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**COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS**

**(Twentieth session,**
**Geneva, 7-16 December l998,**
**agenda item 2 (d))**

## WORK OF THE SUB-COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS

**New proposals**

**Limited quantities**
**Consumer Products and Pharmaceuticals**

**Transmitted by the European Chemical Industry Council (CEFIC)**

## Background

1. In Chapter 1.1 ("*General Provisions*") and in Chapter 3.4 *("Dangerous Goods Packed in Limited Quantities*"), the UN Recommendations on the Transport of Dangerous Goods address application of the regulations to dangerous goods "packaged for retail sale" or "for personal or household use". It is unclear, however, how substances such as drugs, medicines, or cosmetics should be prepared for transport if they are packaged as intended for use although not fully ready for retail distribution. CEFIC believes that transport regulations should be framed so as not to impede the movement of such goods.

2. Pharmaceutical products, animal health products, cosmetics, etc. may contain dangerous components in quantities sufficient to require their classification for transport, when shipped in bulk. As bulk shipments they are packaged, marked, and labeled as dangerous goods. However, the same products (pharmaceuticals, animal health products, cosmetics, etc.) packaged as intended for retail sale to consumers pose little or no danger in transport.

3. It has already been established by the Committee of Experts (ref. paragraphs 1.1.1.2 and 3.4.8) that dangerous goods packaged for retail and intended for personal or household use, pose less danger in transport.

**Discussion**

4. It is unclear whether or not the text of paragraph 3.4.8 applies to animal health products and pharmaceuticals which are administered by medical or veterinary personnel.

5. It is equally unclear as to how the regulations should apply to a product which is packaged for final use, however, not being shipped to a retail outlet. Such shipments may include products which have be formed into tablets and sealed in individual blister packs or filled into inner receptacles (vials, ampoules, bottles, etc.) which still require product labeling in accordance with local or regional requirements and language differences in the country of use. As such they are in fact, packaged in a form "suitable for" retail sale or for use by the consumer.

6. The ICAO Technical Instructions and the IATA DGR have addressed regulation of these substances under the term "CONSUMER COMMODITY" which is defined, in part, to include "…items administered or sold to patients by doctors or medical administrations". This reference to medical uses seems to focus the definition to recognize the method of packaging as a significant factor in addressing the hazard posed by such substances in transport.

**Conclusion**

7. In view of the concerns described above, CEFIC concludes that for effective distribution of pharmaceuticals, animal health products, and various personal care products, intended for personal use by consumers or to be administered by medical and/or veterinary personnel:

(a) the General Provisions in Chapter 1.1 of the Model Regulations should provide for conditions under which such substances are not subject to the transport regulations; and

(b) the Limited Quantity provisions in Chapter 3.4 should be amended to include, when appropriately packaged, dangerous goods intended to be administered or sold to patients (human or animal) by medical/veterinary professionals.

**Proposals**

8. CEFIC makes the following specific proposals in order to accommodate the shipment of pharmaceuticals, animal health products, and various personal use products.

9. Amend paragraph **1.1.1.2** by adding a new subparagraph "(d)" to specify conditions under which certain dangerous goods packaged as intended or suitable for retail sale would not be subject to the requirements for transport. Amended text to read:

"1.1.1.2 These Regulations do not apply to the transport of:

(a) Dangerous goods in bulk…

(b) Dangerous goods that…

(c) Dangerous goods, packaged for retail sale, …

(d) Dangerous goods, which are pharmaceuticals or animal health products, packaged in a form intended or suitable for personal care or household use risk."

10. Amend paragraph **3.4.8** to indicate that "…limited quantities of dangerous goods for personal or household use…" includes substances administered or sold by medical professionals. [Additionally, specify that this provision may apply to such personal or household use products when transported between manufacturing sites for subsequent packaging, labeling, etc., prior to distribution for retail sales.] Amended text to read:

> "3.4.8 Limited quantities of dangerous goods for personal or household use, that are packaged and distributed in a form intended or suitable for sale through retail agencies, may furthermore be exempted from marking of the proper shipping name and UN number on the packaging and from the requirements for a dangerous goods transport document. These include human and animal health care products which are administered or sold to patients by medical or veterinary professionals."

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