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CONNECTING WITH OUR PARTNERS

HSA Health Sciences Authority

SEPTEMBER 2014

Stakeholder Engagement
It's a 2-Way Process

A NEWSLETTER *for our* HEALTH PRODUCTS INDUSTRY & COMMUNITY

From the Editor-in-Chief

Dear readers,

The first half of 2014 had kicked off with exciting initiatives on numerous reviews of the regulatory and legislative frameworks of health products.

Asst Prof Raymond Chua
Group Director, HPRG, HSA

As part of our fundamental role as a regulator to administer the regulations through the various pieces of legislation, it is equally essential that we continuously review them to ensure that the rules remain relevant and up-to-date with the current needs within this fast changing health products regulatory landscape. Our policies and framework will affect our different stakeholders and hence, effective and regular stakeholder engagement is the key foundation of our mission. In this day and age of the internet, many have switched to the mode of writing email but many a time, the solution to a problem is to talk, communicate and seek to understand. Hence, we recognise the value of maintaining regular active dialogues with our diverse group of stakeholders, including industry, healthcare institutions and professionals, other government agencies, consumers and patients. To me, having an open and constructive conversation will enhance and build up the trust, help us to better understand each other's views and requirements and in turn, strengthen the relationship as we work together to ensure the supply of safe and high quality health products in Singapore.

Hence, the theme for this issue, ***'Stakeholder Consultation – It's a 2-way Process'***. This theme summarises our commitment and intent to engage, consult and have 2-way communication with stakeholders through focus groups discussions, pre-consultation and dialogue sessions. These sessions facilitate gathering of feedback and for us to hear from the ground as we refine and review our regulatory policies and framework. The articles on the '***Transfer of Legislative Controls of Therapeutic Products to the Health Products Act***', ***'Complementary Health Products Industry Focus Group Discussions***' and the '***Enhancements to Change Notification for Registered Medical Devices***' are interesting reads which give you some insights on how we are engaging our industry stakeholders through these regulatory reviews. In addition, we are providing a snapshot of the many past initiatives and enhancements implemented in 2012-2013, so that you can provide feedback and seek clarifications on these initiatives, if any.

We are also pleased to share with you personal insights from Associate Professor Thoon Koh Cheng, an expert clinician in the area of infectious diseases for pediatric patients, and one of the winners for the Excellent Team Player Award at the inaugural HSA's Excellent Stakeholder and Partnership Awards 2013 which celebrated HSA's collaboration with KKH on the vaccine adverse event sentinel surveillance program. In this interview article, he shared his thoughts on the future of vaccine research and safety monitoring. To conclude, I would like to seek your support and feedback as we continue our regulatory reviews, specifically for the main consultation planned from August - November 2014 on the transfer of existing legislative controls of clinical trials and therapeutic products to the Health Products Act.

So stay tuned for more 2-way engagements and I wish you an enjoyable read!

Yours sincerely,

Raymond

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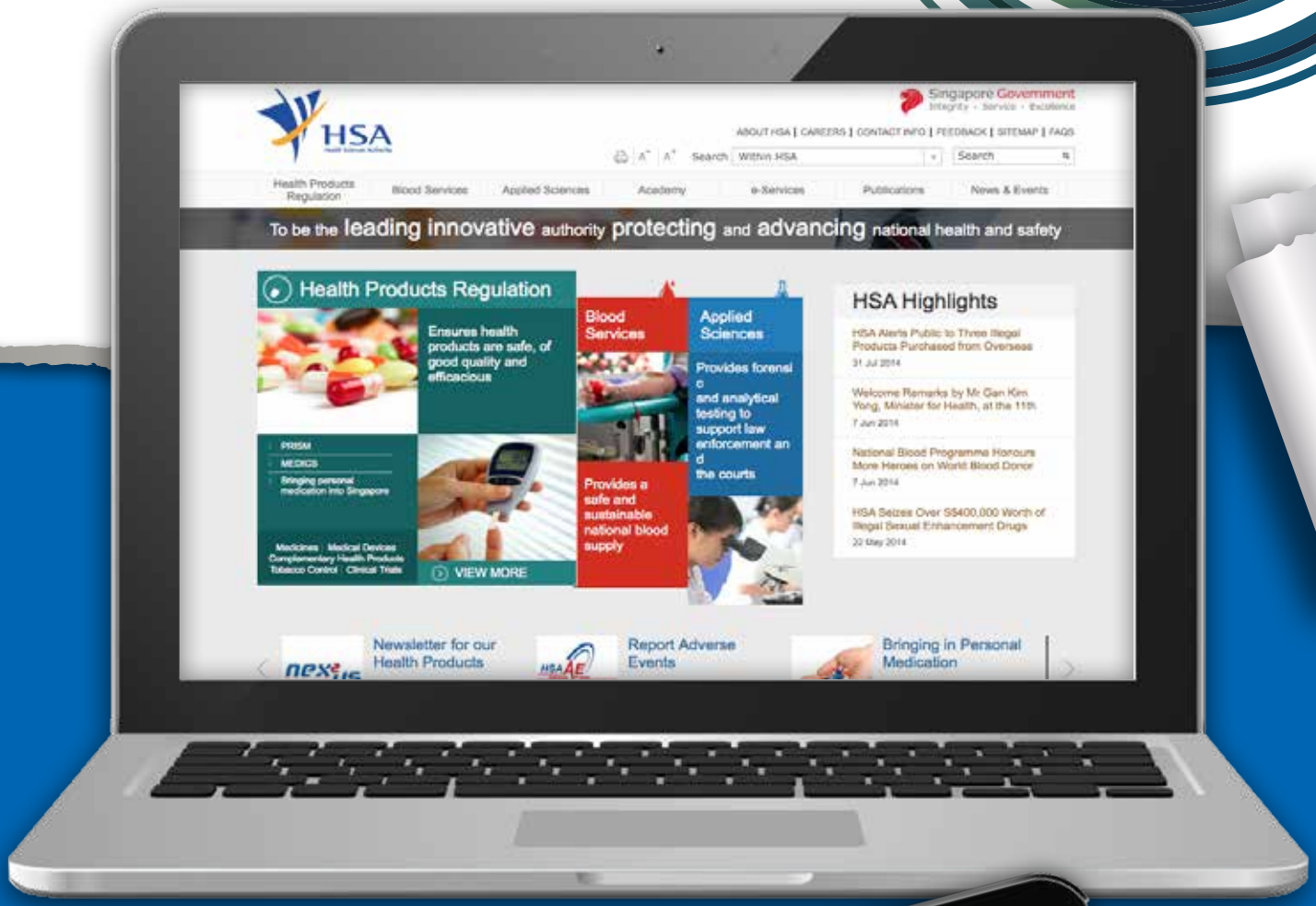


