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CONNECTING WITH OUR PARTNERS

HSA Health Sciences Authority

JANUARY 2014

Celebrating Partnerships

5

A NEWSLETTER *for our* HEALTH PRODUCTS INDUSTRY & COMMUNITY

from the Editor-in-Chief

Dear readers,

2013 has been an exciting year as we embraced the theme "Bridging Minds, Forging Partnerships". This theme was epitomised by two key events organised in the later half of the year.

Assistant Professor Raymond Chua
Group Director, HPRG, HSA

The Health Products Regulatory Conference (HPRC) was an advancement from what was previously known as the 'HPRG Joint Regulatory Workshop'. This platform took on a broader and more international perspective, which encompassed a programme that included the sharing of insights on global regulatory developments and collaboration initiatives by foreign and local speakers from academia, external regulatory authorities, as well as partner agencies and industry players. The conference theme, 'Enhancing Scientific and Regulatory Collaboration in Safeguarding Public Health', signifies HSA's goal to strengthen communication and collaboration with stakeholders globally to protect and advance public health. Not forgetting our other stakeholders, the inaugural Excellent Stakeholders and Partnership Awards (ESPA) ceremony was organised to celebrate the achievements of HSA's partners with whom the Health Products Regulation Group (HPRG) had closely collaborated over the years to advance and protect national health and safety. We were honoured to have the ceremony graced by our Senior Minister of State, Dr Amy Khor, who presented awards to 62 recipients. They were recognised for their dedication and efforts in various initiatives which strengthened the safety monitoring of health products and enforcement of health product regulations. Partner organisations and associations were awarded for their consistent collaboration with HPRG while healthcare professionals were also recognised for their valuable contributions to HPRG's scientific advisory committees. Considering the rapidly evolving healthcare and medical landscape of this century, it is our aim to continue working closely with our industry and healthcare professional partners to continually shape policies and collectively build a well-balanced, holistic and adaptive health products regulatory ecosystem for our country.

As we bid farewell to 2013 and welcome 2014 with great gusto, let's all give ourselves a good pat on the back and look forward to more fruitful collaborations.

Besides the continual review of our regulatory policies and framework, we will soon be actively consulting stakeholders on a major legislative timeline, which will be the portover of the therapeutic products' regulations and its clinical trial controls from the current Medicines and Poisons Act to the Health Products Act. So stay tuned for more updates and consultations coming soon!

I'd like to take this opportunity to wish one and all a very Blessed Joyous 2014 filled with good health, prosperity and success, and since it is the year of the Horse coming at the end of January 2014, a Happy Lunar New Year and GONG XI FA CAI! 马到成功, 生意兴隆, 祝好运、健康、伴你度过一个快乐新年!

Yours sincerely,
Raymond

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TOP 10 HPRG STORIES IN 2013

~ A YEAR IN REVIEW ~

Enforcement Operations

Operation	Quantity Uncovered	Date
Operation Shenton	2,450 bottles of cough syrup	May – August 2013
Operation Focus	800 units of 3.8 litre canisters of cough syrup	May – August 2013
Operation Trident	491 Electronic Cigarettes	2 - 7 September 2013

Signing of Memorandum of Understanding with the Medicines Evaluation Board of the Netherlands
28 January 2013

Enhanced legislation on Tobacco products and packaging in line with WHO's Framework Convention on Tobacco Control
1 March 2013

Co-organised the 2nd Drug Information Association Asia Regulatory Conference
28 - 30 January 2013

Held the revamped HPRG's Health Products Regulatory Conference
9 - 10 September 2013

Co-organised a Medical Device Roundtable and an Industry Symposium with HSA Academy
15 - 16 March 2013

Issued a joint Dear Healthcare Professional Letter with MOH to highly recommend genotyping for HLA-B*1502 allele prior to initiation of carbamazepine therapy in new patients of Asian ancestry
29 April 2013

Convened a session on drug and device regulation in the World Health Summit Regional Meeting 2013 with speakers from Duke-NUS Graduate Medical School, Medicines and Healthcare Products Regulatory Agency
8 - 10 April 2013

Enhanced Medical Device Regulatory Framework

Enhancement	Medical Device Class	Date
Exemption of Good Distribution Practice certification - simpler requirements for Quality Management System for Class A Only medical device importers and wholesalers	Class A	1 January 2013
Expedited evaluation routes	Class C and D	1 January 2013
Additional change notification routes for changes authorised in HSA's reference agencies	Class A and B	1 April 2013

Held HSA's inaugural Excellent Stakeholder and Partnership Awards Ceremony
6 November 2013

ESPA

Visits by Overseas Agencies & Organisations

Over the past months, the International Collaboration Office of the Health Products Regulation Group (HPRG) has received numerous visitors from overseas agencies and organisations. These meetings have been fruitful networking sessions for HSA as they provided opportunities for valuable exchanges and updates.

Visit by Thailand Food and Drug Administration
9 to 10 July 2013

Visit by Department of Thai Traditional and Alternative Medicine
18 July 2013

Visit by Beijing University of Chinese Medicine
23 July 2013

Visit by Hainan Provincial Food and Drug Surveillance Authority Bureau, People's Republic of China
14 October 2013

Visit by Guangzhou Municipal Bureau of Quality and Technical Supervision
7 August 2013

Visit by International Narcotics Control Board (INCB)
1 October 2013

Visit by Swissmedic
17 to 18 October 2013

Health Products Regulatory Conference 2013

The HPRG of HSA held its inaugural Health Products Regulatory Conference (HPRC) on 9 and 10 September 2013 at the Grand Copthorne Waterfront Hotel. This annual platform was previously known as the 'HPRG Joint Regulatory Workshop', which was organised from 2010 to 2012. Its programme has now been enhanced to include international speakers from academia, external regulatory authorities, as well as partner agencies and industry players.

