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DELEGATED ACT ON THE DETAILED RULES FOR A UNIQUE IDENTIFIER FOR MEDICINAL PRODUCTS FOR HUMAN USE, AND ITS VERIFICATION

CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION

INTRODUCTION

1. On 1 July 2011, 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 was published.[1] This Directive amends Directive 2001/83/EC on the Community Code relating to medicinal products for human use.[2]

2. Directive 2011/62/EU introduces obligatory 'safety features' to allow, *inter alia*, verification of the authenticity of medicinal products ('unique identifier'). It places the Commission under an obligation to adopt delegated acts[3] setting out the details relating to the unique identifier.[4]

3. More specifically, in accordance with Article 54a(2) of Directive 2001/83/EC, this delegated act shall set out:

   - The characteristics and technical specifications of the unique identifier;[5]
   - The modalities for verification of the safety features;[6]
   - The provisions on the establishment, management and accessibility of the repositories system in which information on the safety features is to be contained;[7]
   - 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;[8]

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1 OJ L 174, 1.7.2011, p. 74.

2 OJ L 311, 28.11.2001, p. 67. A consolidated version of Directive 2001/83/EC including the amendments by Directive 2011/62/EU is here: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001L0083:20110721:EN:PDF

3 The measures may be contained in one delegated act or several delegated acts. For the purpose of this document, reference is made to 'delegated act'.

4 Article 54a(2) of Directive 2001/83/EC.

5 Article 54a(2)(a) of Directive 2001/83/EC.

6 Article 54a(2)(d) of Directive 2001/83/EC.

7 Article 54a(2)(e) of Directive 2001/83/EC.

8 Article 54a(2)(b) of Directive 2001/83/EC.

- The procedures for the notification of medicinal products by the national competent authorities to the Commission, as regards medicinal products (not) at risk of falsification.[9]

4. The Directive also requires the Commission to carry out an impact assessment with regard to the characteristics of the unique identifier, the detailed procedures for verification, and the repositories system.[10] In this context, the Commission has to assess the costs, benefits and costs-effectiveness. However, the purpose of the impact assessment will not be to assess the impact of introduction of the safety feature itself, as this is now a mandatory requirement in EU legislation.

5. This concept paper is being rolled out for public consultation with a view to preparing both the impact assessment and the delegated act. The structure of this public consultation is based on the structure of an impact assessment, i.e. by identifying various policy options (and possibly sub-options) to address a defined problem/objective and subsequently, for each policy-option, identifying and discussing the socioeconomic impact.[11]

6. This public consultation will also serve as a means of gathering further quantified information on the various policy options. This is critical, as the figures used in the impact assessment for the proposal for Directive 2011/62/EU[12] may now be partially outdated and in need of updating.

7. The adoption of the delegated act is scheduled for 2014.[13]

Stakeholders are invited to comment on this consultation paper, and especially on the boxed text, by 27 April 2012 at the latest. Responses should be sent preferably by e-mail to sanco-pharmaceuticals@ec.europa.eu, or by post to Unit SANCO/D/3, BREY 10/114, BE-1049 Brussels.

When sending your comments and responses, you should state whether you are a stakeholder association or a private individual. If you represent an association, please indicate clearly what type of association this is (patient, manufacturer, wholesale distributor, pharmacy, hospital, etc.). If you represent a company, please state whether it falls within the EU definition of a small and medium-sized enterprise (i.e. less than €50 million annual turnover and fewer than 250 employees).

All comments and responses will be made publicly available on the 'Europa website' on pharmaceuticals once the consultation period is over. If you do not wish your contribution to be made public please indicate this clearly and specifically in the documentation you send us (i.e. not just in the covering letter or e-mail). In this case, only an indication of the contributor will be disclosed.

Professional organisations are invited to register in the Union's Register for Interest Representatives (http://ec.europa.eu/transparency/regrin/) set up as part of the European Transparency Initiative to provide the Commission and the public at large with information about the objectives, funding and structures of interest representatives.

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9 Article 54a(2)(c) and Article 54a(4) of Directive 2001/83/EC.

10 Article 4 of Directive 2011/62/EU.

11 http://ec.europa.eu/governance/impact/key_docs/key_docs_en.htm

12 SEC(2008)2674, see in particular Annex 1 of the impact assessment report (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:2674:FIN:EN:PDF)

13 A Roadmap for the impact assessment is going to be published in due course here: http://ec.europa.eu/governance/impact/planned_ia/roadmaps_2011_en.htm#health.

