



Brussels, **XXX**  
delegated act safety features  
[...](2015) **XXX**

**COMMISSION DELEGATED REGULATION (EU) No .../..**

**of XXX**

**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)

## **EXPLANATORY MEMORANDUM**

### **1. CONTEXT OF THE DELEGATED ACT**

EU pharmaceutical legislation provides for a high level of public health protection through stringent rules guaranteeing the quality, safety and efficacy of the medicines circulating in the EU market. On 8 June 2011, the European Parliament and the Council adopted Directive 2011/62/EU<sup>1</sup>, amending Directive 2001/83/EC<sup>2</sup> on the Community code relating to medicinal products for human use, which strengthens public health protection by providing measures to fight the falsification of medicines even where there is no infringement of intellectual property rights.

Falsified medicines are medicines with false identity (e.g. name, composition), history (e.g. batch number) or source which are passed off as genuine, authorised products. Falsified medicines may contain ingredients, including active ingredients, which are of low quality or in the wrong dosage — either too high or too low. They can be a major health threat. Among the more severe incidents in the last few years, contaminated heparin — a blood thinner — has been connected to dozens of deaths worldwide in 2008, including in the US and in the EU.

Even though most incidents of falsification implicate originator medicines, falsifications of generic medicines have also been reported. Falsified medicines have been detected both in the legal (e.g. authorised pharmacies and wholesalers) and illegal (e.g. supplies from/to unauthorised internet sites) supply chain. Falsification affects both prescription and over-the-counter medicines. Products against sexual dysfunction, heartburn and cancer are among the medicines most targeted by traffickers.

Today, the medicine distribution chain is very complex and provides opportunities to traffickers to penetrate the legal supply chain and offer fake medicines to legal operators, despite the existing regulatory framework and its controls. The problem is that there are no obligatory technology solutions in place that effectively prevent falsified medicines from entering the legal supply chain.

To tackle this problem, Directive 2011/62/EU introduces obligatory 'safety features' (a unique identifier and an anti-tampering device) as part of the outer packaging of prescription medicinal products, although certain derogations apply. In particular, Directive 2011/62/EU places the Commission<sup>3</sup> under the obligation to adopt delegated acts setting out:

- (a) the characteristics and technical specifications of the unique identifier; the modalities for the verification of the safety features; the establishment and management of the repository system containing the unique identifiers;
- (b) the lists containing the medicinal products or product categories which, in the case of prescription medicines shall not bear the safety features, and in the case of non-prescription medicines shall bear the safety features, established according to the criteria defined in Article 54a(2)(b) of Directive 2001/83/EU, as amended;
- (c) the procedures for the notification of medicinal products by the national competent authorities to the Commission, as regards non-prescription medicinal products they

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<sup>1</sup> Directive 2011/62/EU of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of falsified medicinal products, OJ L 174, 1.7.2011, p.74.

<sup>2</sup> 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, OJ L 311, 28.11.2001, p. 67.

<sup>3</sup> Art. 54a(2) of Directive 2001/83/EC

judge to be at risk of falsification or medicinal products they deem not to be at risk, and a rapid system for evaluating and deciding on such notification.

Before adopting these delegated act, Article 4 of Directive 2011/62/EC requires the Commission to perform a study assessing benefits, costs and cost-effectiveness of:

- (a) the technical options for the unique identifier (i.e.: what will be the composition of the unique identifier and the format of the barcode holding it?);
- (b) the options for the extent of verification of the authenticity of the medicinal product bearing the safety features and the practical arrangements for such verification (i.e.: who will check the safety features and when?);
- (c) the technical options for establishing and managing the repository system (i.e.: who will establish and manage the repository system? Who will supervise it?)

To this end, the Commission conducted an impact assessment and published the results in an impact assessment report accompanying the present Delegated Regulation.

The options identified by the impact assessment as the most cost-effective constitute the core elements of this Delegated Regulation and are outlined below:

- (a) The composition, format and carrier of the unique identifier should be fully harmonised across the EU. The unique identifier should be placed in a 2D barcode and contain the product code, a serial number, the national reimbursement number (if requested by Member States), the batch number and the expiry date.
- (b) Medicine authenticity should be guaranteed by an end-to-end verification system supplemented by risk-based verifications by wholesalers. Medicines should be systematically verified before being supplied to the public (e.g. at pharmacy level). Medicines at higher risk of falsification (returned medicines or medicines not being distributed directly by manufacturers, marketing authorisation holders or people acting on their behalf) should additionally be checked at wholesaler level.
- (c) The repositories system containing the unique identifiers should be set up and managed by stakeholders. National competent authorities should however be able to access and supervise the repositories system.

In addition, due consideration was given to the particular characteristics of the supply chain in the Member States and to ensuring that the proposed rules are proportionate with regard the impact of the verification measures on actors in the supply chain.

Finally, in accordance with Article 54a(3) of Directive 2001/83/EC, measures were taken to guarantee the protection of personal data as provided for in Union law, the legitimate interests to protect information of a commercially confidential nature and the ownership and confidentiality of the data generated by the use of the safety features. It should be noted that the present Delegated Regulation does not require any personal data to be stored in the repositories system. The measures are rather preventative and ensure the protection of personal data in case users of the repositories (e.g.: pharmacists) should decide to use the repositories system for purposes which are outside the scope of this Delegated Regulation and involve the use/storage/handling of patient data in the repositories (e.g.: e-prescriptions).

It should be noted that the present Delegated Regulation does not set out the technical characteristics of the anti-tampering device since the Commission mandate, as delegated by the legislators, only covers the technical characteristics of the unique identifier.

The lists containing the medicinal products or product categories which, in the case of prescription medicines shall not bear the safety features, and in the case of non-prescription

medicines shall bear the safety features, were populated in consultation with the Member States and taking into account the risk of and the risk arising from falsification of the medicinal products in accordance with Article 54a(2)(b) of Directive 2001/83/EC, as amended.

## **2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT**

With a view to preparing this Delegated Regulation, the Commission has carried out extensive consultations with both internal and external interested parties.

An internal Inter-Service Steering Group was set up and met on 10 October 2011, 4 March 2013 and 10 June 2013. To gain additional expertise, there were close contacts with the European Medicines Agency on this file.

The Commission has consulted experts from the national competent authorities of all the Member States. An expert group on the delegated act on safety features for medicinal products for human use was set up and met nine times between December 2011 and March 2015. Member States largely agreed to harmonise the technical specifications and to coordinate the verification mechanism for the implementation of the safety features. Member States asked that the unique identifier should contain as much information as possible in particular batch number, expiry date and reimbursement number and should be readable by electronic means. Member States also stressed the need for a system that can be reliably operated across the EU, taking into account the specificities of the supply chain of individual Member States. Member States finally asked the Commission to take into appropriate consideration the fact that, in the EU, there are other parties that can supply medicines to patients besides pharmacies.

In June 2011, the Commission held a first meeting with key European associations representing manufacturers, wholesale distributors, hospitals and pharmacies to collect their first views on possible options for the characteristics and technical specifications of the unique identifier.

On the basis of this preliminary discussion, the Commission submitted for public consultation a concept paper on the delegated act on the detailed rules for safety features for medicinal products for human use. The consultation took place from 18 November 2011 to 27 April 2012. The concept paper put forward various ideas and options for implementing the unique identifier. This public consultation was also used as a means of gathering further quantified information on the costs and effectiveness of the various policy options. In total, 90 replies were received (mainly from industry, wholesale distributors and pharmacies, but also from some Member States). The responses have been published by the Commission on the Europa website<sup>4</sup>.

