# Focus Group Session on Condoms

**3rd November 2014**


**Medical Device Branch**
**Health Products Regulation Group**
**Health Sciences Authority**

# Overview

- Introduction
- Import Consignment Testing Requirements
- Updates on Conditions of Approval for Condoms
- Recap on Product Registration Requirements

# INTRODUCTION

# Introduction

- Condoms (as defined in the International Standard ISO 4074) :
  - Medical device intended for contraceptive purposes and assisting in the prevention of transmission of most sexually transmitted infections (STIs)
  - In general, Class C or D medical devices

- With the implementation of the Health Products (Medical Devices) Regulations, from 10 August 2010, all Class C and D devices are required to be registered with HSA and dealers must be licensed prior to import and supply of medical devices. Pre-market evaluation covers the quality, safety and efficacy aspects of these devices

# IMPORT CONSIGNMENT TESTING REQUIREMENTS

# Conditions of Approval (CoA) for Condoms

## Condition(s) of Approval

1. Post-market Surveillance

PLC001 - Supply of the medical devices is subject to post-market duties as stipulated in the Health Products Act and the Health Products (Medical Devices) Regulation 2010.

2. Advertisement

PLC003 - Any advertisement shall not contain any statement to the effect, whether directly or indirectly, that the use of the above mentioned device is being promoted or endorsed by the Health Sciences Authority.

***PLC009 - Every import of the medical device is subject to batch test by the testing laboratory approved by the authority and continued supply is subject to the authority's acceptance of the above batch test report.***

Listing on the SMDR i… …approved by HSA.

4. Post-Approval Reports for batch release

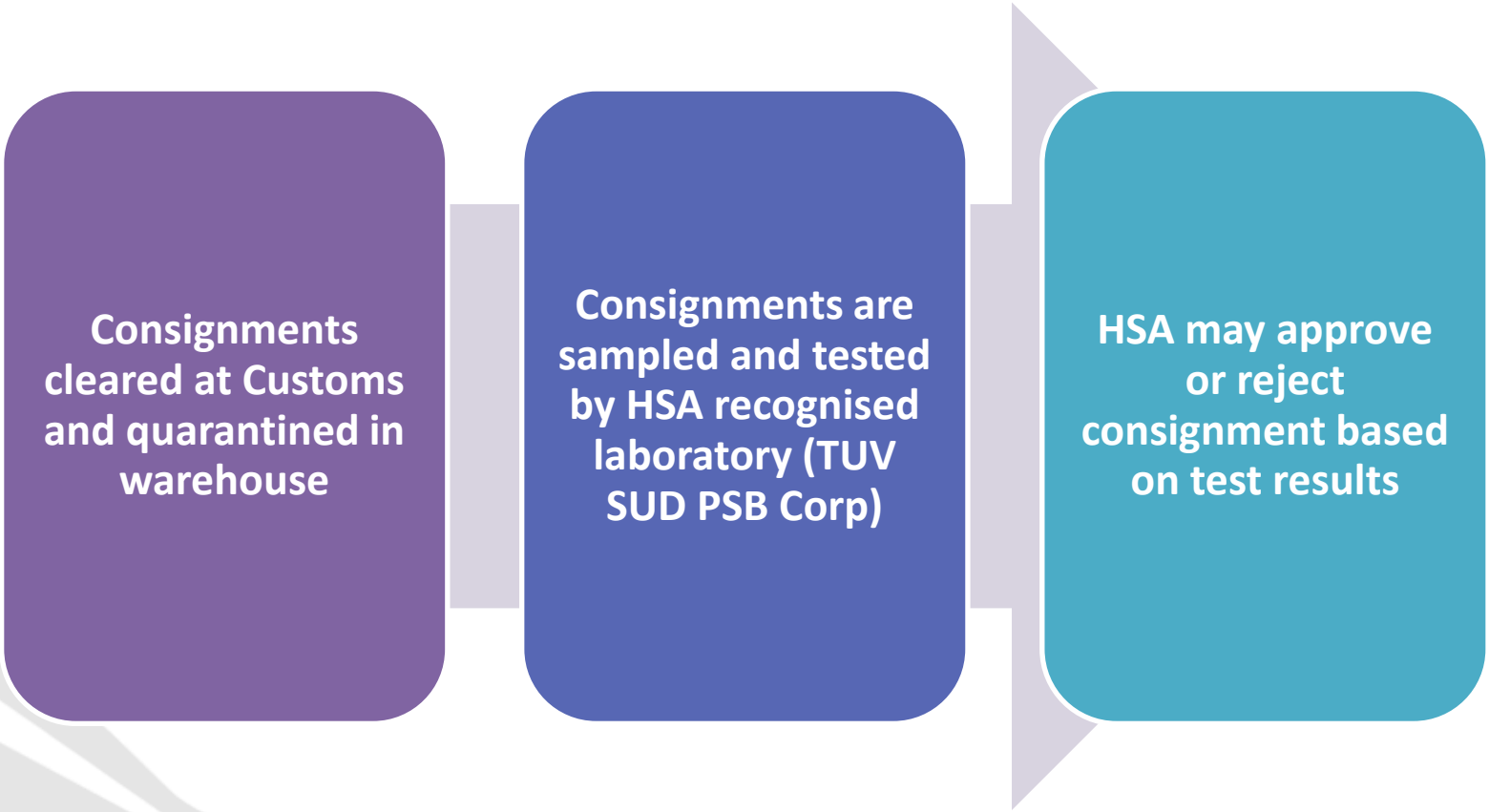
PLC009 - Every import of the medical device is subject to batch test by the testing laboratory approved by the authority and continued supply is subject to the authority's acceptance of the above batch test report.