The key objective of the event remains to be a platform for HPRG to share information and provide the latest updates on regulatory developments to our industry stakeholders, as well as to receive their feedback and comments on the regulatory framework for health products. This year's conference theme, 'Enhancing Scientific and Regulatory Collaboration in Safeguarding Public Health', signified HSA's goal to strengthen communication and collaboration with stakeholders to protect and advance public health. This also stemmed from the overarching stakeholder engagement strategy embodied by the tagline 'Bridging Minds, Forging Partnership'.

"Can see that HSA is becoming more open and has made more efforts to engage stakeholders via HPRC and other focus group sessions."

Programme Highlights

The conference started off with the CEO of HSA, A/Prof John Lim, welcoming our overseas keynote speakers, industry stakeholders and delegates. Dr Hubert Leufkens, the Chair of the Dutch Medicines Evaluation Board, gave the first keynote lecture on regulatory science and its multiple roles in protecting patients, ensuring public health and stimulating innovation. The second keynote lecture was given by Prof Stephen Evans, Professor of Pharmacoepidemiology at the London School of Hygiene and Tropical Medicine. His talk focused on the opportunities and challenges of using pharmacoepidemiology as a risk management tool in the regulation of health products. A third overseas speaker, Mr Mark S. Paxton, a Regulatory Counsel in the Centre for Drug Evaluation and Research (CDER) Office of Compliance, US Food and Drug Administration (US FDA) delivered an engaging talk via a pre-recorded video, providing an overview of international initiatives to enhance global supply chain integrity and security.

Local stakeholders from the medical device and pharmaceutical industries were also invited to share their insights on how industry and regulator can work together to promote public health. Amongst the invited speakers were Mr Kevin Lai,

"Updates on the local regulatory framework are focused, useful and relevant."

Director of Biomedical Sciences at the Singapore Economic Development Board; Mr Alok Mishra, Vice President of Johnson & Johnson Medical Asia Pacific; Mr Henry Tan, President of the Association of Medical Device Industry (Singapore); Mr Wong Kum Cheun, Head of Asia Pacific, Policy & Liaison Drug Regulatory Affairs at Novartis Asia Pacific Pharmaceuticals and Mr Koe Khoon Poh, Managing Director of ICM Pharma Pte Ltd.

continue to next page ...

Our distinguished panel of invited speakers

Q & A session during the symposium

HOT OFF-THE-PRESS

[continued from Health Products Regulatory Conference 2013]

"Good to have a mix of local updates as well as overseas speakers from other regulatory authorities."

CEO of HSA, A/Prof John Lim (centre) with the invited overseas speakers, Prof Stephen Evans (left) and Prof Hubert Leufkens (right)

Symposia were held on both days to provide updates and developments in Singapore's medicinal product and medical device regulatory framework.

HPRC's post-conference events

Delegates were invited for a networking session with HPRG after the conference ended on Day 2. Industry stakeholders were also invited to share their product development pipeline with HPRG in a series of closed door scientific discussions. The networking session and scientific meetings were held with the aim that early exchanges of scientific information will be beneficial to both parties and facilitate faster reviews of health products for registration in Singapore.

Participants

The response was overwhelming with over 500 people signing up for HPRC.

Overall feedback garnered from the participants was encouraging. Almost 95% of participants responded that the overall organisation of the conference was either good or excellent. The majority also indicated that their expectations of HPRC were met. We would like to extend our appreciation to all participants for their support and attendance. We also look forward to more enriching engagement sessions with our stakeholders in 2014.

"Useful to have updates on regulatory matters overseas (for example ASEAN Harmonisation of Regulatory Requirements for Health Products) especially when industry members are unable to attend regulatory conferences held overseas."

Implementation of Risk Management Plan in Singapore

In one of the symposium sessions at the Health Products Regulatory Conference, the Vigilance Branch provided an overview of local risk management plans (RMPs) for registered western medicinal products in Singapore.

Current requirements for components making up the RMPs, like educational materials, letters to doctors, restricted access programme, special licensing terms and conditions, provision of sales data when required, and the potential of including Singapore as a centre for clinical studies were mentioned. In addition, new RMP requirements were introduced at the conference, with plans for further consultation with product licence holders. Following the review of feedback and comments from the consultation, the guidance describing RMP requirements in Singapore is estimated to be implemented by the third quarter of 2014.