HSA Website Refreshes!

The HSA website has been re-launched with a *New and Improved look!*

The new website was conceptualised with the end-users in mind, which took into account the current habits of visitors, feedback from the stakeholders and usability research studies in its content planning and overall design. Users can look forward to a more user-friendly website with enhanced content presentation that enables quicker access to information and easier navigation, particularly for frequently-visited services.

HPRG's industry partners can access a new IT feature, "EXTRANET", to consult and connect with other industry professionals in private, share views and feedback on discussion forums or upload documents. The access rights are specific and granted by invitation only. HSA has launched this new website with effect from late July 2014.

Note: The current favourites, shortcuts or hyperlinks you have created to the existing HSA website would not be valid after the date.

Come visit our new website at **www.hsa.gov.sg** today!

Interview with Associate Professor Thoon Koh Cheng

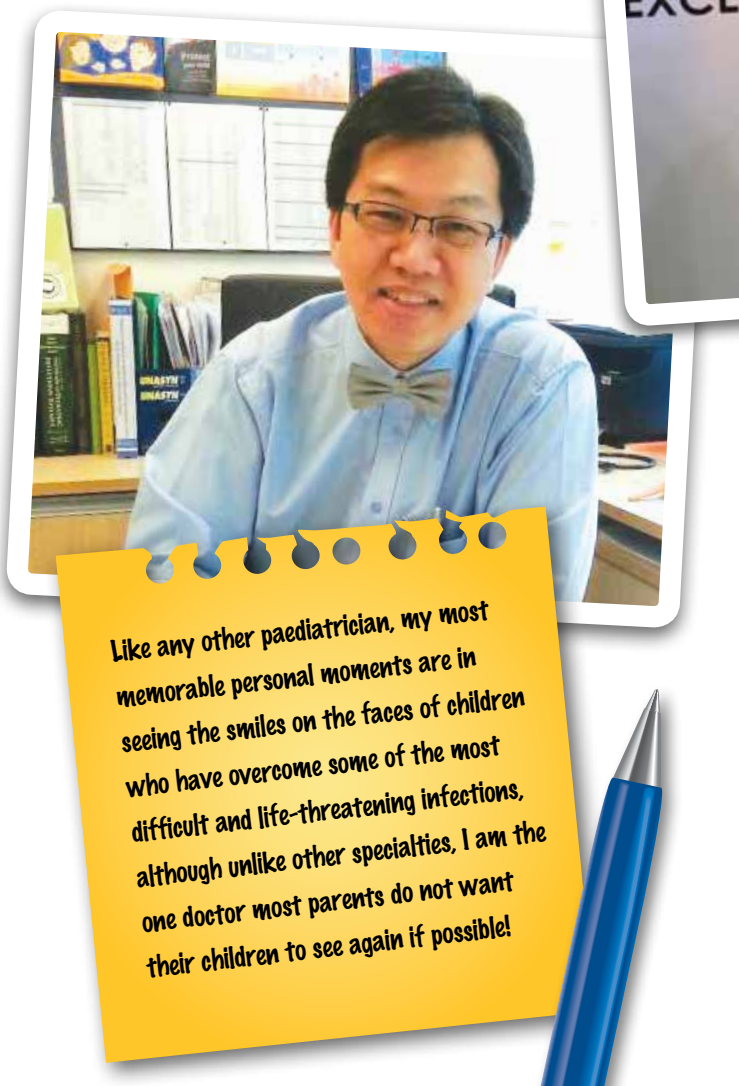
Winner of Excellent Team Player Award at the Inaugural HSA's Excellent Stakeholder and Partnership Awards 2013 for the Vaccine Adverse Event Sentinel Surveillance Program at KKH.

