**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
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PERFORMANCE OF PACKAGINGS, INCLUDING IBCS

Comments on ST/SG/AC.10/C.3/2008/38

Transmitted by the expert from Sweden

**Introduction**

Sweden appreciates the document 2008/38 concerning pharmaceutical aerosols. However, there is still one issue to be solved.

**Discussion**

In Sweden, a product used in the production process for pharmaceutical products is, according to our national health administration (Medical Products Agency) not a product that is manufactured under their authority. Our Medical Products Agency is responsible for products that are to be used on animals or humans as well as for products used in the manufacture of medical devices, not for products whose application may be for non-medical processes. An aerosol used to disinfect working areas is according to Medical Products Agency an “ordinary chemical product”.

In Sweden, there was a case last year where a company produced metal aerosols dispensers containing aqueous isopropanol solution and using nitrogen as the propellant. The aerosols are used for cleaning purposes in pharmaceutical manufacturing applications for which sterility is required.

This company was unable to implement the provisions in 6.2.4.3 as they are written today (UN and ADR). Rather, they were required to implement the provisions in 6.2.4.2.2 concerning an alternative method. Sweden would like to see a change in 6.2.4.3 in the interest of consistency to cover the above mentioned aerosols.

Therefore, the proposed text in document 2008/38 cannot be used since these types of aerosols will not be manufactured under the authority of a national health administration.

One solution is to require that only the substances that are constituent parts of pharmaceutical products be manufactured under the authority of a national health administration.

**Proposal**

**6.2.4.3**

*With the approval of the competent authority, aerosols and receptacles, small, containing non-flammable gases and which contain either:*

*(a)* *other substances that are constituent parts of pharmaceutical products for medical, veterinary or similar purposes; or*

*(b)* *other substances used in the production process for pharmaceutical products and that are required to be sterile but that may be adversely affected by water bath testing;*

*are not subject to 6.2.4.1 and 6.2.4.2, provided:*

*(i)* *an equivalent level of safety is achieved by the manufacturer's use of alternative methods for leak detection and pressure resistance, such as helium detection and water bathing a statistical sample of at least 1 in 2 000 from each production batch; and*

*(ii)* *for pharmaceutical products according to (a) above, they are manufactured under the authority of a national health administration and, if required by the competent authority, follow the principles of Good Manufacturing Practice (GMP) established by the World Health Organization (WHO).*

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