New Requirements for Consultation

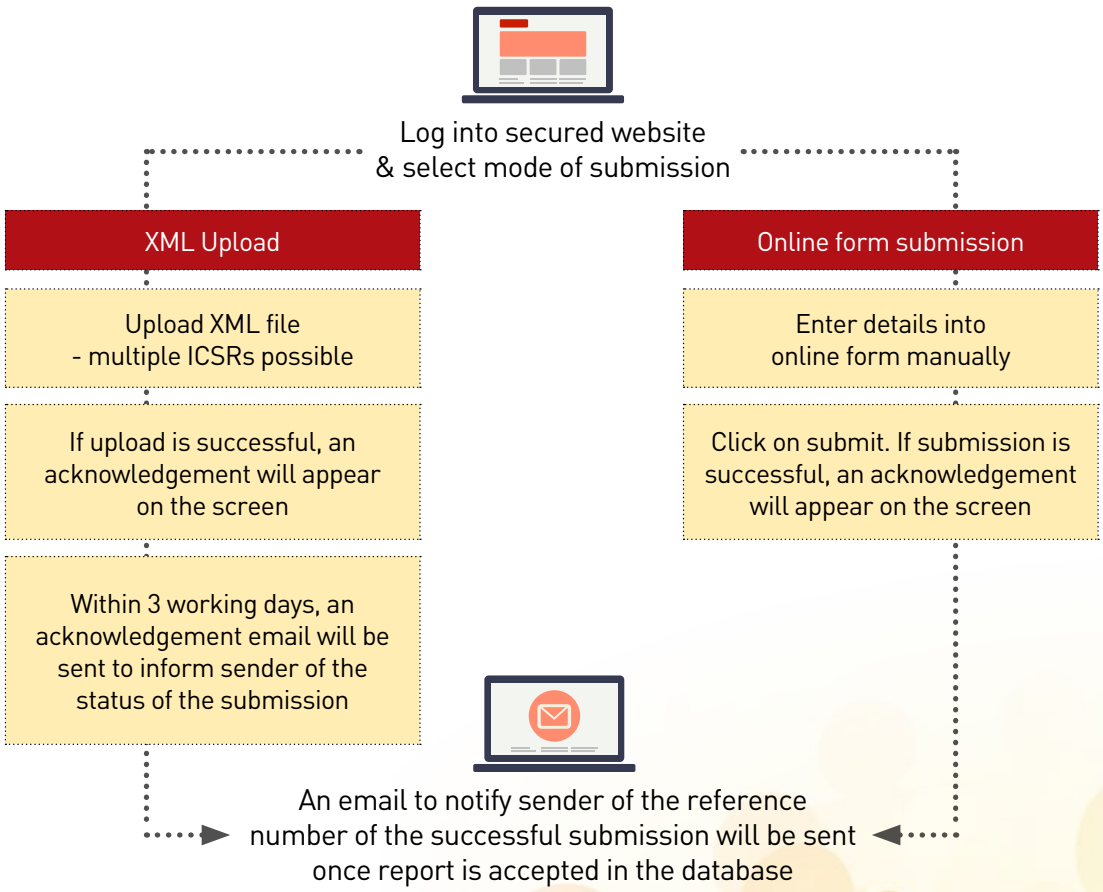
With the revision of the International Conference on Harmonisation (ICH) E2C guidelines, Periodic Safety Update Reports, if requested by HSA, will have to be provided in the Periodic Benefit-Risk Evaluation Report (PBRER) format as described in the ICH E2C (R2) guidelines.

All submissions are to be accompanied with the current local package insert, patient information leaflet (where applicable) and a PBRER submission form. The form serves to facilitate the description of the product's local sales information during the period covered by the PBRER. In addition, companies should provide on the form an assessment as to whether the local package insert and educational materials, if applicable, required updating as a consequence of the content presented in the PBRER.

Moving forward, it will be a requirement for summaries of the EU-RMP or the US Risk Evaluation and Mitigation Strategies (REMS) to be submitted for all NDA-1 and biosimilar applications. HSA may also request for these summaries to be submitted for other products following evaluation of the dossier. Product applicants should provide a Singapore-specific annex with these summary submissions to describe the local RMP that is proposed for the product. The final local RMP for the product will be decided jointly with HSA.

Implementation of ICH* E2B (R2) Requirements for Submission of Individual Case Safety Reports (ICSRs)

HSA will be implementing ICH E2B (R2) requirements for the submission of Individual Case Safety Reports (ICSRs) by the end of 2014 or early 2015.



This is in line with international reporting requirements and will allow Singapore to submit ICSRs to the WHO global ICSR database (VigiBase™) in the preferred ICH E2B format. Currently, local anonymised reports are submitted to the WHO Uppsala Monitoring Centre (UMC) in the old INTDIS (International Drug Information System) text file format.

The electronic transmission of information between organisations relies on the definition of common data elements which are provided in the E2B (R2) document developed by ICH. This standardised reporting format is based on the Extensible Markup Language (XML) format with strict rules on how certain data elements are expressed. Marketing authorisation holders (MAHs) are advised to familiarise themselves with the technical requirements specified in the document so as to better prepare for this implementation.

HSA is in the final stages of system development and will keep MAHs updated on the progress. Companies are encouraged to participate in the pre-launch User Acceptance Testing (UAT) sometime in mid 2014. More information will be made available in the second quarter of 2014. MAHs who can create XML ICSRs from their E2B compliant pharmacovigilance database or who have an automated Gateway software solution can work towards generating ICSRs in XML files for uploading into the HSA secured website.

The chart above gives an overview of the proposed workflow for submission of ICSRs once E2B requirements are implemented. MAHs will be able to either submit individual reports using the online E2B forms or upload multiple ICSRs in XML format.

Should you have further queries, please email us at **HSA_DRUGSAFETY@hsa.gov.sg** or call us at **+65 68663538**.

Inaugural Excellent Stakeholder and Partnership Awards (ESPA)

The Health Products Regulation Group (HPRG) honoured 62 healthcare professionals, partner agencies and associations at its first ever Excellent Stakeholder and Partnership Awards (ESPA) held at the National University of Singapore Society's Kent Ridge Guild House on 6 November 2013.

Excellent Team Player Awards under the 'Protection of Public Health and Safety' Category (Non-Uniformed Group)

Excellent Team Player Awards under the 'Protection of Public Health and Safety' Category (Uniformed Group)

Dr Amy Khor with A/Prof John Lim launching the inaugural Excellent Stakeholder and Partnership Awards at National University of Singapore Society's Kent Ridge Guild House

Prof Fong Kok Yong, receiving the Chairs & Deputy Chairs of HPRG's Advisory Committee Awards from Dr Amy Khor

Chairs and Deputy Chairs of HPRG's Advisory Committee Awards Category

Excellent Partnership Awards Category

Prof Lim Shih Hui receiving the Excellent Team Player Award on behalf of the Pharmacogenetics Team from Dr Amy Khor

ESPA video launch

"It is important for HSA to work in collaboration with its key stakeholders to ensure that the health product regulatory framework is adaptive, efficient and inclusive, without compromising public health."

ESPA recognises the efforts and teamwork of government agencies and public health institutions, as well as clinicians, pharmacists and various associations which have worked collaboratively with HPRG to protect public health and safety, and enhance the regulation of health products. This event will be held biennially.