In a nutshell, all respondents expressed their full support for the Commission's initiative, on the grounds that the unique identifier would create better protection for European patients against falsified medicines. Most respondents supported harmonising the technical specifications of the unique identifier across the Union to ensure interoperability among different manufacturers and different EU Member States. Most stakeholders also supported the checking of the unique identifier at the end of the supply chain, namely at the pharmacy or hospital level. Most industry supported a repository system set up and managed by the stakeholders. On the contrary, two national medicines Agencies out of seven who replied favoured the EU or national governance of the repository system while one authority called

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<sup>4</sup> [http://ec.europa.eu/health/human-use/falsified\\_medicines/developments/2012-06\\_pc\\_safety-features.htm](http://ec.europa.eu/health/human-use/falsified_medicines/developments/2012-06_pc_safety-features.htm)

for national governance only. Their views were also expressed during the meetings of the expert group. The European Consumer Organisation stressed the importance to protect personal data in the repository system.

The Commission further consulted with key European stakeholders in December 2012, December 2013 and April 2014.

In November 2012, with the help of an external contractor, ECORYS, the Commission conducted an ex-ante evaluation of competitiveness proofing of the unique identifier for medicinal products for human use and its verification. The contractor investigated the consequences of the different policy options on the competitiveness of the pharmaceutical industry and identified corrective or mitigating measures. The relevant dimensions of competitiveness analysed in the study were: cost competitiveness, capacity to innovate and international competitiveness.

The information gathered during the public consultation, the input of the Member State expert group and the ex-ante evaluation of competitiveness proofing performed by ECORYS were taken into account when performing the assessment of the benefits, costs and cost-effectiveness ('impact assessment') of the possible policy options for the unique identifier and its verification, as requested by Directive 2001/62/EU.

The impact assessment study was submitted to the Commission impact assessment board for scrutiny. The impact assessment board approved the study on 20 December 2013. The results of the study are summarised in the impact assessment report accompanying the present Delegated Regulation.

Comments stemming from all rounds of consultations as well as the outcome of the impact assessment study were taken into account when preparing this Delegated Regulation.

### **3. LEGAL ELEMENTS OF THE DELEGATED ACT**

The legal basis for this Delegated Regulation is Article 54a, second paragraph, of Directive 2001/83/EC on the Community code relating to medicinal products for human use.

This Delegated Regulation supplements Directive 2001/83/EC.

# COMMISSION DELEGATED REGULATION (EU) No .../..

of **XXX**

## 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<sup>5</sup>, 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<sup>6</sup> 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.
- (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

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<sup>5</sup> OJ L 311, 28.11.2001, p. 67.

<sup>6</sup> Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ L 174, 1.7.2011, p. 74).

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 will 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 shall 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 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 European 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 their decommissioning 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. 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 this 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 consequent 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 up of the repositories system as their early involvement will benefit their subsequent supervision activities.
- (29) Limiting the use of the repository system should not be used for the purpose of gaining market advantage. For this reason, membership of specific organisations should not be a pre-requisite for using the repository system.
- (30) The structure of the repositories system should be such as to ensure that medicinal product verification is possible throughout the Union. This may require the transfer of data and information on a unique identifier between repositories within the repositories systems. In order to minimise the number of necessary connections between repositories and ensure their interoperability, each national and supranational repository part of the repositories system should connect to and exchange data through a central repository acting as information and data router.
- (31) The repositories system should comprise the necessary interfaces providing access, either directly or by means of software, to wholesalers, persons authorised or entitled to supply medicinal products to the public and national competent authorities so that they can comply with their obligations under this Regulation.
- (32) Given the sensitive nature of the information on the legitimate unique identifiers and the potential negative impact on public health should such information fall in the hands of traffickers, the responsibility for ensuring the upload of such information in the repositories system should be placed on the marketing authorisation holder or the person responsible for placing the product bearing the unique identifier on the market.

The information should be retained for a period of time sufficiently long to allow the appropriate investigation of incidents of falsification.

- (33) In order to harmonise the data format and data exchange across the repositories system and guarantee the interoperability of the repositories as well as the readability and the accuracy of the transferred data, each national and supranational repository should exchange information and data using the data format and data exchange specificities defined by the central repository.
- (34) To ensure medicinal product verification without hindering the movement of medicinal products within the single market, it should be possible for wholesalers and persons authorised or entitled to supply medicinal products to the public to verify the authenticity of and decommission a unique identifier in any Member State, regardless of where in the Union the medicinal product bearing that unique identifier was originally intended to be placed on the market. To this end, the status of a unique identifier should be synchronised between repositories and, where necessary, verification queries should be redirected by the central repository to the repositories serving the Member States where the product was intended to be placed on the market.
- (35) In order to ensure that the functioning of the repositories system supports an end-to-end verification of the authenticity of medicinal products, it is necessary to set out the characteristics and operations of the repositories system.
- (36) The investigation of suspected or confirmed incidents of falsification would benefit from knowing as much information as possible on the product subject to the investigation. For this reason, records of all operations concerning a unique identifier, including the users performing those operations and the nature of the operations should be stored in the repositories system, be accessible for the purpose of investigating events flagged as potential incidents of falsification in the repositories system, and be made immediately available to competent authorities upon request.
- (37) In accordance with Article 54a(3) of Directive 2001/83/EC, it is necessary to ensure the protection of personal data as provided for in Union law, the legitimate interests to protect information of a commercially confidential nature and the ownership and confidentiality of the data generated by the use of the safety features. For this reason, manufacturers, marketing authorisation holders, wholesalers and persons authorised or entitled to supply medicinal products to the public should only have ownership of and access to the data they generate when they interact with the repositories system. Although the present delegated Regulation does not require any personal data to be stored in the repositories system, the protection of personal data should be ensured in case users of the repositories use the repositories system for purposes which are outside the scope of this Regulation.
- (38) The information referred to in Article 33(2) of this Regulation and the information on the status of a unique identifier should stay accessible to all parties required to verify the authenticity of medicinal products, as such information is necessary for the proper performing of those verifications.
- (39) In order to avoid potential ambiguities and authentication errors, no unique identifiers having the same product code and serial number should be present in the repositories system at the same time.
- (40) In accordance with Article 54a(1) of Directive 2001/83/EC, medicinal products subject to prescription are to bear the safety features while medicinal products not subject to prescription are not allowed to. However, whether a medicinal product is subject to

prescription is most often decided nationally and may vary across Member States. In addition, Member States may extend the scope of application of the safety features in accordance with Article 54a(5) of Directive 2001/83/EC. As a result, the same medicinal product may be required to bear the safety features in one Member State but not in another. In order to ensure the correct application of this Regulation, national competent authorities should, when requested, make available the information on the medicinal products placed on the market on their territory which shall bear the safety features, including those for which the scope of application of the unique identifier or of the anti-tampering device has been extended in accordance with Article 54a(5) of Directive 2001/83/EC, to the marketing authorisation holders, manufacturers, wholesalers and persons authorised or entitled to supply medicinal products to the public.

