Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (Text with EEA relevance)

COMMISSION DELEGATED REGULATION (EU) 2016/161

of 2 October 2015

supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[(1)], and in particular Article 54a(2) thereof,

Whereas:

(1) Directive 2001/83/EC, as amended, provides for measures to prevent the entry into the legal supply chain of falsified medicinal products by requiring the placing of safety features consisting of a unique identifier and an anti-tampering device on the packaging of certain medicinal products for human use for the purposes of allowing their identification and authentication.

(2) Diverging authentication mechanisms for medicinal products based on different national or regional traceability requirements may limit the circulation of medicinal products across the Union and increase costs for all players in the supply chain. It is therefore necessary to establish Union-wide rules for the implementation of the safety features for medicinal products for human use, with particular regard to the characteristics and technical specifications of the unique identifier, the modalities for the verification of the safety features, and the establishment and management of the repository system containing information on the safety features.

(3) In accordance with Article 4 of Directive 2011/62/EU of the European Parliament and of the Council[(2)] and Article 54a(2) and (3) of Directive 2001/83/EC, the Commission has assessed the benefits, costs and cost-effectiveness of different policy options for the characteristics and technical specifications of the unique identifier, the modalities for the verification of the safety features and the establishment and management of the repository system. The policy options identified as the most cost-effective have been introduced as core elements of this Regulation.

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(4) This Regulation sets out a system where the identification and the authentication of medicinal products is guaranteed by an end-to-end verification of all medicinal products bearing the safety features, supplemented by the verification by wholesalers of certain medicinal products at higher risk of falsification. In practice, the authenticity and integrity of the safety features placed on the packaging of a medicinal product at the beginning of the supply chain should be verified at the time the medicinal product is supplied to the public, although certain derogations may apply. However, medicinal products at higher risk of falsification should be additionally verified by wholesalers throughout the supply chain, to minimise the risk of falsified medicinal products circulating undetected for lengthy periods of time. The verification of the authenticity of a unique identifier should be performed by comparing that unique identifier with the legitimate unique identifiers stored in a repositories system. When the pack is supplied to the public, or is distributed outside the Union, or in other specific situations, the unique identifier on that pack should be decommissioned in the repositories system so any other pack bearing the same unique identifier could not be successfully verified.

(5) It should be possible to identify and verify the authenticity of an individual pack of a medicinal product for the entire time the medicinal product stays on the market and the additional time necessary for returning and disposing of the pack after it has expired. For this reason, the character sequence resulting from the combination of the product code and the serial number sequence should be unique to a given pack of a medicinal product until at least one year after the expiry date of that pack or five years after the product has been released for sale or distribution in accordance with Article 51(3) of Directive 2001/83/EC, whichever is the longer period.

(6) The inclusion of the product code, the national reimbursement and identification number, the batch number and expiry date in the unique identifier contributes to patient safety by facilitating recall, withdrawal and return procedures and pharmacovigilance in this sector.

(7) In order to have a negligible probability that a serial number can be guessed by falsifiers, the serial number should be generated according to specific randomisation rules.

(8) Compliance with certain international standards, while not mandatory, can be used as proof that certain requirements of this Regulation are fulfilled. Where it is not possible to prove compliance with international standards, it should be the responsibility of the persons to whom the obligations are addressed to prove, by verifiable means, that they comply with those requirements.

(9) The unique identifier should be encoded using a standardised data structure and syntax so that it can be correctly recognised and decoded throughout the Union by commonly-used scanning equipment.

(10) The global uniqueness of the product code not only contributes to the unambiguity of the unique identifier but also facilitates the decommissioning of a unique identifier when this operation takes place in a Member State different from the Member State where the medicinal product was initially intended to be placed on the market. A product code

which conforms to certain international standards should be presumed to be globally unique.

(11) To facilitate the verification of the authenticity and decommissioning of a unique identifier by wholesalers and persons authorised or entitled to supply medicinal products to the public, it is necessary to ensure that the structure and printing quality of the two-dimensional barcode encoding the unique identifier allow for high-speed reading and minimisation of reading errors.

(12) The data elements of the unique identifier should be printed on the packaging in human-readable format so to allow the verification of the authenticity of the unique identifier and its decommissioning in case the two-dimensional barcode is unreadable.

(13) A two-dimensional barcode can store more information than the data elements of the unique identifier. It should be possible to use that residual storage capacity to carry further information and avoid the placing of additional barcodes.

(14) The presence of multiple two-dimensional barcodes on the packaging can engender confusion with regard to which barcode should be read for the purpose of verifying the authenticity of and identifying a medicinal product. This may lead to mistakes in the verification of the authenticity of medicinal products and to falsified medicinal products being inadvertently supplied to the public. For this reason, the presence of multiple two-dimensional barcodes on the packaging of a medicinal product for the purposes of identification and verification of the authenticity should be avoided.

(15) The verification of both safety features is necessary to ensure the authenticity of a medicinal product in an end-to end verification system. The verification of the authenticity of the unique identifier aims at ensuring that the medicinal product originates from the legitimate manufacturer. The verification of the integrity of the anti-tampering device shows whether the packaging has been opened or altered since it left the manufacturer, thereby ensuring that the content of the packaging is authentic.

(16) The verification of the authenticity of the unique identifier is a critical step to ensure the authenticity of the medicinal product bearing it and should only be based on the comparison with trusted information on the legitimate unique identifiers uploaded in a secure repositories system by verified users.