In 2009, in preparation for scaled-up nation-wide immunisation with pandemic Influenza A (H1N1) 2009 vaccines, HSA collaborated with KK Women's and Children's Hospital (KKH) to initiate active inpatient surveillance for vaccine adverse events (VAEs) due to H1N1 vaccines, both in adults and children, with the establishment of a sentinel site at KKH. The surveillance was subsequently expanded to include all VAEs following childhood immunisation.

Besides screening daily hospital admissions for possible VAEs, the team at KKH led by A/Prof Thoon Koh Cheng uses hospital electronic databases to assist in signal detection to ensure that cases are not missed. Potential safety signals detected and evaluated by the team include BCG-associated lymphadenitis, intussusception with rotavirus vaccine and hepatitis B immunoprophylaxis failure. For leading a dedicated team to perform the active surveillance of VAEs to ensure that the safety profiles of vaccines continue to be favourable, A/Prof Thoon and his team members were awarded the Excellent Team Player Award at the inaugural HSA's Excellent Stakeholder and Partnership Awards (ESPA) 2013.

Besides his role as the principal investigator of the sentinel site, A/Prof Thoon is a dedicated clinician who heads the Infectious Diseases Services, Department of Paediatrics, KKH and chairs the Hospital Infection Control Committee. He is a member of the Expert Committee on Immunisation which advises the Ministry of Health on the strategies for the control of vaccine preventable diseases through immunisation as well as the safety and efficacy of vaccines.

He is also a member of the National Antimicrobial Taskforce and the Director of the Antimicrobial Stewardship Program. In-conversation is happy to speak with A/Prof Thoon to obtain insights into the meaningful work he is doing and his thoughts on the future of vaccine research and safety monitoring.



Like any other paediatrician, my most memorable personal moments are in seeing the smiles on the faces of children who have overcome some of the most difficult and life-threatening infections, although unlike other specialties, I am the one doctor most parents do not want their children to see again if possible!

As the principal investigator of the KKH sentinel site for monitoring of VAEs, how does active surveillance help in the safety monitoring of vaccines?

The implementation of the national childhood immunisation program in Singapore has led to a drastic reduction of vaccine preventable diseases. Concomitant with such a reduction comes a small price in the form of VAE, which must be evaluated properly using an evidence-based approach. However, the rare nature of most VAEs provides significant methodological challenges. Prior to the establishment of KKH as a sentinel site for active vaccine surveillance, reporting of VAEs has largely been passive and voluntary in nature, and often lacks important clinical data to facilitate in-depth examination of the association or otherwise of the event to the vaccine.

With active surveillance, HSA has been receiving more than 100 reports every year since 2010 collected from KKH alone, compared to the average of 35 VAE reports a year from 2005 to 2008. This program has significantly improved the sensitivity of signal detection compared to the passive reporting system. This is used to generate more accurate incidence figures of VAEs which are submitted to MOH for use in developing national policy on vaccine matters.

Associate Professor Thoon Koh Cheng (right) receiving the Excellent Team Player Award 2013 from Dr Amy Khor, Senior Minister of State for Health and Manpower.

In addition, the absence of a related VAE signal can provide confidence to healthcare practitioners of the safety of vaccines administered within the National Childhood Immunisation Schedule. The study has provided a proof of concept that active surveillance is a vital arm of any national vaccination programme. Active surveillance will contribute towards the minimisation of potential risks associated with the introduction of new vaccines in the future, and any risks that may arise with existing vaccines due to multiple reasons (e.g. change in manufacture, storage, delivery etc.).

My personal belief in this matter is that I find it increasingly unacceptable to not actively monitor for potential adverse events after immunisation, since they are given to healthy people; we should accept a near-zero margin of error.

What advice do you have for the industry in the area of vaccine research and safety monitoring of vaccines?

In the development of new vaccines, the industry will have to ensure they meet stringent safety requirements. This may result in rising costs in the development and post-marketing phase of the product life cycle.

However, in my view, these can be mitigated through creative private-public partnerships that leverage on the strengths of both sectors, with public accountability for the vaccine being developed and safety data that has been generated.

As an infectious disease expert, what is your assessment of the risk of Middle East Respiratory Syndrome coronavirus (MERS-CoV), especially in children?

Currently, there are still many unanswered questions about MERS-CoV that renders any risk assessment potentially faulty; significant gaps include the lack of clarity of the definitive origin and introduction of the virus into human communities, the possible transmission mechanisms, and the true disease profile. At present, the case fatality rate stands at ~30%, and while the World Health Organisation's latest risk assessment indicates that the virus has not acquired the ability to render it more transmissible (there are very few reported cases of human-to-human transmission beyond the 1st generation of contacts), it is unclear if there could be many more undiagnosed asymptomatic contacts who may transmit virus.

However, existing data appears to suggest cases are associated with residence or travel to the countries in the Middle East/Arabian Peninsula, and that more severe disease occurs in older persons who have co-morbidities; the data is also highly suggestive that poor implementation of infection control in healthcare institutions (particularly hospitals) could amplify MERS-COV transmission.

There is only a handful of paediatric cases reported and it may be premature to assess the risk of MERS-COV in them, but so far more serious disease have occurred mainly in children with underlying chronic lung diseases.