- (41) Since a repository may use servers physically located in different Member States, or may be physically located in a Member State which is not the Member State it serves, national competent authorities should be allowed to perform or observe inspections in other Member States, subject to certain conditions.
- (42) The lists containing the medicinal products or product categories which, in the case of prescription medicinal products shall not bear the safety features, and in the case of non-prescription medicinal products shall bear the safety features, should be established considering the risk of and the risk arising from falsification of the medicinal products or product categories, in accordance with Article 54a(2)(b) of Directive 2001/83/EC, as amended. Those risks should be assessed on the basis of the criteria referred to in the said Article.
- (43) In order to avoid disruptions in the supply of medicinal products, transitional measures for medicinal products which have been released for sale or distribution without the safety features before the date of application of this Regulation in the Member State or Member States where the product is placed on the market are necessary.
- (44) At the time of entry into force of Directive 2011/62/EU of the European Parliament and of the Council, Belgium, Greece and Italy already had systems in place for the verification of the authenticity of medicinal products and for the identification of individual packs. Directive 2011/62/EU granted such Member States an additional transitional period for adapting to the harmonised Union system for safety features introduced by that Directive for the same purposes, by allowing them to defer their application of the Directive as regards that system. In order to ensure consistency between the national transposition measures adopted pursuant to the Directive, on the one hand, and the rules of this Regulation, on the other hand, those Member States should be allowed the same additional transitional period for the application of the rules of this Regulation regarding that system.
- (45) In the interest of legal certainty and legal clarity with regard to the applicable rules in those Member States which benefit from an additional transitional period in accordance with this Regulation, each of those Member States should be required to notify the Commission of the date from which the provisions of this Regulation subject to the additional transitional period apply in its territory in order for the Commission to publish the date of application in that Member State in the *Official Journal of the European Union* sufficiently in advance.

HAS ADOPTED THIS REGULATION:

## **Chapter I**

### **Subject matter and definitions**

#### *Article 1* *Subject matter*

This Regulation lays down:

- (a) the characteristics and technical specifications of the unique identifier that enables the authenticity of medicinal products to be verified and individual packs to be identified;
- (b) the modalities for the verification of the safety features;
- (c) the provisions on the establishment, management and accessibility of the repositories system where the information on the safety features shall be contained;
- (d) the list of medicinal products and product categories subject to prescription which shall not bear the safety features;
- (e) the list of medicinal products and product categories not subject to prescription which shall bear the safety features;
- (f) the procedures for the notification to the Commission by national competent authorities of non-prescription medicinal products judged at risk of falsification and prescription medicinal products not deemed at risk of falsification in accordance with the criteria set out in Article 54a(2)(b) of Directive 2001/83/EC;
- (g) the procedures for a rapid evaluation of and decision on the notifications referred to in point (f) of this Article.

#### *Article 2* *Scope*

1. This Regulation applies to:
  - (a) medicinal products subject to prescription which shall bear safety features on their packaging pursuant to Article 54a(1) of Directive 2001/83/EC, unless included in the list set out in Annex I to this Regulation;
  - (b) medicinal products not subject to prescription included in the list set out in Annex II to this Regulation.
2. For the purposes of this Regulation, where reference is made to the packaging in a provision of this Regulation, the provision shall apply to outer packaging or to the immediate packaging if the medicinal product has no outer packaging.

#### *Article 3* *Definitions*

1. For the purposes of this Regulation, the definitions in Article 1 of Directive 2001/83/EC shall apply.

2. The following definitions shall apply:
- (1) ‘unique identifier’ means the safety feature enabling the verification of the authenticity and the identification of an individual pack of a medicinal product;
  - (2) ‘anti-tampering device’ means the safety feature allowing the verification of whether the packaging of a medicinal product has been tampered with;
  - (3) ‘decommissioning of a unique identifier’ means the operation changing the active status of a unique identifier stored in the repositories system referred to in Article 31 of this Regulation to a status impeding any further successful verification of the authenticity of that unique identifier;
  - (4) ‘active unique identifier’ means a unique identifier which has not been decommissioned or which is no longer decommissioned;
  - (5) ‘active status’ means the status of an active unique identifier stored in the repositories system referred to in Article 31;
  - (6) ‘healthcare institution’ means a hospital, in- or out-patient clinic or health centre.

## **Chapter II**

### **Technical specifications of the unique identifier**

#### *Article 4*

##### *Composition of the unique identifier*

1. The manufacturer shall place on the packaging of a medicinal product a unique identifier which complies with the following technical specifications:
  - (a) The unique identifier shall be a sequence of numeric or alphanumeric characters that is unique to a given pack of a medicinal product.
  - (b) The unique identifier shall consist of the following data elements:
    - (i) a code allowing the identification of at least the name, the common name, the pharmaceutical form, the strength, the package size and the package type of the medicinal product bearing the unique identifier (‘product code’);
    - (ii) a numeric or alphanumeric sequence of maximum 20 characters, generated by a deterministic or a non-deterministic randomisation algorithm (‘serial number’);
    - (iii) a national reimbursement number or other national number identifying the medicinal product, if required by the Member State where the product is intended to be placed on the market;
    - (iv) the batch number;
    - (v) the expiry date.
  - (c) The probability that the serial number can be guessed shall be negligible and in any case lower than one in ten thousand.
  - (d) The character sequence resulting from the combination of the product code and the serial number shall be unique to a given pack of a medicinal product until

at least one year after the expiry date of the pack 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.

- (e) Where the national reimbursement number or other national number identifying the medicinal product is contained in the product code, it is not required to be repeated within the unique identifier.

#### *Article 5*

##### *Carrier of the unique identifier*

1. Manufacturers shall encode the unique identifier in a two-dimensional barcode.
2. The barcode shall be a machine-readable Data Matrix and have error detection and correction equivalent to or higher than those of the Data Matrix ECC200. Barcodes conforming to the International Organization for Standardization/International Electrotechnical Commission standard ('ISO/IEC') 16022:2006 shall be presumed to fulfil the requirements set out in this paragraph.
3. Manufacturers shall print the barcode on the packaging on a smooth, uniform, low-reflecting surface.
4. When encoded in a Data Matrix, the structure of the unique identifier shall follow an internationally-recognised, standardised data syntax and semantics ('coding scheme') which allows the identification and accurate decoding of each data element of which the unique identifier is composed, using common scanning equipment. The coding scheme shall include data identifiers or application identifiers or other character sequences identifying the beginning and the end of the sequence of each individual data element of the unique identifier and defining the information contained in those data elements. Unique identifiers having a coding scheme conforming to ISO/IEC 15418:2009 shall be presumed to fulfil the requirements set out in this paragraph.
5. When encoded in a Data Matrix as data element of a unique identifier, the product code shall follow a coding scheme and begin with characters specific to the coding scheme used. It shall also contain characters or character sequences identifying the product as a medicinal product. The resulting code shall be less than 50 characters and be globally unique. Product codes which conform to the ISO/IEC 15459-3:2014 and ISO/IEC 15459-4:2014 shall be presumed to fulfil the requirements set out in this paragraph.
6. Where necessary, different coding schemes may be used within the same unique identifier provided that the decoding of the unique identifier is not hindered. In that case, the unique identifier shall contain standardised characters permitting the identification of the beginning and the end of the unique identifier as well as the beginning and the end of each coding scheme. Where containing multiple coding schemes, unique identifiers which conform to ISO/IEC 15434:2006 shall be presumed to fulfil the requirements set out in this paragraph.

