Summary of Feedback Received From The Public Consultation On The Proposed Health Products (Medical Devices) Regulations

Overview

The Public Consultation for the proposed Health Products (Medical Devices) Regulations was held over an 8-week period from 6 February to 2 April 2007. The Health Sciences Authority (HSA) received a total of 37 responses from the public and medical device industry, including industry associations. Face-to-face briefings were also conducted with 151 participants from 132 companies in the medical device industry.

A summary of the respondent categories is presented in Table 1.

Table 1: Category of Respondents

Category	Number of Respondents
Public	2
Medical Device Companies • Local • Overseas	 23[1] 8
Associations • Local • Overseas	 2[2] 2
Total	37

[1]Some respondents submitted several comments
[2]Includes Singapore Accreditation Council

There was general support from the respondents for a legislated framework for medical devices. They welcomed the open and transparent approach adopted by HSA for the public consultation. Some respondents suggested that HSA continue to engage the stakeholders during implementation of the Regulation.

Some respondents expressed support for the Regulation as it is aligned to the Global Harmonisation Task Force's (GHTF)[1] principles and guidances. One respondent felt that the proposed regulatory approach provides a good balance between regulating medical devices and the business interests of industry. Hence, the proposed Regulation will help to ensure a high level of safety and efficacy for medical devices in Singapore.

The majority of respondents sought clarifications on the rules in the proposed Regulation. These were mostly related to technical requirements specific to a particular aspect of product control (e.g. testing of devices by HSA, labelling of devices). HSA has noted these points and will take them up subsequently as part of the public consultation process when drafting the subsidiary legislation for each respective product type.
Respondents also sought clarification on legal terms and definitions used in the draft Bill. HSA will take these into consideration when finalising the Regulation.

Several respondents provided scenarios of purely commercial transactions in nature, such as supply of parts or service for discontinued products. Such commercial dealings between the company and hospitals or clients are not within the scope of the Regulation.

Summary of Feedback Received and HSA's Responses
The main points of feedback and comments, and the corresponding responses from HSA are summarised in Table 2.

Table 2: Summary of Feedback Received and HSA's Responses

Main Points of Feedback/Comments	HSA's Responses
Manufacturers, Importers and Wholesalers of Medical Devices	
1. Does the licensee need to be located in Singapore? 2. Does each premise need a separate licence?	All licences are only issued to legal entities in Singapore, and the entity needs to be located in Singapore. Each importer or wholesaler needs to hold only one licence, which covers one or more premises used by the importer or wholesaler. All premises need to be authorised by HSA prior to use.
3. Do contract and OEM (Original Equipment Manufacturer)	Manufacturer's licence is issued for the activity of manufacturing finished

[1] GHTF is an international forum of medical device regulators and representatives from device trade associations. Conceived in 1992, with the EU, USA, Japan, Australia and Canada as founding member countries, the purpose of the GHTF is to encourage convergence in regulatory practices relating to medical devices. The GHTF's role is similar to the International Conference on Harmonisation's (ICH) contribution to the regulatory guidances for pharmaceuticals in that it is the key driver in harmonising the way in which medical devices are regulated.

manufacturers need licences? 4. Do the licensing requirements apply to parts and components manufacturers?	medical devices. Parts and components manufacturers are not subjected to manufacturer's licence requirements.
5. Compliance to ISO 13485 should be the quality system requirement for manufacturers.	Manufacturer must have an effective quality management system in place, such as ISO 13485 or its equivalent standard.
Import of Medical Devices	
1. Adverse events from a product not imported by product owner but by a parallel importer, which affects the product owner's reputation.	It is the responsibility of all importers, suppliers and registrants to address any adverse events for all medical devices imported and supplied by them.
2. Control measures against parallel importers of medical devices should be implemented. 3. A free-market policy should be adopted and implementation of the Regulation should not be a stumbling block to parallel importing.	A licensed importer can import a registered medical device for which he has been authorised by the registrant of the medical device or upon approval by HSA. The registrant is the holder of the certificate of registration of the medical device, on behalf of the product owner.
Import for Personal Use	
1. Limit on quantity should be set for the importation of devices for personal use, so as to prevent import of large quantities of medical devices for potential illegal sale.	All imports of medical devices, regardless of purpose, must be licensed or otherwise authorised. Importation for personal use needs to be authorised by HSA. Guidelines will be provided during implementation.
Supply of Medical Devices	
1. Can medical devices be shipped directly from overseas manufacturers to the hospitals?	The supply of medical devices directly to hospitals is deemed as a wholesale activity. A licensed importer holding a wholesaler's licence can import and supply medical devices directly to hospitals.
Medical Devices for Clinical Trials	
1. A risk-based approach should be taken so that only high-risk devices require approval. For example, only	Approval from HSA for the import and supply of any medical device for use in clinical trials in Singapore is required.