> I am extremely gratified to see the widespread impact of vaccines in reducing morbidity and mortality from these preventable diseases, and while not exactly personal, there is much satisfaction and joy derived from knowing that I may have indirectly saved a life or averted disease (and their complications) by advocating for vaccines and best practices in vaccine delivery..

Could you share some of your memorable moments as an infectious disease paediatrician?

Like any other paediatrician, my most memorable personal moments are in seeing the smiles on the faces of children who have overcome some of the most difficult and life-threatening infections, although unlike other specialties, I am the one doctor most parents do not want their children to see again if possible!

Additionally, because of my work in vaccines and vaccine-preventable diseases, I am extremely gratified to see the widespread impact of vaccines in reducing morbidity and mortality from these preventable diseases, and while not exactly personal, there is much satisfaction and joy derived from knowing that I may have indirectly saved a life or averted disease (and their complications) by advocating for vaccines and best practices in vaccine delivery.

Transfer of Legislative Controls of Therapeutic Products to the Health Products Act

The Health Products Regulation Group (HPRG) plans to bring over the existing legislative controls for regulating western pharmaceutical products under the Medicines Act (Cap. 176) and Poisons Act (Cap. 234) to the Health Products Act (Cap. 122D).

This is part of HSA's on-going initiative to update and streamline the regulatory controls, which are currently divided in different Acts, under a single piece of legislation, so as to ensure that the regulatory regime remains relevant and adequate for the rapidly evolving pharmaceutical developments and operational models.

Medical Device was the first category of health products to be regulated under the Health Products Act (HPA), with phased implementation from 2007 to full implementation in 2012. Cosmetic Product regulations under the Act were also implemented in phases from 2008 to 2011. HPRG has commenced preparations to port over the regulations for the next category of health products – Therapeutic Products (TP) from existing legislations to HPA.

Key areas being reviewed for the port-over of TP include

- **The legislative definition of TP**
- **Transfer of Licensing Controls for TP**
- **Changes to Advertisement Controls for TP**
- **Changes to Clinical Trials Regulations for TP**

Mr Foo Yang Tong (left) and Dr Lisa Tan (right) explaining the proposed changes to the clinical trials regulations for therapeutic products.

The preparatory work for porting over of TP regulations to HPA involves policy reviews. To solicit feedback, assess impact and refine the proposed controls, HSA has conducted focus group discussions and a series of pre-consultation sessions with industry associations, industry players and other stakeholders. HSA also reached out to a wider group of stakeholders at the policy review stage through the health products regulatory conference.

These engagement meetings enabled HSA to understand potential stakeholder concerns, problems and issues, seek their views on the proposed amendments as well as identify the need for further refinements/changes to policies so that the regulations would be clearer and simpler.

- Building upon the findings from the series of pre-consultation sessions held in March and April 2014 for targeted audience groups, HPRG will follow up with a round of open consultations before the TP regulations are ported over to HPA.

- HPRG will also hold further communication sessions with the industry, healthcare professionals and other stakeholders on the implementation of TP regulations under HPA at relevant phases of the exercise before its full implementation in end 2015.

Ms Yang Silin from HSA (far right) providing details on the changes to be made to advertisement controls for therapeutic products.

The communication sessions on the transfer of the legislative controls of therapeutic products to the Health Products Act were well-attended by industry members, healthcare professionals and other stakeholders.

Complementary Health Products Industry Focus Group Discussions

HSA is undergoing an initiative to streamline the legislative controls for the various categories of health products regulated under the Medicines Act to the Health Products Act. As such, HSA is reviewing the current legislative controls for Complementary Health Products (CHP) to ensure that the regulatory regimes for CHP remain relevant for the rapidly evolving CHP industry and consumer expectations.

As part of the review process, a series of focus group discussions involving industry stakeholders were conducted in May 2014. The sessions were well-received by stakeholders dealing with various CHP, including Chinese Proprietary Medicines, Traditional Medicines and Health Supplements. Discussions were lively and candid. Participants openly shared their experiences and opinions relating to the controls.

In looking for inputs to future-proof the legislative controls, HSA also gathered feedback from the participants on possible mechanisms for regulating CHP, in particular, relating to product classification, labelling and advertisement, dealer licensing, and Good Manufacturing Practice (GMP) standards. The possible impact of the different regulatory models on commercial operations was also discussed. The feedback gathered from the focus group discussions will be taken into consideration when reviewing the legislative controls for CHP.

Future plans include meeting with the consumer group, and additional follow-up with industry stakeholders to further refine the controls for CHP.

Focus group sessions attended by industry stakeholders of complementary health products.

Enhancements to Change Notification for Registered Medical Devices

With the on-going development and improvement to the medical device regulatory framework, HSA conducted five industry briefing sessions from 24 to 26 February 2014 to update the industry on the enhancements to the Change Notification (CN) process for registered medical devices.

The guidance documents on CN and the Medical Device Information & Communication System (MEDICS) have been revised to facilitate understanding of categorised changes and to ease application submissions of the medical device changes respectively.

The industry briefing presentation slides depicting these improvements can be found here[1].

