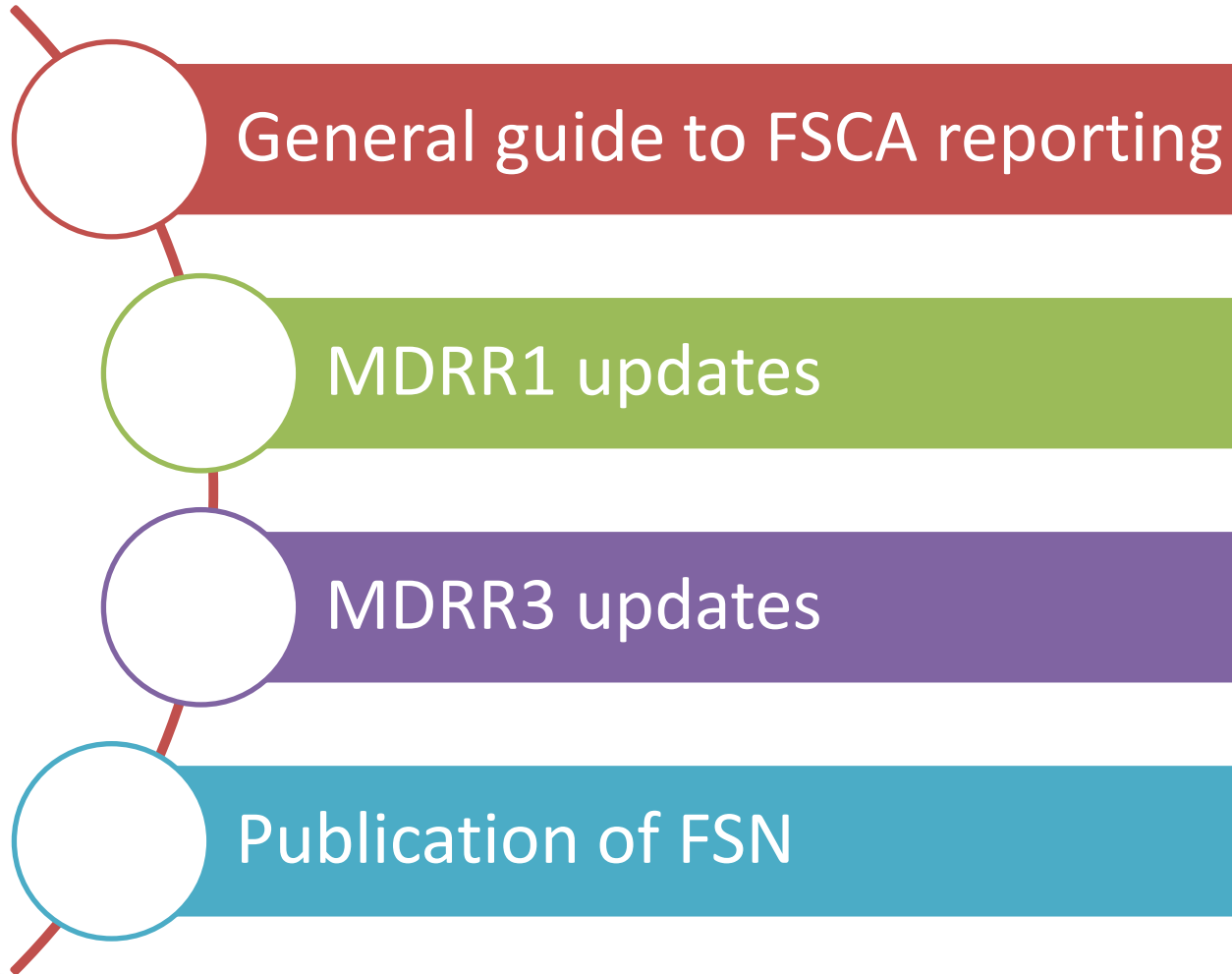


Refinements to Field Safety Corrective Actions (FSCA) Process

28th & 29th March 2016

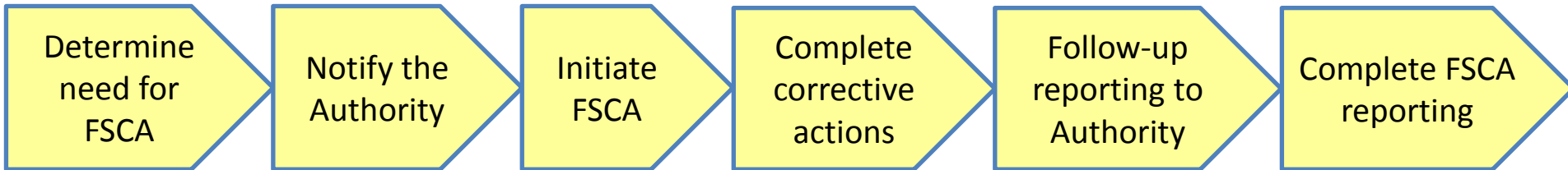
Medical Device Branch
Health Products Regulation Group
Health Sciences Authority

Content



OUTLINE OF STEPS REQUIRED TO CONDUCT FSCA

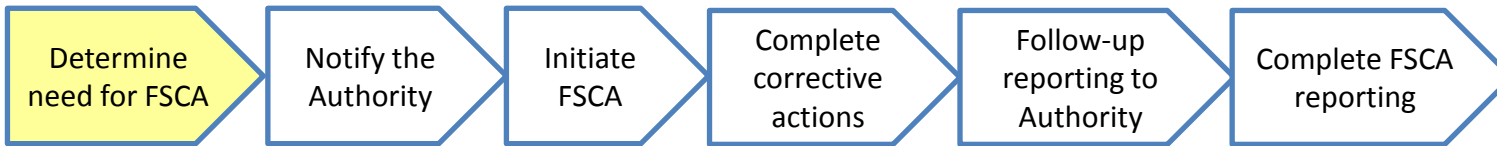
Steps required to conduct FSCA *(simplified concept)*



Who conducts these steps in FSCA?

- Dealers that manufactured, imported or supplied or obtained marketing authorization (Registrant) for the affected device in Singapore

How to determine if it is FSCA?