During the ceremony, a video showcasing these objectives was screened. The video can be found at this link [1].

Dr Amy Khor, Senior Minister of State for Health and Manpower, was the Guest-of-Honour and presented the awards to nine teams from government agencies and hospitals, 11 associations and 10 healthcare experts who provided scientific and technical advice to HPRG. The winners were selected by a panel of judges, based on their contributions and efforts.

Among the award recipients were teams from the Singapore Police Force (SPF), the Immigration & Checkpoints Authority (ICA) and the Central Narcotics Bureau (CNB). These teams worked closely with HPRG's enforcement officers in joint operations which collectively prevented the entry of unregistered and prohibited health products into Singapore. For their contributions towards safeguarding public health in Singapore, they were honoured with the Excellent Team Player Awards under the 'Protection of Public Health and Safety' Category. Click here to download the programme booklet [2].

Other award recipients of the Excellent Team Player Awards included the KK Women's and Children's Hospital and the Health Promotion Board which worked with HPRG to monitor and enhance vaccine safety in Singapore. Another award recipient, a team from the Ministry of Health, developed the Critical Medical Information Store, a national electronic platform available in all public healthcare institutions in Singapore, which allows healthcare professionals to record and access adverse drug reaction reports in the patients' medical records online, and also to submit these reports directly to HPRG.

The Pharmacogenetics Team comprising clinicians and researchers from various institutions (National University Hospital, Singapore General Hospital, Changi General Hospital and A*STAR's Singapore Immunology Network) was another winner of the 'Excellent Team Player Awards'. Since 2009, HPRG had initiated studies with this team to investigate possible genetic associations behind serious drug-induced adverse skin reactions in the local population.

Ten outstanding healthcare experts were also awarded the 'Chairs & Deputy Chairs of HPRG's Advisory Committee Awards' for having provided scientific and technical advice to HPRG on matters relating to pre-market evaluation of product registration as well as post-market health products risk management.

Their contributions, through serving on HPRG's scientific advisory committees and expert panels, have helped in the shaping of sound regulatory decisions and policies that benefitted public health in Singapore. 11 organisations and associations which worked closely with HSA to refine regulatory processes and policies pertaining to health products were also awarded the 'Excellent Partnership Awards'.

Dr Khor said, "It is important for HSA to work in collaboration with its key stakeholders to ensure that the health product regulatory framework is adaptive, efficient and inclusive, without compromising public health."

"The high quality and safety standards of health products in Singapore reflect the strong partnerships established over the years with the different stakeholders gathered and represented here today. Such partnerships are critical for strengthening the robustness and relevance of our health products regulation system. I look forward to widening and deepening this network as we pursue our goal of advancing and protecting national health and safety through the smart and sound regulation of health products in Singapore," said Associate Professor John Lim, HSA's Chief Executive Officer.

International Collaboration for Registration of Generic Drugs

The capacity of a single regulatory agency to promote timely access to safe, efficacious and high quality health products is continually being challenged in the face of the rapid emergence of new technologies, increased globalisation of health products and limited resources.

Recognising these challenges, four like-minded health regulatory agencies formed a consortium to promote regulatory convergence and foster synergy to address scientific and regulatory issues. The four agencies are: the Therapeutic Goods Administration (TGA) of Australia, the Health Products and Food Branch (HPFB) of Health Canada, Swissmedic, the Swiss Agency for Therapeutic Products of Switzerland, and the Health Products Regulation Group of the Health Sciences Authority, Singapore.

This consortium has selected generic drug review as a priority area for collaboration to enhance availability of generic drugs. This will be achieved through convergence of regulatory requirements and approaches, promoting the more efficient use of available resources, reducing regulatory burden and duplication of effort, and improving application approval times. Under this consortium's working group, a comprehensive action plan is being developed, including the sharing of assessment reports, joint reviews of common generic applications, identifying opportunities for regulatory convergence and staff exchanges.

Here is an update on the progress that has been achieved in the following key work areas:

- Common evaluation report template – with the focus on Drug Master Files (DMFs) at this moment, a common evaluation report template will be developed to facilitate the use of another agency's DMF assessment report during the review of a generic application.
- Bioequivalence requirements –the feasibility of regulatory convergence is being explored, especially in the area of Biopharmaceutic Classification System (BCS) biowaivers.
- "Business as usual" process – although unique to each agency, key enablers, such as having a secure IT infrastructure, have been identified. Work to set up a "business as usual" process of sharing information and reports within the consortium using minimal resources is on-going.

At the last meeting hosted by Swissmedic from 24 to 25 October 2013 in Bern, Switzerland, it is envisioned that work-sharing on generic applications within the consortium agencies can come to fruition. We believe that work-sharing will reduce regulatory burden and duplication of effort and that all patients will have faster market access to generic products.

World Health Organisation (WHO) Prequalification Programme of Essential Medicines

The WHO prequalification of medicines is a service provided by the WHO to assess the quality, safety and efficacy of medicinal products for distribution to resource-limited countries via international procurement agencies, such as UNICEF and UNITAID.

The prequalification programme (PQP) helps ensure that medicines supplied by these procurement agencies meet acceptable standards of quality, safety and efficacy. At the end of 2012, the WHO list of Prequalified Medicinal Products contained 316 medicines for priority diseases[3]; furthermore, the PQP has expanded the programme to prequalify active pharmaceutical ingredients and quality control laboratories.

The PQP consists of five components: Invitation, Dossier submission, Assessment, Inspection and Decision.

