_Medicines/Industry_communications.html < 4 > www.bioeng.nus.edu.sg/edu/mdra.html

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