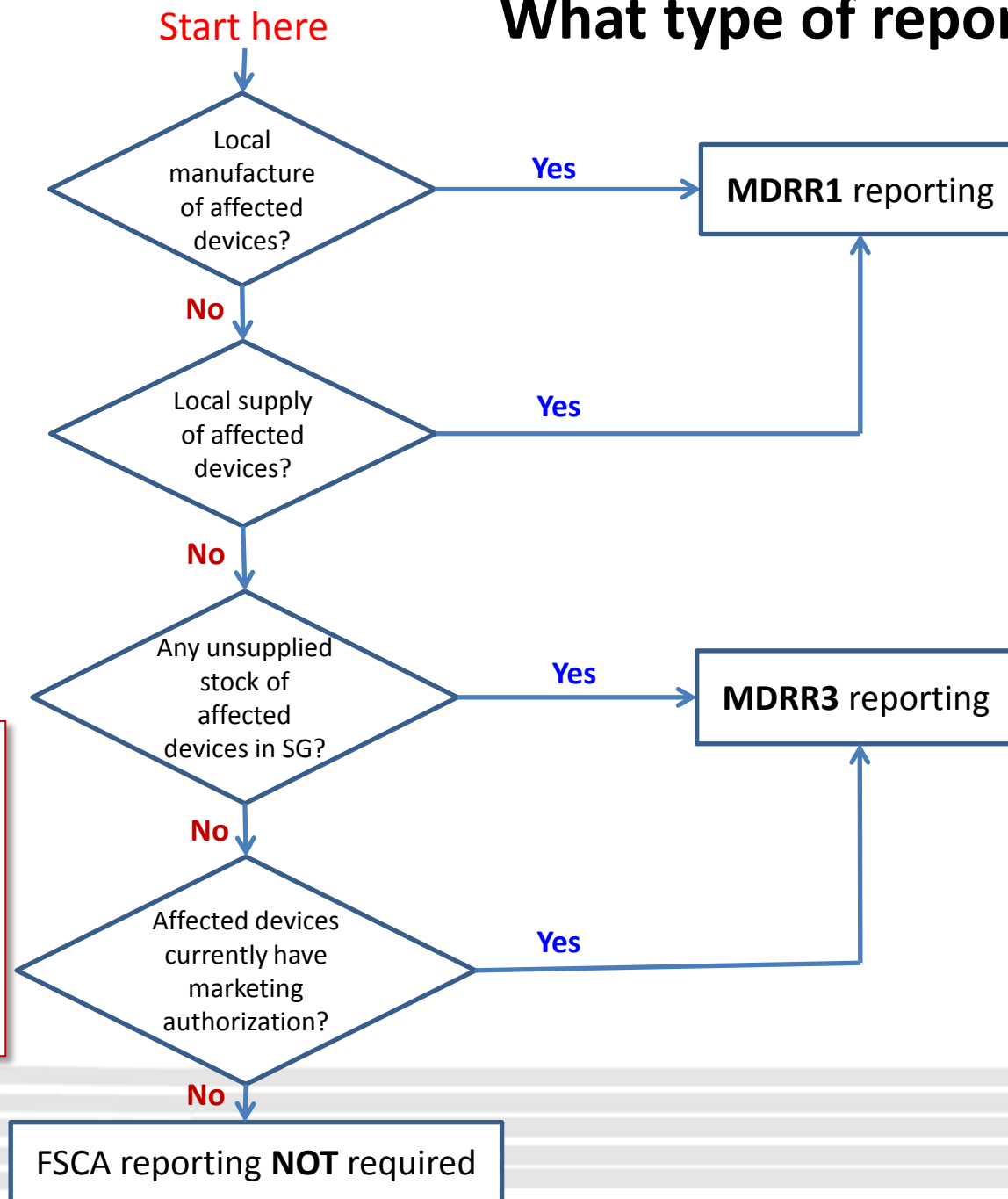


Does it meets the following criteria?

- Any action taken to reduce the risk of death or serious deterioration in the state of health of a person associated with the use of a medical device, including:
 - Return to product owner
 - Replacement or destruction
 - Advice regarding use of device
 - Clinical management of any patient who has used the device
 - Modification
 - Retrofitting
 - Labelling change
 - Software upgrade, including remote upgrade

New

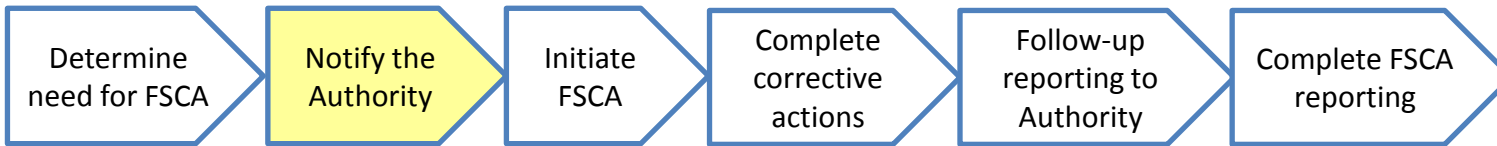
What type of reporting?



Note: Marketing authorization would refer to either

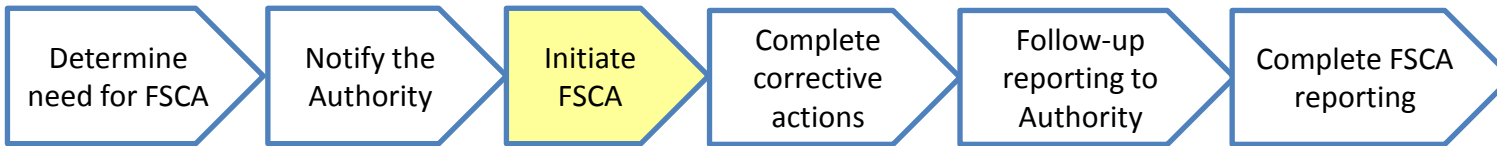
- (i) registration on SMDR, or
- (ii) Special Authorization Route for local supply.

When should FSCA be notified?



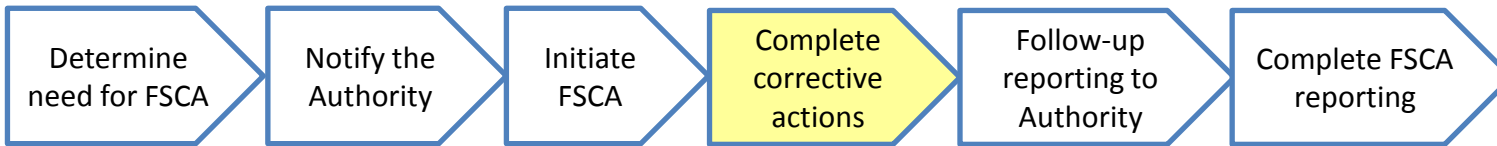
- Once a decision to initiate a FSCA in Singapore has been made, notify HSA **before** initiation of FSCA.

When should FSCA be initiated?



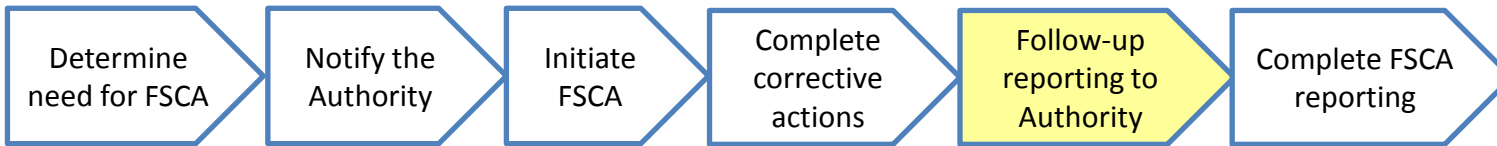
- Prior **approval** to proceed with FSCA initiation is not required
- Some measures could include (*non-exhaustive list*):
 - Dissemination of Field Safety Notice (FSN)
 - Stock recovery
 - Implementation of corrective action
- Dealer should inform all affected consignees of the FSCA (through the initial FSN), as soon as FSCA is notified to HSA.
- FSCA risk communication or FSCA strategy may require amendment if deemed necessary by HSA. Where amendments are required, dealer may be required to issue a subsequent risk communication.