With the introduction of Review Change (applicable to Class A and B medical devices) and Notification route (for all risk classes) on 1 April 2014, Minor Administrative Changes (MAC), CN-1 and CN-2 (applicable to Class B medical devices) were phased out. In addition, CN applications submitted after 1 April 2014 will be subjected to turn-around-time (TAT) and revised fee schedules.

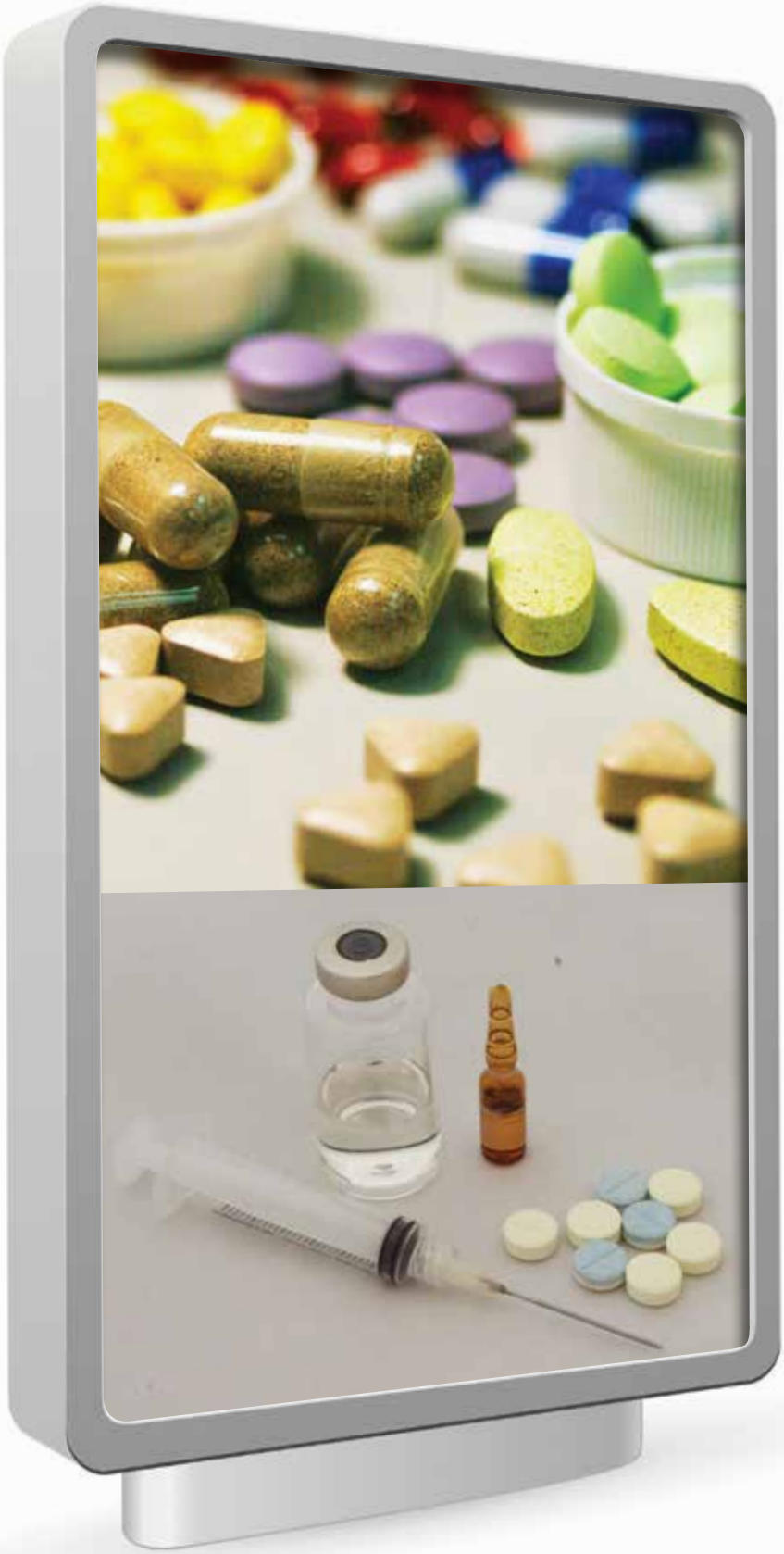
Click here for details[2].

Summary of Enhancements to Change Notification for Registered Medical Devices

Latest revision of GN-21-R3 Guidance for Change Notification is available at the HSA website[3]

CHANGE NOTIFICATION ENHANCEMENTS	POTENTIAL BENEFIT(S) TO HSA'S STAKEHOLDERS
TURN-AROUND-TIME (TAT)	
Change Notification applications submitted after 1 April 2014 will be subjected to TAT.	TAT will be applicable to Change Notification applications for all risk classes.
TAT applicable to all category of changes (i.e. Review, Administrative and Technical Changes) across all risk classes.	The enhancement will result in timely approvals for changed devices to be supplied in Singapore (not subjected to Field Safety Corrective Action (FSCA) related changes).
FEES	
Selected changes that were previously classified as Administrative ($500) and Technical Changes (Class B – $1,100; Class C – $1,700; Class D – $2,800) have been reclassified to Notification (no cost) and/or Review Change ($500).	Lower fees for all changes to Class B medical devices and selected changes for Class C and D medical devices. Overall, reduction in change notification application fees.
NOTIFICATION CHANGE	
Similar to that of Minor Administrative Change (MAC) with wider scope including labelling change that involves addition of contraindications, warnings and/or precautions not arising from safety, quality and efficacy concerns.	Broaden scope for Notification Change across all risk class. The enhancement will result in immediate implementation upon receipt of acknowledgement email from HSA with no additional cost.
REVIEW CHANGE	
Closed list of changes applicable to Class A and B medical devices.	Review changes previously classified as technical change for Class B are subjected to a fee reduction from $1700 to $500. No change of fee for Class A medical devices.

