

nexus²US

CONNECTING WITH
OUR PARTNERS



HSA
Health Sciences Authority

NOVEMBER 2012

The background of the cover is a collage of green-tinted images: a person jumping in the air, a line graph resembling a heartbeat, and laboratory glassware (test tubes and beakers) in the foreground. The entire scene is overlaid with a grid pattern.

Striving *for* Excellence



A NEWSLETTER *for our* HEALTH PRODUCTS INDUSTRY & COMMUNITY

From the Editor-in-Chief

Dear Readers,

We have come to the end of the year! It is usually a time for most of us to reflect and see how best we can improve for the following year. I know that there will always be areas for improvement. HSA has taken on board industry feedback and will strive to do better in partnership with you.



Dr. Raymond Chua,
Group Director, HPRG, HSA

2012 has been most exciting for us. We have rolled out a few initiatives after consultation with our stakeholders.

- In August 2012, HSA announced lower fees for medical devices imported through the Special Authorisation Routes. This will facilitate greater access to unregistered medical devices necessary to fulfil unmet medical needs.
- In September 2012, HSA launched a publicly-accessible clinical trials register. The register is available on the HSA website, and provides relevant clinical trial information to all stakeholders, particularly patients and their health care providers. This is a first step towards greater transparency and fostering evidence-based medicine, which we hope will lead to better health outcomes for all.
- The piece de resistance in this issue is that the enhanced health products regulatory section of the HSA website has gone live on 1 November 2012. Feedback from stakeholders had indicated that the website needed to be enhanced. Hence, we have revamped some elements to make it more intuitive, navigable, and friendlier for industry stakeholders, healthcare professionals and the general public. You can rate our website in the enhanced section and let us know how to further enhance our website.

We will continue to collaborate and engage with the industry stakeholders, regardless whether you are a SME or MNC, a company dealing with drugs or medical devices or traditional medicine or health supplements, or if you understand or do not comprehend our regulatory framework or guidances. Together with you, we will continually review our regulatory framework taking into consideration the fast scientific and technological advancements, complexity of our health products and your feedback.

Please keep the conversation going. If you have any new suggestion or idea, you may write to us at HSA_HPRG_NEX2US@hsa.gov.sg. I look forward to another fruitful year of engagement in 2013 as we continue to work together to assure public health and safety!

Yours sincerely,
Raymond

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editorial team

Editor-in-Chief
Dr Raymond Chua

Executive Editor
Angie Tan

Assistant Editors
Adena Lim,
Diana Koh,
Valerie Wee

Contributing Authors

Beverly Liew, Evelyn Lee, Freddie Foo, Jasmine Ong, Josephine Wong, Liesbet Tan, Marissa Pang, Mark Wong, Michelle Kok, Peh Hwee Leng, Tan Wei Chuen, Tay Swee Ling, Dr Yvonne Koh, Chua Siew Wei, Geraldine Goh, Dorothy Toh

Corporate Content Contributors
Wang Yunshi
Sophus Chong

Advisors
Lee Hui Keng,
Suvarin Chaturapit

HSA Launches Clinical Trials Register

With the launch of the Clinical Trials Register on 1 September 2012, Singapore now joins an increasing number of countries and regions, such as the United States, the European Union, and Australia/New Zealand in providing information on clinical trials conducted locally. This is in line with the global approach towards improving transparency and public availability of information on clinical trials.

What is the HSA Clinical Trials Register?

The HSA Clinical Trials (CT) Register is a publicly-searchable database containing information on clinical trials that have been granted Clinical Trial Certificates (CTC), which is the regulatory approval under the Medicines Act and the Medicines (Clinical Trials) Regulations. Clinical trials with active sites as of 1 September 2012 are listed in the register.

What is the source of the clinical trial information, and how updated is it?

All the information is extracted from the online CTC application and other clinical-trial related forms submitted through Pharmaceutical Regulatory Information System (PRISM) by local sponsors. Local sponsors are required to seek approval from HSA whenever there is a change of key clinical trial information, and submit clinical trial status reports at least on a six-monthly basis. The information is as updated as sponsors maintain it to be so.

Are there plans to extend the HSA CT Register to include clinical trials of other product types?

When HSA implements the Health Products (Clinical Trials) Regulations in 2013, medical device clinical trials that fall within the scope of regulation will be included in the Clinical Trials Register.

How does the HSA CT Register compare with ClinicalTrials.gov and the World Health Organisation (WHO) International Clinical Trials Registry Platform (ICTRP)?

The launch of the HSA CT Register marks an initial step towards fulfilling international norms.



The online register provides the following essential information about clinical trials:

- Protocol Title/ Number
- Phase
- Therapeutic Area
- Name of Study Drug
- Sponsor
- Trial Site
- Principal Investigator
- Status [not started yet, ongoing, premature site closure, terminated or completed]

ClinicalTrials.gov, which was launched in 2000 and maintained by the US National Institutes of Health is undoubtedly the largest, most widely recognised and used registry system. The HSA CT Register was developed using the existing IT system, the (PRISM). The PRISM system has been in use for online regulatory submissions since 2003. Significant enhancements are being planned for the CT Register to display trial information that meets the WHO standard to be considered fully registered. There are currently 20 data elements defined in the WHO Trial Registration Data Set.

The current system will be replaced by a new government-wide licensing system, the Facilitating Reforms for Innovation and Enterprise (FRONTIER) in first half of 2014. FRONTIER will be developed to be able to capture the 20 data elements electronically to be integrated into the CT Register, making it fully recognised by WHO as a Primary Registry. This future initiative will be significant as the International Committee of Medical Journals Editors (ICMJE) will accept registration in any of the primary registries that participate in the WHO ICTRP. This will

help fulfill a key criterion for research publication in an ICMJE journal.