FSCA Strategy



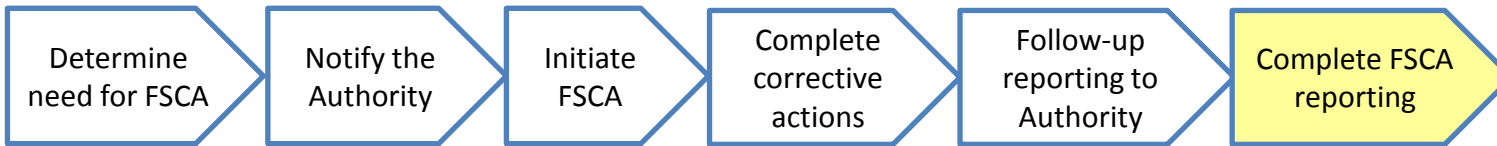
- *FSCA Strategy*: A planned course of actions to be taken in conducting the FSCA
- Effective strategy could include measures:
 - Identify **affected device identifiers** and **lots/batch** in Singapore
 - Identify **quantity of affected devices** in Singapore
 - Identify **list of consignees** supplied with affected devices and **quantity supplied to each consignee**
 - Communicate information (e.g. through FSN/DHCPL) to the consignees
 - Help consignees identify the affected devices and immediately carry out **product owner's instructions** in the risk communication
 - Implement necessary actions: **on-site correction or removal**
 - Identify need to cease distribution of affected devices (based on HSA's notice), and switch to alternatives if applicable

Dealer's follow-up responsibility



- Dealers are responsible in following up with the FSCA reporting requirements under *Reg 47*
 - A Final report shall be submitted within 21 days of initiating the FSCA. If the FSCA has not been completed within 21 days, a Follow-up report shall be submitted to the Authority within 21 days.
- Follow-up to provide status update on the correction of devices affected by the FSCA, and progress report on product owner's **CAPA investigation**.

Complete FSCA Reporting



FSCA reporting obligation will be deemed completed if

- all appropriate corrective actions have been implemented; and
- all information related to the FSCA that are requested by the Authority have been submitted.

FSCA DOCUMENTARY REQUIREMENTS (UPDATES) – MDRR1

1. Affected Identifiers in FSN

- FSN should either:
 - Include the complete **global list of affected identifiers** identified by product owner; *OR*
 - List **only local affected identifiers in Singapore**, and incorporate additional statement to inform the recipient of FSN that there may be other affected identifiers that are affected globally.

2. Acknowledgement receipts/ service reports

- Written acknowledgement receipt/service report shall be obtained from local consignees supplied with affected medical device
 - Acknowledgement receipt required to **confirm the receipt of the FSN/DHCPL**
 - For FSCA that require a software upgrade or device modification, **service report for the completion of the corrective action** specified in the FSN/DHCPL
- Records of completed actions should be fully reconciled against distribution records. To monitor the effective completion and operational conduct of FSCA.
- Written records shall be provided to HSA when requested

NEW!

- Where on-site device modification of affected medical devices is required, the **final outcome of reconciliation shall be provided in a declaration** to HSA

Declaration Template

[To be printed on dealer Letterhead of dealer]

Medical Device Branch
Health Products Regulation Group
Health Sciences Authority

[Date]

Dear Sir/Madam,

Subject: Declaration on completion of correction for Field Safety Corrective Action
Ref No. <Ref No. HSA 600:41:01-xxx/yy/xx>

1. We, *[name of dealer]*, hereby declare that the list of consignees in Singapore supplied with medical device affected by FSCA, *<HSA FSCA Ref No.>*, are limited to:

Consignee Name	Quantity	Status of correction of affected device
<i><Consignee 1, provide full name of clinic or hospital></i>		<i><completed></i>
<i><Consignee 2, provide full name of clinic or hospital></i>		

2. We confirm that we have provided to all affected consignees in Singapore, listed in paragraph 1, a copy of the Field Safety Notice (FSN), and have completed all corrections required to complete the aforementioned FSCA.

3. Written acknowledgements confirming effective completion of the field corrections required as per product owner's FSN have been collected from consignees listed in paragraph 1. Records of acknowledgement receipts will be provided to HSA when requested.

4. We attest the information submitted as part of this declaration has been verified to be true and accurate, and are aware of the penalties that apply under the Health Products Act and its subsidiary legislation for false or misleading submissions.

Yours Sincerely,

[Signature]

[Full Name and Title]

[Dealer stamp]

3. FSCA review documents

The following documents would have to be provided together with the Follow-up/Final Report (MDRR2 report form):

- Root Cause Analysis
- Corrective and Preventive Action (CAPA)
- Summary of CAPA Effectiveness

What you need to know?

What is required to complete FSCA reporting obligation?

CAPA

Requirements of the Standards

ISO 9000: 2005

- **Correction:** action to eliminate a detected non-conformity
- **Corrective action:** action to eliminate the cause of a detected non-conformity or other undesirable situation
- **Preventive action:** action to eliminate the cause of a potential non-conformity or other undesirable potential situation

ISO 13485: 2003

- **Corrective action:** action to eliminate the cause of nonconformities in order to prevent recurrence
- **Preventive action:** action to eliminate the causes of potential nonconformities in order to prevent their occurrence

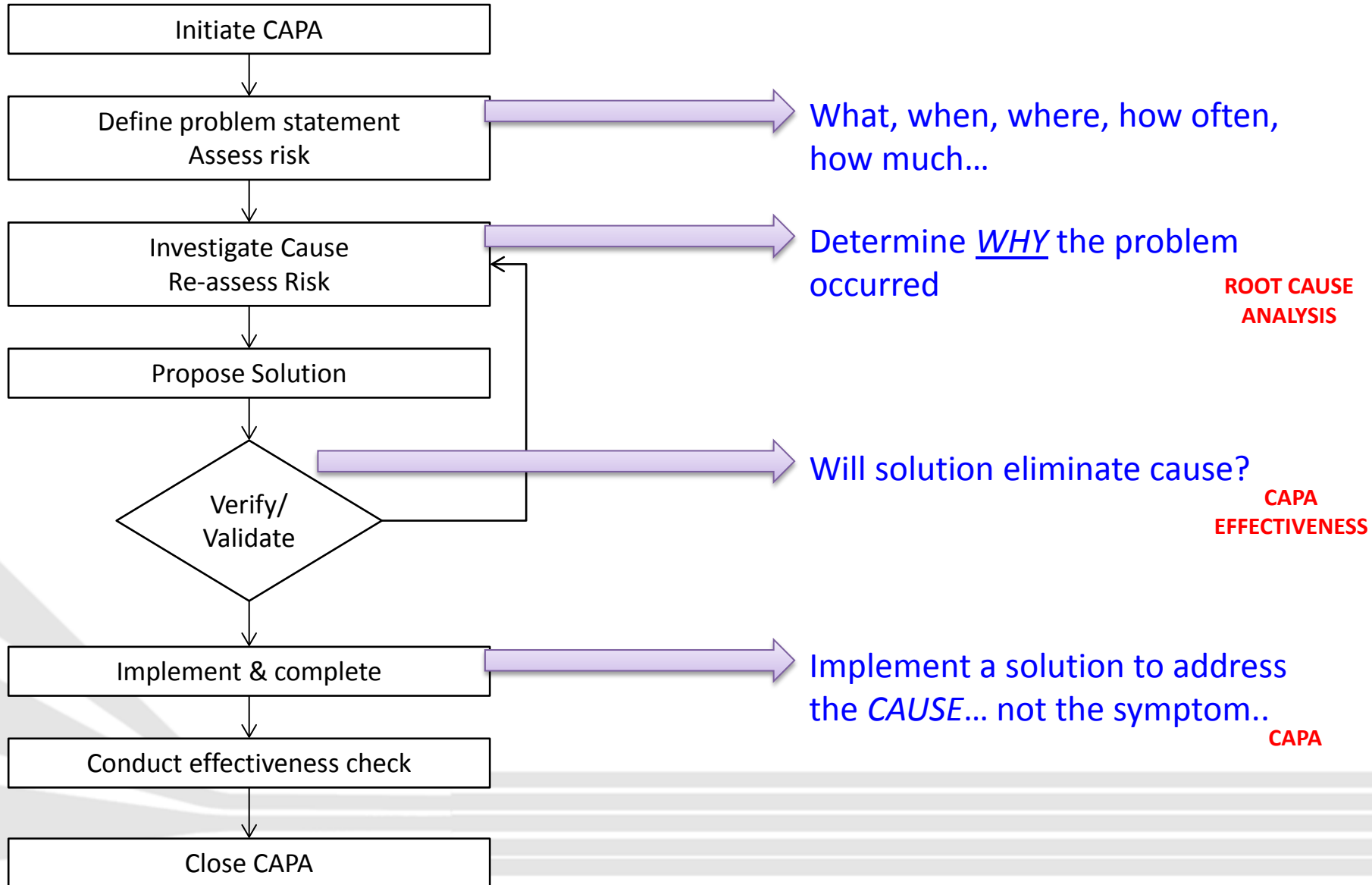
Under ISO 13485:2016, definitions remains similar as above .

