

Approval Criteria:

1. If manufactured and Registered in any country in **Category 1**, second country registration certificate is not required.
2. If Manufactured and registered in any country in **Category 2** it has to be registered in one of the countries in **category 1** **OR** the regulatory authority is to conduct a facility inspection to ensure the quality, safety and efficacy of the product .
3. If manufactured in **Category 3 country**, second country registration in a **category 1** is required **OR** second country registration in **category 2** plus facility inspection done by regulatory authority is required.
4. Products and manufactures prequalified under **WHO prequalification scheme** does not require second county registration certificate.

14 1434 .

26 2013 .