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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-ninth session
Geneva, 3-12 (a.m.) July 2006
Item 5 of the provisional agenda

LIMITED QUANTITIES

Exemption for small quantities of pharmaceutical research and development samples

Transmitted by the International Council of Chemical Associations (ICCA) and the Dangerous Goods Advisory Council (DGAC)

Background

1. The pharmaceutical industry ships thousands of small samples (typically less than 1 gram or 1 milliliter) annually in their efforts to discover innovative therapies for human afflictions such as cardiovascular disease, metabolic and infectious disease, and cancer. The primary facilities involved in supporting their research activities include, but are not limited to, hospitals, universities, research and analytical laboratories, and clinics, a number of which operated by state and federal government agencies. The number of sample shipments will increase over the coming years as the globalization of research and development intensifies.

2. Many materials shipped by the industry are novel compounds. Some have been synthesized in quantities totalling no more than two or three grams at a cost of many thousands of dollars. In the absence of complete classification profiles, compounds are conservatively classified in accordance with the procedures for samples described in paragraph 2.0.4 of the Model Regulations. However, based on the desired therapeutic properties of the compounds

developed, most are found based on subsequent testing to not meet the criteria for classification as dangerous goods. Their potential toxicity is expected to be the primary concern. Of the compounds that do meet the criteria, most fall within Division 6.1, Packing Group III. An analysis of one company's compounds that advanced to a research stage (their therapeutic properties justify further development) showed the following:

	NUMBER OF COMPOUNDS	**PERCENT OF TOTAL**
Current Number of research compounds in active development that are classed for transport	**1547**	**---**
Of those, the total number classed in Division 6.1	**241**	**15.6**
Of those, the total number classed in Division 6.1, PG I	**3**	**0.19**

3. ICCA and DGAC believe that due to their quantity and form, shipments of these compounds, including those novel compounds with incomplete classification profiles, in quantities of less than one gram or one milliliter per inner receptacle present such a low potential risk under any conditions of transport they should not be considered subject to the dangerous goods regulations if proposed conditions are met.

Proposal

4. Introduce the following new paragraph in Chapter 2.0:

"2.0.4.3 Special exception for research and development samples

Pharmaceutical research and development samples developed to investigate their potential as medicines are not subject to any other requirements of these Regulations, providing the following conditions are met:

(a) Each sample substance is classified or tentatively classified based on available information as meeting the Division 6.1 criteria for oral or dermal toxicity at either the Packing Group II or III level and meeting no other hazard criteria;

(b) The net quantity of sample material per inner package is less than or equal to one gram or one millilitre;

(c) Packagings shall meet the provisions of 4.1.1.1, 4.1.1.2, 4.1.1.4, 4.1.1.4.1, 4.1.1.6 and 4.1.1.8.1;

(d) Inner packagings must be packed in outer packagings with sufficient absorbent cushioning material to prevent movement and to absorb the entire contents. Absorbent cushioning material shall be of a type that will not react with sample substances. For solid samples, cushioning material need not be absorbent;

(e) Each inner packaging is fitted with a closure securely held in place by positive means;

(f) Other than dry ice, samples shall not be packed together with other goods;

(g) The aggregate quantity of samples per package may not exceed 500 ml or 500 grams. The gross mass of the completed package shall not exceed 30 kg.”