#### *Article 6*

##### *Quality of the printing of the two-dimensional barcode*

1. Manufacturers shall evaluate the quality of the printing of the Data Matrix by assessing at least the following Data Matrix parameters:

- (a) the contrast between the light and dark parts;
  - (b) the uniformity of the reflectance of the light and dark parts;
  - (c) the axial non-uniformity;
  - (d) the grid non-uniformity;
  - (e) the unused error correction;
  - (f) the fixed pattern damage;
  - (g) the capacity of the reference decode algorithm to decode the Data Matrix.
2. Manufacturers shall identify the minimum quality of the printing which ensures the accurate readability of the Data Matrix throughout the supply chain until at least one year after the expiry date of the pack 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.
  3. When printing the Data Matrix, manufacturers shall not use a quality of the printing lower than the minimum quality referred to in paragraph 2.
  4. A quality of printing rated at least 1.5 in accordance with ISO/IEC 15415:2011 shall be presumed to fulfil the requirements set out in this Article.

#### *Article 7*

##### *Human-readable format*

1. Manufacturers shall print the following data elements of the unique identifier on the packaging in human-readable format:
  - (a) the product code;
  - (b) the serial number;
  - (c) the national reimbursement number or other national number identifying the medicinal product, if required by the Member State where the product is intended to be placed on the market and not printed elsewhere on the packaging.
2. Paragraph 1 shall not apply where the sum of the two longest dimensions of the packaging equals or is inferior to 10 centimetres.
3. Where the dimensions of the packaging allow it, the human-readable data elements shall be adjacent to the two-dimensional barcode carrying the unique identifier.

#### *Article 8*

##### *Additional information in the two-dimensional barcode*

Manufacturers may include information other than the unique identifier in the two-dimensional barcode carrying the unique identifier, where permitted by the competent authority in accordance with Title V of Directive 2001/83/EU.

#### *Article 9*

##### *Barcodes on the packaging*



Medicinal products having to bear the safety features pursuant to Article 54a of Directive 2001/83/EC shall not bear, on their packaging, any other visible two-dimensional barcode than the two-dimensional barcode carrying the unique identifier for the purpose of their identification and verification of their authenticity.

## **Chapter III**

### **General provisions on the verification of the safety features**

#### *Article 10*

##### *Verification of the safety features*

When verifying the safety features, manufacturers, wholesalers and persons authorised or entitled to supply medicinal products to the public shall verify the following:

- (a) the authenticity of the unique identifier;
- (b) the integrity of the anti-tampering device.

#### *Article 11*

##### *Verification of the authenticity of the unique identifier*

When verifying the authenticity of a unique identifier, manufacturers, wholesalers and persons authorised or entitled to supply medicinal products to the public shall check the unique identifier against the unique identifiers stored in the repositories system referred to in Article 31. A unique identifier shall be considered authentic when the repositories system contains an active unique identifier with the product code and serial number that are identical to those of the unique identifier being verified.

#### *Article 12*

##### *Unique identifiers which have been decommissioned*

A medicinal product bearing a unique identifier which has been decommissioned shall not be further distributed or supplied to the public except in any of the following situations:

- (a) the unique identifier was decommissioned in accordance with Article 22(a) and the medicinal product is distributed for the purpose of exporting it outside the Union;
- (b) the unique identifier was decommissioned earlier than the time of supplying the medicinal product to the public, pursuant to Articles 23, 26, 28 or 41;
- (c) the unique identifier was decommissioned in accordance with Article 22(b) or (c) or Article 40, and the medicinal product is provided to the person responsible for its disposal;
- (d) the unique identifier was decommissioned in accordance with Article 22(d) and the medicinal product is provided to the national competent authorities.

#### *Article 13*

##### *Reversing the status of a decommissioned unique identifier*

1. Manufacturers, wholesalers and persons authorised or entitled to supply medicinal products to the public may only revert the status of a decommissioned unique identifier to an active status if the following conditions are fulfilled:
  - (a) the person performing the reverting operation is covered by the same authorisation or entitlement and operates in the same premises as the person that decommissioned the unique identifier;
  - (b) the reverting of the status takes place not more than ten days after the unique identifier was decommissioned;
  - (c) the pack of medicinal product has not expired;
  - (d) the pack of medicinal product has not been registered in the repositories system as recalled, withdrawn, intended for destruction or stolen and the person performing the reverting operation does not have knowledge that the pack is stolen;
  - (e) the medicinal product has not been supplied to the public.
2. Medicinal products bearing a unique identifier which cannot be reverted to an active status because the conditions set out in paragraph 1 are not fulfilled shall not be returned to saleable stock.

## **Chapter IV**

### **Modalities of verification of the safety features and decommissioning of the unique identifier by manufacturers**

#### *Article 14*

##### *Verification of the two-dimensional barcode*

The manufacturer placing the safety features shall verify that the two-dimensional barcode carrying the unique identifier complies with Articles 5 and 6, is readable and contains the correct information.

#### *Article 15*

##### *Record keeping*

The manufacturer placing the safety features shall keep records of every operation he performs with or on the unique identifier on a pack of medicinal product for at least one year after the expiry date of the pack 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, and shall provide those records to competent authorities on request.

#### *Article 16*

##### *Verifications to be performed before removing or replacing the safety features*

1. Before removing or covering, either fully or partially, the safety features in accordance with Article 47a of Directive 2001/83/EC, the manufacturer shall verify the following:
  - (a) the integrity of the anti-tampering device;

- (b) the authenticity of the unique identifier and decommission it if replaced.
2. Manufacturers holding both a manufacturing authorisation according to Article 40 of Directive 2001/83/EC and an authorisation to manufacture or import investigational medicinal products to the Union as referred to in Article 61 of Regulation (EU) No 536/2014 of the European Parliament and of the Council<sup>7</sup> shall verify the safety features and decommission the unique identifier on a pack of medicinal product before repacking or relabelling it for the purpose of using it as authorised investigational medicinal product or authorised auxiliary medicinal product.

#### *Article 17*

##### *Equivalent unique identifier*

When placing an equivalent unique identifier for the purposes of complying with Article 47a(1)(b) of Directive 2001/83/EC, the manufacturer shall verify that the structure and composition of the unique identifier placed on the packaging complies, with regard to the product code and the national reimbursement number or other national number identifying the medicinal product, with the requirements of the Member State where the medicinal product is intended to be placed on the market, so that that unique identifier can be verified for authenticity and decommissioned.

#### *Article 18*

##### *Actions to be taken by manufacturers in case of tampering or suspected falsification*

Where a manufacturer has reason to believe that the packaging of the medicinal product has been tampered with, or the verification of the safety features shows that the product may not be authentic, the manufacturer shall not release the product for sale or distribution and shall immediately inform the relevant competent authorities.

#### *Article 19*

##### *Provisions applicable to a manufacturer distributing his products by wholesale*

Where a manufacturer distributes his products by wholesale, Article 20(a), and Articles 22, 23 and 24 shall apply to him in addition to Articles 14 to 18.

## **Chapter V**

### **Modalities of verification of the safety features and decommissioning of the unique identifier by wholesalers**

#### *Article 20*

##### *Verification of the authenticity of the unique identifier by wholesalers*

A wholesaler shall verify the authenticity of the unique identifier of at least the following medicinal products in his physical possession:

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<sup>7</sup> Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

- (a) medicinal products returned to him by persons authorised or entitled to supply medicinal products to the public or by another wholesaler;
- (b) medicinal products he receives from a wholesaler who is neither the manufacturer nor the wholesaler holding the marketing authorisation nor a wholesaler who is designated by the marketing authorisation holder, by means of a written contract, to store and distribute the products covered by his marketing authorisation on his behalf.