CAPA definition

GN-10 Guidance on Medical Device Field Safety Corrective Action

Corrective And Preventive Action (CAPA): *actions taken to address the identified root cause for the device problem or issue for which the FSCA was initiated. This can include amongst others, post-market surveillance, recalls, or corrective or preventive actions related to the design and manufacture of the device.*

CAPA Process Flow (simplified)



CAPA Effectiveness

- Based on the magnitude of the problem, there are different methods of verifying the effectiveness of CAPA where the extent and timeframe required vary.
- Evidence of CAPA effectiveness can include:
 - CAPA is adequate to address the identified root cause for the FSCA and prevent recurrence
 - CAPA were verified or validated before implementation and does not adversely affect the device
 - Established CAPA verification and validation protocol with planned timeline
- Examples: software validation, review of batch release records, review of training records of employees, monitoring of complaints

Illustrative Case Study

– CAPA Process

FSCA involving an intraocular lens (IOL):

Increase in occurrence rate of inflammation seen in IOL manufactured after a certain date. Product owner voluntarily recalled all stocks manufactured (within a specific period) and ceased manufacture of the affected devices pending completion of CAPA process.

CORRECTION



Product owner's CAPA investigation:

So why did the problem occur?

The surface of affected IOLs were confirmed to have X particles. The X particles were from the washing jig used during washing process. The X coated washing jigs were easily abraded which resulted in lens with trace amount of X.

ROOT CAUSE
ANALYSIS

What did product owner do to address the cause?

CAPA focus on the elimination of X source by replacing the X coated washing jig with a new jig coated with another material.

CAPA

Any verification & validation done on CAPA effectiveness?

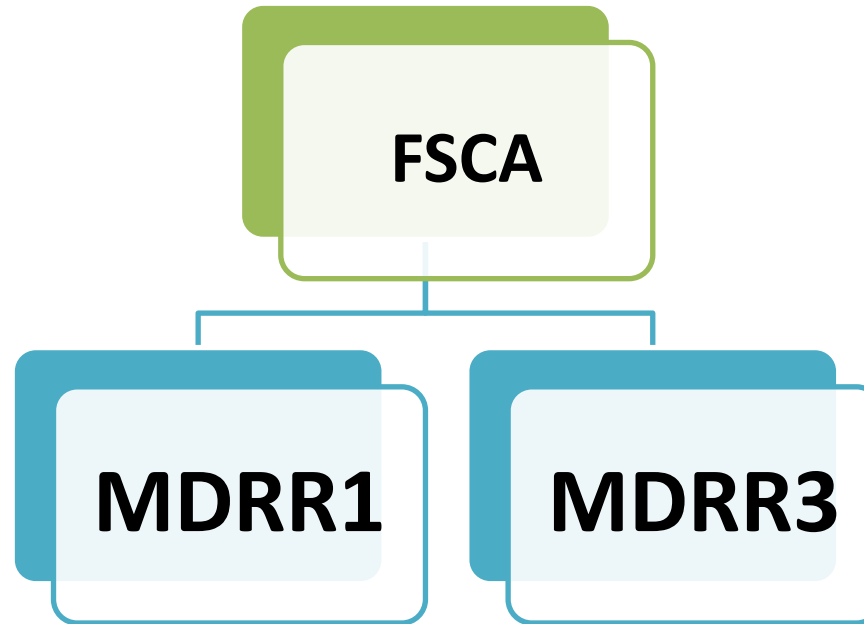
The new washing jig were qualified and determined to meet the corrective action criteria. Qualification checks were performed and effectiveness testing was audited. # amount of lenses had been tested and confirmed no trace amount of X particles were found.

CAPA
EFFECTIVENESS

Long term effectiveness check: Inflammation complaints were monitored on a monthly basis for a period of 2 years.