HSA will also be consulting with various stakeholders (industry, healthcare professionals and the public) on other potential enhancements, such as posting of clinical study results.



Fee Review for Medical Device Special Authorisation Routes


Following the announcement on the series of enhancements made to the medical device regulatory framework in April 2012, HSA continues to gather feedback through numerous communication and engagement sessions with industry and healthcare professionals.

HSA remains committed to bring about further enhancements to the regulatory framework to expedite access and manage regulatory costs, while ensuring that safe and effective medical devices continue to be available for patient care.

On 2 August 2012, HSA announced through a press release [Click * !\[\]\(e78f798d4ea5c530c9db49e7d26e6b95_img.jpg\)](#) on the lowering of fees for medical device brought under Special Authorisation Routes (SAR). With

lower fees, healthcare professionals will have greater access to unregistered medical devices which will in turn fulfil medical needs of their patients. The announcement was also made during a briefing to the industry at the Annual General Meeting (AGM) of the Association of Medical Device Industry (AMDI) on 3 August 2012. After a re-costing exercise for the SAR fees, the revised fee structure with reduced fees had been implemented (refer to Table 1) as of 1 August 2012.

TABLE 1



Revised SAR fees structure Details are available here * 	
INITIATIVE	POTENTIAL BENEFIT(S) TO HSA'S STAKEHOLDERS
<p>Revised SAR Fees structure <i>From 1 August 2012</i></p> <ol style="list-style-type: none"> GN-26 (named-patient; requests by healthcare practitioners to import unregistered medical devices for use in specific named patients due to lack of registered alternatives): \$150 GN-27 (PHMCA licensed facility; requests by licensed importers to import unregistered medical devices for use in specific PHMC-licensed healthcare institutions due to lack of registered alternatives): \$350 GN-28 (import for re-export; requests by licensed importers to import unregistered medical devices for re-export purposes): \$250 GN-29 (non-clinical use; requests by licensed importers to import unregistered medical devices for non-clinical purposes e.g. exhibition, training purposes etc.): \$250 	<p>The original fees were \$500 per application under GN-26 to GN-29. With the revised fees, applicants will benefit from reduced regulatory cost associated with applications to import and supply unregistered medical devices via the Special Authorisation Routes (SAR).</p>

* Please refer to last page for URL addresses

Enhancements to Medical Device Information & Communication System

As a result of Class A and Class B regulatory enhancements for medical devices, operational enhancements were made to the online licensing Medical Device Information & Communication System (MEDICS). Subsequently, four industry briefings were held on 17 and 24 August 2012 to update the industry on the regulatory enhancements for Class A and Class B medical devices. The MEDICS enhancements are summarised in Table 2 below.

TABLE 2

Summary of MEDICS enhancements for Class A and B medical devices (Details are available at the HSA website by clicking on this link icon* 	
MEDICS ENHANCEMENTS	POTENTIAL BENEFIT(S) TO HSA'S STAKEHOLDERS
<p>Class A Medical Devices</p> <ol style="list-style-type: none"> 1. Manufacturers and importers of Class A exempted devices are to provide HSA with half-yearly notifications. 2. At the renewal of dealer's licence module or upon notification, companies will be able to upload their Class A Exemption List which should include the items imported, currently importing and planned to be imported in the next 6 months. 	<p>For Class A exempted medical devices, there will be no application fee of \$25 charged as product registration is not required for the exempted devices. The enhancements will result in faster access for Class A exempted devices.</p>
<p>Class B Medical Devices</p> <p><i>For Immediate Registration (IBR) applications:</i></p> <ol style="list-style-type: none"> 1. Upon submission via the MEDICS, the medical device will be registered immediately and will be listed on the SMDR within an hour. 2. An email notification regarding the successful registration of the device will be sent within 48 hours after submission in MEDICS. 3. Fees will be charged immediately upon successful submission. As devices are registered immediately upon successful submission, applicants are reminded to ensure the devices fulfil ALL the eligibility criteria and that all the required information is entered correctly, accurately and completely. <p><i>For Expedited Registration (EBR) applications:</i></p> <ol style="list-style-type: none"> 1. Upon submission via MEDICS, an application fee will be charged immediately. The application will be verified for eligibility of EBR and the dossier will be verified for completeness and accuracy. 2. Once confirmed, the application will be accepted for evaluation. The evaluation fees will be charged at this point. 3. In view of the shortened turn-around-time of 60 working days, progressive payment will not be an option available for applications submitted via this route. 	<p>For Class B medical devices that qualify for the IBR/ EBR routes, the evaluation fee will be \$900 as compared to the \$1800 evaluation fee charged for abridged evaluations. The enhancements will result in faster access and lower regulatory fees for Class B medical devices that qualify for the new routes.</p>
<p>HSA SMaRT E-guide on MEDICS enhancements for Class A and B medical devices</p> <ol style="list-style-type: none"> 1. The HSA SMaRT E-guide on MEDICS enhancements has been launched on HSA's website. The E-guide may be accessed via this link icon* . 	<p>The E-Guide will aid industry with clearer step-by-step advice on medical device registration dossier submission.</p>

Engaging Our Dentists from the Singapore Dental Association

HSA's dialogue with Singapore Dental Association (SDA) on 17 August 2012 marked the start of SDA-HSA stakeholder-regulator relationship building. This was a culmination of a meeting between HSA and Dr Kuan Chee Keong, SDA President and Dr Kelvin Chye, SDA Vice-President, who expressed the need for more dialogues between medical device regulators and the dental profession. The meeting highlighted the importance of engaging dentists and increasing their regulatory knowledge of medical device regulations as it has a direct impact on the supply and access of dental products. In addition to the dialogue session, HSA also provided a hardcopy update on the current medical device framework and the use of the Singapore Medical Device Register which was circulated to its members.


