

nexus²US

CONNECTING WITH
OUR PARTNERS



MAY 2012

Building Bridges

Collaboration



Consistency



Collectivity



Communication



Collegiality



From the
Editor-in-Chief

Dear readers,

Welcome to the inaugural edition of HSA's NEX2US newsletter – a newsletter for the Health Products Industry & Community in Singapore.

2012 marks a very important milestone for Health Sciences Authority (HSA) as we move into the second decade. Therefore, we have decided to change the name of the newsletter from "HSA Connects Newsletter" to "NEXUS" to represent a greater commitment to collaborate and connect with our stakeholders. To bring the partnership to a higher level, we also added a "2" within NEXUS, to epitomise that you are NEX2US and with the tagline "Connecting with Our Partners".

As HSA grows and matures as a health products regulatory authority to protect and advance Singapore's national health and safety, our industry too has matured and journeyed with us, culminating in a strong relationship between regulator and industry, in terms of professionalism, openness and responsiveness. As we continue this journey, we strive to continuously improve our regulatory systems and we also envisage to make our processes more robust and efficient, share as much information as we can with industry, through various portals of communication, one of which is this NEX2US newsletter. Connecting and engaging with our stakeholders is an ongoing process. This will continue to be a top priority for us.

Just like Singapore has its 5C, HSA has also adopted our own 5C framework in interacting with our stakeholders through:

COMMUNICATION	CONSISTENCY	COLLABORATION	COLLECTIVITY	COLLEGIALITY
Communicating regularly with industry for open and honest feedback through different platforms	Continuously providing consistent and transparent information	Collaborating to produce mutually positive outcomes and solutions	Collective mindset and inclusivity	Collegiality in building reciprocal trusting industry-regulator relationship

In this inaugural issue, we will be sharing with you some of HSA's initiatives to pro-actively engage and solicit feedback from the industry on the medical device regulations and the future implementation of the Health Products (Therapeutic Products) Regulations. The second HPRG Joint Regulatory Workshop organised by HSA was part of our continuous effort to enhance the regulatory knowledge of our stakeholders. We also interviewed a regulatory affairs professional from a SME pharmaceutical company who has witnessed the evolution of the local regulatory landscape over the years and we are happy to share with you highlights of this interview.

I would like to take this opportunity to thank the editorial team for bringing to you this inaugural issue of the NEX2US newsletter. I would like to thank you, our readers for being our partners in health products regulation and for your continuous support and forthcoming feedback to better calibrate our regulatory approaches.

I hope you find this inaugural issue useful and interesting and we welcome any suggestions you may have for future editions.

Yours sincerely,
Raymond



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Connecting with our Medical Device Partners

HSA announces enhancements to the medical device regulatory framework at the Townhall Event with Minister of State (Health), Dr Amy Khor

20 April 2012 proved to be a significant date four months into the full implementation of the Health Products (Medical Devices) Regulations. The audience had gathered at the SPRING auditorium with great anticipation as Dr Amy Khor, Minister of State for Health, was to address the medical device industry for the first time at this townhall meeting, organised by the Singapore Manufacturers' Federation (SMa) and supported by the Ministry of Health and HSA.

Dr Khor's message was clear: Health product regulation is important to assure public health and patient safety. Although the medical device regulatory framework had encountered teething transitional problems, continual refinements have been made, and will continue to take place, as no regulatory framework can be cast in stone, especially in a complex area like medical devices. Conversations should not end at this townhall meeting ; all parties – HSA, industry and other stakeholders should continue to keep channels of communication open and engage one another regularly.

As an expression of that partnership, Dr Khor, HSA's CEO Associate Professor John Lim and SMA's President Mr George Huang, launched the HSA-SMaRT Dossier Submission E-Guide to mark the occasion.

The enhancements to the regulatory framework (refer to Table 1 on page 4), presented by Dr Raymond Chua, were well-received by industry, some of whom expressed appreciation to HSA for being flexible and open to feedback. These sentiments were echoed by two companies who, in their sharing sessions, also provided a few suggestions for refinements, some of which had been addressed by the newly-announced enhancements. The Friday afternoon concluded with a lively panel discussion moderated by Mr Alok Mishra, Chairman of SMA's Medical Technology Industry Group. Industry agreed that it had been a fruitful session and looked forward to more of such engagement sessions with HSA. Feedback or enquiries on the enhancements to the regulatory framework may be made through email, HSA_MD_Info@hsa.gov.sg, or by contacting the Medical Device Branch at telephone hotlines 6866-3560 or 6866-3566.






Mr George Huang, President of Singapore Manufacturers' Federation (left) presenting a token of appreciation to Dr Amy Khor, Minister of State for Health (middle) at the Townhall Meeting with Associate Professor John Lim, Chief Executive Officer of Health Sciences Authority (right).



(From left) Dr Raymond Chua, Group Director, Health Products Regulation Group, Health Sciences Authority; Associate Professor John Lim, Chief Executive Officer, Health Sciences Authority; Dr Amy Khor, Minister of State for Health; Mr Alok Mishra, Chairman of Singapore Manufacturers' Federation Medical Technology Industry Group and Ms Jacqueline C. Monteiro, Vice Chairman of Singapore Manufacturers' Federation Medical Technology Industry Group.