A. CONSULTATION TOPIC N°1: CHARACTERISTICS AND TECHNICAL SPECIFICATIONS OF THE UNIQUE IDENTIFIER

Introduction

8. Directive 2011/62/EU has introduced obligatory safety features for certain medicinal products for human use as part of the labelling of the outer packaging of the medicinal product.[14] The safety features shall enable:

   – to verify that a medicinal product is authentic and to identify an individual pack of medicinal products ('unique identifier');

   – to verify whether the outer packaging has been tampered with ('tamper-evidence').

9. This obligation applies in principle to all medicinal products placed on the EU market, including imported medicinal products.

10. With regard to tamper-evidence, the choice of the technical specification is left to the manufacturer: The manufacturer is best placed to establish how the outer packaging is made tamper-proof.

11. As regards the unique identifier, however, the Commission is tasked to adopt a delegated act setting out the characteristics and technical specifications.

12. The only way to uniquely identify a pack is to give it a number ('serialisation number'). In order to act as an effective authentication tool, the number has to be randomised.[15] A 'carrier' (bar code or other) affixed on the outer packaging 'holds' the serialisation number.

13. The serialisation number on the pack is checked against its entry in a repositories system (see consultation topic n°3), thus verifying its authenticity (see consultation topic n°2).

14. In terms of characteristics and technical specifications, the following policy options can be pursued.

1. Policy option n°1/1: Leaving the choice of the technical specification to the individual manufacturer

15. Under this policy option, the delegated act would create a broad framework, leaving it up to the manufacturer to choose the appropriate technical solution for the serialisation number and its carrier.

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[14] The safety features are part of the labelling. As such, they are integral part of the marketing authorisation. Regarding the marketing authorisation, for changes to an aspect of the labelling not connected with the summary of product characteristics Article 61(3) of Directive 2001/83/EC applies.

[15] A sequential number would facilitate its reproduction.

16. This policy option is very flexible and therefore may be cost-neutral for companies which already have a system of serialisation in place.

17. However, this policy option may lead to a high degree of fragmentation of product coding in the EU. This, in turn, may make it difficult to ensure prompt verification (see consultation topic n°2).

2. Policy option n°1/2: Harmonisation through regulation

18. Under this policy option, the Commission would set out in the delegated act details concerning the serialisation number (see point 2.1) and the carrier (see point 2.2).

19. This may enable a smoother implementation than policy option n°1/1.

Consultation item n°1: Please comment on points 1 and 2 (policy options n°1/1 and n°1/2). Where do you see the benefits and disadvantages of each policy option?

2.1. Regulation of the composition of the serialisation number

2.1.1. Manufacturer product code and pack number

20. In order to allow identification of a pack of medicinal products, a serialisation number would have to contain, as a minimum, a manufacturer product code and the pack number.

21. For the purpose of this public consultation, based on existing international industry standards and global regulatory developments[16], the following composition of the unique identifier is proposed:

Manufacturer Product code (which includes the prefix of the country)	Unique identification number of the pack
XXXXXXXXXXXXX	XXXXXXXXX

Consultation item n°2: Where do you see the advantages and disadvantages of the approach set out in point 2.1.1.? Please comment.

2.1.2. Additional product information

22. The serialisation number allows for inclusion of a range of other product related information.

(a) Batch number

23. The serialisation number could include the batch number of the medicinal product. If the serialisation number is machine-readable (see point 2.2), this would facilitate identification of batches. This may be relevant in view of the obligation of the wholesale distributor to keep records of the batch number in accordance with the

[16] Cf. for example, the guidance document 'Standards for securing the drug supply chain – standardized numerical identification for prescription drug packages', U.S. Department of Health and Human Services, U.S. Food and Drug Administration, March 2010 (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM206075.pdf)

fourth indent of Article 80(e) of Directive 2001/83/EC. It may also facilitate recalls on a batch-level in the distribution chain.

(b) Expiry date

24. The serialisation number could include the expiry date. This may facilitate storage management and verification of expiry dates of medicinal products at the level of wholesale distributors and pharmacists/retailers.

Consultation item n°3: Where do you see the advantages and disadvantages of the approach set out in points (a) and (b) of point 2.1.2? Please comment.