In support of facilitating access of safe, efficacious and quality medicinal products for priority diseases to resource-limited countries, the Health Products Regulation Group invites you to learn more about the WHO PQP for Essential Medicines by accessing the following weblinks:

WHO PQP factsheet [4]
WHO PQP homepage [5]
Expression of Interest [6]
WHO PQP brochure [7]

ASEAN Harmonisation on Pharmaceutical Inspection: A Win-Win-Win Outcome

The 10 ASEAN Member States (AMS) have very diverse racial, religious, socio-cultural, political, economic and geographical backgrounds. Hence, the task of integrating ASEAN is a highly challenging one. However, ASEAN has resolved to create an ASEAN Economic Community (AEC) by 2015 and its key strength is its combined population (and potential market) of more than 600 million people. This can be turned into a big economic advantage if rules and regulations are harmonised and made transparent to all stakeholders.

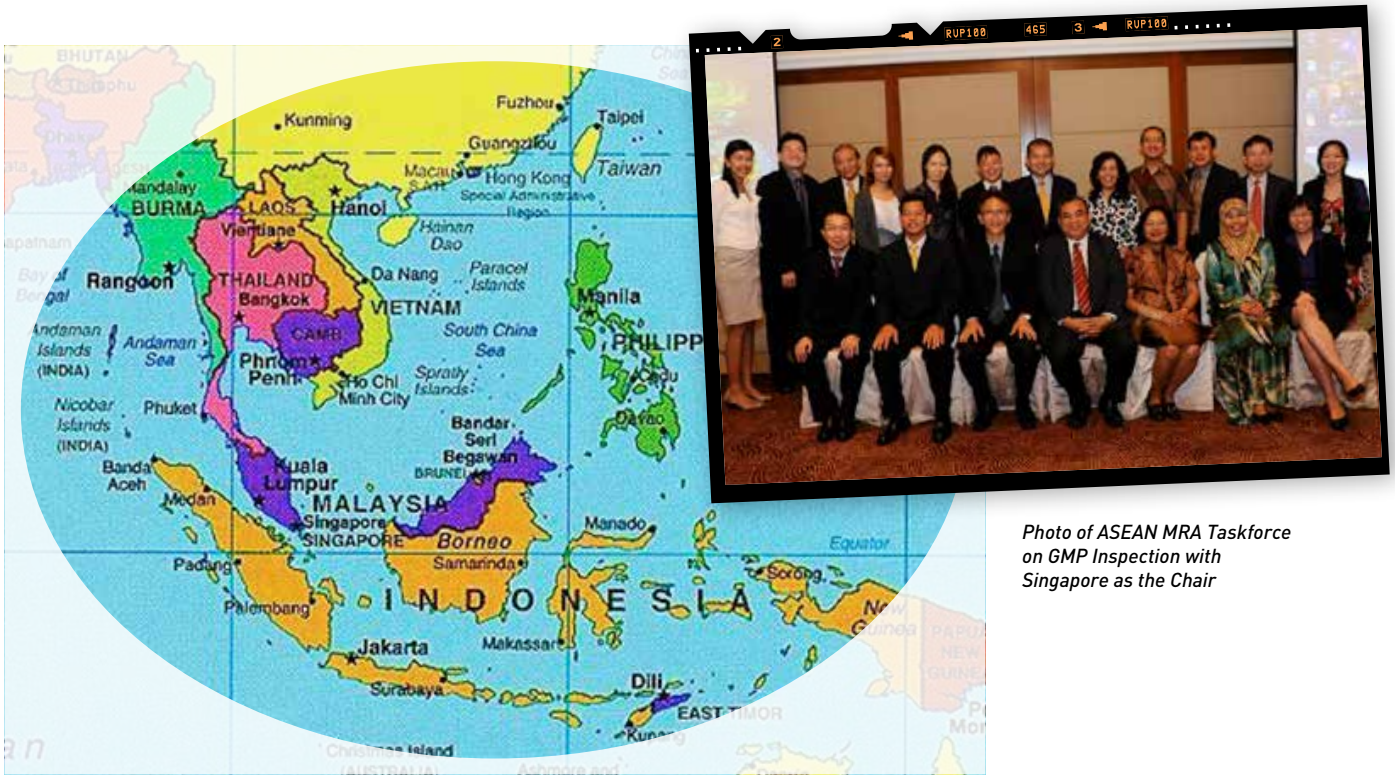


Photo of ASEAN MRA Taskforce on GMP Inspection with Singapore as the Chair

Formation of ASEAN Mutual Recognition Agreement Taskforce on GMP Inspection

The ASEAN Mutual Recognition Agreement (MRA) Taskforce on Good Manufacturing Practice (GMP) Inspection was formed in 2005 with the ASEAN Economic Community (AEC) 2015 as the backdrop. This Taskforce was charged with the responsibility to deliver the ASEAN Sectoral MRA on GMP Inspection for Manufacturers of Medicinal Products and has Singapore and Malaysia as the Chair and Co-Chair respectively. The international Pharmaceutical Inspection Co-operation Scheme (PICS) framework was used as the basis/benchmark for this ASEAN Sectoral MRA on GMP Inspection. This MRA was signed by the Economic Ministers of all 10 AMS on 10 April 2009.

Implementation of the ASEAN Sectoral MRA on GMP Inspection

Currently, the National Drug Regulatory Authorities of three AMS, namely Singapore, Malaysia and Indonesia, are members of PICS. They have been listed and are ready to exchange GMP certificates and inspection reports.

The implementation of this MRA is expected to bring about many benefits to the ASEAN industry, regulatory authorities and patients – a win-win-win outcome. These benefits include:

(i) the avoidance of duplication of GMP inspections (for Listed Inspection Services);

(ii) saving of time, resources and costs for the ASEAN industry and regulatory authorities;

(iii) facilitation of import, export and overall trade in medicinal products across ASEAN; and

(iv) quicker access to medicinal products by ASEAN patients.

