International Civil Aviation Organization

DGP-WG/26-WP/27
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WORKING PAPER

DANGEROUS GOODS PANEL (DGP) WORKING GROUP MEETING (DGP-WG/26)

Centurion, South Africa, 26 to 30 October 2026

Agenda Item 3: Facilitating safe transport of dangerous goods by air (Ref: REC-A-DGS-2029)

ADDITION OF A SPECIAL PROVISION FOR FINISHED PHARMACEUTICAL PRODUCTS

(Presented by B. Firkins)

SUMMARY

This working paper proposes the creation of a special provision to facilitate the transport of finished pharmaceutical products; and to be applied against UN 1293, 1851, 3248, 3249.

Action by the DGP-WG is in paragraph 2.

1. INTRODUCTION

1.1 At the 2016 DGP Working Group Meeting (DGP-WG/16, 17 to 21 October 2016), the European Chemical Industry Council (CEFIC) proposed a new special provision to exempt pharmaceutical products (medicines) ready for use from the Technical Instructions, mirroring SP 601 in the Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) (see paragraph 3.2.3.1 of the DGP-WG/16 report). That proposal did not progress and was not carried forward to the twenty-sixth meeting of the Dangerous Goods Panel (DGP/26, 17 to 27 October 2017). The proposal rested largely on the argument that the European dangerous goods regulations for transport by road, rail or inland-waterways (ADR/RID/ADN) already applied the special provision against sixteen UN numbers to exempt these goods. While a number of comparisons were made to other classes/divisions/entries with higher volume limitations the proposal and proposed text was relying on a packaging-based rationale that did not transfer well to the more restrictive volumes permitted in aviation. Volumes could be larger than that permitted by excepted quantity provisions when considering the full range of sixteen proper shipping names.

1.2 Additionally, a number of the entries in ADR SP 601 (for example ethanol, isopropanol, esters and the environmentally hazardous n.o.s. entries) are broad chemical entries that have been assigned the provision and raises a risk of misuse by potentially allowing consignments of generic solvents and chemical n.o.s. entries to operate under the special provision.

1.3 The paper sets out a rationale for permitting finished pharmaceuticals across four specific UN numbers in quantities not exceeding the excepted quantity limits; and to also not require any additional documentation.

1.4 Many existing finished product pharmaceuticals, being transported from manufacturer and distribution, are eligible for transport under the excepted quantity provisions. Such pharmaceutical products present no risk to personnel during the normal course of air transport yet add significant costs and transport restrictions without delivering any safety benefit. Unit-dose tablets or liquid dose capsules, contained in blister packs and further packed in secondary and tertiary packagings, do not pose a risk to personnel, crew or the aircraft. These substances are produced and intended for application to humans. An accident in which the tertiary, secondary and inner packagings are ruptured, would still not result in the release of substantial amounts of the content; therefore oral, dermal or inhalation admission remains unlikely.

1.5 Finished pharmaceutical supply chains operate through distribution centres that routinely perform pick-and-pack activities for both scheduled and time-critical deliveries. At the point of order fulfillment, the final transport mode is not always known and may subsequently change from road to air, or vice versa, in response to operational requirements or urgent patient needs. Under the current regulatory framework, shipments transported by air may require dangerous goods marks, labels and associated documentation, while the same products may move under ADR Special Provision 601 without corresponding dangerous goods marks when transported by road.

1.6 This creates additional complexity within multimodal distribution networks, particularly where products are selected, packed and staged before a final routing decision is made; and where, for certain pharmaceuticals, considering the standard of packaging that has been applied, there is no risk to personnel or property during the transport chain.

1.7 A dedicated provision for certain finished pharmaceuticals of very small quantities would provide a consistent approach across transport modes, better reflecting modern pharmaceutical distribution practices while maintaining the existing safety controls achieved through good manufacturing practice (GMP) qualified packaging systems.

