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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

Thirty-eighth session
Geneva, 29 November–7 December 2010
Item 4 of the provisional agenda
Listing, classification and packing

Used health care products

Transmitted by the expert from Switzerland[1]

Introduction

1. Hospitals, physicians, pharmacies and patients use diagnostic devices to determine numerous clinically relevant parameters in various biological materials. These devices have to be transported not only when new but also in a used condition, e.g. for major repair and maintenance work, for reasons of quality verification and also for final disposal at the end of their useful lives. These devices range from small pocket-size blood-sugar test devices to complex multi-modular electronic pieces of equipment of several cubic meters of volume. If properly prepared for transportation, these instruments present no infectious risk during the transport although the presence of infectious agents (e.g. hepatitis B or hepatitis C virus) in the innermost parts of these complex devices cannot be totally excluded. Transport of such devices as non-dangerous goods has therefore so far occurred in a grey zone of the transport regulations.

2. The United States have overcome this issue by a special derogation for so called "used health care products" (reference: CFR 49, Chapter 173.134), a term that also includes diagnostic devices. In analogy to these regulations that have proven valuable in everyday practice, we submit the following proposals.

3. For land transport in Europe, the RID and the ADR have also a derogation to their rules in 1.1.3.1 (b).

[1] In accordance with the programme of work of the Sub-Committee for 2009-2010 approved by the Committee at its fourth session (refer to ST/SG/AC.10/C.3/68, para. 118 (b) and ST/SG/AC.10/36, para. 14).

4. No harmonized solution exists for the time being. The following proposals intend to bring an harmonized rule for such necessary transports.

Proposals

5. Add the following definition in 2.6.3.1:

"*Used health care product* means a medical, diagnostic, or research device or piece of equipment, or a personal care product used by consumers, medical professionals, or pharmaceutical providers that does not meet the definition of a diagnostic specimen, biological product, or regulated medical waste. It can be contaminated with potentially infectious body fluids or materials, and is not decontaminated or disinfected to remove or mitigate the infectious hazard prior to transportation.".

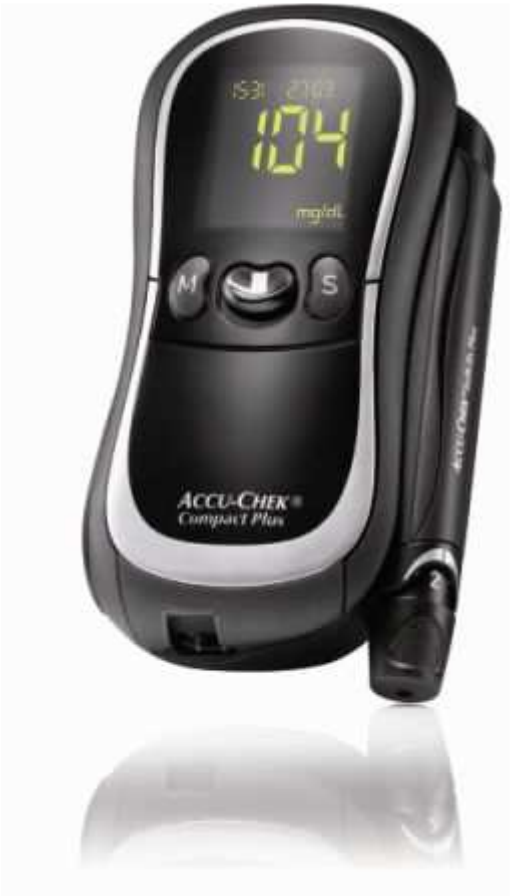
6. Add the following paragraph in 2.6.3.2.3 (Exemptions):

"2.6.3.2.3.x Used health care products are exempted from these Regulations if they have been drained of free liquid and have been decontaminated or disinfected to remove or mitigate the infectious hazard prior to transportation. Small diagnostic devices for single-patient use (e.g. devices for monitoring the blood sugar) need not to be treated by a disinfectant if they are completely free of liquid and show no visible contamination on their outsides.".

Annex

Examples of diagnostic devices

Pocketsize test device



Laboratory equipment