New and Improved Medical Device Post-Market Reporting Forms and Procedures

With effect from 27 September 2013, the Health Products Regulation Group's Compliance Branch has refined the medical device post-market reporting procedures for Field Safety Corrective Actions (FSCA) and Adverse Events (AE). This aims to improve the efficiency of the reporting procedures by making it more convenient to submit a FSCA or AE report. The changes implemented include the forms to be used and the reporting channels for making a submission to HSA.

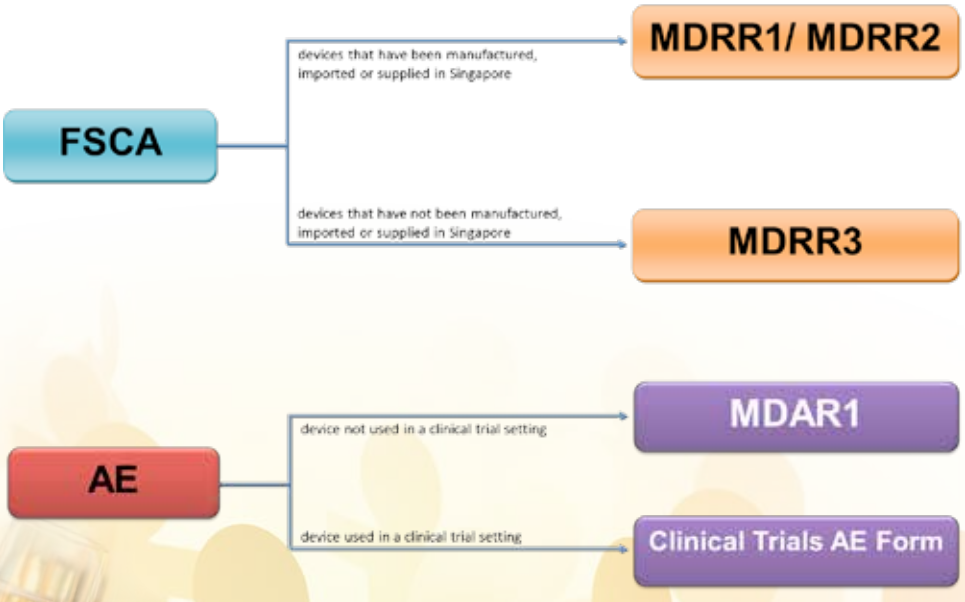
Under FSCA reporting, the Compliance Branch has implemented a new reporting form, MDRR3, for medical device related post-market information. Certain sections in the forms MDRR1 and MDRR2 have been omitted in the MDRR3 Form. This modification will provide clarity on HSA's requirements for such FSCAs for stakeholders.

To ease the preparation of AE reports, an interactive pdf version of the MDAR1 form is now made available for stakeholders. In addition, a new clinical trial medical device AE reporting form is also available for AEs related to a medical device used in a clinical trial setting. Stakeholders will be required to submit such AE reports to the Clinical Trials Branch at **HSA_CT_SAE@hsa.gov.sg** or by fax at **(+65) 6478 9034**.

As part of the refinement to the reporting process, stakeholders may now submit their FSCA or AE (non-clinical trials related) reports via email to **HSA_Medical_Device@hsa.gov.sg**. The scanned copy of the completed report, together with other accompanying documents, should adhere to the email size limit. For submission of reports via email, only official company email addresses can be used.

Reports submitted via fax or postal mail will continue to be accepted. Please note that the fax number has been changed to **(+65) 6478 9038**.

For more information on FSCA and AE reporting, please refer to the following Guidance documents.



AE reporting

GN-05: Guidance on the Reporting of Adverse Events for Medical Devices

FSCA reporting

GN-10: Guidance on Medical Device Field Safety Corrective Action

For email submissions, please send forms MDRR1, MDRR2, MDRR3 and MDAR1 to **HSA_Medical _Device@hsa.gov.sg**. The Clinical Trials AE Form shall be submitted to **HSA_CT_SAE@hsa.gov.sg**

You may contact us at **HSA_Compliance@hsa.gov.sg** should you require further clarification

Interview with Professor Fong Kok Yong

Winner of the Appreciation Awards - Chairs & Deputy Chairs of HPRG's Advisory Committee Awards at the inaugural HSA's Excellent Stakeholder and Partnership Awards (ESPA) 2013.

Professor Fong Kok Yong is the Group Director (Medical) of Singapore Health Services Pte Ltd (SingHealth). He is the Chairman of Medical Board of Singapore General Hospital; Senior Consultant, Department of Rheumatology and Immunology (SGH); Chairman of the Rheumatology and Immunology Resident Advisory Committees, Associate Editor for APLAR Journal of Rheumatology and Singapore Medical Journal.

He is a Fellow of Academy of Medicine, Singapore in Internal Medicine and Rheumatology and Royal College of Edinburgh, UK. Prof Fong has over 100 peer-reviewed publications to-date. He serves as the Senior Associate Dean for the Duke-NUS Graduate School of Medicine and a faculty member of the Yong Loo Lin School of Medicine, National University of Singapore.

Having made extraordinary contributions in the development of rheumatology in Singapore, patient safety and quality care, and establishing the Autoimmunity and Rheumatology Centre in SGH in May this year, he was awarded the National Outstanding Clinician Award at the National Medical Excellence Awards.

As the Chairman of HPRG's Medicines Advisory Committee and Biologics Expert Panel, he was awarded the Appreciation Award at HSA's Excellent Stakeholder and Partnership Awards in November 2013.

We are happy to share with you some insights from the interview with our distinguished and respected award recipient.

As one of the longest-serving Medicines Advisory Committee (MAC) members, what are some of the memorable moments?

Serving as a member of the MAC, there are no specific memorable incidents that stand out. Meetings are understandably serious, but despite the "seriousness", the discussions are generally friendly and often mixed with humour.

Your numerous accolades and leadership roles are a testimony to your passion and dedication as a clinician, teacher and healthcare provider. How do you juggle your time among all your various responsibilities, on top of patient care and research activities?

