Medical Device Industry Briefing

Overview of Regulatory Updates

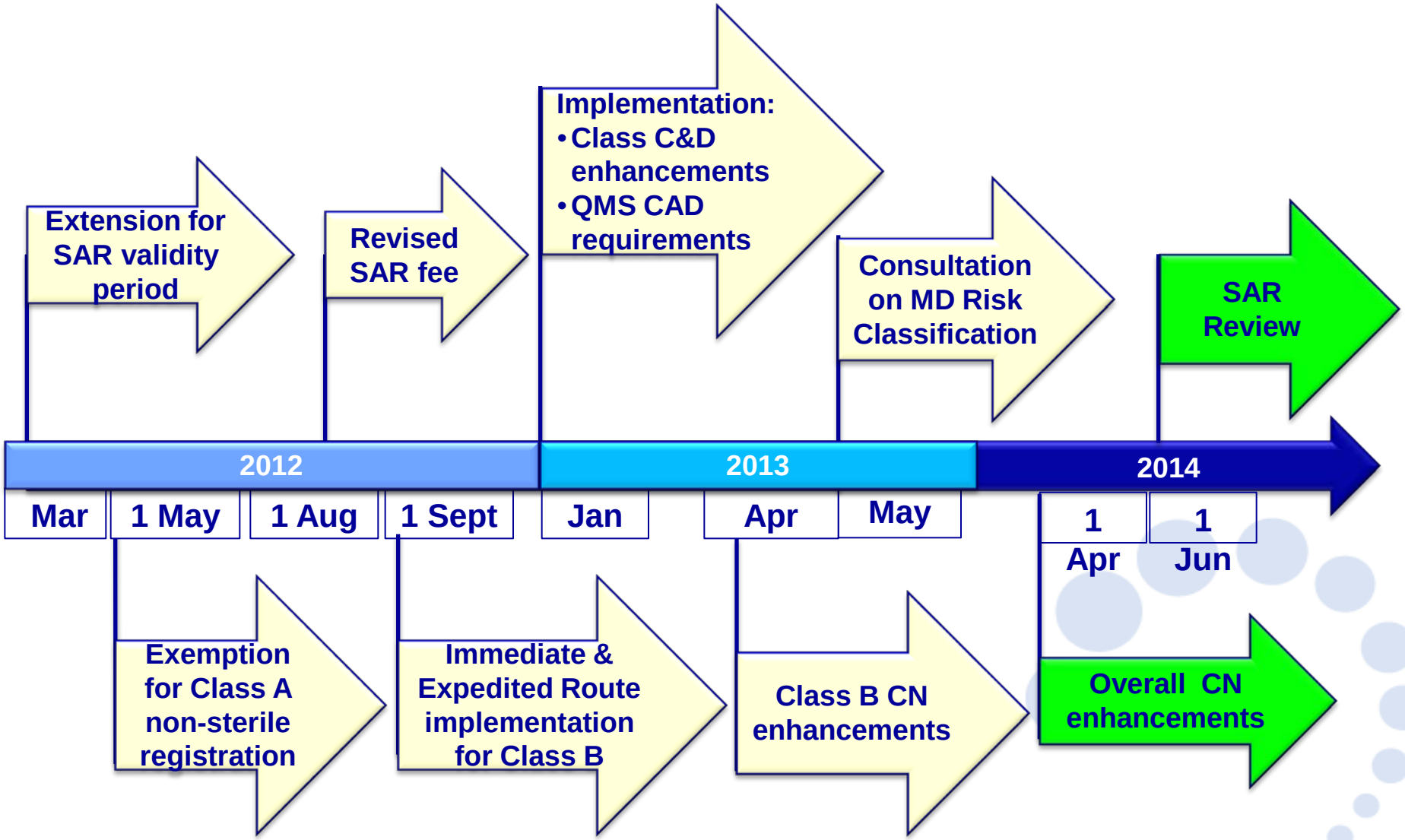
February 2014

Medical Device Branch
Health Products Regulation Group
Health Sciences Authority

Scope

- Special Authorisation Routes (SAR)
- Change of Registrant (CoR)
- Free Sale Certificate (FSC)

Enhancement to MD framework



Special Authorisation Routes (SAR)

Special Authorisation Routes (SAR)