#### *Article 21*

##### *Derogations from Article 20(b)*

Verification of the authenticity of the unique identifier of a medicinal product is not required under Article 20(b) in any of the following situations:

- (a) that medicinal product changes ownership but remains in the physical possession of the same wholesaler;
- (b) that medicinal product is distributed within the territory of a Member State between two warehouses belonging to the same wholesaler or the same legal entity, and no sale takes place.

#### *Article 22*

##### *Decommissioning of unique identifiers by wholesalers*

Wholesalers shall verify the authenticity of and decommission the unique identifier of the following medicinal products:

- (a) products which he intends to distribute outside of the Union;
- (b) products which have been returned to him by persons authorised or entitled to supply medicinal products to the public or another wholesaler and cannot be returned to saleable stock;
- (c) products which are intended for destruction;
- (d) products which, while in his physical possession, are requested as a sample by competent authorities;
- (e) products which he intends to distribute to the persons or institutions referred to in Article 23, where required by national legislation in accordance with the same Article.

#### *Article 23*

##### *Provisions to accommodate specific characteristics of Member States' supply chain*

Member States may require, where necessary to accommodate the particular characteristics of the supply chain on their territory, that a wholesaler verifies the safety features and decommissions the unique identifier of a medicinal product before he supplies that medicinal product to any of the following persons or institutions:

- (a) persons authorised or entitled to supply medicinal products to the public who do not operate within a healthcare institution or within a pharmacy;
- (b) veterinarians and retailers of veterinary medicinal products;

- (c) dental practitioners;
- (d) optometrists and opticians;
- (e) paramedics and emergency medical practitioners;
- (f) armed forces, police and other governmental institutions maintaining stocks of medicinal products for the purposes of civil protection and disaster control;
- (g) universities and other higher education establishments using medicinal products for the purposes of research and education, with the exceptions of healthcare institutions;
- (h) prisons;
- (i) schools;
- (j) hospices;
- (k) nursing homes.

#### *Article 24*

##### *Actions to be taken by wholesalers in case of tampering or suspected falsification*

A wholesaler shall not supply or export a medicinal product where he has reason to believe that its packaging has been tampered with, or where the verification of the safety features of the medicinal product indicates that the product may not be authentic. He shall immediately inform the relevant competent authorities.

## **Chapter VI**

### **Modalities of verification of the safety features and decommissioning of the unique identifier by persons authorised or entitled to supply medicinal products to the public**

#### *Article 25*

##### *Obligations of persons authorised or entitled to supply medicinal products to the public*

1. Persons authorised or entitled to supply medicinal products to the public shall verify the safety features and decommission the unique identifier of any medicinal product bearing the safety features they supply to the public at the time of supplying it to the public.
2. Notwithstanding paragraph 1, persons authorised or entitled to supply medicinal products to the public operating within a healthcare institution may carry out that verification and decommissioning at any time the medicinal product is in the physical possession of the healthcare institution, provided that no sale of the medicinal product takes place between the delivery of the product to the healthcare institution and the supplying of it to the public.
3. In order to verify the authenticity of the unique identifier of a medicinal product and decommission that unique identifier, persons authorised or entitled to supply medicinal products to the public shall connect to the repositories system referred to in Article 31 through the national or supranational repository serving the territory of the Member State in which they are authorised or entitled.

4. They shall also verify the safety features and decommission the unique identifier of the following medicinal products bearing the safety features:
  - (a) medicinal products in their physical possession that cannot be returned to wholesalers or manufacturers;
  - (b) medicinal products that, while in their physical possession, are requested as samples by competent authorities, in accordance with national legislation;
  - (c) medicinal products which they supply for subsequent use as authorised investigational medicinal products or authorised auxiliary medicinal products as defined in Articles 2(2)(9) and (10) of Regulation (EU) No 536/2014.

#### *Article 26*

##### *Derogations from Article 25*

1. Persons authorised or entitled to supply medicinal products to the public are exempted from the obligation to verify the safety features and decommission the unique identifier of medicinal products provided to them as free samples in accordance with Article 96 of Directive 2001/83/EC.
2. Persons authorised or entitled to supply medicinal products to the public who do not operate within a healthcare institution or within a pharmacy are exempted from the obligation to verify the safety features and decommission the unique identifier of medicinal products where that obligation has been placed on wholesalers by national legislation in accordance with Article 23.
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 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.

#### *Article 27*

##### *Obligations when applying the derogations*

Where the verification of the authenticity and decommissioning of the unique identifier is carried out earlier than referred to in Article 25(1), pursuant to Articles 23 or 26, the integrity of the anti-tampering device shall be verified at the time the medicinal product is supplied to the public.

## Article 28

### *Obligations when supplying only part of a pack*

Notwithstanding Article 25(1), where persons authorised or entitled to supply medicinal products to the public supply only part of a pack of a medicinal product the unique identifier of which is not decommissioned, they shall verify the safety features and decommission that unique identifier when the pack is opened for the first time.

## Article 29

### *Obligations in case of inability to verify the authenticity and decommission the unique identifier*

Notwithstanding Article 25(1), where technical problems prevent persons authorised or entitled to supply medicinal products to the public from verifying the authenticity of and decommissioning a unique identifier at the time the medicinal product bearing that unique identifier is supplied to the public, persons authorised or entitled to supply medicinal products to the public shall record the unique identifier and, as soon as the technical problems are solved, verify the authenticity of and decommission the unique identifier.

## Article 30

### *Actions to be taken by persons authorised or entitled to supply medicinal products to the public in case of suspected falsification*

Where persons authorised or entitled to supply medicinal products to the public have reason to believe that the packaging of the medicinal product has been tampered with, or the verification of the safety features of the medicinal product indicates that the product may not be authentic, persons authorised or entitled to supply medicinal products to the public shall not supply the product and shall immediately inform the relevant competent authorities.

## **Chapter VII**

### **Establishment, management and accessibility of the repositories system**

## Article 31

### *Establishment of the repositories system*

1. The repositories system where the information on the safety features shall be contained, pursuant to Article 54a(2)(e) of Directive 2001/83/EC, shall be set up and managed by a non-profit legal entity or non-profit legal entities established in the Union by manufacturers and marketing authorisation holders of medicinal products bearing the safety features.
2. In setting up the repositories system, the legal entity or entities referred to in paragraph 1 shall consult at least wholesalers, persons authorised or entitled to supply medicinal products to the public and relevant national competent authorities.
3. Wholesalers and persons authorised or entitled to supply medicinal products to the public are entitled to participate in the legal entity or entities referred to in paragraph 1, on a voluntary basis, at no cost.

4. The legal entity or entities referred to on paragraph 1 shall not require manufacturers, marketing authorisation holders, wholesalers or persons authorised or entitled to supply medicinal products to the public to be members of a specific organisation or organisations in order to use the repository system.
5. The costs of the repositories system shall be borne by the manufacturers of medicinal products bearing the safety features, in accordance with Article 54a(2)(e) of Directive 2001/83/EC.

