SEP. 22

INFORMATIVE NOTE

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

Labelling requirements for unauthorised investigational and auxiliary medicinal products

Regulation (EU) 536/2014 of the Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use introduced additional requirements for the labelling of investigational and auxiliary medicinal products, in particular, for unauthorised medicinal products, in order to eliminate divergences in approach among Member States. In particular, it introduced the obligation to indicate the expiry date of unauthorised investigational and auxiliary medicinal products on both the outer packaging and on the immediate packaging, without any exception.

The impossibility of omitting the expiry date from the labelling of the immediate packaging under any circumstances, including when the inner packaging is too small or is always used together with the outer packaging, had several disadvantages. First of all, it could entail an increased risk to the quality and safety of clinical trials, for example, if it resulted in prolonged and repeated exposure of sensitive medicinal products to variations in light or temperature, or if it required the disintegration of medicinal products. Moreover, such an obligation could lead to unnecessary complexity in the process of supplying medicinal products and thus result in delays in organising and conducting clinical trials.

This Proposal provides for the possibility to omit the label on immediate packaging where this takes the form of blister packs or units (e.g., ampoules) or is intended to remain next to the outer packaging

Against this background, this Proposal provides for the possibility to omit the label on immediate packaging where this takes the form of blister packs or units (e.g., ampoules) or is intended to remain next to the outer packaging. In these cases, it was considered appropriate and proportionate to the nature and extent of the risk for the expiry date to be omitted from the immediate packaging because the legal obligation to include this information on the outer packaging remains in place.

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Member States have expressed strong support for this amendment through the CTCG, and the draft text reflects the comments of this group.

Member States have expressed strong support for this amendment through the Clinical Trials Coordination and Advisory Group ("CTCG), and the draft text reflects the comments of this group.

If adopted, this amendment will enter into force on the twentieth day following its publication in the Official Journal of the European Union. In this context, it should be recalled that the Clinical Trials Regulation itself only came into force on 31 January 2022, as explained in the February 2022 Information Note. ■

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