REFINEMENTS TO MDRR1 – NEW SUPPLY

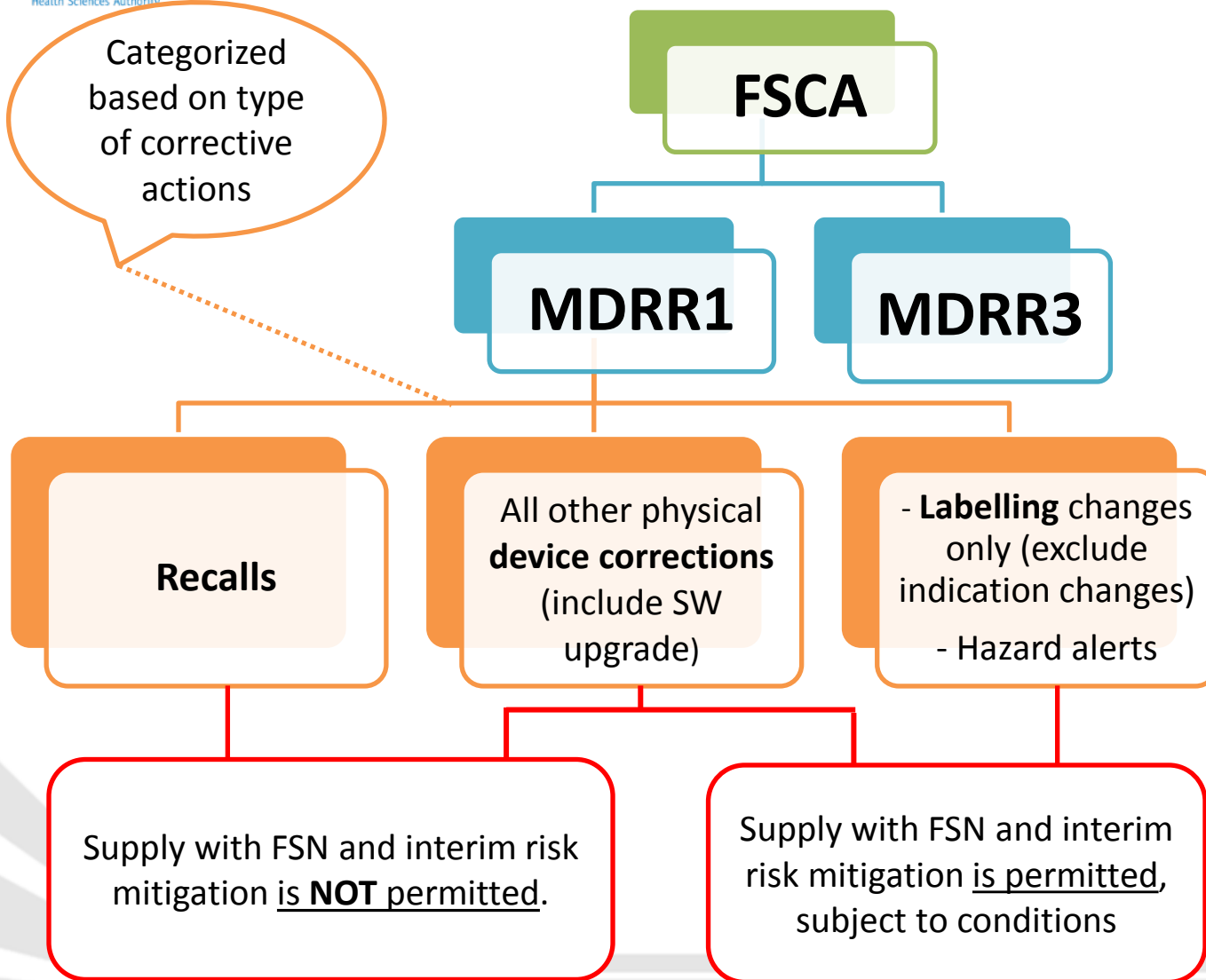
Current approach – New supply



- Stop supply of affected devices during the first notice of acknowledgement except for issues to be addressed by labelling changes only.
- Interim supply approved on a case by case basis by HSA when FSCA is still open
- Closure of FSCA subject to completion of root cause and CAPA review and effectiveness

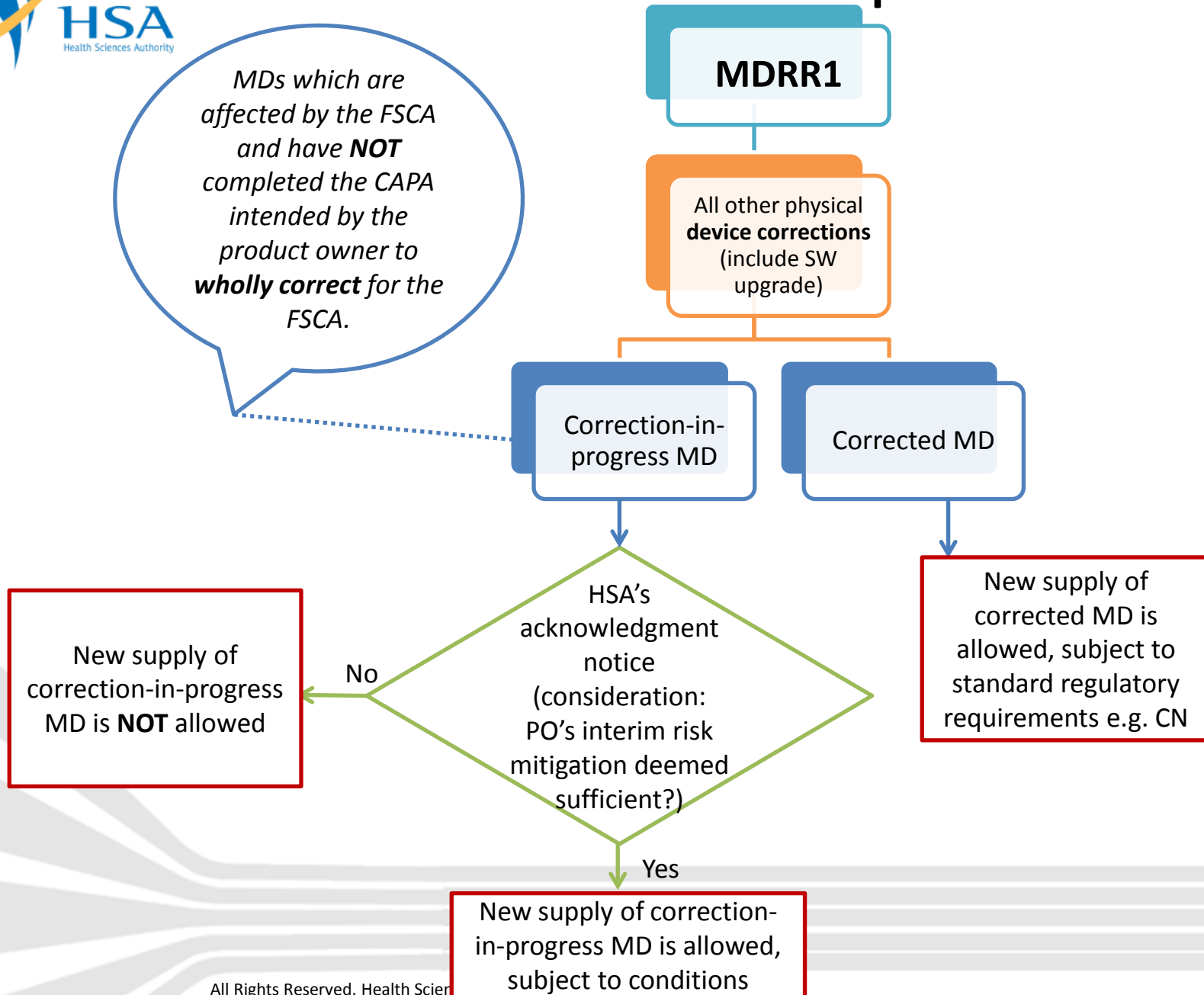
MDRR1 – from 18 April 2016

Categorized based on type of corrective actions



MDRR1 – from 18 April 2016

*MDs which are affected by the FSCA and have **NOT** completed the CAPA intended by the product owner to **wholly correct** for the FSCA.*



MDRR1 – supply of correction-in-progress devices

Examples of supply conditions

- A copy of the **FSN to be provided** to each local consignee, prior to supply
- Once PO's CAPA is available, to **submit CAPA** to HSA for review immediately.
- Upon CAPA availability, all correction-in-progress devices shall undergo **full correction** without further delay;
- Prior to closure of the FSCA, Reporting Person to submit a **declaration** on letterhead to confirm that **full correction for all correction-in-progress** devices supplied in Singapore has been completed;

Can new supply proceed after FSCA is notified?

- Once FSCA is notified, dealer should proceed to disseminate FSN
- Key documents required to be submitted with the FSCA notification include: Root cause analysis, health hazards analysis, CAPA and validation reports where applicable.
- New supply decision will be assessed based on the **completeness** of the information provided in the above documents .
- Upon review, HSA will issue a notice with instructions whether new supply can proceed, and/or subject to conditions within 10 working days .
- If decision on whether new supply is to be allowed cannot be determined due to missing information, a stop supply notice will be issued.

Illustrative Case Study 1



MD type	Disposable biopsy instrument
FSCA type	Recall (limited to specific model and lots)
Issue (based on FSN)	Device unintentionally fires while fully or partially energized. This may lead to tissue injury, delay in procedure if need to replace

Root cause: Manufacturing issue. The instrument is locked into firing position using a locking feature. The mold for the locking component was manufactured without proper defined dimensions resulting in poor engagement of the locking feature.