devices of significant risk require approval by US FDA.	This includes registered medical devices to be used in clinical studies for a new intended use.
Medical Devices for Demonstrations/Exhibitions/Workshops/Conferences	
1. Medical devices for demonstration should be allowed for importation before the device is registered.	Approval from HSA for medical devices brought in for demonstration will be on a case-by-case basis subject to the provisions of the Act and Regulation.
Medical Devices for Export Only	
1. The regulatory control imposed on medical devices meant only for export and not for the Singapore market would be burdensome.	Medical devices that are not meant for supply in the Singapore market are not subjected to product registration. This includes medical devices imported for re-export and those manufactured for export only.
Supply of Medical Devices by Hospitals	
1. Hospitals should be allowed to sell medical devices (both registered and unregistered) to a second hand dealer without the need to be registered as a wholesaler.	HSA currently has no plans to impose specific controls on the transfer of pre-owned medical devices between legal entities as long as they are not placed on the market and do not fall within any activity that is subject to the provisions of the Act and regulations.
Refurbished Medical Devices	
1. The definition and scope of the term “refurbishment” needs to be clarified.	A “Refurbisher” is any person who fully refurbishes a medical device with a view to put the device into use again, “in a as good as new condition”. A refurbisher who is located in Singapore needs to obtain a manufacturer’s licence. Guidelines will be published. The obligations under the regulations, including product registration as a new medical device and post-market adverse incident reporting, will apply to a refurbisher for their refurbished pre-owned medical devices being placed on the market. All refurbished medical devices need to be labelled as “Refurbished”.

Testing of Medical Devices Before Supply	
1. The requirement of performing lot-by-lot testing of medical devices before supply is burdensome and expensive.	The manufacturer is responsible to ensure that the products produced meet the appropriate standards of safety, quality and performance on a consistent basis for every production batch/lot. The lot-by-lot testing requirement will only be imposed on certain types of products. For example, the requirement for testing of male condoms is in line with the World Health Organisation's recommendation that every lot of condoms be tested for compliance by an independent test laboratory before supply.
Modification of Medical Devices	
1. There should be a blanket prohibition on the modification of all medical devices, instead of restricting it to promotion and demonstration only. 2. What about minor changes to the product that do not affect its safety when used as originally intended?	Changing and/or modifying medical devices for the purpose of promotion and/or demonstration are not allowed. If the design of the medical device is modified by the manufacturer as part of product improvement, the registrant is required to notify HSA of the changes as required under duties of the registrant. The intention of rule is to ensure that local companies do not modify medical devices for the purpose of promotion and/or demonstration, as such modifications may expose consumers to unnecessary risks.
"Professional Use Only" Medical Devices	
1. A clearer definition of "professional use only" and a schedule of devices that are for "professional use only" should be provided.	"Professional use only" devices refer to medical devices that require a high degree of technical knowledge to administer/ operate, or which have a high potential to cause harm. Hence the need to for such products to be used by a qualified practitioner. To provide a list of medical devices that

	could be categorized as “professional use only” is not practical due to the wide range of devices available.
Labelling Requirements	
1. Labelling requirements should be harmonised with GHTF labelling guidance.	HSA will incorporate the appropriate sections of GHTF guidance on labelling for medical devices (GHTF/SG1/N43:2005) after reviewing the document.
2. The requirements for Singapore specific information on the label such as import details and registration number are burdensome as most of the products are imported. Some products are too small to include the information.	Singapore-specific labelling requirements will be optional for most medical devices but may be imposed on selected products as deemed necessary by HSA.
Advertisement of Medical Devices	
1. There is a need for timely approval since advertisements need “approval before publishing”.	HSA will develop guidelines on the advertisement of medical devices. However, the intention is for the industry to self-regulate and there is no administrative requirements to seek permit approval from HSA. Any misinformation or misleading statements in the presentation of a medical device will be severely dealt with under the provisions of the Act and Regulation.
2. Advertisement information may not be appropriate to be furnished at the point of product registration.	The information furnished/required at the point of product registration refers to the objective evidence for the intended use and performance of the medical devices. It does not refer to the advertisement information.
Registration of Medical Devices	
1. What is the rationale for CMDR to close the Voluntary Product Registration Scheme (VPRS) ?	The Voluntary Product Registration Scheme (VPRS) was an interim measure introduced on 1 April 2002 as a phased approach to the implementation of the proposed Regulation. At the point of closure in March 2007, the VPRS had been in