Drug Product Stability Data Requirement for New Product Applications



Medicinal Product registration has evolved over time to meet changes in regulatory thinking as the pharmaceutical industry continues to advance.

To make product registration more transparent and thereby facilitate timely market entry of high quality, safe and efficacious medicines into Singapore, the Guidance on Medicinal Product Registration in Singapore (later referred to as the "Guidance") has been revised twice since it was introduced in February 2007.

Continued communication and collaboration with our industry stakeholders has allowed HSA to gather valuable comments and conduct a timely review of the drug product stability data requirements for product registration.

These requirements have been amended to:

- facilitate submissions of new product applications by the revision of the site-specific drug product stability data requirements,
- implement the ASEAN Guideline on Stability Study of Drug Product that was adopted at the 20th ASEAN ACCSQ Pharmaceutical Product Working Group in Bali in May 2013.

Detailed information on the revised stability data requirements and updated sections of the Guidance can be found on HSA's website[4].

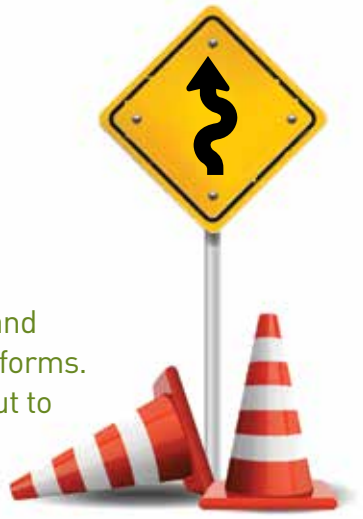
Pharmaceuticals Medical Devices Agency 10th Anniversary Visit

On 8 February 2014, the Pharmaceuticals Medical Devices Agency (PMDA) held a forum themed "Globalisation of PMDA", in commemoration of its 10th Anniversary. The meeting was graced by Ms Shinako Tsuchiya, Senior Vice Minister, Ministry of Health, Labour and Welfare (MHLW), Japan and Dr Fumimaro Takaku, President of Japanese Association of Medical Sciences.

Distinguished speakers from international regulatory agencies including Prof Guido Rasi, Director of European Medicines Agency, Mr Jung H. Schnetzer, Executive Director of Swissmedic, Dr Chung Seung, Minister of Ministry of Food and Drugs Safety, Korea, Dr M. Hayatie, Permanent Secretary of National Agency of Drug and Food Control, Mr Kees de Joncheere, Director of Essential Medicines and Health Products, World Health Organisation and A/Prof John Lim, former Chief Executive Officer of Health Sciences Authority, delivered presentations on "PMDA from the international Perspective-Future Collaboration and Expectation for PMDA".

Their ideas highlighted the importance of global cooperation to ensure the expeditious delivery of innovative medical products to patients worldwide. Dr Tatsuya Kondo, Chief Executive of PMDA, also highlighted the remarkable progress made by PMDA within the decade tobecome one of the world's most important regulatory agencies which helped to internationalise Japanese medical innovations.

In recent years, PMDA had advanced its pursuit of regulatory science with the establishment of a high level consultative science board which comprised front-line researchers in specialised fields to convene discussions on emerging and current mechanisms and issues of novel scientific technology. A delegation from HSA's Health Products Regulation Group also met with the counterparts from MHLW and PMDA for a bilateral meeting to discuss deepening collaborations in the area of Good Manufacturing Practice for medicinal products, new drug evaluations and capacity building and sharing of best practices on regenerative medicines.



A Snapshot of HPRG's Regulatory Initiatives in 2012/13 and what to expect for 2014

The Health Products Regulation Group conducts regular review of our rules and regulations based on industry partners' feedback at various engagement platforms. In the past years, many new initiatives and enhancements have been rolled out to further refine our regulatory framework and streamline our workflow to better serve the industry, while at the same time protecting patient safety.

Past Initiatives (2012 – 2013)

Phased implementation of ASEAN Variation Guidelines (AVG) requirements

Phase 1 will involve the following, starting on 1 April 2014:

- Amending the current Minor Variation (MIV) checklist for chemical products to align the technical requirements & terminology with and to add new MIV categories that are within the adopted AVG;
- Amending the current MIV checklist for biologic products to align the terminology with the adopted AVG;
- Adding new MIV categories to both checklists based on the common queries submitted via the MIV Inquiry Form;
- A 6-month grace period for implementing Phase 1 will be in effect if there is difficulty in meeting the revised variation requirements after 1 April 2014;

Implementation of phase 2 is targeted for 2015.

Review of Site Specific Stability Data Requirement

The required site specific stability dataset at time of submission was reduced and implemented on 1 January 2014. Details of the requirements are available on the HSA website[5].