FSCA strategy:

- Disseminate FSN to inform users of the issue and to return to company
- CAPA: Manufacturing process changes; e.g. drawing improvements, validation of mold dimensional outputs, complaint monitoring

HSA’s assessment on new supply:

New supply of affected MD with FSN is **NOT** permitted

Supply of medical devices not affected by this FSCA may proceed

Illustrative Case Study 2

Labelling



MD type	IVD reagent
FSCA type	Labelling; all lots
Issue (based on FSN)	Update of labelling information on new found rare interference that has potential to cause falsely high results

FSCA strategy:

- Disseminate FSN to inform of the new found rare interference that can cause falsely high results.
“In rare cases (less than 1 reported case per 100,000 tests) certain immunoglobulins can cause a non-specific agglutination leading to falsely high results”
- Update IFU to include the above labelling information

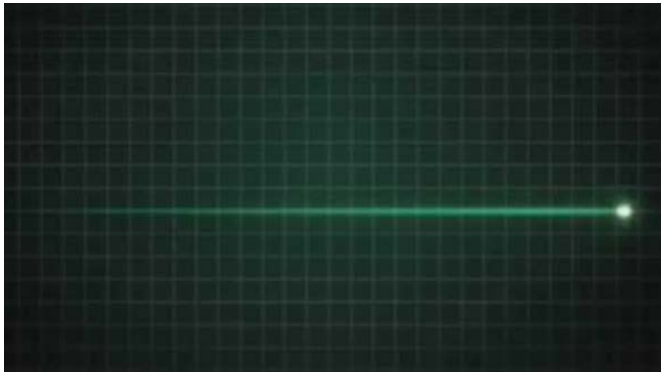
HSA’s assessment on new supply:

New supply of affected MD with FSN is permitted

Illustrative Case Study 3

Device Correction

MD type	Automated External Defibrillator (AED)
FSCA type	Hardware change (specific models and serial numbers)
Issue (based on FSN)	In either manual or automated mode, when a shock is initiated, the device can abort delivery of a shock therapy. When this occurs, error message will be displayed followed by alert indicator. The ECG waveform may display a non-physiologic flat line rhythm.



Illustrative Case Study 3

Device Correction



Root cause: Change in hardware components resulted in low voltage contacts causing the device to abort delivery of shock therapy.

FSCA strategy:

- Software upgrade.
- In the interim, disregard the message and alert, restart the defibrillator and continue to administer shock therapy.
- If the problem is not resolved, treat patient per existing protocol. Ensure backup defibrillator is made available.

HSA's assessment:

Not clear how software will be able to address hardware issue.

There is a probability of recurrence, and the severity of the issue is high.

HSA advised company to inform all users

- To cease use of device completely until problem is resolved
- To switch to alternative AED immediately

New supply of correction-in-progress devices is **NOT** permitted

Illustrative Case Study 4

Device Correction

MD type	IVD analyzer
FSCA type	SW issue (specific SW versions affected)
Issue (based on FSN)	Potential reporting error with analyzer. When the XXX function is disabled, the error alert codes will be suppressed. Potential for the parameters measured to be reported wrongly.

Root cause: XXX function is enabled as default, but operator can disable it. Disabling may occur after cleaning of the components. The technicians could have forgotten to reconnect XXX after replacement or after service.

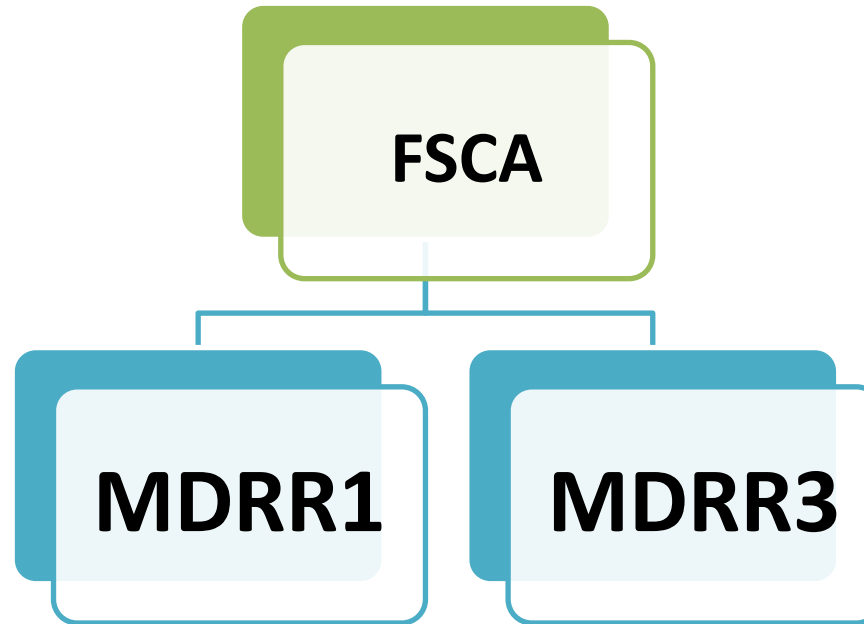
FSCA strategy: SW upgrade. In the interim, to advise users via FSN to check if XXX is turned on before use. FSN instructs users on how to turn it on if it is ‘offed’.

HSA’s assessment:

The parameters measured are not sole determinant of the diseases but adjunct in the clinical evaluation of medical conditions. In view that the [manual workaround is able to mitigate the risk of reporting error](#), Pending software upgrade, new supply of correction-in-progress devices is permitted.

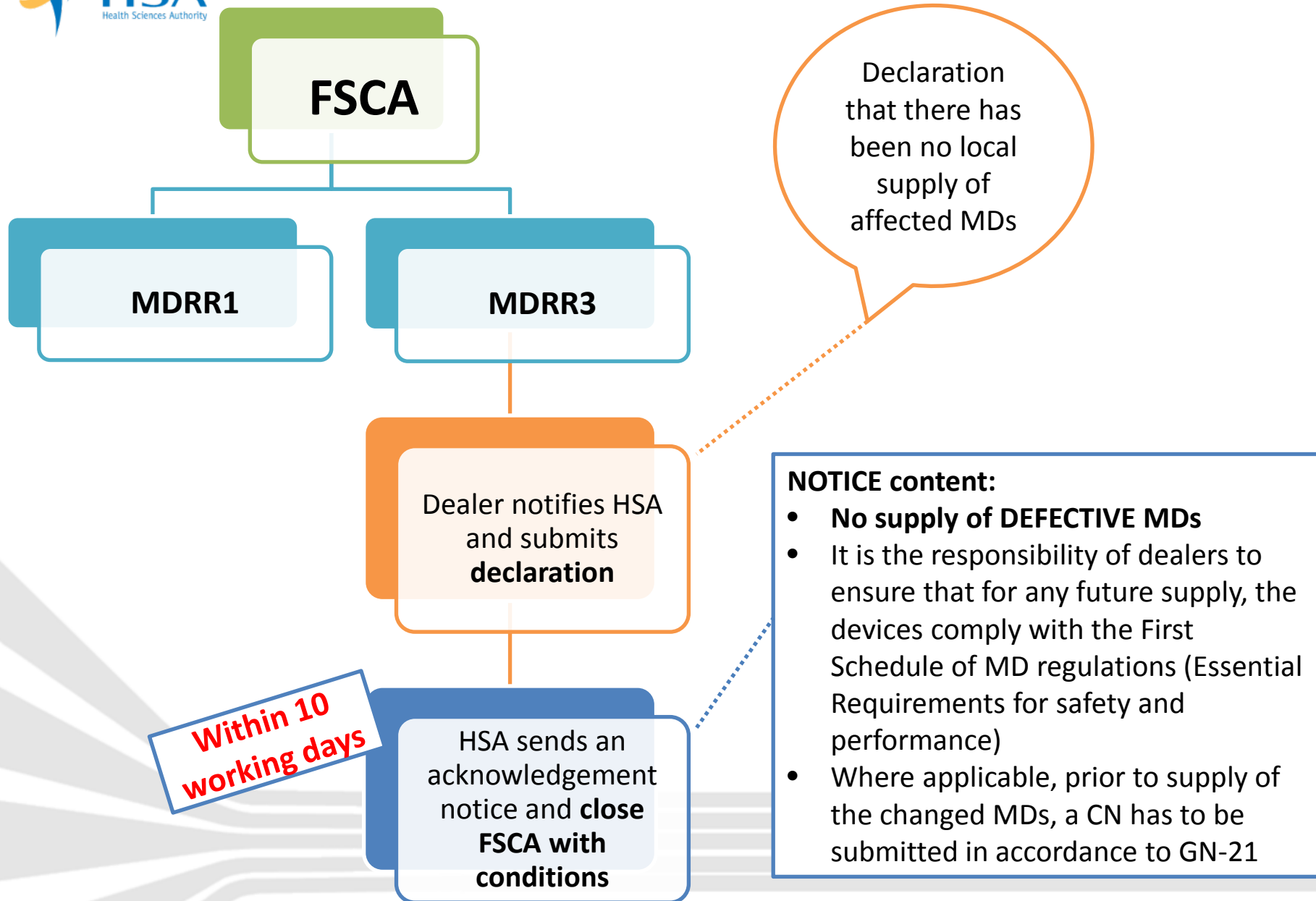
REFINEMENTS TO MDRR3 – CLOSURE AND NEW SUPPLY

