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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

Thirtieth session
Geneva, 4-12 (a.m.) December 2006
Item 2(a) of the provisional agenda

PROPOSALS OF AMENDMENTS TO THE RECOMMENDATIONS ON THE TRANSPORT OF DANGEROUS GOODS

Limited quantities

Exemption for small quantities of pharmaceutical research and development substances

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

Background

1. At the twenty-ninth session of the Sub-Committee, ICCA and DGAC presented a proposal to provide an exemption in the Model Regulations for small quantities of pharmaceutical research and development substances (ST/SG/AC.10/C.3/2006/49).

2. As noted in the report of the session (ST/SG/AC.10/C.3/58, para. 48), a number of delegations supported the principle of such an exemption but raised issues regarding substances included in Packing Group I, the maximum quantity per package or per vehicle, the classification principles in 2.0.4.1, a possible link with work on excepted quantities and conditions of transport in packagings containing dry ice.

3. The pharmaceutical industry ships thousands of small quantities of substances annually (typically in amounts less than or equal to 0.2 g for solids or 0.2 ml for liquids, and usually in a

non dangerous medium) 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 shipments will increase over the coming years as the globalization of research and development intensifies.

4. Many substances 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. While most compounds are non dangerous, 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.

5. The desired therapeutic properties of these compounds (i.e., they are developed to provide a health benefit) suggest and testing confirms that most do not meet the criteria for classification as dangerous goods. 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 classified for transport	**1547**	**---**
Of those, the total number classified in Division 6.1	**241**	**15.6**
Of those, the total number classified in Division 6.1, PG I	**3**	**0.19**

6. The low danger levels of most compounds evaluated in pharmaceutical research and development efforts and the quantity and form of these compounds suggests that shipments, including shipments of novel compounds with incomplete classification profiles, in quantities of less than or equal to 0.2 g or 0.2 ml per inner receptacle, present an insignificant risk under any conditions of transport. On this basis it is proposed that they not be subject to the dangerous goods regulations if proposed conditions are met.

7. Bearing in mind the comments from experts at the twenty-ninth session, the proposal has been changed:

(a) to differentiate the proposal from provisionally accepted requirements for excepted quantities by reducing the quantity of substance per inner packaging to less than or equal to 0.2 g or 0.2 ml - one fifth the size of the upper limit for excepted quantities at the packing group I level even though the vast majority do not meet the criteria for packing group I;

(b) to differentiate between the pharmaceutical research and development substances and samples addressed in 2.0.4.1 by providing a new 2.0.5;

(c) to recognise that some substances may meet criteria for Packing Group I;

(d) to eliminate reference to dry ice, since dry ice, when it is used as a coolant, is in an overpack and not in the actual package containing the pharmaceutical substances and is, therefore, subject to existing transport requirements for dry ice; and

(e) to reduce the maximum quantity per package from 500 g or 500 ml to 100 g or 100 ml. An overall package gross mass limit was not deemed necessary since the quantity of substance is already limited and any limit on the overall mass would only serve to limit the amount of packaging material.

Given industry practice of shipping only a few packages in a consignment and the small quantity of substance present, including a maximum number of packages per vehicle was considered unnecessary.

Proposal

8. Introduce the following new paragraph in Chapter 2.0:

"2.0.5 Transport of substances for pharmaceutical research and development

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

(a) this provision shall only apply to substances classified as Division 6.1, Packing Group I**,** II or III for oral or dermal toxicity based on available information and shall not meet any other criteria for classification as dangerous goods;

(b) the net quantity of substance under investigation per inner package shall be less than or equal to 0.2 g for solids or 0.2 ml for liquids. Substances under investigation may be held in a medium not subject to these Regulations;

(c) the aggregate quantity of substances under investigation per package shall not exceed 100 g or 100 ml.

(d) 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;

(e) 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 the substances. For solid substances, cushioning material need not be absorbent;

(f) each inner packaging shall be fitted with a closure securely held in place by positive means; and

(g) the outer package and an accompanying document shall include the name and telephone number of a person who can be contacted for information while the package is in transport.