Extension of Validity of Good Manufacturing Practice (GMP) Certification from 2 years to 3 years

Product Registration Routes for Medical Devices

- Turnaround time for product registration of Class A (sterile) devices was reduced from 60 to 30 working days with effect from 1 May 2012.
- Shorter turnaround time for product registration of Class B, C and D medical devices which qualify for the new immediate/ expedited evaluation routes (as compared with the existing abridged/ full evaluation routes). The new routes for Class B devices were introduced on 1 September 2012. For Class C and D devices, the new routes were introduced on 1 January 2013.

Update of Guidelines of the ASEAN Cosmetic Directive (ACD)

The annexes have been updated to keep industry informed of the revised requirements for cosmetic ingredients under the ACD. More information can be found on the HSA website "Annexes of the ASEAN Cosmetic Directive"[6].

Allow the Sale of Chinese Proprietary Medicines (CPM) Containing Naturally-occurring Berberine

Information on test reports submission for CPM listing application has been uploaded on the HSA website to provide more details for submission of CPM listing applications. This has allowed CPM importers to have better clarity on the requirements.

See "Requirements of Test Reports"[7].

Upcoming Initiatives (2014)

Therapeutic Products Branch

- A pilot project to track the screening of dossier timelines from the time of submission to its acceptance for evaluation.
- Allowing the submission of multiple export clearance for the same import for re-export (IFR) Notification. Notification alerts will be sent at 60 days and 30 days from the re-export due date.

Audit and Licensing Division

Enhancing the Licence Amendment Module on MEDICS :

1. Update of company information
   (Company business address, contact person, email/telephone no./fax no.) via :
   - Global change of Business Info eService in CRIS. The updated information will be auto-populated across all three dealers licences held by a company OR
   - Amendment of individual Medical Device Dealer's Licence.

2. Certification information will be reflected on the dealer's licence :
   - Quality Systems, Certification Body and Expiry Date.
   - Approved Site Address(es).
   - Approved Scope of Operations.

Medical Device Branch

Enhancing the Special Authorisation Routes (SAR)

- For companies dealing with GN-28 (Import for re-export) and GN-29 (Import for non-clinical purpose), Importer's/ Wholesaler's licence will not be required.

Free sale certificate (FSC)

- Validity of FSC to be extended from 1 year to 2 years.
- Date of implementation: 1 April 2014.

Better clarity in guidance documents

- GN-13 risk classification of general medical devices.
- GN-14 risk classification of in-vitro diagnostic devices.

Change Notification (CN)

- Revised GN-21 guidance.
- CN routes: technical (for registered Class C and D devices), administrative, review changes (for registered Class A and B devices) and notifications.
- Announcement of turn-around time (TAT) for non-FSCA applications.
- Date of implementation: 1 April 2014.

Complementary Health Products Branch

Regular updates on Health Supplements Guidelines[8] and step-by-step guide on cosmetic product notification[9] through HSA website.

For further information and/or clarifications, please contact us at:
Audit and Licensing Division, Licensing & Certification Branch: hsa_certification@hsa.gov.sg
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Clinical Trials Branch: HSA_CT@hsa.gov.sg
Complementary Health Products Branch: HSA_CPM@hsa.gov.sg
Medical Device Branch: hsa_md_info@hsa.gov.sg
Therapeutic Products Branch: HSA_MedProd_Registration@hsa.gov.sg OR HSA_MedProd_Enquiry@hsa.gov.sg

Industry Outreach to Retailers at Golden Mile Complex and Lucky Plaza

In November 2013, the Cosmetics Control Unit (CCU) and Enforcement Branch (EB) jointly conducted an outreach programme at Golden Mile Complex and Lucky Plaza. This programme was initiated as part of our educational efforts to increase the awareness of existing regulatory controls concerning cosmetics in our aim to ensure that cosmetics sold in Singapore are safe for public use.

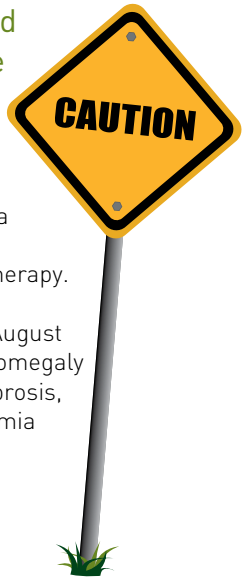
HSA continuously receives reports from the public regarding safety concerns associated with cosmetic products. These reports are judiciously investigated, to ensure that regulations are adhered to and public safety is not compromised.

During the outreach initiative, officers from CCU and EB visited a total of 28 retailers within the two buildings. The retailers were receptive to the educational outreach programme. It was noted that a majority of these retailers were unaware of the existing regulatory controls for supplying cosmetic products and HSA took the opportunity to educate them on the regulatory requirements. Retailers were also given advisory letters on the various obligations required under the Health Products Act.

Following the initial outreach, a post-market surveillance was conducted between December 2013 and January 2014 with the same 28 retailers. The post-market surveillance revealed that the retailers had since proceeded to have their products notified with HSA and were more mindful when dealing with their products. Following the success of this outreach initiative, HSA is identifying similar educational initiatives to help enhance the compliance of laws among the retailers as part of our continuous effort to educate and enhance awareness of the regulation.