(c) National reimbursement number

25. Directive 2011/62/EU lays down exhaustive rules on labelling for medicinal products as regards authenticity and identification.[17] Member States are not allowed to create additional requirements in this respect.

26. In addition, Directive 2011/62/EU provides that Member States may, *inter alia* for the purposes of reimbursement, extend the scope of application of the unique identifier to include any medicinal product that is subject to prescription or to reimbursement.[18]

27. Most Member States have national product codes for reimbursement purposes in place ('national reimbursement number'). Therefore, two alternative options could be considered:

28. Option 1: the national reimbursement number is replaced by the abovementioned serialisation number.

29. Option 2: The abovementioned serialisation number includes the national reimbursement number. In this case, the serialisation number could be composed as follows:

Manufacturer Product code (which includes the prefix of the country)	Unique identification number of the pack	National reimbursement number (see point c)	Expiry date (see point b)	Batch number (see point a)
XXXXXXXXXXXXX	XXXXXXXXX	XXXXXXXX	XXXXXX	XXXXX

Consultation item n°4: Which of the two options set out under point (c) of point 2.1.2 is in your view preferable? Where do you see advantages and disadvantages? Please comment.

[17] Fourth indent of Article 57 of Directive 2001/83/EC.

[18] First subparagraph of Article 54a(5) of Directive 2001/83/EC.

2.2. Regulation of the technical characteristics of the carrier

30. Various ways to carry the serialisation number on the outer packaging could be considered:

2.2.1. Linear barcode

31. This carrier is widely used for all industrial and consumer goods.

32. It is used currently in Belgium, Greece and Italy as a carrier for the serialisation number of medicinal products. Linear barcode readers are now present in almost every pharmacy in Europe.

33. There may be difficulties with regard to the amount of information that needs to be stored in this code (see point 2.1). This applies in particular in the case of small outer packagings.

2.2.2. 2D-Barcode

34. This carrier is being used increasingly for industrial and consumer goods.

35. This carrier is able to carry a large number of data on a small label. However, many pharmacies in Europe are not currently equipped with a suitable reader to read a 2D barcode.

2.2.3. Radio-frequency identification (RFID)

36. RFID uses radio waves to exchange data between a reader and an electronic tag attached to an object.

37. RFID has been discussed in the context of the identification of pharmaceuticals.[19] However, at present, it is relatively expensive in comparison with other carriers. Moreover, little is known about how the RFID technology may interfere with the quality of certain medicines.

Consultation item n°5: Please comment on the three concepts described under point 2.2. Where do you see the benefits and disadvantages of each of the three concepts. What are the costs for each concept? Please quantify your reply, wherever possible, by listing for example:

[19] See, for example, the Communication from the Commission to the Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 15 March 2007 - "Radio Frequency Identification (RFID) in Europe: steps towards a policy framework" (COM(2007) 96).

- costs for reading devices for the different carriers;

- costs for adapting packaging lines of medicines packaged for the EU market.

B. CONSULTATION TOPIC N° 2 - MODALITIES FOR VERIFYING THE SAFETY FEATURES

Introduction

38. The concept of a unique identifier to verify the authenticity of medicinal products only works if there is a reliable verification system in place. It is easy to reproduce a (randomised) serialisation number *per se*. Therefore, the security of a serialisation number is based on the fact that a (randomised) serialisation number is checked into a repositories system, and subsequently 'checked out' of this repositories system (see consultation topic n°3).[20]

39. If the repositories system does not contain this number (because it was never checked in or is already checked out) this highlights a security issue to be followed up.

40. Thus, the check-out of the safety feature is a key element in the process of ensuring the detection of falsified medicines in the supply chain and, by extension, the protection of public health.

41. In addition, there is the possibility to verify the serialisation number without a check-out of that number from the repositories system.

42. Thus for the purpose of this concept paper the following terminology shall be used:

    - 'Verification of the serialisation number': checking the number against the entry in the repositories system, without checking out that number from the repositories system;

    - 'Check out of the serialisation number': the number is verified and checked out of the repositories system.

43. Various actors in the supply chain may be involved in this verification or check-out. This includes in particular

        - re-packagers;

        - wholesale distributors; and

        - pharmacies/retailers.

44. Directive 2011/62/EU already includes an obligation for re-packagers (such as parallel traders) to verify the safety feature.[21]

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[20] The delegated act shall include provisions about the verification of the anti-tampering device (Article 54a(2)(d) of Directive 2001/83/EC). This verification activity would be limited to the final dispensing person (pharmacist or retailer).