#### *Article 32*

##### *Structure of the repositories system*

1. The repositories system shall be composed of the following electronic repositories:
  - (a) a central information and data router ('hub');
  - (b) repositories which serve the territory of one Member State ("national repositories") or the territory of multiple Member States ("supranational repositories"). Those repositories shall be connected to the hub.
2. The number of national and supranational repositories shall be sufficient to ensure that the territory of every Member State is served by one national or supranational repository.
3. The repositories system shall comprise the necessary information technology infrastructure, hardware and software to enable the execution of the following tasks:
  - (a) upload, collate, process, modify and store the information on the safety features that enables the verification of the authenticity and identification of medicinal products;
  - (b) identify an individual pack of a medicinal product bearing the safety features and verify the authenticity of the unique identifier on that pack and decommission it at any point of the legal supply chain.
4. The repositories system shall include the application programming interfaces allowing wholesalers or persons authorised or entitled to supply medicinal products to the public to query the repositories system by means of software, for the purposes of verifying the authenticity of the unique identifiers and of decommissioning them in the repositories system. The application programming interfaces shall also allow national competent authorities to access the repositories system by means of software, in accordance with Article 39.

The repositories system shall also include graphic user interfaces providing direct access to the repositories system in accordance with Article 35(1)(i).

The repositories system shall not include the physical scanning equipment used for reading the unique identifier.

#### *Article 33*

##### *Uploading of information in the repositories system*

1. The marketing authorisation holder or, in case of parallel imported or parallel distributed medicinal products bearing an equivalent unique identifier for the purposes of complying with Article 47a of Directive 2001/83/EC, the person responsible for placing these products on the market, shall ensure that the



information referred to in paragraph 2 is uploaded to the repositories system before the medicinal product is released for sale or distribution by the manufacturer, and that it is kept up to date thereafter.

The information shall be stored in all national or supranational repositories serving the territory of the Member State or Member States where the medicinal product bearing the unique identifier is intended to be placed on the market. The information referred to in paragraphs 2(a) to (d) of this Article, with the exception of the serial number, shall also be stored in the hub.

2. For a medicinal product bearing a unique identifier, at least the following information shall be uploaded to the repositories system:
  - (a) the data elements of the unique identifier in accordance with Article 4(b);
  - (b) the coding scheme of the product code;
  - (c) the name and the common name of the medicinal product, the pharmaceutical form, the strength, the package type and the package size of the medicinal product, in accordance with the terminology referred to in Article 25(1)(b) and (e) to (g) of the Commission Implementing Regulation (EU) No 520/2012<sup>8</sup>;
  - (d) the Member State or Member States where the medicinal product is intended to be placed on the market;
  - (e) where applicable, the code identifying the entry corresponding to the medicinal product bearing the unique identifier in the database referred to in Article 57(1)(l) of Regulation (EU) No 726/2004 of the European Parliament and the Council<sup>9</sup>;
  - (f) the name and address of the manufacturer placing the safety features;
  - (g) the name and address of the marketing authorisation holder;
  - (h) a list of wholesalers who are designated by the marketing authorisation holder, by means of a written contract, to store and distribute the products covered by his marketing authorisation on his behalf.
3. The information referred to in paragraph 2 shall be uploaded to the repositories system either through the hub or through a national or supranational repository.

Where the upload is performed through the hub, the hub shall store a copy of the information referred to in paragraph 2(a) to (d), with the exception of the serial number, and transfer the complete information to all national or supranational repositories serving the territory of the Member State or Member States where the medicinal product bearing the unique identifier is intended to be placed on the market.

Where the upload is performed through a national or supranational repository, that repository shall immediately transfer to the hub a copy of the information referred to

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<sup>8</sup> Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council (OJ L 159, 20.6.2012, p. 5).

<sup>9</sup> Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

in paragraph 2(a) to (d), with the exception of the serial number, using the data format and data exchange specifications defined by the hub.

4. The information referred to in paragraph 2 shall be stored in the repositories where it was originally uploaded for at least one year after the expiry date of the medicinal product 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.

#### *Article 34*

##### *Functioning of the hub*

1. Each national or supranational repository composing the repositories system shall exchange data with the hub using the data format and data exchange modalities defined by the hub.
2. When the authenticity of the unique identifier cannot be verified because a national or supranational repository does not contain a unique identifier with the product code and serial number that are identical to those of the unique identifier being verified, the national or supranational repository shall transfer the query to the hub in order to verify whether that unique identifier is stored elsewhere in the repositories system.

When the hub receives the query, the hub shall identify, on the basis of the information contained therein, all national or supranational repositories serving the territory of the Member State or Member States where the medicinal product bearing the unique identifier was intended to be placed on the market, and shall transfer the query to those repositories.

The hub shall subsequently transfer the reply of those repositories to the repository which initiated the query.

3. Where notified by a national or supranational repository of the change of status of a unique identifier, the hub shall ensure the synchronisation of that status between those national or supranational repositories serving the territory of the Member State or Member States where the medicinal product bearing the unique identifier was intended to be placed on the market.
4. When it receives the information referred to in Article 35(4), the hub shall ensure the electronic linking of the batch numbers before and after the repacking or relabelling operations with the set of unique identifiers decommissioned and with the set of equivalent unique identifiers placed.

#### *Article 35*

##### *Characteristics of the repositories system*

1. Each repository in the repositories system shall satisfy all of the following conditions:
  - (a) it shall be physically located in the Union;
  - (b) it shall be set up and managed by a non-profit legal entity established in the Union by manufacturers and marketing authorisation holders of medicinal products bearing the safety features and, where they have chosen to participate, wholesalers and persons authorised or entitled to supply medicinal products to the public;

- (c) it shall be fully interoperable with the other repositories composing the repositories system; for the purposes of this Chapter, interoperability means the full functional integration of, and electronic data exchange between repositories regardless of the service provider used;
  - (d) it shall allow the reliable electronic identification and authentication of individual packs of medicinal products by manufacturers, wholesalers and persons authorised or entitled to supply medicinal products to the public, in accordance with the requirements of this Regulation;
  - (e) it shall have application programming interfaces able to transfer and exchange data with the software used by wholesalers, persons authorised or entitled to supply medicinal products to the public and, where applicable, national competent authorities;
  - (f) when wholesalers and persons authorised or entitled to supply medicinal products to the public query the repository for the purposes of verification of authenticity and decommissioning of a unique identifier, the response time of the repository, not considering the speed of the internet connection, shall be lower than 300 milliseconds in at least 95% of queries. The repository performance shall allow wholesalers and persons authorised or entitled to supply medicinal products to the public to operate without significant delay;
  - (g) it shall maintain a complete record ('audit trail') of all operations concerning a unique identifier, of the users performing those operations and the nature of the operations; the audit trail shall be created when the unique identifier is uploaded to the repository and be maintained until at least one year after the expiry date of the medicinal product bearing the unique identifier 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;
  - (h) in accordance with Article 38, its structure shall be such as to guarantee the protection of personal data and information of a commercially confidential nature and the ownership and confidentiality of the data generated when manufacturers, marketing authorisation holders, wholesalers and persons authorised or entitled to supply medicinal products to the public interact with it;
  - (i) it shall include graphic user interfaces providing direct access to it to the following users verified in accordance with Article 37(b):
    - (i) wholesalers and persons authorised or entitled to supply medicinal products to the public, for the purposes of verifying the authenticity of the unique identifier and decommissioning it in case of failure of their own software;
    - (ii) national competent authorities, for the purposes referred to in Article 39;
2. Where the status of a unique identifier on a medicinal product intended to be placed on the market in more than one Member State changes in a national or supranational repository, that repository shall immediately notify the change of status to the hub, except in case of decommissioning by marketing authorisation holders in accordance with Articles 40 or 41.