# Background

- The import of male condoms was controlled under the Medicines Act prior to the implementation of the Health Products Act, to ensure that all condoms imported into Singapore are of appropriate quality.

- To maintain a continuous quality monitoring assurance considering exposure and risk to public, batch testing requirement for import clearance of condoms was retained and administered as a licensing condition – PLC009, under the Health Products Act.

# Overview of Current Import Consignment Testing Requirements



# Upcoming Change in CoA

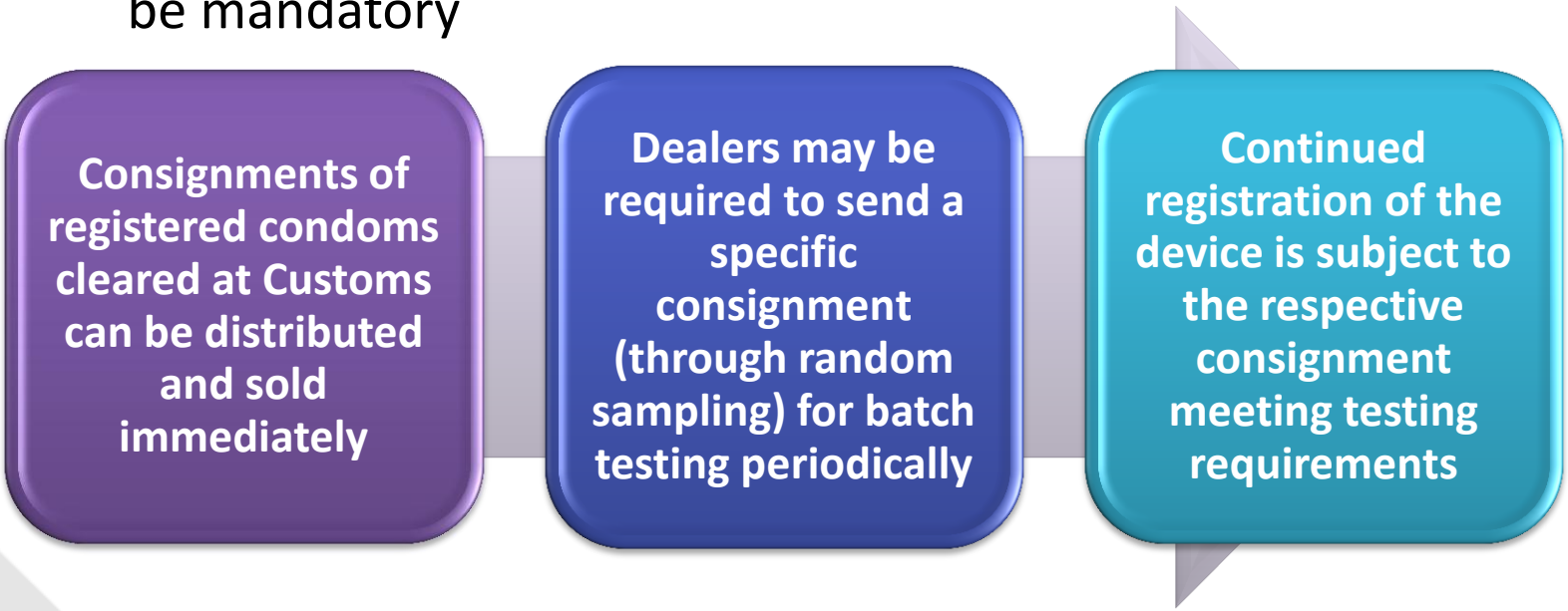
- Safety, performance and quality aspect have been reviewed as part of product registration
- Current requirements in PLC009 – batch testing for every consignment of import will **no longer** be mandatory
- Updated Condition of Approval as continuous quality monitoring assurance:

***"Medical devices included in this registration may be subject to batch test by the testing laboratory approved by the authority periodically as required by the authority and the continued registration of the device is subject to the device meeting these testing requirements."***

*Note: all other pre-market requirements and post market activities for condoms still apply.*

# Overview of Updated CoA

- New importation requirements
  - Batch testing requirement for every consignment will **no longer** be mandatory




- Quality testing requirements have been incorporated into the product registration requirements → **Pre-market evaluation** will cover batch testing aspect

# What to Expect?

- Pending applications – **Updated** PLC009 will apply accordingly
- Registered condoms on SMDR
  - Registrant of affected listings will be contacted via email on the updates to CoA
  - New registration conditions will be updated by **1st February 2015**

# RECAP ON PRODUCT REGISTRATION REQUIREMENTS

# Recap on Product Registration Requirements

a) Grouping of Condoms for the Purpose of Product Registration

b) Eligibility Criteria for Abridged/Expedited Evaluation Route

- Marketing history
- Reference agency approval, of each condom variant

c) Product Claims

d) Essential Principles: Safety and Performance Requirements for Medical Devices

# Grouping of Condoms - FAMILY

A medical device FAMILY is a collection of medical devices and **each** medical device FAMILY member:

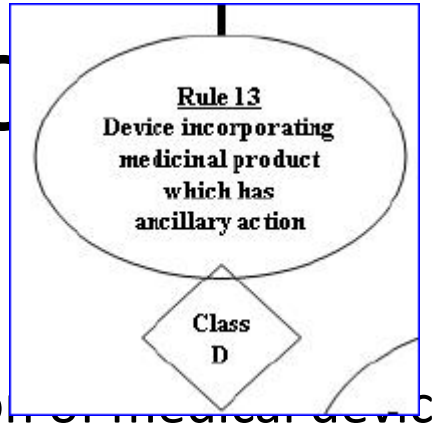
- Is from the same product owner;
- Is of the same risk classification class;
- Has a common intended purpose;
- Has the same design and manufacturing process; and
- Has variations that are within the scope of permissible variants per Annex 2 of GN-12

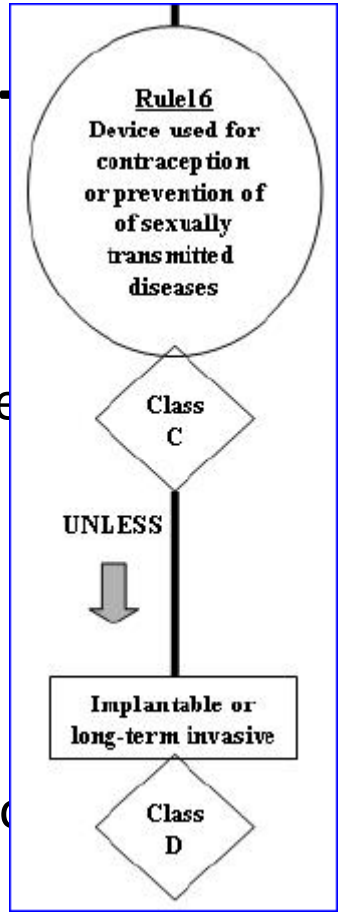
# Grouping of Condoms - FAMILY

- List of permissible variants per Annex 2 of GN-12
  - General: colour, diameter, length, shape, size etc.
  - Product Specific: texture, flavour

- Condoms that differ in colour, size, flavour and texture but are manufactured from the same material, same manufacturing process and share a common intended purpose can be registered as a FAMILY