You are right that these are many hats to wear. The key to managing all these portfolios is to have good time management and appropriate delegation of duties whenever possible. However, for research activities, it is inevitable that I have to gradually scale down from being a principal investigator driving a research project (which demands intensive time investment) to being a collaborator.

Could you share with us some of your proudest achievements as a medical doctor?

There are many proud moments but these are not those times when I received national or institutional awards. I consider my proudest achievements as those times when patients are still very grateful, appreciative and understanding even when they have disabilities despite our best efforts. As a doctor, I consider this a great achievement and testament to the doctor-patient relationship and a demonstration that healing is not only about full recovery, but also helping the patient with our best efforts and accepting the outcome.

How do you think HSA can further advance our scientific and regulatory standards in the regulation of drugs in Singapore?

To-date, HSA has been doing a good job in maintaining regulatory standards, thus ensuring that drugs registered for use by Singaporeans are safe. There are always external pressures (directly or indirectly) to push for lower standards, but I would strongly urge HSA to continue on the path where patient safety and welfare trumps everything else.

What advice do you have for HSA regulatory evaluators who are aspiring to contribute actively to the advancement of medical science in Singapore?

As in all areas related to scientific advancement, one needs to have an inquiring mind, be thorough in searching the relevant literature, challenge existing paradigms and not jump to conclusions too readily.

Do you set aside time for leisure activities during your off-work hours, and what kind of activities do you engage in?

My activities now are somewhat sedentary i.e., reading of novels, walking around the garden to relax the mind. Chinese chess used to be one of my hobbies but you need to find another player to compete. Nowadays, one can play against a computer programme but it is somewhat impersonal.

Determining the Product Classification of Your Product

Depending on the product formulation, indications, dosing directions and presentation, a product could fall under the broad grouping of drugs, medical devices, traditional medicines, health supplements, food or other categories. As regulatory controls of various categories of products may differ, dealers are encouraged to determine the appropriate classification of their products and the corresponding requirements before importing and/or manufacturing them for local sale and supply. Obtaining confirmation of a product's classification from HSA may also help to expedite customs clearance of the product.

How does one confirm the product classification with HSA?

Dealers may make a product classification enquiry by submitting our latest Health Product Electronic Enquiry Form, which is available here [8]

To fill up and submit the Health Product Enquiry Form, simply follow the steps below:

1. **Provide your particulars and your company's information**

SECTION A - PARTICULARS OF ENQUIRER (询问人资料)			
Salutation 称呼			
Name 姓名			
Designation 职位			
Company Name 公司名称			
Company Address 公司地址			
Block / House No. 门牌号码		City 市	
Street Name 街道名称		State / Province 州 / 省	
Level 楼层		Country 国家	
Unit 单位号码		Postal Code 邮政编码	
Building 大厦			
Contact Information 联络信息			
Telephone Country Code 国家电话代码		Office Tel 办公电话	
Mobile 手机号码		Fax No. 传真号码	
Home Tel 住宅电话		Email Address 电邮地址	

2. **Indicate the purpose and history of enquiry**
If you had enquired on the same product previously, please check "Yes" and provide the date of the previous enquiry.

SECTION B - PURPOSE & HISTORY OF ENQUIRY (询问目的及询问历史)

(i) Enquiry on this product in relation to (询问内容涉及):

☐ Import 进口 ☐ Wholesale / Retail 批发/零售 ☐ Manufacture 制造
☐ Assembly 分装 ☐ Advertisement 广告
☐ Developmental product with incomplete information on formulation / concentration / label *
研发中的产品其成分/浓度/标签* 的资料不完整
☐ Others (specify) 其它（请注明）:
* Delete as appropriate (请删除不适用项)

(ii) Have you enquired on this product previously (以前是否曾咨询过该产品)?

☐ No 无 ☐ Yes 有

If yes (如有):

a) **Please state the date of the previous enquiry (请注明上次询问的时间):**
b) **Please state the agency / unit where the enquiry was sent to (请注明曾向哪个机构/部门提交过咨询):**

3. Fill in the basic product details

The product details provided in Section C will facilitate our classification of the product. If more information is required, a request will be sent via email. For Medical Devices and/or developmental products, please fill in where applicable.

SECTION C - PRODUCT DETAILS (产品资料)

SECTION C1 - BASIC PRODUCT DETAILS (基本资料)	
(i) **Brand Name** 商标名称	
(ii) **Product Name** 产品名称	
(iii) **Name of Manufacturer** 制造商名称	
(iv) **Country of Manufacture** 制造商国家	
(v) **Classification in Country of Manufacture** 产品在原产国的分类	☐ Medicinal Product 西药 ☐ Medical Device 医疗器械 ☐ Health Supplement 保健品 ☐ Cosmetic Product 化妆品 ☐ Chinese Proprietary Medicine (CPM) 中成药 ☐ Traditional Medicine (TM) 传统药 ☐ Others (specify)其它（请注明）:
(vi) **Intended use / Indications of use in Singapore** *(i.e. functions / claims)* 产品在新加坡的适应症（如：功能/宣称）	

SECTION C2 - STATUS OF PRODUCT IN OTHER COUNTRIES (产品在其它国家的情况) *[Please attach a separate sheet if space is insufficient (如表中位置不够，请另附一页).]*

Country 国家	**Marketed? 已上市?**		**Product Classification in the Country 产品在该国的分类**
	Yes 是	**No 否**	
Australia 澳洲	☐	☐	
Canada 加拿大	☐	☐	
European Union (EU)欧盟	☐	☐	
United States 美国	☐	☐	
Japan 日本	☐	☐	
China 中国	☐	☐	
Hong Kong 香港	☐	☐	
India 印度	☐	☐	
Malaysia 马来西亚	☐	☐	
South Korea 韩国	☐	☐	
Taiwan 台湾	☐	☐	
Others 其它 –	☐	☐	
Others 其它 –	☐	☐	
Others 其它 –	☐	☐	
Others 其它 –	☐	☐	