GN-26

Import and Supply of Unregistered Medical Devices for Supply on Named-Patient Use

GN-27

Import and Supply of Unregistered Medical Devices for Supply to a Clinical Laboratory, Medical Clinic or Private Hospital licensed under the PHMC Act

GN-28

Import of Medical Devices solely for Export

GN-29

Import of Unregistered Medical Devices for Non-Clinical Purpose

GN-30

Import of Medical Devices on Consignment Basis

Registered/ Unregistered Devices

Criteria for SAR Approval

1. Device type
   - Single use, multiple use, capital equipment/fixed infrastructure
2. Clinical justification for request of unregistered medical device
   - Must reflect “Special Clinical Need”

Criteria for SAR Approval

1. Device type

- Single use:
  - *Eg. Suction cannula, Biliary stents…*
- Multiple use:
  - *Eg. Mobile ultrasound devices…*
- Capital equipment/ Fixed infrastructure:
  - Medical devices installed as part of the hospital's fixed infrastructure
  - *Eg. X-ray machines, CT scanners, MRI machines ...*

Criteria for SAR Approval

- ✓ Unregistered Single Use/ Multiple use
  - May be authorised via SAR (subject to approval)
- ✘ Unregistered capital equipment/fixed infrastructure
  - Shall not be authorised via SAR
  - Product registration will be required.

Reminder…

- *NOTE in section 2.2 Grouping of devices of GN-26 and GN-27*

Criteria for SAR Approval

2. **Clinical justification** for request of unregistered MD **MUST** reflect "*special clinical need*".
   - Regulation 8 (a) and (b) of Health Products (Medical Device) Regulation:
     - permit the import of an unregistered medical device by a qualified practitioner (doctor or dentist) or a PHMC licenced healthcare facility for the use of a patient under his/ their care.
     - serves to facilitate access to treatment where there is a "special clinical need ".

Regulation 8(a) & (b)

Exception for medical devices for patients' use

8. Without prejudice to any other provision in this Division, the prohibition in section 15(1) of the Act against the supply of an unregistered health product shall not apply to the supply of an unregistered medical device by or on behalf of, or procured by or on behalf of —

(*a*) a qualified practitioner for the use of a patient of that qualified practitioner; or

(*b*) a private hospital, medical clinic or clinical laboratory licensed under the Private Hospitals and Medical Clinics Act (Cap. 248) for the use of a patient of that private hospital, medical clinic or clinical laboratory,

if the Authority has granted an importer's licence or a wholesaler's licence in respect of the medical device for such use.

Defining “Special Clinical Need”

- **Special Clinical Need**

  i. Medical devices on compassionate use basis

  ii. Alleviation of stock-out situation

  iii. Novel or established medical device or upgraded version of established medical devices (new models/ new features)

  iv. Established medical devices with history of use

Defining “Special Clinical Need”

i. Medical devices on compassionate use basis

- Absence of treatment option; *or*
- Available alternative treatments failed or deemed ineffective or unsuitable for the patient according to the doctor’s or the dentist’s clinical judgement; ***and***
- Patient’s health will be clinically compromised without the requested treatment

ii. Alleviation of stock-out situation

- The unregistered medical device is needed to minimise disruption to the continued supply of a similar registered medical device

Defining “Special Clinical Need”

iii. Novel or established medical device or upgraded version of established medical devices (new models/ new features)

- Absence of registered alternatives or lack of a specific feature in registered medical device; *or*
- Available registered medical devices or models are deemed ineffective or unsuitable for the patient according to the doctor’s or the dentist’s clinical judgement; *or*
- User’s (doctor or dentist) familiarity or expertise in terms of device technology, design and/or operation that is likely to support or enhance the safety outcomes of the procedure or treatment for the patient; *and*
- Patient’s health will be clinically compromised without the requested medical device

Defining “Special Clinical Need”

iv. Established medical devices with history of use

- The unregistered medical device has been used
  - before 1 January 2012
  - in a licensed private hospital as approved by the relevant authority of that healthcare institution; or
  - in a licensed medical clinic as required by the doctor or dentist, ***and***
- There are no known safety issues related to the use of the device