Current approach – New supply



- Stop supply of affected devices during the first notice of acknowledgement except for issues to be addressed by labelling changes only.
- Interim supply approved on a case by case basis by HSA when FSCA is still open
- Closure of FSCA subject to completion of root cause and CAPA review and effectiveness.

MDRR3 – from 18 April 2016



MDRR3 – from 18 April 2016

- MDRR3 reporting is applicable only for circumstances where there is no affected devices in use locally
- Under circumstances where there is a clinical need for the devices affected by the FSCA, a review and follow-up on the full correction would be required
- For such cases, a subsequent MDRR1 report will be required by the authority

MDRR3 Post market information report

Revised

FSCA information (where applicable)	
Have the medical devices affected by the FSCA been manufactured, imported or supplied in Singapore?	<input type="checkbox"/> Yes <input type="checkbox"/> No

FSCA information (where applicable)	
Have the medical devices affected by the FSCA been manufactured, imported or supplied in Singapore?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<i>*If yes, please report using the MDRR1 report form instead.</i>	
Summary of Product Owner's Root Cause Analysis for the FSCA	
Summary of Product Owner's Corrective and Preventative Action (CAPA) for the FSCA	A copy of the FSCA communication (as an attachment)
Summary of CAPA effectiveness studies conducted by product owner	Date of commencement of FSCA by product owner (dd/mm/yyyy)
A copy of the FSCA communication (as an attachment)	
Date of commencement of FSCA by product owner (dd/mm/yyyy)	
Local Tel No. (for publication on HSA website)	Local Fax No.
Local Email Address (for publication on HSA website)	

Previous

I attest that the information submitted is true and accurate, and that I am authorized to submit this form on behalf of the company.

Prior to any future supply of the devices corrected of this FSCA, I will verify if a Change Notification (CN) submission through MEDICs is required. If MEDICs CN submission is required, new supply of devices corrected of this FSCA shall not proceed unless prior approval from HSA has been received.

I declare that any new supply of devices corrected of this FSCA shall conform to the Essentials Principles in the First Schedule of the Health Products (Medical Devices) Regulations 2010, and any other applicable regulatory requirements.

Signature :
 Name of Reporting Person :
 Date of this notification : (dd/mm/yyyy)
 Company stamp :

NEW – 'Declaration' section

MDRR3 – from 18 April 2016

REPORTING OF OVERSEAS FIELD SAFETY CORRECTIVE ACTION (FSCA) FOR «MD_NAME»

1. The Health Sciences Authority (“HSA”) is issuing this Notice pursuant to the Health Products Act (“HPA”) and its subsidiary legislation. The HPA and its subsidiary legislation may be accessed via the following website: <http://statutes.agc.gov.sg>
2. This Notice is issued with reference to Medical Device Information Report for «MD_Name», which we received on «Notification Date», from «Local_Submitter_of_FSCA». The Medical Device Information Report referred to in this Notice is attached. The reference number allocated to this overseas FSCA is «FSCA_Reference_Number».
3. «Local_Submitter_of_FSCA» has declared that there has been no manufacture, imports or supplies in Singapore of medical devices affected by this overseas FSCA.
4. This Branch acknowledges that «Local_Submitter_of_FSCA» has performed its reporting obligation under the Health Products (Medical Devices) Regulations 2010. The Authority would inform «Local_Submitter_of_FSCA» should any information in relation to this FSCA be required.
5. «Local_Submitter_of_FSCA» shall ensure that the following measures are undertaken in relation to this overseas FSCA:
 - a. Ensure that future supply of medical devices is not defective and conform to the Essential Principles of the First Schedule of the Health Products (Medical Device) Regulations 2010;
 - b. For recalls, medical device affected by the FSCA shall not be supplied. Unless otherwise clarified by HSA, affected medical device would refer to medical devices to which the FSCA applies, based on the product owner’s Field Safety Notice (FSN);
 - c. (*Applicable to registered devices only*) Prior to new supply of medical devices corrected for this FSCA, verify whether a Change Notification (CN) submission through the Medical Device Information & Communication System (MEDICS) is required. Refer to GN-21: Guidance on Change Notification for further information. If a MEDICS CN submission and approval is necessary, new supply shall not proceed unless prior approval from HSA has been received. Any new supply shall be subject to the conditions or restrictions that may be imposed as part of HSA’s approval. Measures to ensure strict compliance to these conditions or restrictions shall be undertaken by Reporting Person. More information on CN is available on our website at <http://www.hsa.gov.sg/>

Affected Identifiers in FSN for MDRR3 cases

- FSN should:
 - Include the complete **global list of affected identifiers** identified by product owner

Existing open MDRR3 cases

- With these proposed changes, HSA to review the pending cases and a notice will be sent out to confirm completion of FSCA reporting obligation where applicable.
- Conditions of new supply will be aligned to new approach.

PUBLICATION OF FIELD SAFETY NOTICE (FSN)

Publication of FSN

Requirements of FSN:

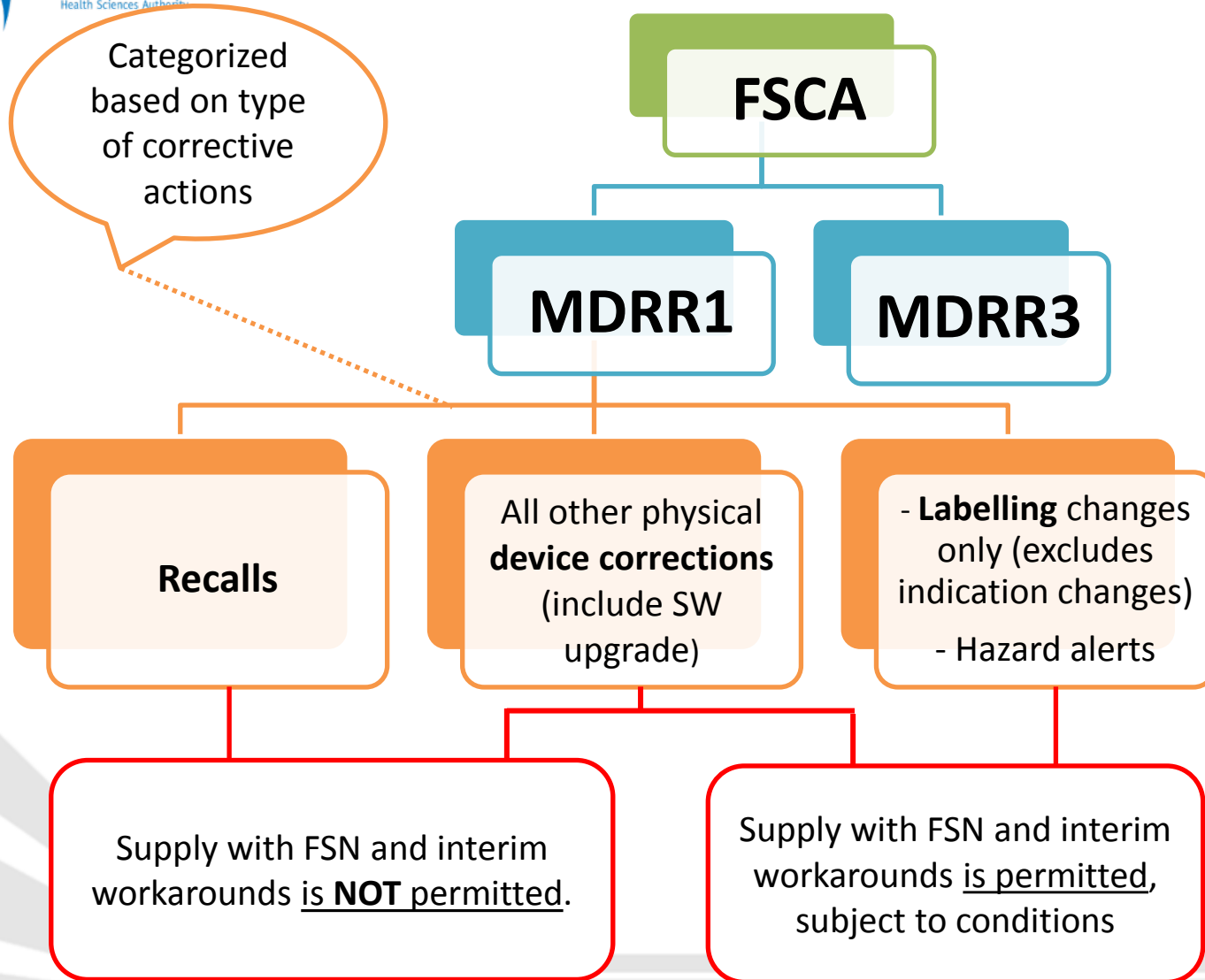
- FSN should be submitted as a single Adobe PDF document instead of a Microsoft Word document.
- FSN should not be tagged as “Draft”.
- Any edits or amendments to the FSN should be authorized by the product owner.
- FSN should not contain any third party marks (e.g. contact details of consignees).
- As FSN contain safety-related information, information in the FSN should be accessible to any person who may have received the affected devices. Therefore, the presence of “Privileged and Confidential” or “Restricted” tags in the FSN is strongly discouraged. The Authority would request for removal of such tags if they are present in the FSN.

CONCLUSION & SUMMARY

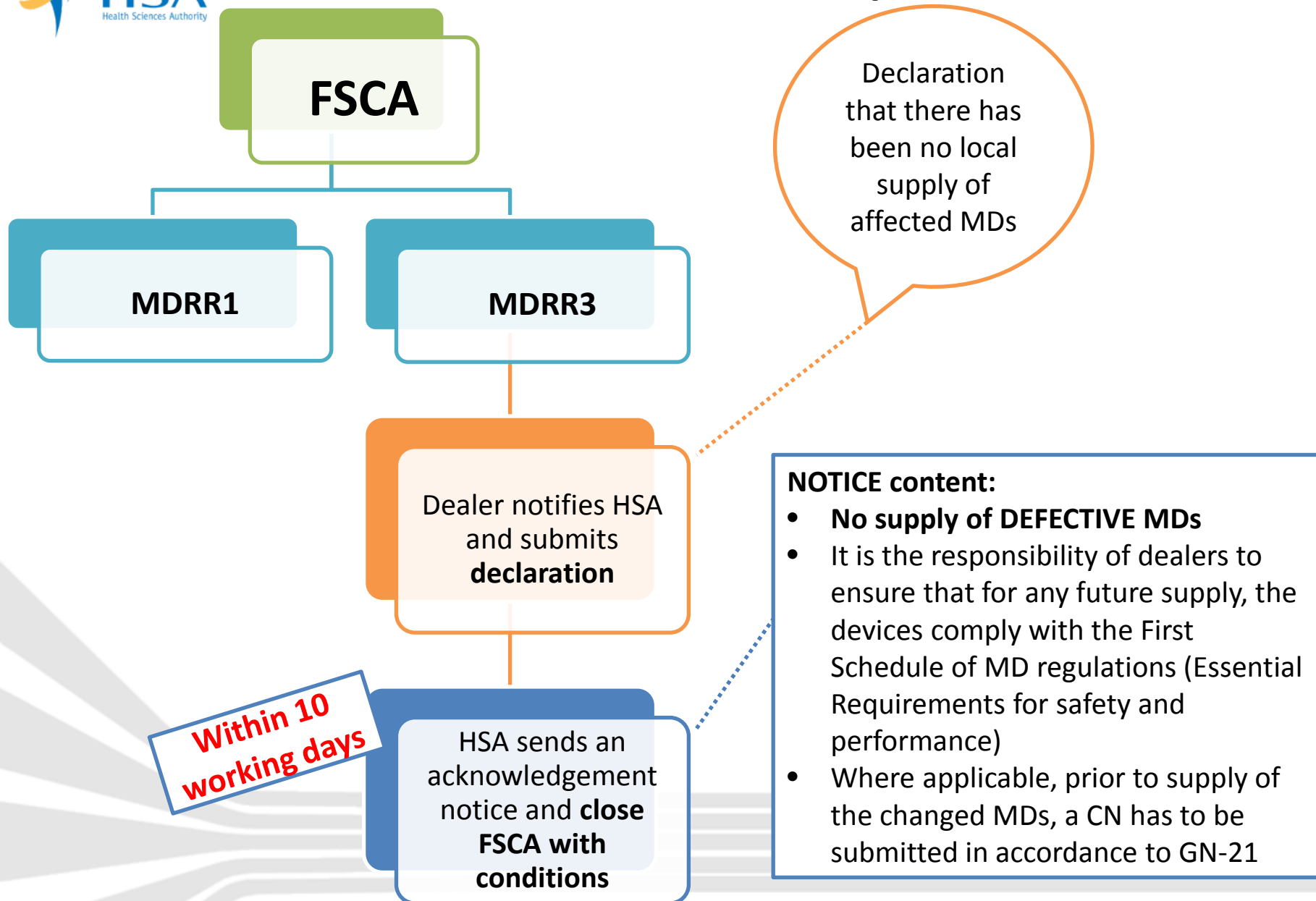
Timelines

- The revised guidance, GN-10, and the revised FSCA forms will be uploaded on our website on **08 April 2016**
- Refinements would apply to all FSCAs notified from **18 April 2016** onwards.

MDRR1 – from 18 April 2016



MDRR3 – from 18 April 2016



Concluding note (FSCA strategy)

When notified of FSCA by the product owner/legal manufacturer or HSA,
DEVELOP COHERENT FSCA STRATEGY!

Which includes among other things:

1. Identify whether affected supply exists in Singapore – Initiate FSCA as soon as possible*
2. Gather accurate manufacture, import and/or supply/distribution data for reporting to HSA
3. Plan correction schedule
4. Ascertain whether change notification applies
5. Take measures to identify immediate shipments
6. Prepare root cause, CAPA, CAPA effectiveness documentation for submission of FSCA Notification

* An unwarranted delay to initiate a FSCA constitutes an offence under the MD Regs.

Thank you

For MD post-market related enquiries, please write in to:
hsa_medical_device@hsa.gov.sg