	operation for five years. The VPRS was closed to allow HSA to concentrate its resources to prepare for the implementation of the Regulation.
2. What would be the status of medical devices registered under the VPRS?	All medical devices registered under the VPRS will be transferred over to the product register when the new Regulation is implemented. There is no need for re-registration of these products. However, HSA may request for additional information of the registered products, where necessary.
3. The implementation timeline for the Regulation would cause adverse disruption to the supply of medical supplies. 4. Companies will not be given sufficient time to register all the products once the Regulation is implemented.	A transition or grace period of up to two years will be introduced to allow all existing medical devices in the Singapore market to be registered prior to the enforcement of the Regulation. Thereafter, all legally available medical devices in Singapore must be registered. Supply of any unregistered medical devices will be prohibited unless authorised by HSA under specific provisions of the Act and Regulations.
5. Would the product registration requirements change with the implementation of the Regulation? How would this affect the products already registered?	The registration requirements will be the same as product registration under VPRS. Products that were registered under the current requirements will not be affected when the mandatory registration starts, but HSA may request for additional information of the registered products, where necessary.
Authorised Representatives for Medical Device Registration	
1. Local authorised representatives may start registering products under the overseas manufacturer's name without their knowledge, especially after cancellation of the authorised representatives by the manufacturer.	A registrant is able to register a particular medical device only when authorised by the product owner. For product registration, appropriate documentation must be submitted to HSA, including furnishing sufficient evidence that the registrant is an authorised representative of the product owner. The product owner may authorise the

	registrant to register all devices under the product owner's name or only a selected list of products. The authorisation may also be for products from selected manufacturing locations only, based on the decision of the product owner. If a product owner decides to change its authorised representative(s) in Singapore, he needs to inform HSA in writing and advise on the status of stocks and records that are held by the current representative(s).
2. Registration of the same product by multiple registrants should be allowed as it is a practice by some overseas manufacturers to appoint more than one distributor in Singapore.	More than one registrant may register the same product with HSA. Each individual registrant is required to provide evidence of authorisation by the product owner and submit the necessary technical documentation. Each application will be treated as a new application and no reference to any of the previous application or registered products is allowed. Each registrant is also required to perform all the prescribed duties and obligations under the regulation.
Registration of Low Risk Medical Devices	
1. Why did CMDR stop registering the low risk medical devices under VPRS?	The VPRS was meant for the registration of higher risk medical devices only. The registration of low risk medical devices under the VPRS was a pilot trial to test the MEDICS module. The pilot trial was closed after sufficient feedback was collated. Low risk devices submitted under the trial are accepted and processed for listing on the register.
2. Low risk medical devices should only be listed and there is no need for submission of documents or evaluation fees.	The submission of documents for low risk medical devices is necessary to allow HSA to verify that the product submitted is indeed a low risk medical device. For low risk medical devices that are sterile and/or with measuring function, HSA will review the application to determine if the

