CALL FOR THE USE OF DIGITAL DELIVERY DOCUMENTATION

Position Paper

The European Union has a high priority for furthering the digital economy. The Digital Single Market is a Juncker Commission's top priority[1]. This also applies for delivery documentation in the scope of the EU regulatory framework for medicinal products.

Article 82 of Directive 2001/83/EC, as amended,[2] provides:

For all supplies of medicinal products delivered to a person authorized or entitled to supply medicinal products to the public, the supplying authorized wholesale distributor must enclose a document, which makes it possible to ascertain:

— the date,
— the name and pharmaceutical form of the medicinal product,
— the quantity supplied,
— the name and address of the supplier and consignor,
— the batch number of the medicinal products at least for products bearing the safety features referred to in point (o) of Article 54;

Member States shall take all appropriate measures to ensure that persons authorized or entitled to supply medicinal products to the public are able to provide information that makes it possible to trace the distribution path of every medicinal product.

The Directive asks that a document be enclosed with supplies, which makes it possible to ascertain certain information about the delivery, however it does not prescribe that the information must be explicitly mentioned on the document enclosed. The enclosed document should allow one to find out the necessary information.

Chapter 5.8 of the European Commission guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use[3] provides:

> *For all supplies, a document (e.g. delivery note) must be enclosed stating the date; name and pharmaceutical form of the medicinal product, batch number at least for products bearing the safety features; quantity supplied; name and address of the supplier, name and delivery address of the consignee (actual physical storage premises, if different) and applicable transport and storage conditions. Records should be kept so that the actual location of the product can be known.*

[1] European Commission Press Release, Digital Single Market: Commission calls for swift adoption of key proposals and maps out challenges ahead

[2] DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011.

[3] European Commission Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01)

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However, the General Documentation provisions of the European Commission Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use) provide in Chapter 4.2 para 9 and 10 that records must be kept either in the form of purchase/sales invoices, delivery slips, or on computer or any other form, for any transaction in medicinal products received, supplied or brokered and must include at least the following information: date; name of the medicinal product; quantity received, supplied or brokered; name and address of the supplier, customer, broker or consignee, as appropriate; and batch number at least for medicinal products bearing safety features.

To date, wholesalers in most countries are asked by authorities to enclose paper documentation to provide information such date; name and pharmaceutical form of the medicinal product, *batch number at least for products bearing the safety features* (applicable as of 9th February 2019 for products carrying safety features).

This paper would like to underline that the European GDP Guidelines already allows for any form for the record to be provided as it indeed has the aim to reduce paper consumption and to use digital means which offer advanced capabilities in terms of documentation, support control and archiving. Moreover, it is anticipated that digitalisation will become common business practice, bring efficiency gains, and become part of corporate social responsibility, with the aim to reduce waste, costs and to develop environmental friendly policies.

European pharmaceutical full-line wholesalers deliver daily more than 33 million packs[4] in a matter of hours. Providing the above-mentioned information for all medicines on paper would cause additional, extensive organisational changes, due to the necessity to reconfigure the warehouse (systems, procedures, layout) without any improvement in security, thereby losing the advantages of digitalisation.

Companies would need to modify their IT infrastructure, as well as invest in high-output printers at the end of the order preparation process for delivery, involving a costly adaptation of the conveying equipment. These expenses will not be compensated by any additional benefits as information such as the batch number[5] delivered on paper cannot be easily or sensibly processed further by pharmacies or other wholesale distributors.

GIRP therefore highlights the added-value benefits of electronic transmission of information on medicinal products supplied to the consignor and asks for a direct application of Chapter 4.2 para 9 and 10 by the Member States for all provided records. This is already common practice in Spain and Finland and complies with modern business practices as well as with the Corporate Social Responsibility approach that the European Commission recognizes as important for the sustainability, competitiveness and innovation of enterprises in the EU economy.

Pharmaceutical full-line wholesalers are convinced of the necessity to provide accompanying electronic documentation with every delivery to ensure that customers' orders can be fully identified. Transmission of information on paper is outdated and inefficient, especially in view of increasing digitalisation in the economy, which includes the healthcare sector.

[4] European wholesalers deliver to 180 000 dispensing points with an average frequency of 2,2 deliveries/day every day. Including a hard copy delivery note in each delivery, currently results in a stack of paper higher than an average 10 story residential building being wasted per day, every day.
[5] Article R5124-58 of the French Public Health Code

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