Connecting with Our Medical Device Partners

TABLE 1

Overview of key initiatives announced on 20 April 2012 Details are available on the HSA website by clicking on the link icon 	
INITIATIVE	POTENTIAL BENEFIT(S) TO INDUSTRY
<p>Enhancement of the regulatory framework for lower risk (Class A and B) medical devices</p> <p>Class A Medical Devices From 1 May 2012</p> <ul style="list-style-type: none">• All Class A medical devices, except sterile devices, will be exempted from registration• Turnaround time for registration of Class A (sterile) medical devices will be reduced to 30 working days <p>Class B Medical Devices From 1 Sep 2012</p> <p>HSA will be implementing the following new registration routes</p> <ul style="list-style-type: none">• Immediate Registration Route for Class B medical devices that have already been approved by two of HSA's independent regulatory reference agencies (US FDA, EU Notified Bodies/Australian Therapeutic Goods Administration, Health Canada & Japan Ministry of Health, Labour and Welfare) and marketed without any safety concerns for at least three years in these jurisdictions• Expedited Registration Route for<ol style="list-style-type: none">a. Class B devices which have already been approved by two of HSA's independent regulatory reference agencies; orb. Class B devices which have already been approved by at least one of HSA's independent regulatory agencies and marketed in this jurisdiction or Singapore without any safety concerns for at least three years• Regulatory fees for the two new routes will be reduced to \$1,400• Turnaround time for the expedited registration route will be 60 working days	<p>The enhancements will result in faster and expedited access for Class A and B medical devices.</p> <p>Industry will also benefit from lower regulatory fees for registration of Class B products that qualify for the new routes.</p>
<p>Enhancement of special authorisation routes (SAR) From 1 May 2012</p> <ul style="list-style-type: none">• Fees for SAR will be temporarily absorbed by HSA if all the devices listed in the SAR application are the subject of pending product registration or change notification applications that have been submitted by 31 December 2012• Validity period of all approved SAR applications will be extended to 12 months• Process for GN-27 SAR (for applications to import unregistered devices for supply to clinical laboratories, medical clinics or private hospitals licensed under PHMC Act) has been enhanced to allow consolidation of an identical list of unregistered medical devices for different healthcare facilities into a single application	<p>Industry will benefit from reduced paperwork and regulatory cost associated with applications to import and supply unregistered medical devices via the special authorisation route</p>
<p>Notification route for minor administrative changes From 1 May 2012</p> <ul style="list-style-type: none">• Certain minor administrative changes may be implemented immediately upon submission to HSA; the fees will be absorbed by HSA 	<p>Industry will be encouraged to keep administrative details up-to-date in product registration dossiers without incurring additional cost</p>
<p>HSA SMaRT E-Guide</p> <p>The HSA SMaRT E-Guide has been launched on HSA's website. The E-Guide may be accessed by clicking on the link icon </p>	<p>The E-Guide will provide industry with clearer step-by-step advice on medical device registration dossier submission. This will potentially help minimise delays in regulatory decision due to incomplete documentation.</p>
<p>Appeals</p> <p>Appeals on submissions may be made in writing to the Group Director's Office at the following email address: HSA_MD_Query@hsa.gov.sg</p>	<p>This provides industry a clear and transparent avenue for appeals on regulatory decisions.</p>

Dialogue Sessions with the Association of Medical Device Industry (Singapore) and the Singapore Manufacturer's Federation

On 21 March 2012, HSA conducted a stakeholder dialogue session with the Association of Medical Device Industry (Singapore) (AMDI) at the Chui Huay Lim Club, a quaint Teochew clubhouse. The objective of this dialogue session was to have an open sharing and discussion on how the regulations have affected the industry, as well as operational and financial challenges encountered by the industry in their attempts to adhere to the regulatory requirements for the registration of medical devices in Singapore.

The dialogue session started with a strong show of support from 49 of its members. After a welcome address and opening speech by Mr Henry Tan, the President of AMDI, Dr Raymond Chua, Group Director, HPRG conveyed HSA's intention to understand the issues faced on the ground and to work on improving the processes and system especially in areas of increasing manpower resources. He acknowledged that there were also pertinent cost structure issues which may require a slightly longer period of time to assess and make changes. Nonetheless, he encouraged the AMDI members who were present to be honest and open about the constraints and challenges they face and to provide specific details as to what their areas of concerns were. He ended the presentation with the mantra 'Help us to help you'.

Immediately thereafter, the round table face-to-face dialogue sessions started with a flurry of movements

as each HSA representative moved from one table to another, soliciting feedback and actively listening to what the participants had to share. With great candor, suggestions were given on communication channels, device risk classification, change notification, special authorisation routes and Good Distribution Practices for Medical Devices (GDP-MDS). The participants even proposed an innovative "test-market" route for HSA to consider.

At the end of the sharing session, Mr Henry Tan expressed his appreciation to HSA for availing themselves for the dialogue session. He was also very heartened to see that HSA was very willing to understand the concerns and proposals brought from those present, and take back the feedback for consideration in refining the medical device regulatory framework.

In a similar manner, HSA also held a focus group session with the Medical Technology Industry Group (MTIG), one of 11 industry groups of the Singapore Manufacturer's Federation (SMa).

The first segment of the session in the early afternoon of 4 April 2012 saw HSA interacting with 31 eager participants representing 17 multinational companies, at the SPRING building in Bukit Merah, where the SMa office is located. With great camaraderie and a show of unity, the participants came fully prepared with a list of proposals for HSA, covering a range of topics such as

change notification, turnaround time, labelling issues and special authorisation routes. At the end of the two-hour session, the participants conveyed their appreciation to HSA for initiating the focus group session and looked forward to other regulators in the region following suit in their engagement with the industry. They also expressed their hope that HSA will consider some of the proposals and refine the regulatory framework, so that Singapore's system may be cited and adopted as a best practice for the region.

After tea break, HSA engaged with close to 20 representatives from 11 Small and Medium Enterprises (SME) companies, many of whom were managing directors, general managers, pharmacists and regulatory affairs managers. This group of stakeholders echoed the sentiments of the AMDI members.