The dialogue session was held at Orchard Parade Hotel and was well attended by 109 SDA members. Dr. Kuan kicked off the session with a thought-provoking opening speech, setting the tone for the dialogue session, and encouraged his fellow members to be open and provide honest feedback. Dr Sethuraman Rama from HSA presented on the current initiatives based on the recent enhancements to the medical device regulatory framework. She further provided a brief overview of future initiatives on the review of change notification route for Class B medical device applications, Good Distribution Practice for Medical Devices (GDPMDS) for Class A devices, expedited route for Class C & D devices and the review of regulatory fees framework to better stratify the whole fee structure for devices. She also made reference to common dental products to illustrate how the new enhanced regulatory framework applies to this group of devices.

This was followed by a panel discussion which comprised Dr Raymond Chua, Group Director, Health Products Regulation Group (HPRG); Dr Lou Huei-Xin, Division Director (Pre-market), HPRG and Dr Sethuraman Rama, Senior Manager, Medical Device Branch, HPRG. The discussion saw active participation from SDA members, highlighting concerns of access and supply of dental products, providing their inputs on HSA's risk-stratified regulatory approach and highlighting regulatory fee issues which had impacted the cost of treatment to dental patients.

HSA's panellists actively listened to feedback from a very participative audience and clarified any misconceptions on medical device regulations. Dr Raymond Chua wrapped up the session by sharing that it was through such active dialogues and feedback that HSA is able to calibrate policies and regulations such that there

is judicious and wise administration of regulations in line with HSA's vision of ensuring public safety and mission of wise regulation of health products. In the process, the business and clinical practice needs of our stakeholders will be also need to be taken into consideration.

The session was a good start towards better communication and mutual understanding between the regulator and stakeholders. HSA would like to take this opportunity to thank our dental professionals for their active participation at the dialogue session and would like to assure them that their feedback has been heard and will be taken into consideration.

More information on the dialogue session can be found at 'Regulatory Updates on Medical Device*'  on our HSA website.



Left to right: Dr Kelvin Chye, Vice-President of SDA; Dr Sethuraman Rama, Senior Manager, HSA; Dr Raymond Chua, HPRG Group Director, HSA; Dr Lou Huei-Xin, Division Director, Pre-Marketing Division, HSA



Safeguarding Public Health: The Enforcers

Heroes behind the scenes

The HSA Enforcement Branch is staffed with a team of dedicated officers whose work is radically different from their colleagues within the Health Products Regulation Group.

The work of the Enforcement officer stems from the Enforcement Branch's ethos to safeguard public health and safety. The Branch's efforts to this end include carrying out various activities such as combating the supply of counterfeit health products, battling against syndicates involved in the illegal sale of codeine cough mixtures and conducting raids and seizures of large quantities of illegal sexual enhancement medicines.

Frequently viewed as a job that is fast-paced and exciting, the daily work of HSA Enforcement officers are steeped with challenges as they interview witnesses and offenders, develop and pursue leads as well as identify and collect evidence. Prosecution of offenders in court is routine for the officers, who ensure that all cases they investigate are rigorous enough to withstand legal challenges in court.

In the ongoing fight against illegal health products, the Enforcement Branch works closely with other law enforcement agencies both internationally and locally such as the INTERPOL, the Police, Central Narcotics Bureau, Immigration and Checkpoints Authority and the Singapore Customs. In addition, the Branch also plays an integral role in supporting the overall health products regulation framework through post-market surveillance activities where health products are acquired from the market and tested for compliance to safety and regulatory requirements.

Armed with a sound knowledge of health products' laws and a passionate heart to serve, the Enforcement officers frequently work behind the scenes to remove potentially unsafe health products from the market and apprehend offenders of these laws. Their efforts are often unseen by the public eye but their work is crucial in the overall safeguarding of public health and safety.

However, protecting the public from potentially hazardous health products cannot be wholly achieved without the help and cooperation of HSA's stakeholders, such as the industry. Dealers of health products can play an important role to ensure the safe supply of health products to consumers and prevent unsafe health products from entering the market. Dealers are advised to familiarise themselves with the relevant regulatory controls and to work together with HSA to safeguard public health.




.....
“Dealers of health products can play an important role to ensure the safe supply of health products to consumers.”
.....

New & Revamped HSA Webpages! Navigating the New Health Products Regulation and Medical Devices Webpages

In response to feedback by the industry, HSA has embarked on revamp of the HSA website in phases, starting with the Health Products Regulation Group (HPRG) and Medical Devices (MD) webpages.

The objective of this project is to improve the navigability and user-friendliness of our webpages, as well as enhance their visual appeal.

Health Products Regulation (HPRG) site* 

Medical Devices (MD) site* 


The first major change to the HPRG homepage is the introduction of tabs to toggle between 3 interest groups: Our industry stakeholders, healthcare professionals and the general public. Each Unit within HPRG webpage is now represented by image icons, and 'quicklinks' within each section targeting information relevant to each respective Branch without having to click further within the regulatory Branch pages.

For example, one may access the MD Regulatory Guidances webpage directly from the HPRG main page without needing to first access the MD webpage.

Other changes include:





- An 'Announcements' section displaying the latest updates of news and events from HPRG.

- Visual banners to make the links to PRISM and MEDICS more prominent.

- An improved, more comprehensive contact listing of the various HPRG Branches, under the 'Contact Info' section* 

- A section containing links specific to industry tagement and development.