	manufacturer has performed his due diligence in ensuring that such critical product specifications are validated.
Cancellation of Medical Device Registration	
1. Is it necessary to cancel the product registration for products that are no longer supplied in Singapore? 2. What are the conditions for cancellation and can the products be sold at wholesale and/or retail level after the registrant cancels the registration?	For a product that is no longer being supplied to the Singapore market, the registrant may cancel its registration. Once the registration is cancelled, that product can no longer be imported for supply in the market, as it is an unregistered medical device. However, the obligations with regards to records, complaints, adverse events reporting, etc, will continue to be applicable for the product already supplied to the market, subject to the projected useful life of the device.
Certificates of Export	
1. What is the difference between a certificate of registration and a certificate of free sales or export certificate? 2. It will be very burdensome to obtain an export certificate before a medical device can be exported from Singapore.	Certificate of Free Sales and Export certificate are issued upon application by the registrant, if required by the importing country. These certificates are not required by HSA for exporting medical devices from Singapore. A certificate of registration contains details of the medical device that is registered with HSA, including all its conditions of registration, if any. It is available as an electronic certificate. A registrant who wishes to obtain a hard copy of the certificate of registration shall apply to HSA. The certificate will be issued upon payment of an application fee.
Keeping of Records	
1. What type of records should a wholesaler keep to demonstrate that they have sold or installed equipment only to licensed users of medical devices?	All licensees must ensure that proper records of supply are kept for the purpose of ensuring traceability of all medical devices that they deal with. This obligation to keep records is applicable to all medical devices,

	registered or otherwise.
Compliance with Essential Principles	
1. Not all essential principles are applicable to every device. For example, essential principles regarding electrical safety do not apply to non-active devices.	The essential requirements specified in the Third Schedule apply to all medical devices. Some of the design and manufacturing requirements for safety and performance are relevant to each medical device. The manufacturer selects which of the design and manufacturing requirements are relevant to a particular medical device and documents the reasons for excluding the others.
2. Importers may not be the manufacturer and most likely will not have the technical data to demonstrate compliance. It is burdensome for importers to keep copies of all documents to show compliance to the essential principles.	HSA has reviewed the requirements for demonstrating compliance with the essential principles by the importer. Only the manufacturer and registrant, not the importer, are obligated to ensure compliance of medical devices with relevant essential requirements, by keeping objective evidence and undertaking procedures to establish that the medical device conforms with those essential requirements.
Implant Records	
1. The scope of "orthopedic implant" as listed in the Third Schedule may include bone screws and plates. The obligation on practitioners to keep implant records will be unreasonably burdensome. 2. Other implantable medical devices such as biliary/peripheral stents should be included. A general inclusion statement should be used.	HSA will review this requirement in detail after consultation with the healthcare professionals and institutions.
Complaint Records	
1. The complaint handling procedure is being dictated. It should be left to the manufacturer to determine the procedure as part of their quality system.	The activities of receipt, review and evaluation of complaints are standard procedures in handling complaints. The company's procedures must specify how these activities are monitored by the different entities.

Adverse Event Reporting	
1. It is unclear which party has the ultimate responsibility and how "echo reporting" of the same event by different parties will be avoided.	HSA is aware of the possibility of multiple reporting of the same adverse event. However, all licensed manufacturers, wholesalers or distributors are still obligated to report adverse events of the affected medical devices.
2. Definition of adverse events should follow the EU Medical Device Directives or GHTF/SG2/N21R8. The definition from the Health Products Act has a much broader scope than that of GHTF or the EU as it does not only include death or serious injuries but any harmful event. The definition should be adjusted to the internationally accepted and enforced definition. 3. It is not necessary to report defects if there was no serious injury or death related with the defect in the device.	The following types of events which are aligned to GHTF recommendation are required to be reported: (a) Adverse events that result in unanticipated death or unanticipated serious injury or represent a serious public health threat must be reported by the manufacturer as soon as possible, but not later than 10 days; (b) All other reportable events, where no death or serious injury has occurred, but might lead to death or serious injury in event of occurrence, must be reported as soon as possible but not later than 30 days.
4. "To report within 48 hours" in Rule 26(1)(a) of the Regulation is unique and it is extremely difficult to fulfil.	The 48 hours' timeframe is not unique to Singapore. This is practised in Australia and EU for reporting adverse incidents involving a serious public health threat.
5. Reports should be confined to only serious threats for products that are sold in Singapore or events occurring in Singapore. Overseas' reports can be supplied upon request.	All adverse events related to a medical device that is registered with HSA must be reported to HSA regardless of where the event had occurred.
Notification of Changes Concerning Licences	
1. The requirement is quite broad in that it encompasses "any change" to particulars that have not been described. It is suggested that the specific changes, which require notification, should be described	HSA will take the feedback into consideration when finalising the Regulation. Guidelines for the industry will be published.