HSA would like to thank all the companies that had participated in the focus group sessions. We remain committed to continual and regular engagements with stakeholders. We would like to assure companies that their feedback has been heard, and will be taken into consideration and acted upon in phases. As has been in the past, HSA will strive to be responsive to the needs of the industry, healthcare professionals and the public as we further enhance the medical device regulatory framework in Singapore.



Partnership in combating the sale of counterfeit coloured contact lenses in Singapore

In July 2011, HSA together with CIBA VISION managed to stop the further distribution of counterfeit contact lenses which were fraudulently labelled as “FreshLook® ColorBlends®” Contact Lenses from CIBA VISION and protect members of the public from the harms of using these counterfeit lenses.

The lenses were sold for aesthetic purposes and for the correction of short sightedness. This was the first case of counterfeit contact lenses being sold by optical shops in Singapore.

Background

HSA was notified of the counterfeit lenses by CIBA VISION in mid June 2011. The company was first alerted to this when it received stocks of “FreshLooks® ColorBlends®” contact lenses for exchange from several optical shops. Upon investigations, CIBA VISION confirmed that these products were counterfeits as they were not manufactured by them.

Laboratory analysis of these counterfeit lenses by HSA and CIBA VISION confirmed them to be unsafe, of poor quality and deficient in many aspects. The solution which the

lenses were packed in was found to be contaminated with a harmful bacterium, *Pseudomonas aeruginosa* which has been known to cause serious eye infections. The counterfeit lenses in general have lower water content and were thicker in the centre of the lens. These defects minimise oxygen penetration to the eye through the contact lenses. The lack of oxygen supply to the eye and several other defects found in the counterfeit lenses can give rise to severe eye irritation, discomfort and pain, in addition to the risk of eye infections.

Actions taken by HSA

Acting on this information, HSA conducted raids on suspected optical shops and found them to be in possession of the counterfeit contact lenses. All counterfeit lenses from these shops were seized. Further investigation led to information relating to possible suppliers of the counterfeit coloured contact lenses. The seven accused, including the owners of the optical shops and their suppliers, were charged under the Health Products Act.

As of 22 March 2012, one of the accused pleaded guilty in court to two charges from HSA for supplying a counterfeit health product and was fined \$6,000. Four other similar charges were taken into account in sentencing. The same accused was also fined another \$6,000 for one charge under the Trade Marks Act.

A Press Release was also issued on 20 July 2011 to alert members of the public on this issue and to warn them on the dangers of using counterfeit lenses. Members of the public were



“HSA takes a serious view on the dealing of counterfeit health products. The public trusts owners of optical shops and registered optometrists/opticians which are part of the legitimate supply chain of eyecare services and products. HSA will not hesitate to take punitive action against sellers who peddle counterfeit products.”

- Associate Professor Chan Cheng Leng, Deputy Group Director, Health Products Regulation Group, warns sellers of counterfeit contact lenses

also advised to seek medical advice if they experienced adverse reactions from using these lenses.

A word from CIBA VISION

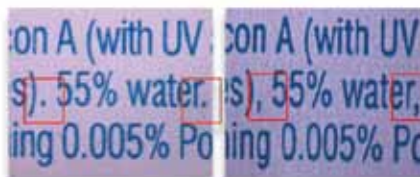
In the Press Release issued by HSA, Mr Raymond Yew, Business Unit Head of Singapore, Malaysia and Brunei, CIBA VISION also commented, “CIBA VISION was able to detect the counterfeit FreshLook® ColorBlends® lenses due to our strict monitoring processes and product security features. We promptly reported this issue to HSA as consumer safety is our top priority.” He added that CIBA VISION viewed counterfeiting as a serious offence. The company had worked with HSA to identify, investigate and seize counterfeit contact lenses from the market.

BLISTER PACK



Counterfeit

Authentic



An example of typographical errors found on the counterfeit pack.

Call to combat counterfeit and illegal health products and medical devices

Drawing from this experience, HSA hopes to continue to work closely with members of the industry to combat the sale of counterfeit and illegal health products and medical devices. The partnership between HSA and the industry is imperative in our mission of safeguarding public health and safety. Members of the industry are advised to contact HSA's Enforcement Branch at Tel: 6866 3485 or email hsa_is@hsa.gov.sg once they are aware of the sale of counterfeit or illegal health products and medical devices.

Acknowledgement

The editorial team would like to thank the Enforcement Branch for its contribution to the above article.

Risky to buy contact lenses online

"The Singapore Optometric Association applauds the Health Sciences Authority and Ciba Vision, manufacturers of the FreshLook coloured lenses, for their alertness in detecting counterfeits and bringing them to the attention of the public.

All contact lenses, including coloured ones, are classified as medical devices and can be legally prescribed and dispensed only by registered contact lens practitioners"

- Dr Koh Liang Hwee, President, Singapore Optometric Association

Source: THE STRAITS TIMES Forum,
Published on 25 July 2011

Engaging TCMs in Vigilance of Health Products

As part of HSA's efforts to reach out to Traditional Chinese Medicine Practitioners (TCMPs) to promote the awareness of safety monitoring of complementary medicines, the topic "Vigilance of Complementary Health Products" was shared with the TCM community at the Nanyang Technological University- Traditional Chinese Medicine (NTU-TCM) symposium by Ms Belinda Tan from the Vigilance Branch.

This inaugural symposium titled "Furthering TCM in Singapore" was organised by the NTU Chinese Medicine Alumni Association on 11 March 2012. This association was set up by the graduates of NTU's double degree programme in Biomedical Sciences and Chinese Medicine.

About 120 participants attended the symposium, which included TCMPs, members from the academic institutions and Traditional Chinese Medicine (TCM) industry association. Dr Amy Khor, Minister of State for Health was the guest-of-honour and the other speakers were Prof Hong Hai, Prof Ng Han Seong, Dr Cheng Sim Kim and Prof Koh Hui Ling.