HSA Approved in 2013 – New Drug Applications (NDA-1s)

In 2009, HSA established the criteria for priority review of new drug applications submitted via the abridged evaluation route. Those applications designated for priority review will be allocated priority attention and resources for the evaluation in order to facilitate timely access to life-saving medicines.



These medicines must be intended to treat life-threatening conditions and have demonstrated the potential to address unmet medical needs. Disease conditions that are of local public health concerns such as cancer and infectious diseases will be considered for priority review.

In 2013, Stivarga (regorafenib) and Jakavi (ruxolitinib) were evaluated and approved under the priority review programme. Stivarga (regorafenib) was approved by HSA on 7 June 2013 for the treatment of metastatic colorectal cancer (CRC) in patients who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-vascular endothelial growth factor (VEGF) therapy, and if Kirsten rat sarcoma viral oncogene homolog (KRAS) wild type, an anti-epidermal growth factor receptor (EGFR) therapy.

Jakavi (ruxolitinib) was approved by HSA on 22 August 2013 for the treatment of disease-related splenomegaly and/or symptoms in adult patients with myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis.

Details on new drug approvals are published monthly on the HSA website[10].

Product Name	Active Ingredient(s)	Pharmacotherapeutic Group
GIOTRIF film-coated tablet	Afatinib	Antineoplastic agent
EYLEA solution for injection in vial; EYLEA solution for injection in prefilled syringe	Aflibercept	Ophthalmological agent
LASTACAF ophthalmic solution	Alcaftadine	Ophthalmological agent
INLYTA tablet	Axitinib	Antineoplastic agent
INFASURF intratracheal suspension	Calfactant	Lung surfactant
CIMZIA solution for injection in pre-filled syringe	Certolizumab	Immunosuppressant
NIMBEX injection; NIMBEX forte injection	Cisatracurium	Muscle relaxant
PICOPREP powder for oral solution	Citric acid, magnesium oxide, sodium picosulfate	Laxative
FIRMAGON powder and solvent for solution for injection	Degarelix	Antineoplastic & immunomodulating agent
EMADINE sterile ophthalmic solution 0.05%	Emedastine	Ophthalmological agent
SEEBRI BREEZHALER inhalation powder, hard capsule	Glycopyrronium	Preparation for obstructive airway disease
AFLUNOV suspension for injection 0.5ml in pre-filled syringe	H5N1 influenza virus surface antigen	Pandemic vaccine
MYCAMINE powder for solution for infusion	Micafungin	Systemic antimycotic agent
TYSABRI concentrate for solution for infusion	Natalizumab	Immunosuppressant
SIGNIFOR solution for injection	Pasireotide	Systemic hormonal preparation
HIDRASEC infants granules for oral suspension; HIDRASEC children granules for oral suspension	Racecadotril	Antidiarrhoeal agent
STIVARGA tablet	Regorafenib	Antineoplastic agent
EDURANT film-coated tablet	Rilpivirine	Antiviral agent
SODIUM FLUORIDE F18 injection	Sodium fluoride F18	Diagnostic radiopharmaceutical agent
JAKAVI tablet	Ruxolitinib	Antineoplastic agent
ZELBORAF tablet	Vemurafenib	Antineoplastic agent

Priority review of medicinal products for early access.

FUN LEARNING

HEALTH PRODUCTS SCRAMBLE!

How to play? The objective of the game is to rearrange the alphabets to form words to solve each question.

A) Lycopene is a phytonutrient found in red fruits and vegetables such as

S O A M E O T T

B) A device used in angioplasty to widen narrowed or obstructed arteries

E T S T N

C) A traditional ingredient that is beneficial to kidneys and helps to improve overall vision

R F E L W Y O R B

D) A strong solvent used in nail polish removers

N E C T A E O

E) Used in the treatment of gastroesophageal reflux disease

P O Z A E L O E M R

F) Clinical trials are conducted to gather additional information about a drug's

A F Y I E C F C

G) Tobacco smoke contains over 4000 chemicals in which one of them is acetic acid, the primary acid found in

A I E R G V N

H) Gorochana pills are produced using the ancient Hindu science of healing known as

D R V A E A U Y

I) A waxy component in many skincare products that acts as a barrier mechanism and provides moisture

X E A B S E W

J) A device used in ear-nose-throat as well as plastic or reconstructive surgeries

E N O B S I E C H L

K) Lexapro and Prozac treat anxiety disorders by increasing the production of this chemical in the brain

T N E O S R N I O

L) A traditional herb that resembles a human structure

E S N G I G N

M) A family of bacteria that helps to maintain a healthy digestive system

P S C H A L I D I U O

N) An ingredient found in egg whites used in various skincare products such as wrinkle smoothers

U A M B N I L

O) A device designed to limit the motion of the spine in cases of fracture or post-surgical procedures

K C A B R E C A B

Answers: a) Tomatoes, b) Stent, c) Wolfberry, d) Acetone, e) Omeprazole, f) Efficacy, g) Vinegar, h) Ayurveda, i) Beeswax, j) Bone Chisel, k) Serotonin, l) Ginseng, m) Acidophilus, n) Albumin, o) Back Brace

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