

## **Annex I, Part 9(iii)**

# **GUIDELINE FOR ANTIBACTERIAL HYGIENE WASH PRODUCT**

### **1. OBJECTIVE**

The objective of the guideline is to ensure that antibacterial hygiene products in the market demonstrate sufficient effectiveness in accordance to the defined requirements for its use.

### **2. SCOPE**

This guideline applies only to antibacterial wash, wipes, deodorant and talc.

### **3. COMMON ANTIBACTERIAL AGENTS**

Antibacterial claim is allowed if the product contains:

- i. Substance listed in Annex VI and also listed in Annex III.
- ii. Substance listed in Martindale as antibacterial in particular products e.g. hand wash.
- iii. Substance listed as antibacterial agent in NPRA reference countries e.g. US, Canada, UK, Australia, Sweden, Switzerland, Japan, and France.

### **4. REQUIREMENTS FOR PRODUCTS CONTAINING NOVEL ANTIBACTERIAL AGENTS**

- i. The finished product must pass basic bactericidal suspension test e.g. relevant European or American Standard for Testing Method (ASTM)
- ii. Fulfil all of the following criterion:
  - a. Consist of substance(s) having antibacterial activity (MIC, MBC, established reference).
  - b. Test is done without modification. If modification applies, reasonable justification must be provided.

- c. The test result shows log reduction.
- d. Test product formulation must be comparable to actual product in the market.

**Note:** This is not an exhaustive requirement and will be reviewed when necessary.