Other Educational Efforts

HSA had, in 2011, sent out three letters and two posters to all



registered TCMPs to share reports of Adverse Events (AE) associated with illegal adulterated health products. These illegal products were fraudulently labelled as Traditional Medicines (TM) and tested by HSA to contain undeclared western medicines. In our letters, TCMPs were encouraged to report their suspicion of adulterated products and adverse reactions observed in their patients who have taken such products. The response from TCM physicians to our letters was very encouraging, which subsequently led to the detection of more illegal adulterated products. More information about these illegal

"I think it is an innovative approach and a good start to establish communication with the TCM community. The community will feel more involved when they are well informed. They will be more vigilant against adulterated TCM proprietary medicine. I would like to suggest that HSA holds discussion and feedback session with the community from time to time to foster a stronger tie."

- A TCM physician shared his thoughts on HSA's vigilance efforts

products is available at HSA's website: www.hsa.gov.sg/press_releases

To further improve our communication with TCMPs, feedback was sought from a few participants at the NTU-TCM symposium.

HSA appreciates the positive feedback from the TCM community and looks forward to a meaningful partnership with them in our mission of safeguarding public health.

HPRG Joint Regulatory Workshop 2012


Following the positive feedback of the Inaugural Joint Regulatory Workshop in 2011, the Health Products Regulation Group (HPRG) of HSA held the 2nd Joint Regulatory Workshop from 15 -17 February 2012 at the Swissotel Merchant Court as part of our continuing efforts to be an enabler in increasing regulatory knowledge and awareness in both local and international regulatory updates and information.

This joint workshop aimed to provide industry participants an insight into the latest development pertaining to the regulation of health products in Singapore, where the participants had the option of attending six different workshops covering updates on regulatory control of western medicines, medical devices, complementary health products, cosmetic products and clinical trials

Dr Christina Lim, Senior Director, International Relations and Dr Raymond Chua, Group Director of HPRG opened each of the three days of the workshop with speeches that focused on HSA's efforts to be more robust and efficient in our regulatory systems and processes and sharing of information with the industry through publication of guidelines and updates on HSA's website, regular communication sessions and conducting training workshops. Examples of continual engagement with the industry included the hosting of the 18th Meeting of the ASEAN Consultative Committee for Standards and Quality Product Working Group (PWG) held in Singapore in June 2011 and participating in product working group meetings like Medical Device PWG, the Traditional Medicines and Health Supplements PWG and the ASEAN Cosmetic Committee. Behind the scenes, HPRG has reviewed and consolidated four main advisory committees to provide expert advice on matters pertaining to safety, efficacy and quality aspects and registration of the various product groups. These advisory committees include the Medicines Advisory Committee for medicinal products, Medical Device Advisory Committee, Complementary Health Products Advisory Committee, and Product Vigilance Advisory Committee. Information on these advisory committees will soon be available on our website.

Launch of NEX2US Engagement and Service Campaign

In line with the vision of taking HPRG's interactions with our stakeholders to greater heights, an engagement and service campaign was launched at the Joint Regulatory Workshop. The theme of this initiative is "NEX2US - Connecting with Our Partners" which represents HSA's commitment to collaborate and connect with our stakeholders. This year, we will continue with our rules review and transparency efforts. At the same time, HSA would also like to solicit feedback and suggestions from our stakeholders, and to work closely

with them to further improve the robustness and efficiency of our systems and processes. The launch showcased the NEX2US video, which can be viewed at our website through the following link icon 



Updates on Good Manufacturing Practice (GMP) for medicinal products

Industry members were also updated on the current status of Pharmaceutical Inspection Cooperation Scheme (PIC/S), and the changes to the PIC/S GMP Guide and related guidance documents including the requirements on Quality Risk Management (QRM) and the explanatory notes for pharmaceutical manufacturers on the preparation of a Site Master File.


At the session, participants were apprised of the updates from PIC/S, which included the following:

- the acceptance and accession of new competent authorities into PIC/S,
- pending applications to accede to PIC/S,

- updates on the review of sections of the GMP guidelines by PIC/S and EU.

General principles and practical examples of Quality Risk Management (QRM) were presented. Poring over a practical case study on "Review of a Quality System Procedure", each participant had hands-on experience reviewing a quality system procedure on supplier qualification. The case study was well received and participants commented that it was a good example of the application of GMP principles in actual practice and helped to bring across the requirements of a GMP audit.

It was also announced that the revised PIC/S Explanatory Notes for Pharmaceutical Manufacturers on

the Preparation of a Site Master File (PE 008-4) would be implemented as a guidance for manufacturers of medicinal products on preparation of a Site Master File (SMF). On 1 January 2011, the revised document was officially published as a PIC/S document. The main objectives of the revision were to simplify the document and to implement the requirements in relation with quality risk management. A copy of the revised PIC/S Explanatory Notes for Pharmaceutical Manufacturers on the Preparation of a Site Master File (PE 008-4) can be obtained from the HSA website at the following link icon 

Acknowledgement

The editorial team would like to thank our colleagues Mr Boon Meow Hoe, Dr Chan Wai Yee, Dr Lai Weng Fai and Mr Ng Liong Thiam from the Audit & Licensing Division for their contribution to the GMP updates section.

