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CLINICAL RESEARCH MATERIAL (CRM) NOTIFICATION FOR CLINICAL RESEARCH INVOLVING MEDICAL DEVICES

Scenario

Benedict has been assigned as the main Clinical Research Coordinator for a new clinical research study involving a medical device that is manufactured locally by a medical technology start-up to simplify a complex medical procedure. He is unsure of the regulatory requirements and documentation applicable to medical devices. His mentor, Sally a senior study coordinator explained and referred him to the Health Sciences Authority (HSA) website for more information.

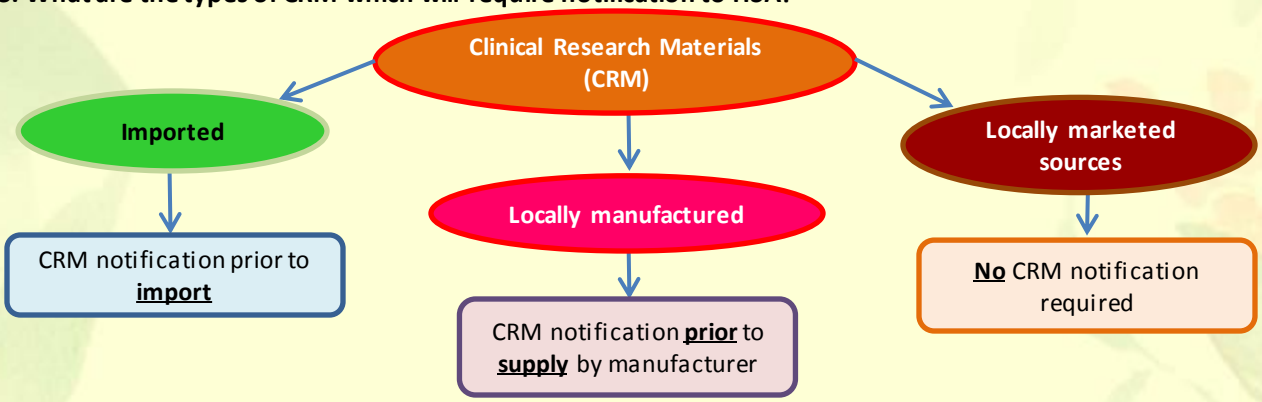
1. What are Clinical Research Materials (CRM)?

CRM (e.g. therapeutic products, medicinal products, placebo and medical device) refers to any registered or unregistered TP, licensed or unlicensed MP or placebo, that is manufactured, imported or supplied for the purpose of being used in any clinical research in accordance with the research protocol. *[Refer to the HSA, Regulatory Guidance, Clinical Trials Guidance – Clinical Research Materials (GN-CTB-2-001C-001) for more details on Duties and obligations of local manufacturers, importers and suppliers of CRM.]*

2. When is CRM notification to HSA required?

The import and supply of medical devices used for a clinical purpose in any clinical research is regulated as a Clinical Research Material (CRM), it is thus subject to regulatory requirements under the Health Products (Medical Devices) (Amendment) Regulations 2016.

3. What are the types of CRM which will require notification to HSA?



4. What documentation does Benedict need to check to be in place for the study?

Benedict needs to ensure that the documents for CRM notification process are in place and submitted by the local manufacturer before the initiation of the study.

*Note: For enquiries on the regulation of clinical research materials, please contact the Health Sciences Authority (HSA), Clinical Trials Branch, Health Products Group (HSA_CT@hsa.gov.sg).

References:
- GN-CTB-2-001C-001 (2 May 2017) Clinical Trials Guidance: Clinical Research Materials

Additional Reading:
- Regulatory Guidance : www.hsa.gov.sg > Home > Health Products Regulations > Innovation Office & Clinical Trials > Overview > Regulatory Guidance

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