Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
(Medical Devices & Diagnostics Division)

Food & Drugs Administration Bhawan,
Kotla Road, New Delhi-110002

File.No. 29/Misc./03/2017-DC (285) **Date:** 31 OCT 2017

Office Memorandum

SUB:- Clarification for dealing with imported consignments of Medical Devices & IVDs held at the Port offices, 1) due to slight confusions in the name of the product vis-a-vis name in Registration Certificate/Import Licence, 2) due to inprocess applications, during change in constitution because of mergers/acquisition etc., 3) due to varying shelf-life issues in multicomponents kits - Regarding.

It has been brought to the notice that despite holding the valid Registration Certificate and Import Licenses by the Importers, some of the Medical devices and Diagnostics consignments are being withheld at the various Port offices by the office of ADC(I) 1) due to slight confusions in the name of the product vis-a-vis name in Registration Certificate/Import Licence, 2) due to inprocess applications, during change in constitution because of mergers/acquisition etc., 3) due to varying shelf-life issues in multicomponents kits, which is creating hurdles for importers, regulators and other stakeholders.

Therefore, in such cases of confusions in names of products, it is to clarify that if the Authorized Person of the importing firm furnishes the undertaking to office of ADC(I) at port that the imported product are the registered ones only, despite the apparent differences (to be described), then such consignment shall be released and the copy of undertakings, bill of entries, Registration Certificate and Import Licenses shall be forwarded to CDSCO (HQ) through a separate e-mail undertakingmd@gmail.com.

Further, in case of change in constitution due to merger/acquisition etc for existing Registration Certificate/Import Licenses, if the Courts or Competent Authority have endorsed the change, it may be accepted by the O/o ADC(I) at ports, if the Importers have applied for such changes in Registration Certificate/Import Licenses within 90 days & their consignments shall be released accordingly based on existing valid Registration Certificate/Import Licenses, as per rule, based on such proofs & undertaking of their application for change to CDSCO, HQ.

Further, in multicomponent kits, the assigned shelf life as per Form 10 or claim of products, can vary due to multicomponent, in such cases, the component/reagent etc having lowest expiry date shall be considered for calculation of shelf life or residual shelf life.

These clarifications are issued for better patient safety & enforcement compliances in line with the actions for ease of doing business.

Yours faithfully,

VGS

(Dr. V.G. Somani)
Joint Drugs Controller (I)

To,

1. All the Port / Zonal / Sub-zonal Offices of CDSCO
2. CDSCO Website