3. National or supranational repositories shall not allow the upload or storage of a unique identifier containing the same product code and serial number as another unique identifier already stored therein.
4. For each batch of repacked or relabelled packs of a medicinal product on which equivalent unique identifiers were placed for the purposes of complying with Article 47a of Directive 2001/83/EC, the person responsible for placing the medicinal product on the market shall inform the hub of the batch number or numbers of the packs which are to be repacked or relabelled and of the unique identifiers on those packs. He shall additionally inform the hub of the batch number of the batch resulting from the repacking or relabelling operations and the equivalent unique identifiers in that batch.

### *Article 36*

#### *Operations of the repositories system*

The repositories system shall provide for at least the following operations:

- (a) the repeated verification of the authenticity of an active unique identifier in accordance with Article 11;
- (b) the triggering of an alert in the system and in the terminal where the verification of the authenticity of a unique identifier is taking place when such verification fails to confirm that the unique identifier is authentic in accordance with Article 11. Such an event shall be flagged in the system as a potential incident of falsification except where the product is indicated in the system as recalled, withdrawn or intended for destruction;
- (c) the decommissioning of a unique identifier in accordance with the requirements of this Regulation;
- (d) the combined operations of identification of a pack of a medicinal product bearing a unique identifier and verification of the authenticity and decommissioning of that unique identifier;
- (e) the identification of a pack of a medicinal product bearing a unique identifier and the verification of the authenticity and the decommissioning of that unique identifier in a Member State which is not the Member State where the medicinal product bearing that unique identifier was placed on the market;
- (f) the reading of the information contained in the two-dimensional barcode encoding the unique identifier, the identification of the medicinal product carrying the barcode and the verification of the status of the unique identifier , without triggering the alert referred to in point (b) of this Article;
- (g) without prejudice to Article 35(1)(h), the access by verified wholesalers to the list of wholesalers referred to in Article 33(2)(h) for the purposes of determining whether they have to verify the unique identifier of a given medicinal product.
- (h) the verification of the authenticity of a unique identifier and its decommissioning by manually querying the system with the data elements of the unique identifier;

- (i) the immediate provision of information concerning a given unique identifier to the national competent authorities and the European Medicines Agency, upon request;
- (j) the creation of reports that allow competent authorities to verify compliance of individual marketing authorisation holders, manufacturers, wholesalers and persons authorised or entitled to supply medicinal products to the public with the requirements of this Regulation or to investigate potential incidents of falsification;
- (k) the reverting of the status of a unique identifier from decommissioned to active, subject to the conditions referred to in Article 13;
- (l) the indication that a unique identifier has been decommissioned;
- (m) the indication that a medicinal product has been recalled, withdrawn, stolen, exported, requested as a sample by national competent authorities, indicated as a free sample by the marketing authorisation holder, or is intended for destruction;
- (n) the linking, by batches of medicinal products, of the information on unique identifiers removed or covered to the information on the equivalent unique identifiers placed on those medicinal products for the purposes of complying with Article 47a of Directive 2001/83/EC.
- (o) the synchronisation of the status of a unique identifier between the national or supranational repositories serving the territory of the Member States where that medicinal product is intended to be placed on the market.

#### *Article 37*

#### *Obligations of legal entities establishing and managing a repository which is part of the repositories system*

Any legal entity establishing and managing a repository which is part of the repositories system shall perform the following actions:

- (a) inform the relevant national competent authorities of its intention to physically locate the repository or part of it in their territory and notify them once the repository becomes operational;
- (b) put in place security procedures ensuring that only users whose identity, role and legitimacy has been verified can access the repository or upload the information referred to in Article 33(2);
- (c) continuously monitor the repository for events alerting to potential incidents of falsification in accordance to Article 36(b);
- (d) provide for the immediate investigation of all potential incidents of falsification flagged in the system in accordance with Article 36(b) and for the alerting of national competent authorities, the European Medicines Agency and the Commission should the falsification be confirmed;
- (e) carry out regular audits of the repository to verify compliance with the requirements of this Regulation. Audits shall take place at least annually for the first five years after this Regulation becomes applicable in the Member State where the repository is physically located, and at least every three years

thereafter. The outcome of those audits shall be provided to competent authorities upon request;

- (f) make the audit trail referred to in Article 35(1)(g) immediately available to competent authorities upon their request;
- (g) make the reports referred to in Article 36(j) available to competent authorities upon their request.

#### *Article 38*

##### *Data protection and data ownership*

1. Manufacturers, marketing authorisation holders, wholesalers and persons authorised or entitled to supply medicinal products to the public shall be responsible for any data generated when they interact with the repositories system and stored in the audit trail. They shall only have ownership of and access to those data, with the exception of the information referred to in Article 33(2) and the information on the status of a unique identifier.
2. The legal entity managing the repository where the audit trail is stored shall not access the audit trail and the data contained therein without the written agreement of the legitimate data owners except for the purpose of investigating potential incidents of falsification flagged in the system in accordance with Article 36(b).

#### *Article 39*

##### *Access by national competent authorities*

A legal entity establishing and managing a repository used to verify the authenticity of or decommission the unique identifiers of medicinal products placed on the market in a Member State shall grant access to that repository and to the information contained therein, to competent authorities of that Member State for the following purposes:

- (a) supervising the functioning of the repositories and investigating potential incidents of falsification;
- (b) reimbursement;
- (c) pharmacovigilance or pharmacoepidemiology.

## **Chapter VIII**

### **Obligations of marketing authorisation holders, parallel importers and parallel distributors**

#### *Article 40*

##### *Products recalled, withdrawn or stolen*

The marketing authorisation holder or, in case of parallel imported or parallel distributed medicinal products bearing an equivalent unique identifier for the purposes of complying with Article 47a of Directive 2001/83/EC, the person responsible for placing the medicinal product on the market shall promptly take all the following measures:

- (a) ensure the decommissioning of the unique identifier of a medicinal product which is to be recalled or withdrawn, in every national or supranational repository serving the territory of the Member State or Member States in which the recall or the withdrawal is to take place;
- (b) ensure the decommissioning of the unique identifier, where known, of a medicinal product which has been stolen, in every national or supranational repository in which information on that product is stored;
- (c) indicate in the repositories referred to in points (a) and (b) that that product has been recalled or withdrawn or stolen, where applicable.

#### *Article 41*

##### *Products to be supplied as free samples*

The marketing authorisation holder intending to supply any of his medicinal products as a free sample in accordance with Article 96 of Directive 2001/83/EC shall, where that product bears the safety features, indicate it as a free sample in the repositories system and ensure the decommissioning of its unique identifier before providing it to the persons qualified to prescribe it.

#### *Article 42*

##### *Removal of unique identifiers from the repositories system*

The marketing authorisation holder of a medicinal product or, in case of parallel imported or parallel distributed medicinal products bearing an equivalent unique identifier for the purposes of complying with Article 47a of Directive 2001/83/EC, the person responsible for placing the medicinal product on the market shall not upload unique identifiers in the repositories system before having removed from therein, where present, older unique identifiers containing the same product code and serial number as the unique identifiers being uploaded.