(17) It should be possible to revert the status of a unique identifier that has been decommissioned in order to avoid the unnecessary waste of medicinal products. It is however necessary to subject the reverting of the status to strict conditions to minimise the threat to the security of the repositories system that such operation could generate if abused by counterfeiters. Those conditions should apply regardless of whether the decommissioning operation took place at the moment of supply to the public or at an earlier point in time.

(18) Competent authorities should be able to access information on the safety features of a medicinal product while this product is in the supply chain or after it has been supplied to the public, recalled or withdrawn from the market. To this end, manufacturers should retain records of operations with or on the unique identifier of a given medicinal product after the identifier has been decommissioned from the repositories system for a

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minimum of one year after the expiry date of that medicinal product or five years after the pack has been released for sale or distribution in accordance with Article 51(3) of Directive 2001/83/EC, whichever is the longer period.

(19) Past incidents of falsification show that certain medicinal products, such as those returned by persons authorised or entitled to supply medicinal products to the public or wholesalers, or medicinal products distributed by persons who are neither the manufacturer nor a wholesaler holding the marketing authorisation nor a designated wholesaler, are at higher risk of being falsified. The authenticity of those medicinal products should therefore be subject to additional verifications by wholesalers throughout the supply chain to minimise the risk that falsified products entering the legal supply chain freely circulate in the Union territory until they are verified at the time of supply to the public.

(20) The verification by wholesalers of the authenticity of medicinal products at higher risk of being falsified would be equally effective whether performed by scanning individual unique identifiers or an aggregated code allowing the simultaneous verification of multiple unique identifiers. In addition, the verification could be performed at any time between the reception of the medicinal product by the wholesaler and its further distribution, to equal results. For those reasons, it should be left to the choice of the wholesaler whether to scan individual unique identifiers or aggregated codes, where available, or the timing of the verification, provided that the wholesaler ensures the verification of all unique identifiers of those products at higher risk of falsification in his physical possession, as required by this Regulation.

(21) In the complex Union supply chain, it may happen that a medicinal product changes ownership but remains in the physical possession of the same wholesaler, or that a medicinal product is distributed within the territory of a Member State between two warehouses belonging to the same wholesaler or the same legal entity, but no sale takes place. In those cases, the wholesalers should be exempted from performing a verification of the unique identifier as the risk of falsification is negligible.

(22) As a general principle, in an end-to-end verification system, the decommissioning of the unique identifier in the repository system should be performed at the end of the supply chain when the medicinal product is supplied to the public. Certain packs of medicinal products, however, may not eventually be supplied to the public and it is therefore necessary to ensure the decommissioning of their unique identifiers at a different point of the supply chain. This is the case of products which, inter alia, are to be distributed outside the Union, intended for destruction, requested as samples by competent authorities, or are returned products which cannot be returned to saleable stock.

(23) Although Directive 2011/62/EU introduced provisions to regulate the sale of medicinal products at a distance to the public and mandated the Commission to establish the modalities of verification of the safety features by persons authorised or entitled to supply medicinal products to the public, the supply of medicinal products to the public is still mostly regulated at national level. The end of the supply chain may be organised differently in the different Member States and involve specific healthcare professionals.

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It should be possible for the Member States to exempt specific institutions or persons authorised or entitled to supply medicinal products to the public from the obligation of verification of the safety features, in order to accommodate the particular characteristics of the supply chain in their territory and ensure that the impact of the verification measures on those parties is proportionate.

(24) The verification of the authenticity of a unique identifier is not only paramount to the authentication of a medicinal product but also informs the person performing the operation of whether that product is expired, recalled, withdrawn or indicated as stolen. Persons authorised or entitled to supply medicinal products to the public should verify the authenticity and decommission a unique identifier at the time the medicinal product is supplied to the public so to access the most up-to-date information concerning the product and avoid that products which are expired, recalled, withdrawn or indicated as stolen are supplied to the public.

(25) 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.

(26) In certain Member States, the persons authorised or entitled to supply medicinal products to the public are allowed to open a pack of a medicinal product in order to supply part of that pack to the public. It is therefore necessary to regulate the verification of the safety features and the decommissioning of the unique identifier in this specific situation.

(27) The effectiveness of an end-to-end verification system in preventing falsified medicinal products from reaching the public depends upon the systematic verification of the authenticity of the safety features and the subsequent decommissioning of the unique identifier of every supplied pack, so that that unique identifier cannot be re-used by traffickers. It is therefore important to ensure that such operations, should they not be performed at the time the medicinal product is supplied to the public due to a technical problem, are performed as soon as possible thereafter.

(28) An end-to-end verification system requires the setting up of a repositories system which stores, inter alia, the information on the legitimate unique identifiers of a medicinal product and can be queried for the purposes of verifying the authenticity of and decommissioning a unique identifier. This repositories system should be established and managed by the marketing authorisation holders, since they are responsible for placing the product on the market, and by the manufacturers of medicinal products bearing the safety features, since they bear the costs of the repositories system in accordance with Article 54a(2)(e) of Directive 2001/83/EC. However, wholesalers and persons authorised or entitled to supply medicinal products to the public should be entitled to participate to the establishment and management of the repositories system, should they wish to, as their daily work will depend upon the correct functioning of the repositories system. In addition, national competent authorities should be consulted in the setting