UNITED NATIONS **ST**

Secretariat

Distr.
GENERAL

ST/SG/AC.10/C.3/2008/38
11 April 2008

Original: ENGLISH

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

Thirty-third session
Geneva, 30 June-9 July (a.m.) 2008
Item 3 of the provisional agenda

PERFORMANCE OF PACKAGINGS, INCLUDING IBCS

Pharmaceutical Aerosols

Transmitted by the expert from the United Kingdom*

Background

1. At the 24th session of the Sub-Committee the expert from the United Kingdom submitted a proposal to amend paragraph 6.2.4.3 of the UN Model Regulations (ST/SG/AC.10/C.3/2003/36 and INF.62/Rev.1). The paper addressed the issue of pharmaceutical aerosols manufactured for use in sterile conditions, where the use of the hot water bath test was not considered the most appropriate method of testing, as such a process could potentially cause bacteria to form and render the aerosols non-sterile. The Sub-Committee adopted the proposal which was incorporated into the 14th revised edition of the UN Model Regulations.

2. Paragraph 6.2.4.3 of the UN Model Regulations refers to the principles of Good Manufacturing Practice (GMP), which is defined by the World Health Organisation (WHO) as "that part of quality assurance which ensures that products are consistently produced and

* In accordance with the programme of work of the Sub-Committee for 2007-2008 approved by the Committee at its third session (refer to ST/SG/AC.10/C.3/60 para. 100 and ST/SG/AC.10/C.3/34, para. 14).

controlled to the quality standards appropriate to their intended use and as required by the marketing authorization."

3. There has been some confusion over the intent of 6.2.4.3 with some competent authorities. GMP guidelines address not only finished products but also raw materials, sterility of working areas and substances needed for sterilisation. WHO standards on GMP require all components in the manufacture of the finished product to be subject to GMP procedures and not only the pharmaceuticals themselves. Thus chemical components, disinfectants, packaging etc must be produced under the same sterile system.

Proposal

4. The expert from the United Kingdom believes that the current text in paragraph 6.2.4.3 of the UN Model Regulations needs to be clarified to ensure that the full range of activities that can be exempt from 6.2.4.1 and 6.2.4.2 can be considered for competent authority approval, provided that GMP guidelines produced by the World Health Organisation are followed. It is therefore proposed that the text in paragraph 6.2.4.3 is amended to read:

> "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
>
> a) 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 if:
>
> (Existing 6.2.4.3 (a) and (b)...."

_____