and approval should be limited to "significant" changes.	
Notification of Changes Concerning Registered Medical Devices	
1. Change notification process takes place in every manufacturing site daily, as this process maintains and ensures compliance to the manufacturer's quality system. Therefore, reporting these changes will be burdensome. 2. Manufacturers should only be required to notify HSA of significant changes, and not seek approval. 3. Changes that significantly affect the safety or efficacy of the product or conformity with the essential principles should be subjected to prior approval. However, certain changes may be implemented without notice or reported periodically (eg annually). 4. Review by the authority of change notifications should be timely. Foreign manufacturers have very tight manufacturing deadlines to meet and cannot wait for one small market to respond before proceeding.	HSA will publish guidelines to clarify the change reporting for registered medical devices. As stated in Rule 28(3) in the Regulation, changes affecting safety, quality or efficacy of the device needs approval prior to supply of the product.
Reporting of Product Recalls by Registrant and Licensee	
1. What is the "prescribed time" that the registrant and licensee have to notify the authority of product recalls?	Registrant and licensee of a medical device must notify HSA <u>at least 2 days before</u> undertaking a recall or intends to recall the device and the reasons for the recall.
Medical Device Classification Rules	
1. Risk classification nomenclature has changed from the European Medical Device Directive nomenclature of Class I, IIa, IIb and III to the GHTF nomenclature of	As expressed in the consultation paper, the regulatory framework will be harmonised with GHTF concepts and principles. HSA will adopt the device class nomenclature of GHTF (Class A,

Class A, B, C, and D. Some of the risk classification of medical devices may be changed.	Class B, Class C or Class D). Although the device class nomenclature of EU and GHTF may differ, the rules for the classification of medical devices into four broad classes are essentially the same. Hence, a Class D medical device is a Class III medical device according to EU nomenclature.
Medical Devices Registered Under Other Regulations / By Other Agencies	
1. Some medical devices are currently registered or require consultation/ registration under additional regulations. Should the Centre for Medical Devices (CMDR) provide one-stop service for registration, so as to reduce confusion for the industry? a) Medical devices that require other agencies such as radiation devices or telemetry (IDA) b) Medical devices that are registered under Centre for Radiation Protection (CRP)	All medical devices need to be registered with HSA under the Medical Devices Regulation before being sold in Singapore. The manufacturer, importer and wholesaler need to ensure that the products meet all applicable legislative requirements before supplying the products. Registration of a product under the Medical Devices Regulation does not exempt it from the other requirements of applicable regulations that are in force in Singapore. It must be recognised that other regulatory instruments address requirements not within the scope of Medical Devices Regulation. Hence, the same product may require registration with different agencies.
2. Medical devices currently subjected to drug registration by Centre for Drug Administration (CDA) should be regulated as medical devices and be transferred to CMDR.	HSA will review any health products that are medical devices by their principal mode of action but are currently registered by CDA. We will inform the licence holder with regards to any change in the product reclassification.
3. Current control of test kits for drug of abuse in Singapore is burdensome compared to other countries, as the contents of abused drugs are in minute quantities. These products should	In accordance with the definition of *In Vitro* Diagnostic Devices (IVD) in the Regulation, IVDs such as those used for parentage and kinship testing, drug tests used in sports and tests for alcohol and illicit drugs for forensic

not require a pharmacist to provide the information or be required to have a Poisons licence. 4. Drug of abuse test kits for forensic purpose should not be regulated as a medical device as it is not within the definition of *in vitro* diagnostic kit as defined in the Regulation.	purposes are not within the scope of the Medical Devices Regulation.
Fees	
1. Fees should not be charged during the transition period in the company's current financial year, as it would not have been budgeted for. 2. High fees would increase the operating costs of companies. 3. No fees should be charged until the transition period has ended.	HSA recognises the cost concerns by the industry and is mindful about adding any unnecessary or inappropriate regulatory costs. HSA will take this feedback into consideration.
Duties of End-Users	
1. The Regulation should prescribe the duties of end-users, especially those related to the re-use of medical devices labelled as "single-use" and intended to be used only once.	The scope of the subsidiary legislation for medical devices is not intended to regulate the end-users of medical devices. With regards to "single-use" medical devices, manufacturers and suppliers of medical devices should put in more effort to educate the end-users on the proper use of medical devices as instructed in the labelling.

Conclusion

HSA would like to thank all respondents for their valuable feedback in this public consultation.