## **Chapter IX**

### **Obligations of the national competent authorities**

#### *Article 43*

##### *Information to be provided by national competent authorities*

National competent authorities shall make the following information available to the marketing authorisation holders, manufacturers, wholesalers and persons authorised or entitled to supply medicinal products to the public, upon their request:

- (a) the medicinal products placed on the market on their territory which shall bear the safety features in accordance with Article 54(o) of Directive 2001/83/EC and this Regulation;
- (b) the medicinal products subject to prescription or subject to reimbursement for which the scope of the unique identifier is extended for the purposes of reimbursement or pharmacovigilance, in accordance with Article 54a(5) of Directive 2001/83/EC;

- (c) the medicinal products for which the scope of the anti-tampering device is extended for the purpose of patient safety, in accordance with Article 54a(5) of Directive 2001/83/EC.

#### *Article 44*

##### *Supervision of the repositories system*

1. National competent authorities shall supervise the functioning of any repository physically located in their territory, in order to verify, if necessary by means of inspections, that the repository and the legal entity responsible for the establishment and management of the repository comply with the requirements of this Regulation.
2. A national competent authority may delegate any of its obligations under this Article to the competent authority of another Member State or to a third party, by means of a written agreement.
3. Where a repository not physically located in the territory of a Member State is used for the purpose of verifying the authenticity of medicinal products placed on the market in that Member State, the competent authority of that Member State may observe an inspection of the repository or perform an independent inspection, subject to the agreement of the Member State in which the repository is physically located.
4. A national competent authority shall communicate reports of supervision activities to the European Medicines Agency, which shall make them available to the other national competent authorities and the Commission.
5. National competent authorities may contribute to the management of any repository used to identify medicinal products and verify the authenticity of or decommission the unique identifiers of medicinal products placed on the market in the territory of their Member State.

National competent authorities may participate to the management board of the legal entities managing those repositories to the extent of up to one third of the members of the board.

## **Chapter X**

### **Lists of derogations and notifications to the Commission**

#### *Article 45*

##### *Lists of derogations from bearing or not bearing the safety features*

1. The list of medicinal products or product categories subject to prescription which shall not bear the safety features are set out in Annex I to this Regulation.
2. The list of medicinal products or product categories not subject to prescription which shall bear the safety features are set out in Annex II to this Regulation.

#### *Article 46*

##### *Notifications to the Commission*

1. National competent authorities shall notify the Commission of non-prescription medicinal products which they judge to be at risk of falsification as soon as they



become aware of such risk. For that purpose, they shall use the form set out in Annex III to this Regulation.

2. National competent authorities may inform the Commission of medicinal products which they deem not to be at risk of falsification. For that purpose, they shall use the form set out in Annex IV to this Regulation.
3. For the purposes of the notifications referred to in paragraphs 1 and 2, national competent authorities shall conduct an assessment of the risks of and arising from falsification of such products taking into account the criteria listed in Article 54a(2)(b) of Directive 2001/83/EC.
4. When submitting to the Commission the notification referred to in paragraph 1, national competent authorities shall provide the Commission with evidence and documentation supporting the presence of incidents of falsification.

#### *Article 47*

##### *Evaluation of the notifications*

Where, following a notification as referred to in Article 46, the Commission or a Member State considers, on the basis of casualties or hospitalisations of citizens of the Union due to exposure to falsified medicinal products, that rapid action is required to protect public health, the Commission shall assess the notification without delay and at the latest within 45 days.

## **Chapter XI**

### **Transitional measures and entry into force**

#### *Article 48*

##### *Transitional measures*

Medicinal products that have been released for sale or distribution without the safety features in a Member State before the date in which this Regulation becomes applicable in that Member State, and are not repacked or relabelled thereafter, may be placed on the market, distributed and supplied to the public in that Member State until their expiry date.

#### *Article 49*

##### *Application in Member States with existing systems for the verification of the authenticity of medicinal products and for the identification of individual packs*

1. Each of the Member States referred to in Article 2, paragraph 2, second subparagraph, point (b), second sentence, of Directive 2011/62/EU shall notify the Commission of the date from which Articles 1 to 48 of this Regulation apply in its territory in accordance with the third subparagraph of Article 50. The notification shall take place at the latest 6 months before that application.
2. The Commission shall publish a notice of each of the dates notified to it in accordance with paragraph 1 in the Official Journal of the European Union.

*Article 50*  
*Entry into force*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [3 years after publication].

However, the Member States referred to in Article 2, paragraph 2, second subparagraph, point (b), second sentence, of Directive 2011/62/EU shall apply Articles 1 to 48 of this Regulation at the latest from [9 years after publication].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*  
*The President*  
[...]



Brussels, **XXX**  
Annexes Del. Act Safety Features  
[...] (2015) **XXX** draft

ANNEXES 1 to 4

## **ANNEXES**

**I to IV**

**to the**

**Commission Delegated Regulation (EU) No .../... of **XXX****

**supplementing Directive 2001/83/EC of the European Parliament and of the Council  
with regard to the detailed rules for the safety features appearing on the packaging of  
medicinal products for human use**

## ANNEX I

### List of medicinal products or product categories subject to prescription that shall not bear the safety features, referred to in Article 45(1)

Name of active substance or product category	Pharmaceutical form	Strength	Remarks
Homeopathic medicinal products	Any	Any	
Radionuclide generators	Any	Any	
Kits	Any	Any	
Radionuclide precursors	Any	Any	
Advanced therapy medicinal products which contain or consist of tissues or cells	Any	Any	
Medicinal gases	Medicinal gas	Any	
Solutions for parenteral nutrition having an anatomical therapeutical chemical ('ATC') code beginning with B05BA	Solution for infusion	Any	
Solutions affecting the electrolyte balance having an ATC code beginning with B05BB	Solution for infusion	Any	
Solutions producing osmotic diuresis having an ATC code beginning with B05BC	Solution for infusion	Any	
Intravenous solution additives having an ATC code beginning with B05X	Any	Any	
Solvents and diluting agents, including irrigating solutions, having an ATC code beginning with V07AB	Any	Any	
Contrast media having an ATC code beginning with V08	Any	Any	
Tests for allergic diseases having an ATC code beginning with V04CL	Any	Any	
Allergen extracts having an ATC code beginning with V01AA	Any	Any	

## ANNEX II

**List of medicinal products or product categories not subject to prescription that shall bear the safety features, referred to in Article 45(2)**

Name of active substance or product category	Pharmaceutical form	Strength	Remarks
omeprazole	gastro-resistant capsule, hard	20 mg	
omeprazole	gastro-resistant capsule, hard	40 mg	

### ANNEX III

<b>Notification to the European Commission of medicinal products not subject to prescription judged <u>to be at risk of falsification</u>, pursuant to article 54a(4) of Directive 2001/83/EC</b>					
<b>Member State:</b>			<b>Name of competent authority:</b>		
Entry No	Active substance (Common Name)	Pharmaceutical form	Strength	Anatomical Therapeutical Chemical (ATC) Code	Supporting Evidence <small>(please provide evidence of one or more incidents of falsification in the legal supply chain and specify the source of the information).</small>
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
Note: The number of entries is not binding.					

## ANNEX IV

<b>Notification to the European Commission of medicinal products judged <u>not to be at risk of falsification</u>, pursuant to article 54a(4) of Directive 2001/83/EC</b>					
<b>Member State:</b>			<b>Name of competent authority:</b>		
Entry No	Active substance (Common Name)	Pharmaceutical form	Strength	Anatomical Therapeutical Chemical (ATC) Code	Comments / Complementary information
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
Note: The number of entries is not binding.					