"Good workshop and continue the good work. Good, friendly and knowledgeable officers"

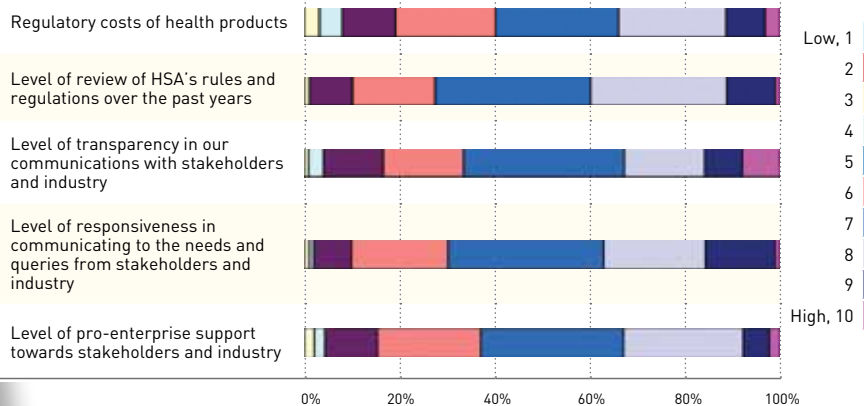
"Very well organised in general. Keep up the good work as I can see vast improvements. Thank you!"

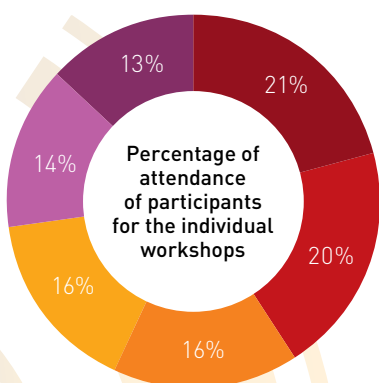
"Interesting case study. Something new! HSA was helpful in explaining. Thank you! Very informative and please keep having this workshop every year!"

- feedback from Joint Regulatory Workshop participants

Joint Regulatory Workshop

PRO-ENTERPRISE RATINGS FOR HPRG BASED ON JOINT REGULATORY WORKSHOP SURVEY RESULTS





- WS1
- WS2
- WS3
- WS4
- WS5
- WS6

Participants

The response for the workshop was very encouraging. All the workshops were well attended by between 160 and 260 participants for each workshop.

We truly appreciate the feedback given to better meet the needs of the industry. We would like to extend our appreciation to all participants for their immense support during the 3-day workshop.

More information on the Joint Regulatory Workshop 2012 can be found on the HSA website via this weblink 'Joint Regulatory Workshop 2012'.

Workshop Participation		
WORKSHOP NUMBER	WORKSHOP	NUMBER OF INDUSTRY PARTICIPANTS
WS1	Regulatory Controls of Medicinal Products	240
WS2	Good Manufacturing Practice for Medicinal Product Manufacturers	193
WS3	Regulatory Controls of Medical Devices	260
WS4	Medical Device Clinical Trials	169
WS5	Regulatory Controls of Complementary Health Products	200
WS6	Regulatory Controls of Cosmetic Products	165

Refer to pie-chart above left

Insights to the Regulatory Controls of Medicinal Products

Updates on the Health Products (Therapeutic Products) Regulations

A new piece of subsidiary legislation, the Health Products (Therapeutic Products) Regulations, will be promulgated under the Health Products Act. This set of regulations aims to amalgamate the legal provisions for the control of western medicines under the Medicines Act (Cap. 176) and the Poisons Act (Cap. 234) into a single piece of legislation. The transition of legislative controls from existing laws to the Health Products Act is expected to be a lateral transfer of the licensing regime with fine-tuning of the regulatory controls. Existing regulatory policies will remain fundamentally unchanged. The draft regulations will be published for consultation prior to the actual implementation.

Dossier Filing for New Products (Administrative Documents and Quality)

There will be some changes on the administrative and quality aspects of Dossier Filing for new products. The aim of the changes is to provide the industry with additional guidance and clarity for new dossier submissions, hence reducing the number of queries and input requests during screening for faster turnover time. An example is the revision of screening checklists in the Guidance to Medicinal Product Registration in Singapore.

Consequential Changes in Minor Variation (MIV) Applications

Previously, many changes are grouped into one MIV application. This initiative is to allow only consequential changes to be grouped as one MIV.

This initiative was implemented to align with the best practices of other international agencies e.g. European Medicines Agency and to facilitate evaluation/approval of MIV-1 applications so that the timelines for completion will be more predictable for the industry.

Fresh Perspectives on Medical Device Regulations

Paving the way ahead at the Medical Device Industry Training Workshop

Following the phased implementation of regulatory controls for medical devices under the Health Products Act, HSA has embarked on new initiatives to train and engage the medical device industry through numerous stakeholder briefings and consultation sessions. As part of such educational initiatives, HSA ran a full-day Medical Device Industry Training Workshop on 15th March 2012 to provide stakeholders with insights on performing clinical evaluation of medical devices.

The workshop, though initially planned for 100 participants, opened to a strong showing of over 400 representatives from more than 200 different companies. HSA's CEO, Associate Professor John Lim launched the workshop with an opening speech, highlighting HSA's commitments to the medical device industry. He also introduced the salient theme of "NEX2US", which aptly describes HSA's desire to connect and interact with the industry. He explained the necessity of the ongoing changes in the medical device legislation, and emphasised the importance of HSA's collaborative efforts with the industry to achieve robust standards of clinical research and regulation in Singapore.

Ms Danielle Giroud, the keynote speaker at the workshop, is a highly regarded clinical research and regulatory expert within the global medical device industry. Ms Giroud's vast experience in the medical device arena includes being a convener for the expert group on clinical investigations, involvement in the working group for the ISO 14155 and the European Union Commission-Clinical Investigation and Evaluation task force.