SECTION C3 - DESCRIPTION OF FINISHED PRODUCT (产品资料) *[For Medical Devices, please fill in only where applicable (医疗器械产品仅填写相关部分).]*

(i) **Dosage form 剂型** *(e.g. tablet, syrup, injection, powder, etc)（如片剂，糖浆剂，注射剂，散剂等）*	Others (specify) 其它（请注明）:
(ii) **Route of Administration 用法** *(e.g. oral, topical, intravenous, inhalation, etc)（如口服，外用，静脉给药，吸入等等）*	Others (specify) 其它（请注明）:

(iii) **Ingredients** – herbs should be specified by botanical names and Chinese name, where applicable (*成份-草药成份需注明植物拉丁名和中文名 [如有]*)	(iv) **Strength*** *含量(e.g. IU, mg, mcg, %, etc)*	(v) **To select 请选择**	
		Active 活性	**Inactive 非活性**
1.		☐	☐
2.		☐	☐
3.		☐	☐
4.		☐	☐
5.		☐	☐
6.		☐	☐
7.		☐	☐
8.		☐	☐
9.		☐	☐
10.		☐	☐
11.		☐	☐
12.		☐	☐
13.		☐	☐
14.		☐	☐
15.		☐	☐
16.		☐	☐
17.		☐	☐
18.		☐	☐
19.		☐	☐
20.		☐	☐
21.		☐	☐
22.		☐	☐
23.		☐	☐

* Based on the product classification in the country of manufacture (根据产品在原产国的分类):
- For Chinese Proprietary Medicines (CPMs), Traditional Medicines (TMs) & Health Supplements, state the actual quantity of the ingredient (IU, mg, mcg, etc) in the product per unit measure (e.g. per capsule, per 5ml dose, per scoop, etc) [对于中成药，传统药和保健品，请注明单位重量（如每粒胶囊，每 5ml，每匙等）中含有的成份量（国际单位（IU），毫克，微克等）].
- For Cosmetic products, state the percentage (%) of the ingredient in the product [对于化妆品，请注明产品中成份的百分含量（%）].
- For Medicinal Products & Medical Devices (if applicable), state the strength of the ingredient in the product as reflected in the product label [对于西药和医疗器械（如适用），请根据产品标签填写成份含量].

4. Finally, accept the declaration and submit the enquiry form

Click on the "Declaration" checkbox at Section D. Then, click on the "Save" button to validate the form before submission. The enquiry form can only be submitted when all required information has been provided.

SECTION D – DECLARATION

☐ I declare that the particulars given in this application are true and that the supporting documents enclosed are authentic or true copies.

Save

5. Important Note: Please download the form using Internet Explorer and save each form using Adobe Reader as a pdf file

To enable the successful transfer of your data, we recommend that the required information be entered in the eForm. After the eForm has been completed, please save the eForm as a pdf file using Adobe Reader software (please avoid using other forms of file readers) and then email the eForm and the corresponding product packaging material as attachments to **HSA_Prod_Class@hsa.gov.sg**. The time taken for our response to each product classification depends on several factors including the completeness of the documents provided and the risk profile of the concerned product.

For more information on the regulatory controls of the various health product types, dealers may refer to the HPRG webpage [9]

CORPORATE SOCIAL RESPONSIBILITY

Hair Loss is Hair for Hope's Gain!

On the bright and sunny morning of 12 July 2013, the Health Sciences Authority witnessed its first-ever charity shave in support of the Hair for Hope (HfH) for the Children's Cancer Foundation. Organised by the HSA's Health Products Regulation Group Recreation Club, the satellite event was held at the Helios building located at Biopolis.

Before the start of the event, HSA CEO A/Prof John Lim gave an impassioned speech that was so inspiring that two more staff signed up for the charity shave on the spot! A/Prof John Lim then 'shaved-off' the event by shearing the first few strands of hair off Asst Prof Raymond Chua, Group Director of HPRG.

Besides the 14 'shavees', staff also busied themselves with selling memorabilia and soliciting donations for the Children's Cancer Foundation". A total of $12,680 was eventually raised by staff, who were generous in contributing to this worthy cause.

From left: A/Prof John Lim, Asst Prof Raymond Chua, Sebastian Lau, Benedict Lee, Yean Kian Meng, Dr Sun Kai, Mark Wong, Wong Soon Lee, Ashton Quek, Muhammad Fareez Bin Yahya, Toh Tiong, Soo Peng Lam and Johnny Lee

The HSA HPRG Recreation Club aims to organise this on an annual basis and hopes to have its first-ever female 'shavee' soon.....

With hair... ... and shaved!

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.

Your Newsletter
Your Comments

URL Address Listings **< 1 >** http://www.youtube.com/watch?v=wW7A7EHE6SI **< 2 >** http://www.hsa.gov.sg/publish/etc/medialib/hsa_library/health_products_regulation/events/espa2013.Par.84492.File.tmp/ESPA_Programme_Booklet%20(A5).pdf **< 3 >** http://www.who.int/mediacentre/factsheets/fs278/en/ **< 4 >** http://www.who.int/mediacentre/factsheets/fs278/en/ **< 5 >** http://apps.who.int/prequal/ **< 6 >** http://apps.who.int/prequal/info_general/topics_index.htm **< 7 >** http://apps.who.int/prequal/info_general/documents/advocacy/Advocacy_booklet_2012.pdf **< 8 >** http://www.hsa.gov.sg/publish/etc/medialib/hsa_library/health_products_regulation/crm.Par.90932.File.tmp/Product%20Enquiry%20eForm.pdf **< 9 >** http://www.hsa.gov.sg/publish/content/hsaportal/en/health_products_regulation.html

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