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COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS AND ON THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS

Sub-Committee of Experts on the Transport of Dangerous Goods
(Twenty-fourth session, 1-10 December 2003, agenda item 4 (c))

PACKAGINGS

Aerosols (UN 1950) and receptacles, small, containing gas (UN 2037), used for medicinal purposes

Transmitted by the expert from the United Kingdom

Background

1. At the 23rd session of the Sub-Committee the expert from the United Kingdom proposed in his paper, ST/SG/AC.10/C.3/2003/6, that medicinal aerosols that have undergone extensive medical trials and are manufactured under the provisions of Good Manufacturing Practice (GMP), which includes meeting ISO 9002, could be exempted from the provisions of the water bath test.

2. The Sub-Committee recognised that there was a problem with aerosols where the contents are affected by significant rises in temperature that would render them unusable for their original purpose. A number of those present identified other heat sensitive products, such as foodstuffs, where there might be problems created by applying the water bath test.

3. It was also noted at the same time that the FEA intend to put forward proposals to permit alternatives to the water bath test for a wide range of aerosols.

4. While aware of the view expressed by some members of the Sub-Committee that pharmaceutical products should not be considered in isolation from other products in aerosols, the expert from the United Kingdom nevertheless believes that the Sub-Committee should consider the issue of the medicinal aerosols separately from any future FEA proposal. It is clear now that there are many aerosols for medical purposes that cannot use the water bath method of leak testing and an FEA proposal that covers a wider range of aerosols is likely to need longer consideration, possibly beyond the current biennium.

5. Taking into account the comments made at the July Sub-Committee meeting the United Kingdom proposal is set out below.

6. Proposal

Add a new 6.2.4.3 as follows:

"With the approval of the Competent Authority, receptacles containing pharmaceutical products and non flammable gases manufactured under the authority of a national medical administration and following the principles of Good Manufacturing Practice (GMP) laid down by the World Health Organization for this purpose, need not be subject to the hot water bath test in 6.2.4.1, provided adequate measures to test for leakage are incorporated into manufacturers' procedures, such as helium detection or water bathing a statistical sample from each production batch."