At the medical device training workshop, Ms Giroud broached the topic of clinical evaluation by first distinguishing between the key concepts of device performance and effectiveness. While the performance of a device could earn it a CE mark, its market popularity would largely be



(from left) Associate Professor John Lim, Chief Executive Officer, HSA; Ms. Danielle Giroud, founder of WMDO; Mr. Foo Yang Tong, Director (Clinical Trials Branch), HSA; Dr. Aw Swee Eng, Chairman, Centralised Institutional Review Board, SingHealth; Dr. Christina Lim, Senior Director, International Relations, HSA.

"In the clinical evaluation of medical devices, the safety, performance and effectiveness of the device are key considerations."

– Ms Danielle Giroud, founder of the World Medical Device Organisation (WMDO) and the keynote speaker at HSA's Medical Device Industry Training Workshop.

determined by its clinical effectiveness in patients. Having established the basis for clinical evaluations, her presentations progressed to performing medical device clinical investigations and subsequently post-market surveillance.

The workshop concluded with closing remarks by Mr Foo Yang Tong, Director, Clinical Trials Branch, expressing gratitude to Ms Giroud for taking the audience through the "organised jungle" of medical device intricacies and lauding Ms Giroud as a true pioneer in her area of expertise.

Feedback from workshop participants

Industry representatives were appreciative that HSA had offered this training opportunity. Ms Christina Keok, regulatory manager at Bristol-Myers Squibb (Singapore), commended the trainer on her ability to use realistic examples encountered in the clinical setting to exemplify practical concerns regarding the usage of medical devices in patients. Ms Tyu Suat Hong, principal quality system specialist at Medtronic Singapore Operations, had found the information presented extremely

useful for the conduct of medical device clinical trials.

Concluding remarks

Reflecting on the pearls of wisdom shared by Ms Giroud, one may introspectively extrapolate the notion of performance and effectiveness beyond the realm of medical devices. The performance of the regulator is appraised by the industry and the medical community in measures of turnaround times and other quantitative performance indicators. The effectiveness of a regulator is defined by the ability to safeguard public health while facilitating research. Such is the delicate balance between the two, and the litmus test for each lies in meeting industry expectations of our performance standards as well as public expectations of our duty to improve healthcare options and safeguard their health. It is therefore the prerogative of the agency to ensure that both performance and effectiveness indicators are met, such that the interests of the industry, medical community and general public are duly considered in the regulatory process.

A Candid Talk with Ms Stella Ang

After her graduation from the National University of Singapore with Bachelor of Science (Pharmacy), Stella practised as a hospital pharmacist to gain patient-care insights before moving on to join the pharmaceutical industry. She has now more than 10 years of working experience in regional regulatory affairs.



In her current position as Regulatory Affairs Manager of Hyphens Pharma, she works closely with a team of regulatory affairs personnel in various Hyphens' offices in South East Asian (SEA) countries including Singapore, Malaysia, Indonesia, Vietnam and the Philippines. She has shared that one of her key roles is to ensure successful and timely registration of a wide range of products, ranging from pharmaceuticals, cosmetics, health supplements and medical devices. She also oversees post-market activities that need to be carried out after the products have been marketed.

How long have you been working as a “Regulatory Affairs” professional and can you share with us the challenges you face in this job ?

I have been working in this place for more than 10 years. Based on my experience, there is an increase in complexity of the regulatory environment with the evolving nature and amount of data for registration required. As such, I believe the regulatory professionals have to grasp all these technical knowledge and latest development via continuous learning in order to perform their roles adequately. I see a need to have in place a structured training programme in this area of specialisation.

You have been dealing with HSA’s Health Products Regulation Group over the last few years and witnessed many changes in our processes and regulatory requirements, could you share with us the areas you think we have done well?

I can see a strong partnership being forged between the industry and HSA. There are now many channels for the industry to feedback to the agency.

Our suggestions are put into actions and we really see things changing for the better. For example, previously, to classify a health product, it was cumbersome for the industry to communicate with different product branches to ascertain the product classification. However since the health product enquiry form was introduced, it is easier and quicker to identify the correct classification of a product.

The Singapore Pharmaceutical Manufacturer’s Council (SPMC) / Singapore Pharmaceutical Trade Organisation (SPTO) meetings and dialogue sessions are also useful. It is through these meetings and sessions that we are informed in a timely manner of not only changes that HSA plans to implement, but as well as updates on specific issues such as the ASEAN stability requirements. One of the outcomes

of these meetings was the adjustment of the HSA timeline to gradually implement the ASEAN stability requirements. We really appreciate the move to allow the industry more transition time for building up our internal processes to meet these requirements.

HSA also conducts regular briefings and training to prepare the industry well prior to changes on existing regulatory framework or implementation of new regulatory requirements.

Which areas would you think we should focus on improving in the immediate term i.e. one to two years?

As I had mentioned earlier, the regulatory environment is getting more complex and there is a need for trained regulatory personnel to file submissions to HSA. It would be great if there is training for regulatory personnel on filing submissions to HSA. There are some government bodies eg. Workforce Development Agency (WDA) & SPRING Singapore that can work together with relevant statutory boards to facilitate and develop capability for these initiatives

I can see the groundwork for harmonisation is actively taking place across the world. Despite these efforts, country-specific requirements exist even after harmonisation and this poses a problem for us. Nonetheless, I believe with continued sharing sessions on harmonisation with the other ASEAN countries, we would be able to see the fruits of such interaction. It is also rather challenging to navigate the PRISM system and we hope to see improvements when the new IT system is implemented.

