

# UN/SCETDG/24/Inf.62

**Related document : ST/SG/AC.10/C.3/2003/36 (United Kingdom)**

**Aerosols for medical purposes**

## **6. Proposal**

Add a new 6.2.4.3 as follows:

“With the approval of the competent authority aerosols and receptacles small containing pharmaceutical products and non flammable gases which are required to be sterile need not be subject to the hot water bath test in 6.2.4.1 if:

- a) aerosols and receptacles are manufactured under the authority of a national health administration and following the principles of Good Manufacturing Practice (GMP) established by the World Health Organisation (WHO); and
- b) the manufacturer incorporates into procedures tests for leakage and pressure resistance, such as helium detection and water bathing a statistical sample (at least 1 in 2000) from each production batch.”