SAR Updates

For

Companies

dealing in

- **GN28** – Import For Re-export

Or/and

- **GN29** – Import for Non-clinical purpose

ONLY

Dealers holding valid Importer's/ Wholesaler's licence

Import MDs solely for Re-export and/or Supply for Non-clinical Purpose only

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Apply for SAR i.e. GN-28/GN-29 to allow for import and/or supply of unregistered MD

Current:
New SAR License Issued upon approval of SAR

SAR Updates

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Apply for SAR i.e. GN-28/GN-29 to allow for import and/or supply of unregistered MD

Moving Forward: New SAR Licence Issued

SAR Updates

For Companies dealing in

- GN26 – Import For Named Patient
- GN27 – Import for PHMC facilities
- GN28 – Import For Re-export
- GN29 – Import for Non-clinical purpose
- GN30 – Import on Consignment Basis

Dealers holding valid Importer's/ Wholesaler's licence

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Dealers holding valid Importer's/ Wholesaler's licence

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Apply for SAR to allow for import and/or supply of unregistered MD

Moving Forward: SAR Approval to be an addendum to existing Dealer's Licence

SAR Updates

- For companies holding valid dealer's licences
  - SAR Approval to be an addendum to existing Dealer's Licence
  - Approval will still be via email as current
  - No significant impact on the stakeholders

SAR Updates

- Email hsa_md_info@hsa.gov.sg for any queries/ feedback
  - Subject of email: SAR Updates
  - Closing Date: 1 Apr 2014

- Proposed Implementation: **1 June 2014**

- Email Communication to stakeholders to be sent prior to implementation

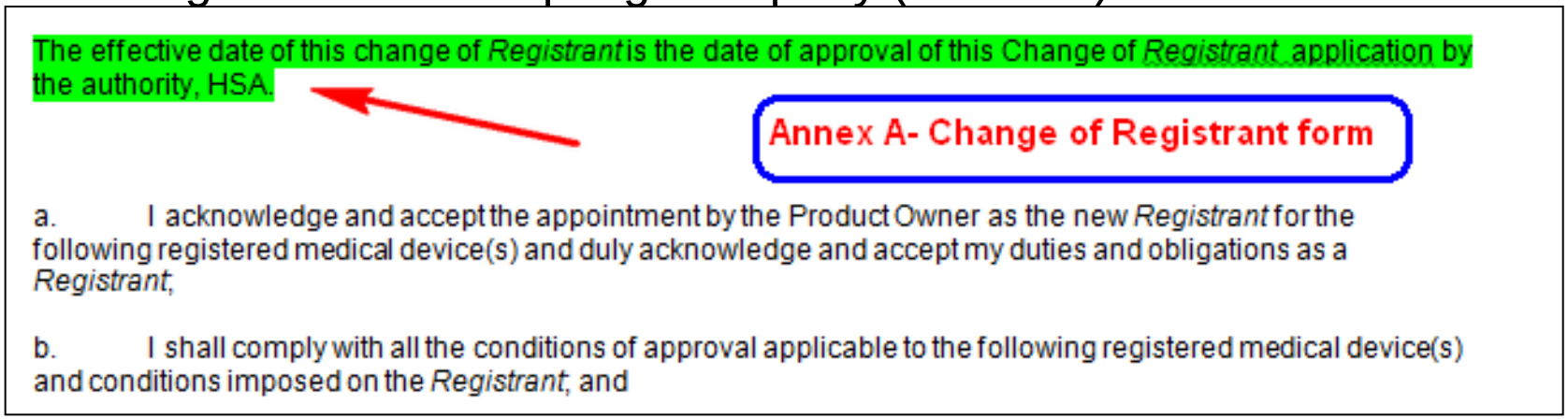
Change of Registrant (CoR)

Change of Registrant (CoR)