UN No.	Proper shipping name (ADR 2025)	Class	PG (SP 601)
1293	Tinctures, medicinal	3	II, III
1851	Medicine, liquid, toxic, n.o.s.	6.1	II, III
3248	Medicine, liquid, flammable, toxic, n.o.s.	3 (6.1)	II, III
3249	Medicine, solid, toxic, n.o.s.	6.1	II, III

1.8 Pharmaceuticals meeting the criteria for classification in Packing Group I are intentionally excluded. This limitation reflects the greater potential hazard associated with Packing Group I substances and ensures that the proposal remains focused on finished pharmaceutical products presenting a lower transport risk and already subject to extensive GMP packaging, quality and distribution controls. The exclusion of Packing Group I substances supports the proportionate and narrowly targeted nature of the proposal

1.9 Volumes per finished pharmaceutical are as per maximum quantity limits per inner and outer packaging aligned with the quantities currently accepted under the excepted quantities provisions of the Technical Instructions. These limits provide a conservative and internationally recognized upper boundary while recognizing that finished pharmaceuticals in approved final distribution packaging

present a substantially lower transport risk than the dangerous goods for which the excepted quantities provisions were originally developed.

1.10 The proposed quantities should be viewed as a risk boundary rather than a transport condition. The purpose of the special provision is to remain focused on small-volume finished pharmaceutical products in final distribution packaging. The combination of qualified GMP packaging, small primary receptacles, multiple levels of packaging protection and restricted shipment quantities provide a robust and proportionate safety framework found in drug manufacturing and finishing frameworks (such as the US FDA with 21 CFR Part 211 and the EU EudraLex Volume 4 GMP guidelines for medicinal products for human use), exceed the standard of packaging for excepted quantities and so an EQ mark is not considered necessary.

1.11 As these are commercially generated finished medicines, in final retail packagings for consumer consumption, it is intentional that the proposal does not require the addition of a statement on the air waybill regarding the application of the special provision. Requiring a statement would provide no value to personnel in the supply chain and only introduce compliance costs.

2. ACTION BY THE DGP-WG

2.1 The DGP-WG is invited to provide their views on the creation of a special provision for assignment to four entries in the dangerous goods list, as presented in the appendix to this working paper.

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APPENDIX

AMENDMENTS TO THE TECHNICAL INSTRUCTIONS

Part 3

DANGEROUS GOODS LIST, SPECIAL PROVISIONS AND LIMITED AND EXCEPTED QUANTITIES

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Chapter 2

ARRANGEMENT OF THE DANGEROUS GOODS LIST (TABLE 3-1)

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Table 3-1. Dangerous Goods List

Name	*UN No.*	*Class or division*	*Sub-sidiary hazard*	*Labels*	*State varia-tions*	*Special provi-sions*	*UN packing group*	*Excepted quantity*	*Passenger and cargo aircraft*		*Cargo aircraft only*	
									Packing instruction	*Max. net quantity per package*	*Packing instruction*	*Max. net quantity per package*
1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*
Tinctures, medicinal	1293	3		Liquid flammable		A3 A2XX	II III	E2 E1	353 Y341 355 Y344	5 L 1 L 60 L 10 L	364 366	60 L 220 L
Medicine, liquid, toxic, n.o.s.	1851	6.1		Toxic		A3 A2XX	II III	E4 E1	654 Y641 655 Y642	5 L 1 L 60 L 2 L	662 663	60 L 220 L
Medicine, liquid, flammable, toxic, n.o.s.	3248	3	6.1	Liquid flammable & Toxic		A3 A80 A2XX	II III	E2 E1	352 Y341 355 Y343	1 L 1 L 60 L 2 L	364 366	60 L 220 L
Medicine, solid, toxic, n.o.s.	3249	6.1		Toxic		A3 A2XX	II III	E4 E1	669 Y644 670 Y645	25 kg 1 kg 100 kg 10 kg	676 677	100 kg 200 kg

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Chapter 3

SPECIAL PROVISIONS

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Table 3-2. Special provisions

TIs	*UN*	
A2xx		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 these Instructions provided the quantities per package do not exceed the maximum allowed quantities for excepted quantities as determined by the applicable excepted quantity code.

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