# Grouping of C
# FAMI




- A medical device FAMILY is a collectio
  medical device FAMILY member:
  - Is of the same risk classification class

i) Non-medicated condoms - Class C Rule 16

ii) Condoms containing benzocaine (topical analgesic) / n
(spermicide) as active ingredients

- Class C Rule 16; Class D Rule 13
- Multiple rules, highest risk rule applies → **Class D**

→ Different risk classification, shall NOT be considered members of a FAMILY

# Grouping of Condoms – SINGLE

- A SINGLE medical device is a medical device from a product owner identified by a medical device proprietary name with a specific intended purpose. It may be offered in a range of package sizes.
- E.g. **Condoms** that are sold in packages of 3, 6, 12 and 144 can be submitted as SINGLE grouping type.
- Applicant to include all possible package configurations to be supplied in Singapore in the Annex 2 List of Configurations.

# Eligibility Criteria for Abridged/Expedited Evaluation Route

- The abridged and expedited evaluation routes are set out according to a confidence based approach, leveraging on the approvals by HSA's medical device reference regulatory agencies (RAs) and/or prior safe marketing history.

# Eligibility Criteria for Abridged/Expedited Evaluation Route

| Expedited Route | | Abridged | FULL |
|---|---|---|---|
| **ECR-1** | **ECR-2/EDR** | | |
| Medical device with identical intended use as that approved by HSA medical device reference agencies (RA) | | | NA |
| ▪ Approved in 1 RA<br>▪ Marketed in the above agency jurisdiction or in Singapore for ≥ 3 years<br>▪ No safety issues globally | ▪ Approved in 2 independent RAs* | Approved in 1 RA | Not approved in any of the RA |

**** EU and TGA Australia considered as one reference agency approval if approved based on Australian-EC Mutual Recognition Agreement (MRA)***

# Applicant's Responsibility..

- To ensure **each** condom variant to be registered fulfils the eligibility criteria of the selected evaluation route set out in "*GN-15 Guidance on Medical Device Product Registration*".

- E.g. HSA family of condoms has 2 condom variants:

  HSA Deluxe 3's – approved in EU since 2008

  → Qualifies for ECR-1 /Abridged evaluation route

  HSA Natural 3's – approved in EU since 2013

  → Qualifies for Abridged evaluation route

  HSA family of condoms qualifies for **Abridged** evaluation route.

- In the event that the application does not qualify for the selected evaluation route (e.g. ECR1/ECR2/EDR), application will be re-routed to the appropriate evaluation route and respective evaluation fee shall apply.

# Product claims

- Condoms meeting the requirements of ISO 4074 or equivalent may be used for contraceptive purposes and to help protect against sexually transmitted infections.
- Any additional claims shall be justified (e.g. claims for improved efficacy shall be substantiated by appropriate clinical investigation to demonstrate superiority).
- All information supporting additional claims shall be made available on request to regulatory authorities.

# Essential Principles: Safety and Performance Requirements for Medical Devices

*First Schedule of Health Products (Medical Device) Regulations*

- Compliance with Essential Principles can be demonstrated via -
  - Compliance to standards such as those published by:
    - International Standards Agency (IEC, ISO etc.)
    - Pharmacopoeia (USP, Ph. Eur.)
    - Regional Standard Agency (CEN, CENELEC, ETSI)
    - National Standards (SPRING Singapore, AAMI, ASTM)
  - Or **<u>equivalent</u>**

# List of Standards for Condoms (Informative)

- ISO 4074:2014 Natural latex rubber condoms - Requirements and test methods
- ASTM D3492-08 Standard Specification for Rubber Contraceptives (Male Condoms)
- ASTM D7661-10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms
- ASTM D6324-11 Standard Test Methods for Male Condoms Made from Polyurethane
- ISO 16037:2002 Rubber condoms for clinical trials - Measurement of physical properties [Including: Amendment (2011)]
- ANSI/ASQ Z1.4-2008 Sampling Procedures and Tables for Inspection by Attributes
- ASTM D6499-12 Standard Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and Its Products
- ISO 16038: 2005 Rubber condoms -- Guidance on the use of ISO 4074 in the quality management of natural rubber latex condoms
- ISO 25841:2014 Female condoms -- Requirements and test methods

# Thank you!

**For enquiries, please contact Medical Device Branch (MDB) at**

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**MDB generic email: hsa_md_info@hsa.gov.sg**