Bundesverband Deutscher Krankenhausapotheker e.V.

DEUTSCHE KRANKENHAUS GESELLSCHAFT

Bundesverband der Krankenhausträger in der Bundesrepublik Deutschland

Position Paper

of the German Hospital Federation (DKG) and the Federal Association of Hospital Pharmacies (ADKA)

on the

Implementation of the European Commission Delegated Regulation (EU) 2016/161 for safety features appearing on the packaging of medicinal products in hospitals

March 15th, 2017

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Summary

By publishing the Delegated Regulation (EU) 2016/161 on 9th February 2016, the European Commission laid down detailed rules for the safety features appearing on the packaging of medicinal products for human use. The German Hospital Federation (DKG – Deutsche Krankenhausgesellschaft) and the Federal Association of Hospital Pharmacies (ADKA – Bundesverband Deutscher Krankenhausapotheker) are strongly supportive for measures to enhance the protection against counterfeit medicines. However, the implementation of the Delegated Regulation does not contribute to this aim in the hospital sector. In fact, hospitals are facing insolvable problems. Therefore, an adaption of the Delegated Regulation seems inevitable.

Hospital pharmacies in over 90 percent of the cases directly purchase medicines directly from the manufacturer. Thus, a supply chain where counterfeit medicines potentially could be channelled in does not exist and the comprehensive vigilance system cannot provide any effect. The additional bureaucratic burden for hospitals is unjustified in these cases.

The detailed rules in the Delegated Regulation are tailored for the disposal of single packages by public pharmacies and cannot be matched by hospitals as the processes there are not comparable to public pharmacies. Major differences are especially the direct supply by manufacturers to hospitals and the logistic requirements for large bulks of drugs in hospitals. In big hospital pharmacies, up to 5 million drug packages yearly are admitted. In the future, they would have to be checked and verified individually. This would cause an unjustified burden for hospitals without the protection against counterfeit medicines would be enhanced.

It is problematic, that with February 2019 drugs only can be dispensed after verification even they were directly purchased from the manufacturer. Thus the supply of patients in hospitals with drugs could be seriously endangered and hospital pharmacies only could be operated with disproportionate efforts. This is contrary to all endeavours of hospitals to ensure the provision with drugs for the patients at the highest level.

Therefore, a rapid adaption of the Delegated Regulation seems inevitable. The special circumstances of the provision of drugs in hospitals must be considered. There must be installed exemptions from the verification system requested by the Delegated Regulation for the cases in which a manufacturer directly supplies hospitals with drugs.

This finally would lead to a situation in which hospitals would be obliged to verify safety features of drugs where this can enhance the protection against counterfeit medicines but would not apply for those cases in which no added value would be realised.

Detailed Comments

Amendment of Delegated Regulation (EU) 2016/161

In principle, the Delegated Regulation demands the installation of a technically complex end-to end verification system, with which the authenticity of a medicinal product can be confirmed. All drug packages should be verified at the beginning of the supply chain (the manufacturer) and at its end (in hospitals and public pharmacies), complemented by risk based verifications of wholesalers. The impact assessment of the European Commission expects one billion Euros of investment costs for the instalment of the verification system for the pharmaceutical industries and another one billion Euros annually for the running costs for all involved parties.

The Delegated Regulation just applies the detailed verification procedures which have been tailored to public pharmacies to hospitals without taking into consideration the specialities of the latter's' pharmacies, like e.g. the direct supply of the manufacturer to the hospitals and the handling of bulk amounts of drug packages in the hospital pharmacies.

The Delegated Regulation thus should be concretely amended in Article 26, adding the direct and secure supply as an additional element of derogation from Article 25. Additional, Article 23 should be amended by clarifying, that in cases of direct supply, the unique identifier should be deactivated at the time of supplying it to the public.

As such, the special circumstances in supply chains in Member States could be respected and would help realising the aim provided by Recital 25 of the Delegated Regulation:

„In order to avoid an excessive impact on the daily operations of healthcare institutions, it should be possible for the Member States to allow persons authorised or entitled to supply medicinal products to the public operating within healthcare institutions to perform the verification of the authenticity and the decommissioning of a unique identifier earlier than the time the medicinal products is supplied to the public, or exempt them from such an obligation, subject to certain conditions."

With this it would be assured that hospitals would be obliged to verify safety features of drugs where this can enhance the protection against counterfeit medicines such as supply by wholesalers or parallel imports and all supply chains, in which counterfeit drugs could potentially be channelled in. But the need for verification would not apply for those cases in which no added value would be realised as in the cases of direct supply by the manufacturers to the hospitals.

Concrete proposals for amendment (marked in bold):

Article 23 of the Delegated Regulation (EU) 2016/161

A new paragraph 2 should be added:

„2. Member States may require, where necessary to accommodate the particular characteristics of the supply chain on their territory, that a manufacturer verifies the safety features and decommissions the unique identifier of a medicinal product before he supplies that medicinal product directly to a healthcare institution."

Article 26 of the Delegated Regulation (EU) 2016/161

Amending paragraph 3:

„3. Notwithstanding Article 25, Member States may decide, where necessary to accommodate the particular characteristics of the supply chain on their territory, to exempt a person authorised or entitled to supply medicinal products to the public operating within a healthcare institution from the obligations of verification and decommissioning of the unique identifier, provided that ***the healthcare institution directly purchased the medicinal product from the manufacturer. This exemption applies also if*** *the following conditions are met:*

(a) the person authorised or entitled to supply medicinal products to the public obtains the medicinal product bearing the unique identifier through a wholesaler belonging to the same legal entity as the healthcare institution;

(b) the verification and decommissioning of the unique identifier is performed by the wholesaler that supplies the product to the healthcare institution;

(c) no sale of the medicinal product takes place between the wholesaler supplying the product and that healthcare institution;

(d) the medicinal product is supplied to the public within that healthcare institution."