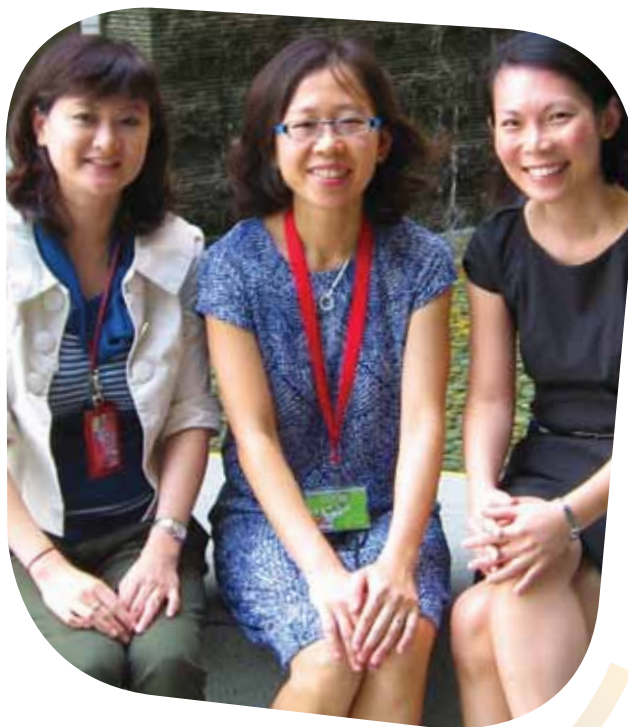
Like all government agencies, HPRG carries out public consultation before changes are introduced. For example, we have organised several forums to solicit feedback from the industry on the implementation of new regulatory requirements. Is there any suggestion on how we can reach out further to industry stakeholders?

Face-to-face dialogue sessions would be a useful platform to solicit feedback instead of surveys as it allows more flexibility in terms of back-and-forth discussion. An optimum size for a dialogue session would comprise of around 20 to 25 company representatives so that there would be sufficient opportunities within the session timeframe for different companies to raise their concerns and interact with one another. Two dialogue sessions a year would be good and ad hoc sessions may be organised whenever there are specific issues to be addressed.

If you could use one word or phrase to express your experience in your interaction with HPRG – what would it be?

HSA has a robust system in place and is open to feedback and suggestions. I appreciate that HSA understands the dynamics of the regulatory landscape and is constantly evolving to address industry needs while fulfilling its mission of ensuring safety.

“HSA also conducts regular briefings and trainings to prepare the industry well prior to changes on existing regulatory framework and implementation of new regulatory requirements.”



Ms Stella Ang (middle), flanked by HSA interviewers Ms Michelle Kok (left) and Ms Valerie Wee (right)

Update on Implementation of Therapeutic Regulations under Health Products Act

The Health Products Act (HPA) was enacted in November 2007 with the intent to regulate the manufacturing, importation, supply, presentation and advertisement of health products. The Act serves to consolidate the controls for regulating medicines, which currently reside in various pieces of legislation, into one omnibus Act, providing better clarity for those dealing in health products such as healthcare industry and practitioners.




Controls for the various health product groups are being brought under HPA's regulatory umbrella in stages. Medical devices and cosmetic products were the first two categories of health products brought under the regulation of

the HPA in 2007 and 2008 respectively. The entire spectrum of regulations for these product groups covering pre- and post-market controls were implemented in phases, to facilitate smooth transition of operations for HSA and its stakeholders.

The next product group that will be brought under the HPA will be therapeutic products, or commonly known as western medicines. Over the past two years, the Health Products Regulation Group (HPRG) has conducted multiple focus group consultation with various stakeholders as well as communication sessions with the industry to ensure a smooth transition of controls from existing laws to the HPA. A public consultation on the proposed definition for therapeutic products was conducted early this year and no significant change to the draft definition was needed based on the comments received.

The regulations for therapeutic products are being drafted and HPRG plans to conduct a stakeholders consultation on the draft regulations before finalisation. Transitional and grace period arrangements will be taken into consideration in the implementation of the regulations.

Industry stakeholders who need further information or clarifications may email your queries to HSA_Industry_News@hsa.gov.sg.

***More information on the proposed changes to the Health Products (Therapeutic Products) Regulations can be found on the HSA website via the 'Industry Dialogue' webpage** 



Updates on Complementary Health Products

Review of limits of aconite alkaloids in Chinese Proprietary Medicines (CPM)

In response to industry request and feedback, HSA had initiated a review on the allowable limit for the trace presence of aconite alkaloids in CPM with herbal ingredients documented to contain such substances in a naturally occurring manner.

In the past, CPM containing such herbal ingredients were required to be tested to show the absence of aconite alkaloids. However, with the advancement of laboratory equipment in testing capabilities and the increased sensitivity of the equipment, trace levels of these substances can be easily detected. Following a review, with effect from January 2012, the allowable limit for the trace presence of naturally occurring aconite alkaloids in CPM has been set at 60mcg/day.

Companies dealing with CPM containing these ingredients with naturally occurring aconite alkaloids can submit to HSA the relevant test reports issued from an accredited laboratory reflecting the quantity of aconite alkaloids present for review – a step forward to removing regulatory barriers.

For further clarifications, please email our CPM officers at HSA_CHP@hsa.gov.sg

Consolidated email account for Complementary Health Products


To ensure that customers are able to provide their feedback and enquiries on the different types of complementary health products in an efficient and seamless manner, the two email addresses for Chinese Proprietary Medicines and Health Supplements have been consolidated into a single email address: HSA_CHP@hsa.gov.sg. We are pleased to announce that all correspondences on Chinese Proprietary Medicines and Health Supplements may now be channelled to this consolidated email address and customers can expect a timely response as a result of this pro-enterprise initiative.



Step-by-step guide on Cosmetic Product Notification Procedures

Another pro-enterprise initiative that has been implemented is the publication of a Step-by-Step Guide on Cosmetic Product Notification Procedures online in November 2011. This guide aims to allow cosmetic dealers have a better understanding on how to submit product notifications online.

