# POLICY FOR INSPECTION OF MANUFACTURER ABROAD (FOR IMPORTED DRUGS).

(i) Dosage form specific inspection of manufacturer abroad will be carried out before grant of registration.

(ii) cGMP inspection will also be conducted at the time of renewal of registration.

(iii) The fee for grant of registration and renewal will be payable as already notified vide SRO.1117(I)/2012.

(iv) Facility (dosage form manufacturing facility or whole production facility") approved by regulatory authorities of US FDA, EU EMA, PMDA Japan, Australia TGA, Health Canada, Switzerland or any of regulatory authority of former erstwhile Western Europe (United Kingdom, Germany, France, Switzerland, Netherlands, Austria, Belgium, Denmark, Finland, Sweden, Italy, Ireland, Luxemburg, Norway, Scotland and Spain) or minimum three stringent regulatory bodies of former erstwhile Eastern Europe may be exempted from inspection of manufacturing facility, irrespective of the fact that the manufacturing unit is not located in these countries.

(v) The product pre-qualified by the World Health Organization will also be exempted from inspection of manufacturing units abroad.

(vi) In case of cancellation or suspension of registration of the product from the importing country or WHO pre-qualification, the registration holders will be bound to inform the Registration Board about this cancellation or suspension with in fifteen days of such suspension. In case of non-compliance, the Registration Board will take action against the Importer, which may also lead to the cancellation of registration of that product or prosecution.