The Medical Devices webpage has also undergone minor enhancements. Weblinks to MD webpages are tagged with an icon and displayed prominently on the main section of the webpage instead of being displayed at a left-hand sidebar previously. The weblink to the MEDICS banner is again displayed prominently, and we have an 'Announcements' section focused on the latest news and events on medical devices. Category icons have also been introduced to allow easier search of information based on the following categories :

-  A general 'overview' icon for introduction to regulatory updates, framework & legislation
-  A 'technical' icon for technical and specific regulatory information & E-services platforms
-  A 'safety reporting/consumer advisory' icon
-  A 'help' icon for FAQs, E-guides & regulatory guidance



Screenshot of New HPRG Main Page

Screenshot of New MD Home Page

Health Products Regulation

The Health Products Regulation Group ensures that drugs, innovative therapeutics, medical devices and health-related products in Singapore are wisely regulated to meet appropriate standards of safety, quality or efficacy throughout the life cycle of these products. The Group comprises:

- Pre-marketing Division
- Vigilance, Compliance and Enforcement Division
- Audit and Licensing Division
- Group Director's Office

For more information on the organisation structure of HPRG, please [click here](#).

Click tabs for quicklinks catered to each group

For Industry | For Healthcare Professionals | For Public

Western Medicines

- Guidelines on Drug Registration
- Apply and Manage Applications and Licenses @ PRISM
- Licenses and Fees
- FAQs
- ...more

Medical Devices

- Regulatory Guidances
- Apply and Manage Applications @ MEDICS
- Fees and charges
- FAQs
- ...more

Complementary Health Products

- Food-Health Product Classification Tree
- Health Supplements
- Traditional Medicines and Homeopathic Medicines
- Raw Medicinal Herbs
- Chinese Proprietary Medicines (CPM)

Announcements

- HSA Allows Chinese Proprietary Medicines Containing Berberine for Sale in Singapore from 1 January 2013
- HSA Lowers Fees for Medical Device Special Authorisation Routes
- HSA Alerts Public to Ilegal and Adulterated Capsules That Have Caused Serious Adverse Reactions

Latest HPRG news

Rate our page

Quick Links

Online Search

Medicinal & Health Products Search

e-Services & Forms

PRISMTM Pharmaceutical Regulatory Information System

MEDICSTM Medical Device Information & Communication System

Do you want to find out the PRODUCT CLASSIFICATION of your product?

Medical Devices

Medical devices are critical to the delivery of healthcare.

The term "Medical Devices", as defined in the [Health Products Act 2007](#), covers a wide range of medical instruments used in the treatment, mitigation, diagnosis or prevention of disease or abnormal physical condition.

Medical devices vary in complexity from simple products such as tongue depressors, surgical sutures and contact lenses to more complex devices such as implantable defibrillators, prosthetic heart valves and diagnostic imaging systems

Announcements

- HSA Lowers Fees for Medical Device Special Authorisation Routes
- Industry Consultation: Draft Guidance on Registration of Class B Medical Devices

Quick Links

Online Search

- Singapore Medical Device Register (SMDR)

e-Services & Forms

MEDICSTM Medical Device Information & Communication System

General

- About Medical Device Branch
- Contact Info
- Pre-submission Consultation Request

Other Links

- Applied Sciences
- Blood Services
- Health Products Regulation

Overview

Learn more about what is a medical device and the principles of classification of medical devices.

Regulatory Updates

News updates, safety alerts on medical devices and guidance documents.

SMDR

Search the Singapore Medical Device Register (SMDR)

Regulatory Framework

Provisions of the Contact Lens Practitioners Act, Radiation Protection Act, Medicines Act and implementation of regulatory controls.

Medical Devices Advisory

For healthcare professionals, industry and consumers.

Fees and charges

Registration, Retention, Amendment, Dealers Licence and other Fees

MEDICS (Medical Device Information & Communication System)

Carry out transactions with MED and view device information online.

Transition List

Information on the Transition List (T-List)

Authorisation routes

Other e-services and Forms

CRS: Pre-submission consultation, Grouping enquiry

HSA Smart E-Guide

A step by step video guide on registration of medical devices

Regulatory Guidances

Guidance documents and draft guidance of consultation.

FAQs

Tradenet controls

Impact of medical devices in Singapore through Tradenet

Field Safety Corrective Action Reporting

Guidance on submitting FSAR

Adverse Event Reporting

How to report adverse events to MED

Rate the Health Products Regulation Group

Thank you for using our website. As part of our on-going efforts to provide better customer service, we would appreciate if you can take a few moments to fill in the survey form below. Please note * are required fields.

Is the information easy to understand? If not, please provide comments in the box *

1 2 3 4 5

Is it easy for you to find the information you were looking for? If not, please provide comments in the box *

1 2 3 4 5

Are the contents relevant to your needs? If not, please provide comments in the box *

1 2 3 4 5

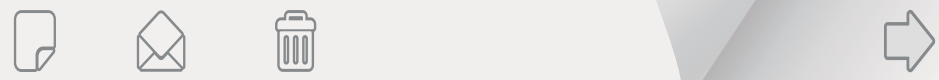
Provide feedback on webpage here

More prominent links to e-services

Links displayed on main screen instead of side column

Category icons for visual appeal

Quick links



ASEAN Consultative Committee for Standards and Quality (ACCSQ)

As part of the efforts to enhance and facilitate economic integration within ASEAN with the aim to reduce technical barriers to trade, the ASEAN Consultative Committee for Standards and Quality (ACCSQ) was formed in 1992. Within the ambit of HSA, four product working groups for health products were established under the ACCSQ to work towards the realisation of an ASEAN Economic Community in the ASEAN market. The groups under the ACCSQ for health products are:

- ASEAN Cosmetic Committee (ACC)
- Pharmaceutical Product Working Group (PPWG)
- Medical Device Product Working Group (MDPWG)
- Traditional Medicines and Health Supplements Product Working Group (TMHS PWG).