In Singapore, companies or persons responsible for placing cosmetic products in the market are required to notify HSA before placing their cosmetic products for local sales or supplies with a declaration of self-compliance to the ASEAN Cosmetic Directive (ACD). The product notification can be submitted via HSA online system PRISM (Pharmaceutical Regulatory Information System).

You can access the guide available on HSA's website by clicking on this link. 


For enquiries, please contact the Cosmetics Control Unit at HSA_Cosmetics_Control@hsa.gov.sg




As part of HPRG's ongoing pro-enterprise effort, the HSA website is regularly updated so to provide industry stakeholders with relevant information. In this section of the newsletter, we would like to highlight some of the updates that we have made to our website since the last publication which may be of interest to you.

Do you know...

The FAQs pertaining to clinical trials involving the use of medicinal products were updated in May 2012

>> **Click on the link to find out more.** 

The import and export of Controlled Drugs and Psychotropic Substances can now be reported through clearance@prism


>> **Click on the link to find out more.** 

The guidance document which describes the step-by-step procedure on how to submit cosmetic product notifications to HSA was revised in Nov 2011

>> **Click on the link to find out more!** 

The screening checklists for NDA/GDA application submission were revised in Feb 2012 to include additional pointers on dossier requirements

>> **Click on the link to find out more.** 

Not sure how your health product is classified
Cracking your head as to which product enquiry form to use and where to send it to? Just visit this link 
to access our single HPRG product enquiry form and return your form to our one-stop email address HSA_Prod_Class@hsa.gov.sg.
For enquiries and feedback, please contact the HPRG Connects Centre at Tel: 6866 3400
Fax: 6478 9076.

UPCOMING EVENTS

17th ASEAN Consultative Committee for Standards and Quality Traditional Medicines and Health Supplements Product Working Group meeting

The 17th ASEAN Consultative Committee for Standards and Quality (ACCSQ) Traditional Medicines and Health Supplements Product Working Group (TMHS PWG) meeting will be held in Singapore from 25 – 30 June 2012 at the Grand Copthorne Waterfront Hotel.

Established in 2004, the key objectives for ACCSQ TMHS PWG are to implement measures for the integration of traditional medicines and health supplements stipulated in

the ASEAN Healthcare Integration Roadmap, to harmonise technical requirements and to eliminate technical barriers to trade without compromising public health and safety to the ASEAN population. This is an excellent platform for regulators and industry from the ASEAN Member States to collaborate and discuss technical guidelines and regulatory requirements in relation to ASEAN harmonisation in traditional medicines and health supplements.



Do you have any comments/feedback on the articles published or how we can improve our newsletter?

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.

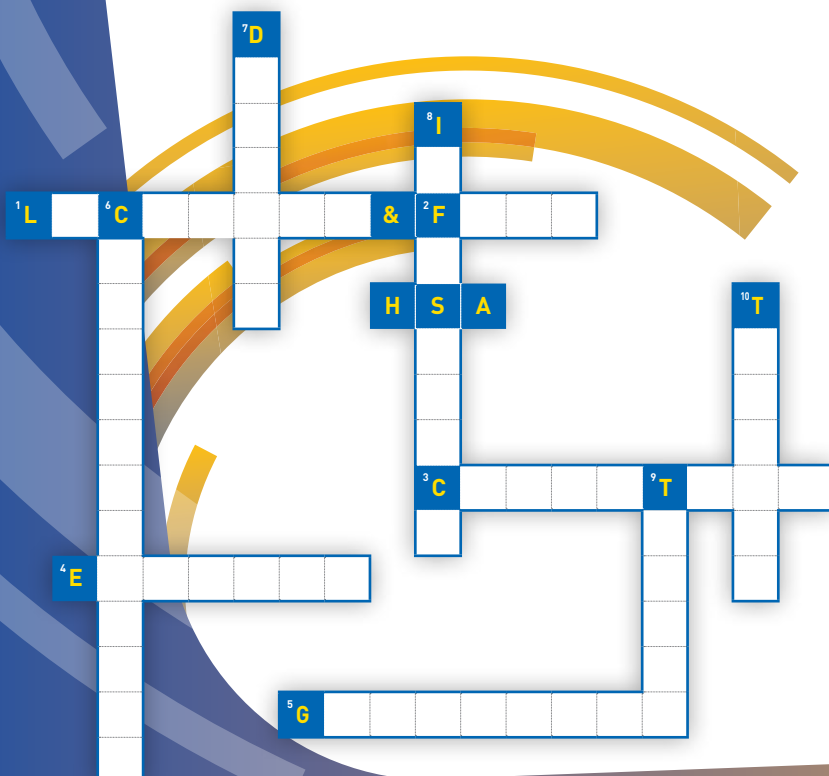
*Your Newsletter
Your Comments*

FUN LEARNING

Navigating through HSA HPRG website

Learn to locate the right information through this WORD GAME!

Check your answers by clicking on the blue boxes and be directed to the website.



Down

- health products branch: manages the regulation of chinese proprietary medicines, other traditional medicines and health supplements
- Medical covers a wide range of health or medical instruments which are critical to the delivery of healthcare
- for medicinal products: this search provides listing of all licensed medicinal products in singapore as well as their current approved package inserts
- Clinical branch: oversees clinical research activities in singapore
- This regulatory branch was set up in 1989 to administer and enforce the act, and aims to reduce the prevalence of smoking among Singaporeans

Across

- Issued upon approval of every product
- Another word for charges
- control unit: regulates products such as skincare items, make-up colours, bath and shower preparations.
- Health product form: for queries on product classification and regulatory control of health products
- Regulatory provides guidelines for industry and applicants