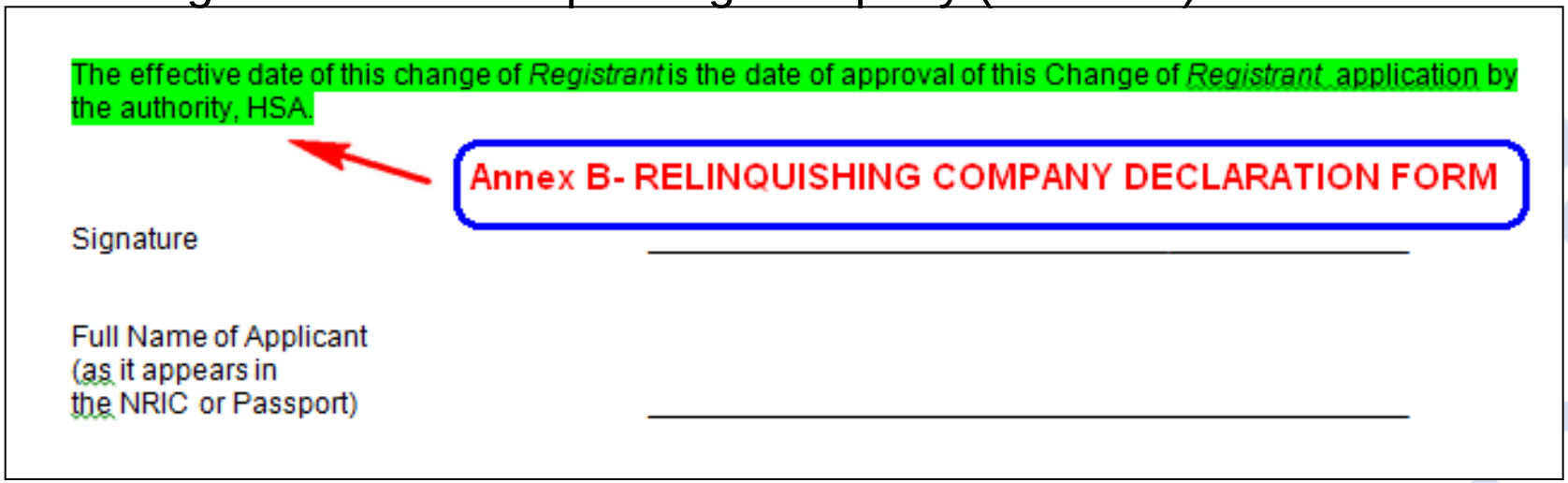
S/N	Updates	Current version: (Aug 2009)	Moving Forward: Updated version (Jan 2014)
1.	**Effective date of the change of registrant**	• Effective date is stated under various sections: 1. Product owner's letter of request for CoR 2. Relinquishing company's declaration 3. Accepting Company's declaration	• ***Legally***, the effective date of the change of registrant is the **date of approval** of the Change of Registrant application by the authority, HSA • Relinquishing company's declaration • Accepting Company's declaration

Change of Registrant (CoR)

- Page 2 of 3 – Accepting Company (Annex A)



- Page 2 of 2 – Relinquishing Company (Annex B)