Represented by national drug regulatory agencies, ASEAN Secretariat, as well as industry participants, the working groups come together at least once a year to discuss and develop harmonisation strategies and explore areas for integration. These meetings provide an excellent platform for regulators and industry in ASEAN to discuss technical guidelines and regulatory requirements on the harmonisation of health products. With this harmonised regulatory regime, the entry requirements for companies into the Southeast Asian markets for health products will be similar and the public will be able to enjoy quicker access to high quality, safe, novel and affordable products.



Key Updates on Product Working Groups

Hosting of 17th ACCSQ Traditional Medicines and Health Supplements Product Working Group Meeting in Singapore

HSA successfully hosted the 17th ACCSQ TMHS PWG meeting and its related events from 25 to 30 June 2012 in Singapore. The event saw intensive meetings held by the ASEAN TMHS Scientific Committee (ATSC), TMHS Good Manufacturing Practice (GMP) Task Force and Task Force on ASEAN Regulatory Framework for TMHS over six days. HSA would like to extend our appreciation to the 122 participants from 10 ASEAN member states including regulators and industry players for their support during the event.

Harmonised Technical Requirements for Pharmaceutical Products

Since 2003, the PPWG achieved the implementation of the ASEAN Common Technical Dossier (ACTD) and ASEAN Common Technical Requirements (ACTRs) which harmonised technical requirements and submission dossier format for drug applications within ASEAN. Discussions to update and improve the ACTD and ACTR documents are ongoing. One of the recent initiatives was to develop an ASEAN Variation Guideline with harmonised technical requirements for variation applications.

With discussions and inputs contributed by the Member States since 2009, the finalised guidelines were adopted during the 19th PPWG meeting in July 2012, with a target date implementation of July 2012.



[From left] Pn Siti Aida Abdullah, Co-Chair, TMHSPWG; Dr Raymond Chua, Group Director, Health Products Regulation Group, Health Sciences Authority; Mrs Marie Tham, Chair, TMHSPWG



An excellent platform for regulators and industry from ASEAN Member States to collaborate and discuss technical guidelines and regulatory requirements.

Regulators and industry players


First ASEAN Cosmetic Public Private Forum for ASEAN Cosmetic Committee


With an aim to provide a two-way communication mechanism on issues related to the cosmetic sector, the ACC held the first ASEAN Cosmetic Public Private Forum during the 17th ACC Meeting in July 2012. At the same time, ASEAN industry stakeholders shared their experience on the implementation of the ASEAN Cosmetic Directive (ACD) while the European Commission updated on the latest developments on cosmetics regulation in Europe. The Cosmetic Testing Laboratory Network (ACTLN) also reviewed a list of proposed new ASEAN Cosmetic Methods (ACMs).

Harmonisation of Medical Device Regulations

The MDPWG is in the process of drafting and developing the ASEAN Medical Device Directive (AMDD) which decrees the framework for the ASEAN community to harmonise the regulation of medical devices in the region. Major features include the ASEAN Common Submission Dossier Template (CSDT), a harmonised medical device classification system and a platform for the sharing of post-market surveillance alerts such as adverse event reporting and recalls. When developing the framework, comments from the medical device industry were solicited and public consultation among the industry was carried out for the integration process in August 2012.

Get Updates on ASEAN Product Working Groups!

For Harmonisation of Standards and Technical Requirements for Traditional Medicines and Health Supplements, click* 

For Developments on the ASEAN Cosmetic Directive, click* 

For updates on the Product Working Group on Medical Device (MDPWG), click* 

UPCOMING EVENTS

Asia Regulatory Conference 2013– Focus on Best Practices and Global Challenges

The Asia Regulatory Conference, organised by the Drug Information Association (DIA) and co-hosted by the Health Sciences Authority (HSA), will be taking place from 28 – 30 January 2013 at the Raffles City Convention Centre.

The objective of this three day conference is to offer the opportunity for stakeholders from regulatory health authorities, pharmaceutical companies and clinical researchers to meet and exchange views, discuss on various topics of interest and to identify focus areas for ongoing efforts to increase patient access to new and improved medicines.

Representatives from the World Health Organisation (WHO), regulatory health authorities and pharmaceutical industries from ASEAN and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) member countries will be leading discussions on regulatory aspects of the ICH, Asia-Pacific Economic Cooperation (APEC) and Association of Southeast Asian Nations (ASEAN) convergence initiatives, as well as on topics such as global drug development, good regulatory practices and pharmacovigilance.

This conference will provide a forum to facilitate discussion on common issues in the regulatory and technical areas, encourage greater convergence of regulatory requirements especially within the Asian community, and to strengthen cooperation between regulatory authorities and the pharmaceutical industry. The themes for each of the three days are as follow:

Day One – Research and Development
Day Two – Good Regulatory Practices
Day Three – 21st Century Global Regulatory Challenges.



Professionals involved in or interested in the aspects surrounding registration of medicinal products and regulatory convergence initiatives in Asia are encouraged to attend this conference. This conference would be relevant for professionals involved in regulatory affairs, clinical research and development safety and pharmacovigilance, clinical trial and project management, as well as those involved in handling information pertaining to quality, manufacturing and controls.

Information on the programme can be found at the following website:
<http://www.diahome.org/AsiaCon2013>

Medical Device Seminar

Look out for more information on HSA's website for the Medical Device (MD) seminar to be held from 15-16 March 2013 for our industry partners and healthcare professionals.

