

## Economic Commission for Europe

### Inland Transport Committee

#### Working Party on the Transport of Dangerous Goods

101st session

Geneva, 8–11 November 2016

Item 6 of the Provisional agenda

**Interpretation of ADR**

10 October 2016

### Define the scope of the special provision 601 of chapter 3.3

Transmitted by the Government of Switzerland

#### *Summary*

**Executive summary:** The scope of the SP601 should be better defined in order to avoid misunderstandings. Does this SP also apply to medicines intended for retail sale or distribution for personal or household even if these medicines are not yet carried in the final packaging? For example by consignments between the production plant to the packing site?

**Action to be taken:** .

**Background documents:**

#### **Introduction**

1. Recently we have been confronted with the question of interpretation of the scope of the special provision 601.

2. The 1999 edition of RID/ADR contained a NOTE both in Class 3, marginal (2)301 under items 19° and 32° and in Class 6.1, marginal (2)601 under item 90°. This NOTE read as follows:

«Pharmaceutical products ready for use, e.g. cosmetics, drugs and medicines, which are substances manufactured and packed in packagings of a type intended for retail sale or distribution for personal or household consumption, which would otherwise be substances of item xx°, are not subject to the provisions of RID/ADR.»

This wording remain intact until the 2007 edition of ADR.

3. Following a German proposal in document TRANS/WP.15/AC.1/2004/4 and informal document INF.30 of the RID-ADR session from September 2004 the texts were proposed to be adapted as follows:

601 Pharmaceutical products (medicines) ready for use, which are substances manufactured and packed in packagings of a type intended for retail sale or distribution for personal or household consumption are not subject to the requirements of RID/ADR/ADN.»

In the final report of this session however the text adopted was slightly different and reproduces the actual wording of the SP601 in ADR but no explanation of this change appears in the report of this session:

601 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 RID/ADR/ADN.”

4. From the original wording we observe that the words “in packaging of a type” have been deleted in the final version.

Some people interpret this deletion as meaning that the exemption of SP601 does not only apply to Pharmaceutical products (medicines) packed in packagings intended for retail sale or distribution but also to pharmaceutical products (medicines) not packed in packagings but which are still “intended for sale or distribution”.

6. However in contradiction to this interpretation a multilateral agreement M287 seems to presuppose that at least in case of wastes, the SP601 only shall apply in presence of packagings of a type intended for retails or distribution.

#### “2.3 Medicines

Special provision 601 of Chapter 3.3 of ADR shall also apply to wastes of medicines if they are no longer packed in packagings of a type intended for retail sale or distribution.”

This text would imply that, even without mentioning it in the SP601, this special provision only shall apply for medicines packed in packagings of a type ready for use. The exemption would thus not apply for consignments of blister packs of pills in big amounts between production plants and packing sites where the preparation of the final packaging of small boxes and documents for use for the consumer is performed. This only because those blisters are not contained in the final packaging as it appears in the chemist shop.

7. We are interested to know the opinion of the delegates of the WP.15 about the right interpretation of the SP601. This means, it should be answered to the question if the exemption in SP601 applies also for medicines as long as they are intended for retail sale or distribution even in the case that those medicines are not carried in the final packaging. That is for example, before they are introduced in the final packaging with all the information for the users, consigned from a production plant at a packing plant where the packaging will be performed.

8. If this would be the sense of the mentioned deletion in the ADR20107 it would probably be necessary to add explanatory text in the SP601 in order to avoid misunderstandings. This could be done for the next meeting of the RID-ADR-AND in March.

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