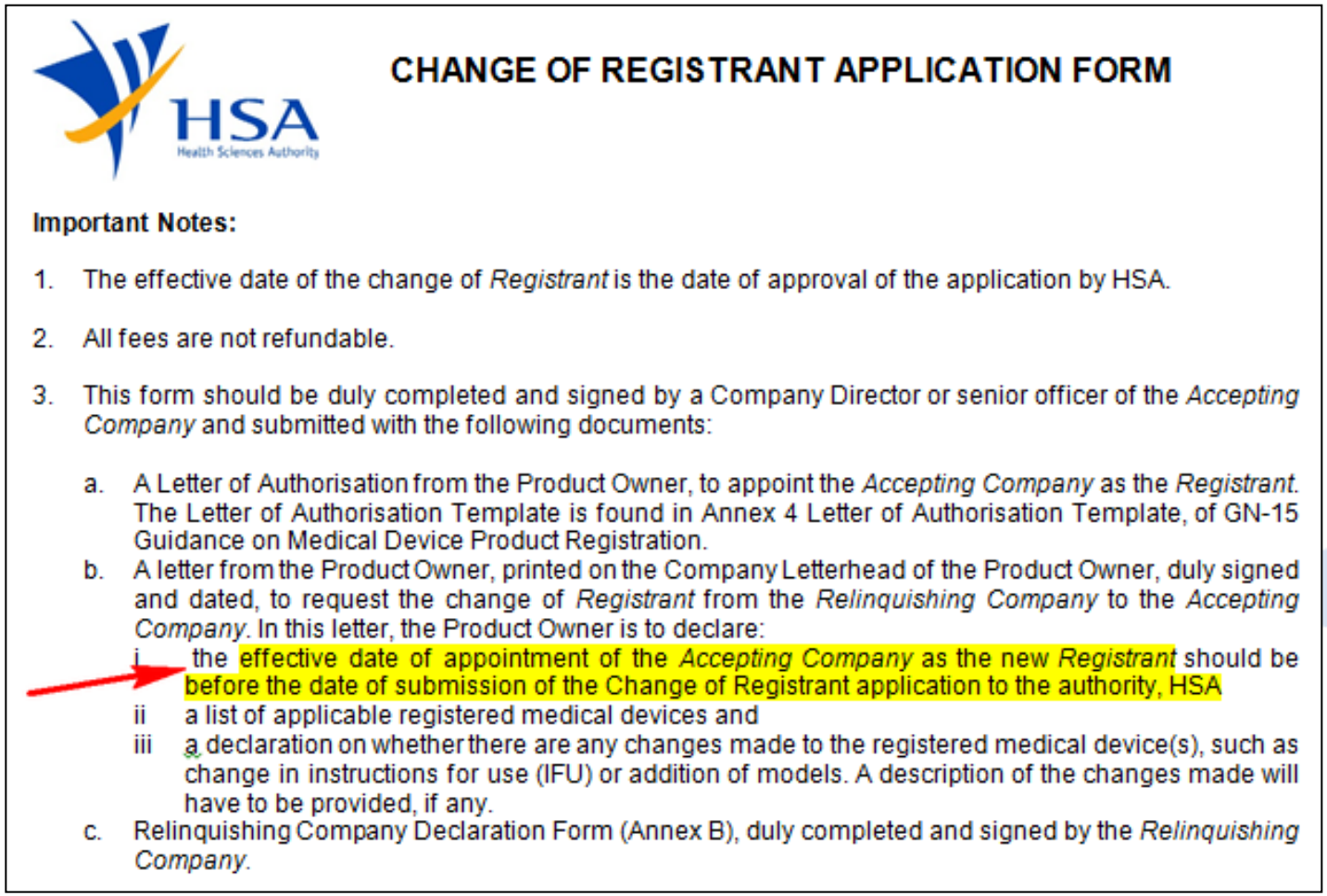


Change of Registrant (CoR)

S/N	Updates	Moving Forward: Updated version (Jan 2014)
2.	Effective date of appointment of new registrant by Product Owner	The effective date of appointment of the *Accepting Company* as the new *Registrant* should be before the date of submission of the Change of Registrant application to the authority, HSA

Change of Registrant (CoR)

- Page 1 of 3



CHANGE OF REGISTRANT APPLICATION FORM

Important Notes:

1. The effective date of the change of *Registrant* is the date of approval of the application by HSA.
2. All fees are not refundable.
3. This form should be duly completed and signed by a Company Director or senior officer of the *Accepting Company* and submitted with the following documents:
   a. A Letter of Authorisation from the Product Owner, to appoint the *Accepting Company* as the *Registrant*. The Letter of Authorisation Template is found in Annex 4 Letter of Authorisation Template, of GN-15 Guidance on Medical Device Product Registration.
   b. A letter from the Product Owner, printed on the Company Letterhead of the Product Owner, duly signed and dated, to request the change of *Registrant* from the *Relinquishing Company* to the *Accepting Company*. In this letter, the Product Owner is to declare:
      i the effective date of appointment of the *Accepting Company* as the new *Registrant* should be before the date of submission of the Change of Registrant application to the authority, HSA
      ii a list of applicable registered medical devices and
      iii a declaration on whether there are any changes made to the registered medical device(s), such as change in instructions for use (IFU) or addition of models. A description of the changes made will have to be provided, if any.
   c. Relinquishing Company Declaration Form (Annex B), duly completed and signed by the *Relinquishing Company*.

Change of Registrant (CoR)

- Implementation: **1 April 2014**
- Website updates:
  - GN-24: Guidance on Change of Registrant
  - Revised Annex A and B

Free Sale Certificate Updates

Free Sale Certificate updates

- Free Sale Certificate (FSC)
  - Validity of the FSC to be extended to 2 Years
  - Implementation date: **1 April 2014**

Thank You

Email: hsa_md_info@hsa.gov.sg.