A panel of renowned international experts will be invited to give us a global perspective on pre- and post- market Medical Device Regulations. Details will be posted on our website in early February 2013.

Perspectives from Ms Ng Lee Choon

“In Conversation” is a special column where HSA gets first-hand insights & perspectives from our stakeholders through face-to-face interviews.

In this 2nd edition of our NEX2US newsletter, we had a candid talk with Regional Regulatory Affairs Director (Asia Pacific) of Molnlycke Healthcare (a global establishment dealing in surgical and wound care products), Ms Ng Lee Choon on the recent enhancements to the medical device regulatory framework announced on 20 April 2012.

A pharmacist by training, Lee Choon has been in the regulatory affairs industry for more than 17 years. She started her career in 1995 handling regulatory affairs for pharmaceuticals and consumer goods then medical device regulations, taking on her current position as Regional Regulatory Affairs Director for Asia-Pacific at Molnlycke Healthcare where she handles regional regulatory affairs and quality assurance.

Can you share with us some of the opportunities & challenges that you faced as a regulatory professional from managing regulatory affairs in a pharmaceutical company which deals mainly with medicinal drugs to Multinational Corporation (MNC) which manufactures and supplies medical devices in Singapore?

Medicinal products have been regulated by HSA for decades, making the registration process more established, and the evaluation criteria is also robust and consistent. In comparison, regulatory controls for medical devices have a shorter track record, starting in 2007 from the Phase 1 implementation of the regulatory controls under the Health Products Act to January 2012 where the last phase of implementation commenced.

With your vast experience dealing with HSA’s Health Products Regulation Group (HPRG) over the last few years and having witnessed the enhancement of the Medical Device Framework announced on the 20 April 2012, can you share with us your perspective on these changes and how it has had an impact on the medical device industry?

With the new routes (immediate and expedited registration routes) implemented for Class B devices, the shortened turnaround time is especially welcomed. Unlike drugs, the lifespans of medical devices tend to be shorter. Moreover, multiple or concurrent changes in devices can occur over a short period of time. Hence, the short time frame cannot accommodate a long review timeline. The reduction in regulatory fees will also benefit the industry.

Together with the exemption of the Class A non-sterile devices, the enhancements will especially be of aid to small and medium enterprises (SMEs) which have fewer resources and which may tend to deal with less complicated devices.

Can you share with us further on the specific initiatives which HPRG has done well with regards to the announced enhancement of the MD regulatory framework, and what else we can do better?

The enhancements made to the Special Authorisation Routes (SAR) resulting in lowered fees and a longer validity period of 12 months certainly has a positive impact on the industry. The enhancements result in more simplified paperwork and lower cost barriers for the low cost, low volume devices. This can facilitate market access of unregistered medical devices to healthcare professionals to fulfil urgent medical needs. At the end of the day, patients who are the end-users of the devices will benefit.

It is also heartening to note that HSA has displayed that it is willing to listen to feedback from the industry stakeholders through its consultations with the industry. Putting up draft guidances on the website and holding engagement sessions provide an excellent opportunity to solicit feedback from the industry. With the active solicitation of feedback, we can see customer responsiveness on the part of HSA.

It is also good to continue the practice of sending updates on regulation and enhancements via email blasts to the industry. The uploading of regulatory guidances and FAQs posted on the regulatory updates page of the Medical Device Branch have also been very useful.

Many enhancements have been announced in 2012. It is very important that HSA continues to communicate and work closely with the industry.



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?

I think that in addition to holding industry engagement sessions, HSA can go one step further by conducting surveys among industry members. This will enable more opinions to be captured, as some may not voice out their concerns during the sessions. Another suggestion would be to hold separate dialogue sessions for (MNCs) and the (SMEs) as these two groups may have different concerns. By holding separate sessions, the SMEs may have also more opportunities to speak out. In addition, efforts should also be made to seek feedback from healthcare professionals.

If there was one thing you can change with regards to the MD regulatory framework, what would it be?

I would like to see shorter turnaround time for evaluation and change notification for medical devices, especially for those that have already been approved by HSA’s reference agencies. Even though regulatory fees for certain sectors of the framework have been reduced, further reduction of regulatory fees would be welcome a given that some medical devices have low sales volume.



Ms Ng Lee Choon (centre),
with HSA interviewers Valerie Wee and Beverly Liew
at Biopolis

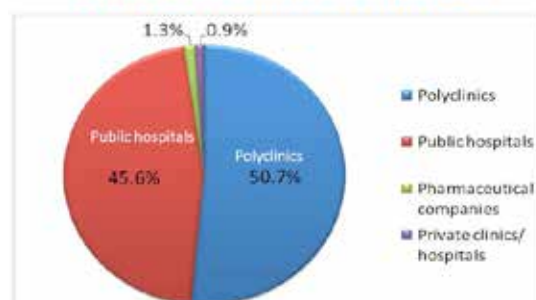
“I would like to see shorter turnaround time for evaluation and change notification for medical devices, especially for those that have already been approved by HSA’s reference agencies.”

Keeping a Watchful Eye on Health Products Safety

Spontaneous Adverse Event (AE) reporting by the healthcare professionals forms the cornerstone of post-marketing safety surveillance and remains one of the most important ways of monitoring the safety of a health product throughout its marketed life. Since expanding its scope of activities to cover all health products regulated by the Health Products Regulation Group, the Vigilance Branch (VB) has put in place the national adverse event monitoring system - “HSA Adverse Event Watch (AE Watch)”. This is a system of spontaneous AE reporting complemented with active surveillance of vaccine adverse events in the sentinel site of KK Women’s and Children’s Hospital.

