Frequently Asked Questions

General FAQs

Q: What is the updated Post-Licensing Condition and how will it affect condom's importation requirements?

A: Original 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.

Updated PLC009:- 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.

Currently, upon approval of product registration of condoms, a condition of approval (PLC009) will be imposed as a post-licensing condition, mandating every import of the medical device to batch testing prior to supply. Consignments cleared at Customs will be quarantined in the warehouse. The consignment is then sampled and tested by TUV SUD PSB Corp and HSA will approve or reject the consignment based on test results.

Moving forward, batch testing requirement of every consignment import prior to supply will be lifted. Company can supply registered condoms which have cleared Customs immediately. Through random sampling, HSA will periodically pick and inform company to do a batch test for their next import. Sampled consignment should meet testing requirements in order to remain registered on SMDR.

Q: Is this requirement in updated PLC009 only applicable for new companies or all companies in the market?

A: This requirement will apply to all companies. As part of post-market surveillance, HSA will select products randomly and companies will send samples from their next consignment for batch testing.

Q: What are the implications to the condoms on the market if my company is chosen for batch testing?

A: There is no implication to current batch that has been imported into Singapore. Companies are only required to send samples from their next import consignment for testing.

Q: If my company already has arrangements with TUV SUD PSB, can we continue to do batch testing?

A: Companies may continue to send every batch for testing. However, this is not mandatory. Dealers are most welcome to do batch testing if it adds confidence to them.

Q: With regards to labelling requirement changes in the 2014 revision of ISO 4074, what is the grace period allowed for companies to come into compliance with the labelling changes?

A: For condoms that claim conformity to ISO 4074 during product registration, dealers shall inform their principal of the latest changes in standard and their principal should have plans in place for the necessary updates to meet the revised requirements. Bringing product labelling to compliance should be in the principal's pipeline and registrant shall notify HSA via Change Notification if any of the changes fall within scope of GN-21.

Q: When will the new licence condition be implemented?

A: For registered condoms on SMDR, we target to update the registration conditions by 1st February 2015. Registrant of affected listings will be notified via email on updates to CoA. Currently pending applications will be approved with the updated PLC009 Licence Condition.