International Civil Aviation Organization

DGP-WG/16-WP/4
7/9/16

WORKING PAPER

DANGEROUS GOODS PANEL (DGP)
WORKING GROUP MEETING (DGP-WG/16)

Montreal, 17 to 21 October 2016

Agenda Item 2: Development of recommendations for amendments to the *Technical Instructions for the Safe Transport of Dangerous Goods by Air (Doc 9284) for incorporation in the 2019-2020 Edition*

2.1: Part 1 — General

PHARMACEUTICAL PRODUCTS (MEDICINES) READY FOR USE

(Presented by the European Chemical Industry Council – CEFIC)

SUMMARY

This working paper recommends that pharmaceutical products (medicines) ready for use, which are substances manufactured and packaged for retail sale or distribution for personal or household consumption, which are assigned to defined UN numbers, are not subject to the Technical Instructions.

Action by the DGP-WG: The DGP is invited to consider a new Special Provision AXXX for pharmaceutical products (medicines) ready for use, which are substances manufactured and packaged for retail sale or distribution for personal or household consumption in Part 3 of the Technical Instructions as shown in the appendix to this paper.

1. INTRODUCTION

1.1 Pharmaceutical products (medicines) ready for use, which are substances manufactured and packaged for retail sale or distribution for personal or household consumption are not subject to the European Dangerous Goods Regulations for road transport — ADR (European Agreement Concerning the international Carriage of Dangerous Goods by Road — ADR), rail — RID (European Agreement Concerning the international Carriage of Dangerous Goods by Rail) and inland-waterways — ADN (European Agreement Concerning the international Carriage of Dangerous Goods by Inland Waterways). This exemption is implemented by Special provision (SP) 601 which reads as follows:

> Pharmaceutical products (medicines) ready for use, which are substances manufactured and packaged for retail sale or distribution for personal or household consumption are not subject to the requirements of ADR/RID/ADN.

1.2 Special Provision 601 is assigned to Packaging Groups II and III of the following UN numbers:

UN 1169 **Extracts, aromatic, liquid**
UN 1170 **Ethanol or Ethanol solution**
UN 1197 **Extracts, flavouring, liquid**
UN 1204 **Nitroglycerin solution in alcohol**
UN 1219 **Isopropanol**
UN 1293 **Tinctures, medicinal**
UN 1851 **Medicine, liquid, toxic, n.o.s.**
UN 1987 **Alcohols, n.o.s.**
UN 1993 **Flammable liquid, n.o.s.**
UN 3077 **Environmentally hazardous substance, solid, n.o.s.**
UN 3082 **Environmentally hazardous substance, liquid, n.o.s.**
UN 3175 **Solids containing flammable liquid, n.o.s.**
UN 3243 **Solids containing toxic liquid, n.o.s.**
UN 3248 **Medicine, liquid, flammable, toxic, n.o.s.**
UN 3249 **Medicine, solid, toxic, n.o.s.**
UN 3272 **Esters, n.o.s.**

1.3 Pharmaceutical products (medicines) for retail sale or distribution for personal or household consumption are usually shipped in combination packagings as blistered tablets or as liquids or solids packed in primary (inner) receptacles with few millilitres or grams content. The primary (inner) receptacles are packed in a secondary (intermediate) packaging used as distribution units. For shipping, the secondary packagings are packed in a tertiary packaging (shipping box).

1.4 It is recommended that such products be excepted from the Technical Instructions.

1.5 **Justification**

1.5.1 The UN hazard classes represented by the UN-numbers listed in paragraph 1.2 are Class 3 (flammable liquids), Division 4.1 (flammable solids), Division 6.1 (toxic substances) and Class 9 (in this case only environmentally hazardous substances). Packaging groups represented are Packing Group II — medium danger and Packing Group III — low danger.

1.5.2 Using De Minimis exceptions according to the Technical Instructions, Part 3;5.6 is limited to 1 g or 1 mL per primary (inner) packaging, which is not applicable in many cases. As well, using excepted quantities according to the Technical Instructions, Part 3;5 is in many cases (e.g. Code E4 assigned to UN 3249 PG II) limited to 1 g or 1 mL per primary (inner) packaging and therefore not applicable.

1.5.3 In practice, GMP and clean room requirements exclude some materials as packaging material from being used in clean room areas (e.g. fibreboard). This requires additional manual repackaging steps outside the filling area to pack primary (inner) receptacles into the secondary (intermediate) and tertiary, UN-approved outer packagings.

1.5.4 Environmentally hazardous substances (UN 3077 and UN 3082) in combination packaging containing a net quantity per inner packaging of 5 L or less for liquids or having a net mass of 5 kg or less for solids can be shipped largely exempted from the Technical Instructions by applying Special Provision A197.

1.5.5 An aqueous solution containing 24% or less alcohol by volume is not subject to the Instructions (Special Provision A58, assigned to UN 1170 Ethanol solution).

1.5.6 ID 8000 (Consumer Commodity) and related Packaging Instruction Y963 are intended for primary (inner) packagings up to 500 mL. Additionally, some Class 2 substances are covered by ID 8000, which are not in the scope of Special Provision AXXX.

1.5.7 Liquid or solid pharmaceutical products are packed in primary (inner) receptacles with a capacity of approximately 2 to 20 mL, further packed in secondary and tertiary packagings.

1.5.8 Tablets or capsules, blistered and further packed in secondary and tertiary packagings, do not pose a risk to passengers, crew or staff. These substances are produced and intended for application to humans. Even if, in case of an accident, the tertiary and secondary packaging would be ruptured, release of substantial amounts of the content and oral, dermal or inhalative admission are very unlikely.

2. ACTION BY THE DGP-WG

2.1 The DGP-WG is invited to introduce a new Special Provision AXXX as shown in the appendix to this working paper.

2.2 Assignment to UN-numbers:

Assign Special provision AXXX to the following entries in the Dangerous Goods List (Table 3-1):

UN 1169 **Extracts, aromatic, liquid**
UN 1170 **Ethanol or Ethanol solution**
UN 1197 **Extracts, flavouring, liquid**
UN 1204 **Nitroglycerin solution in alcohol**
UN 1219 **Isopropanol**
UN 1293 **Tinctures, medicinal**
UN 1851 **Medicine, liquid, toxic, n.o.s.**
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APPENDIX

PROPOSED AMENDMENT TO PART 3 OF THE TECHNICAL INSTRUCTIONS

Part 3

DANGEROUS GOODS LIST, SPECIAL PROVISIONS AND LIMITED AND EXCEPTED QUANTITIES

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Chapter 3

SPECIAL PROVISIONS

Parts of this Chapter are affected by State Variations AE 3, AU 1, AU 2, CA 7, HR 3, IR 3, JM 1, KP 2, MO 2, NL 1, US 11, ZA 1; see Table A-1

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Table 3-2. Special provisions

TIs	*UN*	
AXXX		Pharmaceutical products (medicines) of Packaging Group II and III, ready for use, which are substances manufactured and packaged for retail sale or distribution for personal or household consumption are not subject to these regulations. The words “Pharmaceutical products (medicines) in compliance with Special provision AXXX” must be included on the air waybill, when an air waybill is used. The information should be shown in the “Nature and Quantity of Goods” box of the air waybill.

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