Since the set-up of the AE monitoring system in 1993, Singapore has taken the world lead in terms of the number of valid reports per million inhabitants that was submitted to the World Health Organisation (WHO) global database from year 2007 to 2012 (reference: WHO Uppsala Monitoring Centre Report October 2012). In the year 2011, VB received a total of 30,175 reports, of which

Source of AE Reports (2011)

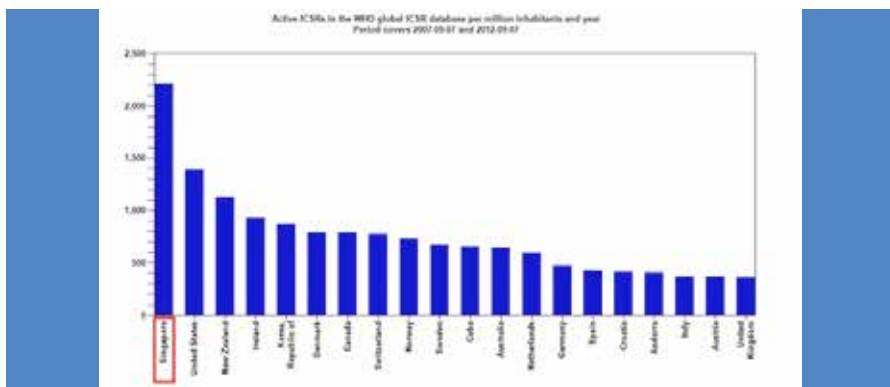


23,724 reports were captured into the database as valid reports. Reports lacking important details such as names of suspected health products and AE descriptions are considered as invalid reports and will not be captured into the national AE database as they cannot be assessed for causality. Most of the reports were from healthcare professionals working in the government clinics (50.7%), followed by public hospitals (45.6%), pharmaceutical companies (1.3%) and private clinics/hospitals (0.9%). The majority of the reports analysed were associated with pharmaceuticals/biologics (98%) followed by vaccines (1.3%). Chinese Proprietary Medicines, health supplements and other traditional medicines accounted for 0.5% of the reports.

Good quality AE reports are imperative in facilitating the prompt detection of potential health product-related safety signals leading to appropriate actions taken to safeguard public health. The Vigilance Branch would like to take this opportunity to thank healthcare professionals and industry for their active participation in the national adverse event monitoring programme of health products.

Riding on the established framework of post-marketing surveillance for pharmaceutical products, HSA continues to expand its scope of activities to maintain a vigilant watch on other health products regulated by the HSA.

We have embarked on a series of stakeholder engagements with healthcare professionals and Traditional Chinese Medicine (TCM) practitioners to improve awareness and reporting of medical device and TCM safety issues and will continue to engage all our stakeholders to promote patient and public safety.



Educational Programme Regarding Association of HLA-B*1502 and Carbamazepine-induced Stevens -Johnson syndrome

Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) are life-threatening adverse skin reactions with mortality rates of up to 5% and 40% respectively (refer to figure 1). Drugs are most often implicated as the suspected cause of SJS and TEN.

Carbamazepine (CBZ), indicated for the treatment of epilepsy, neuropathic pain and bipolar disorder, is known to be associated with an increased risk of causing adverse cutaneous skin reactions, including SJS and TEN. The occurrence of these rare serious skin reactions is about 25 in 10,000 based on a Taiwan study and has been found to be associated with HLA-B*1502 in certain populations such as Thailand and Malaysia. In an effort to understand the relevance of genetic association with adverse drug reactions among the diverse ethnic groups (Chinese, Malays and Indians) in the local population, the HSA Pharmacogenetics Team embarked on a pharmacogenetics-based programme together with scientific collaborators from various public institutions, hospitals and research institutes.

The study also aimed at investigating other possible genetic associations that may be responsible for the adverse drug-induced skin reactions observed locally. Currently, this research study has yielded interim results suggesting a linkage between CBZ-induced SJS and TEN and HLA-B*1502 and this is in agreement with international data. In addition, a cost-effectiveness study conducted in collaboration with Duke-NUS

Medical School has shown that genotyping for HLA-B*1502 and providing alternate antiepileptic drugs only to those who test positive is cost-effective for Singaporean Chinese and Malays, compared with no genotyping and providing CBZ to all. In view of these findings, HSA has commenced outreach programmes to raise awareness of these findings. In addition, HSA started a consultation process with various stakeholders to discuss practicalities of screening for HLA-B*1502 in new CBZ patients. The initiation of screening is expected to reduce this serious adverse drug reaction to CBZ treatment.

The first outreach session was held as part of a continuing education programme organised by the Singapore Epilepsy Society on 27 Jun 2012. This event was held at Goodwood Park Hotel and was attended by over 20 neurologists from both the public and private practice in Singapore.

Ms Dorothy Toh, Director of the Vigilance Branch, presented on the "Association between HLA-B*1502 and CBZ-induced Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)". She shared the results of HSA's ongoing pharmacogenetics study, and sought feedback from the audience on the practicalities of genotyping for HLA-B*1502 in Singapore. Ms Dong Di, PhD student from Duke-NUS Medical School also presented the results of the cost-effectiveness study conducted in collaboration with HSA which showed that genotyping for HLA-B*1502 is cost effective for

Singapore Chinese and Malays. The presentation was well-received by the clinicians.

Scientific advancements have led to new genetic discoveries that could have the potential to prospectively identify individuals who may be at risk of serious adverse drug reactions. The Pharmacogenetics Team at HSA aims to evaluate applications of pharmacogenetic associations in the local population with the aim of protecting and safeguarding public health.

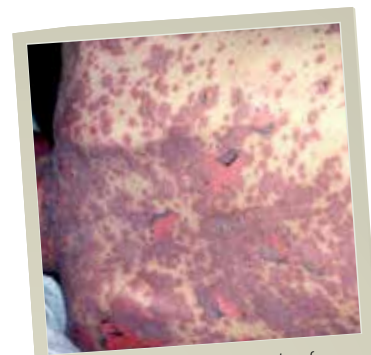


Fig 1: A case example of Stevens-Johnson syndrome



Presentation by Ms Dorothy Toh, Director of Vigilance Branch, HSA

HSA signs Memorandum of Understanding with Saw Swee Hock School of Public Health

The Health Sciences Authority (HSA) signed a Memorandum of Understanding (MOU) with the National University of Singapore (NUS) Saw Swee Hock School of Public Health (SSHSPH) on 1 October 2012. The MOU signing ceremony between Associate Professor John Lim, Chief Executive Officer of HSA and Professor Chia Kee Seng, Dean, NUS Saw Swee Hock School of Public Health was witnessed by Dr Amy Khor, Minister of State, Ministry of Health and Ministry of Manpower. The ceremony was held in conjunction with the 1st Singapore International Public Health Conference.

The MOU seeks to encourage knowledge exchange, enhance academic and professional competencies and develop scientific leadership to promote the protection of public health and the advancement of public health science. It covers four public health domains of epidemiology, biostatistics, health promotion/education, and health systems and policy. In line with the theme of the 1st Singapore International Public Health Conference, the MOU seeks to also “translate public health research into practice” and advance issues from a global and regional perspective linked to HSA’s key areas of focus in regulatory, forensic and analytical science, and transfusion medicine.

The areas of cooperation include the following:

- a. Participation in joint research projects that are of common research interest such as in the area of pharmacogenomics.
- b. Developing of a health information system that enables researchers to analyse health and disease, and policymakers to evaluate the long-term outcomes of proposed healthcare and public health policies and interventions.
- c. Providing exposure to both SSHSPH students and HSA staff through attachments.
- d. Developing and conduct regulatory and/or scientific courses as well as certification programmes to meet national talent needs within regulatory science, blood services and applied science domains and validate the appropriate skill sets.

Pharmacogenomics is an area that exemplifies the synergy of HSA and SSHSPH’s collaboration. The two organisations have been developing tools to allow comparisons of genetic variation between the main ethnic groups in Singapore - Chinese, Malays and Indians and the other populations from around the world, by using the genetic variation databases which SSHSPH maintains. The team’s aim is to develop a user-friendly internet portal to the database in 2013 to enable regulators, clinicians, and scientific researchers to better understand and assess how drug response established in one population or ethnic group might differ in another. By knowing the effect of genes on drug response and metabolism, clinicians can tailor the treatment and drug dose for each individual patient. HSA will also be able to assess the advisability of genetic testing to improve efficacy and safety of treatments, thereby protecting and advancing overall public health.



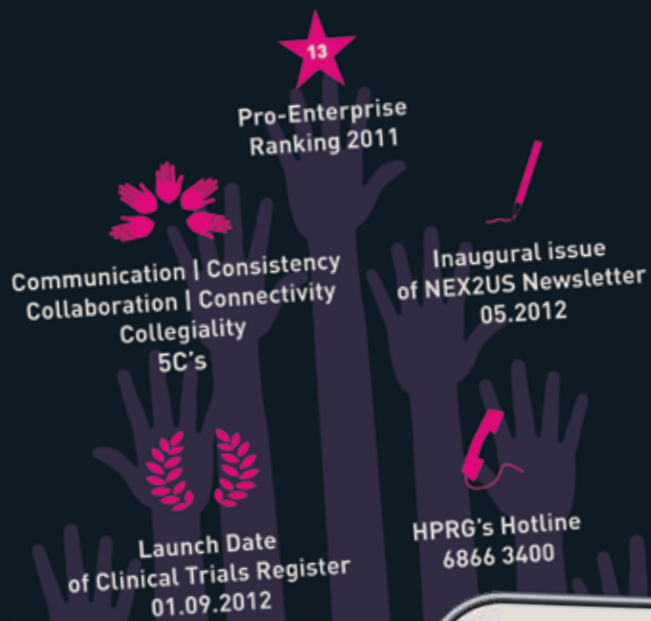
Left to right: Professor Chia Kee Seng, Dean, NUS; Dr. Amy Khor, Minister of State, Ministry of Health and Ministry of Manpower; Associate Professor John Lim, CEO, HSA

Left to right: Dr. Raymond Chua, Group Director, HPRG; Professor Chia Kee Seng, Dean, NUS Saw Swee Hock School of Public Health; Professor Saw Swee Hock, Distinguished Benefactor to the NUS Saw Swee Hock School of Public Health; Dr. Amy Khor, Minister of State, MOH and MOM; Associate Professor John Lim, CEO, HSA; Mr Roy Quek, Deputy Secretary (Health), Ministry of Health; Professor John Wong, Chairman, HSA



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New Initiatives in Medical Device Regulation

Faster access routes for Class C and D devices are targeted to be implemented on 1 Jan 2013.

Lower fees for devices brought under the Special Authorization Routes (SAR) were implemented on 1 Aug 2012.

As of 1 Sept 2012, Class B devices qualifying for immediate and expedited evaluation routes will have faster turnaround time.

COST ISSUES

ACCESS ISSUES

HSA is working with the Singapore Manufacturers' Federation (SMF) to provide a concierge service aimed to provide more support to the industry in meeting regulatory requirements. This is planned to commence in 2013.

HSA remains committed to bring about further enhancements to the regulatory framework to expedite access and manage regulatory costs, while ensuring that safe and effective medical devices are introduced to Singapore.