[21] Article 47a(1)(a) of Directive 2001/83/EC.

45. For other actors in the supply chain, the detailed procedures for verification are to be established in the delegated act[22] following an impact assessment.[23] The Commission is placed under an obligation, when establishing those modalities, to take into account the particular characteristics of the supply chain in Member States and the need to ensure that the impact of the verification measures on particular actors in the supply chain is proportionate.[24]

1. Policy option n°2/1: Systematic check-out of the serialisation number at the dispensing point

46. In this option the pack is checked out following the reading (scanning) of the serialisation number at the end of the supply chain i.e. by a retailer or a pharmacy, including a hospital pharmacy. In this policy option, the wholesale distributor is not required to check out or verify the serialisation number.

47. This policy option ensures that any medicinal product with security/safety issues is detected before it is dispensed to the patient.

48. Under this policy option the authenticity of the medicinal product is verified at a late stage in the distribution chain. If the serialisation number is copied several times, and subsequently channelled into the distribution chain, packs with falsified medicines may circulate for months in the Union before they are detected.

49. In terms of costs, the following actors may have to be equipped with suitable reading systems:

- Pharmacies, including hospital pharmacies; and
- Retailers who dispense medicinal products which have to include the safety feature.

Consultation item n°6: Regarding point 1 (policy option n°2/1), are there other points of dispensation to be considered? How can these be addressed in this policy option?

2. Policy option n°2/2: As in policy option n°2/1, but with additional random verifications at the level of wholesale distributors

50. In this policy option, in addition to the systematic check out at the point of dispensation, wholesale distributors perform random verifications of the serialisation number.

51. In this case the serialisation number can not be checked out by the wholesale distributor from the repositories system.[25]

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22 Article 54a(2)(d) of Directive 2001/83/EC.

23 Article 4(b) of Directive 2011/62/EU.

24 Article 54a(2)(d) of Directive 2001/83/EC.

25 If the number was checked out of the system, it would lead to confusion with regard to the later, systematic, check out at the point of dispensation.

52. A verification of the serialisation number without check out provides only limited additional protection as it can not always detect duplicates of the serialisation number.

53. On the other hand, it can be argued that, even if duplication of serialisation numbers cannot be always detected, this policy option is likely to be preventive and dissuasive, and therefore helps to protect against falsification of medicines in the distribution chain.

54. This policy option requires additional investments for wholesale distributors. It may delay the preparation of delivery orders.

3. Policy option n°2/3: As in policy option n°2/1, but with additional systematic verification by the wholesale distributors

55. In this policy option, in addition to the systematic check out at the point of dispensation, each actor in the supply chain (i.e. all wholesale distributors) has to verify the individual pack.

56. As in policy option n°2/2, the serialisation number would not be checked out by the wholesale distributor from the repositories system. Therefore, the weakness of the checks in the distribution chain as set out above (point 2) remains.

57. However, this policy option does ensure the traceability of each individual pack. To date, traceability is usually ensured by referring only to the name of the medicinal product and the batch.[26] This policy option would thus facilitate the recall of medicines, including individual packs, at any stage of the distribution chain. This policy option may also make it easier to trace back the trade flow of falsified medicines.

58. However, this policy option involves major additional operational costs, in particular for wholesalers. The systematic scanning of each pack will delay the preparation of the orders and this increases the human resources needed for these operators.

Consultation item n°7: Please comment on the three policy options set out in points 1 to 3. Where do you see the benefits and disadvantages? Please comment on the costs of each of these policy options. Quantify your response, wherever possible. This applies in particular to the:

- number of wholesale distribution plants;

- costs for adapting such plants;

- duration of scanning of the serialisation number;

- number of pharmacies, including hospital pharmacies;

- number of medicinal products dispensed by pharmacies and a hospital pharmacy.

[26] Article 80(e) of Directive 20018/83/EC.

C. CONSULTATION TOPIC N°3 - PROVISIONS ON THE ESTABLISHMENT, MANAGEMENT AND ACCESSIBILITY OF THE REPOSITORIES SYSTEM

Introduction

59. In order to verify the authenticity of the medicinal product, the serialisation number has to be checked against the information stored in a repositories system.[27] The delegated act shall contain provisions on the establishment, management and accessibility of the repositories system, following an impact assessment.[28]

60. Independently of the policy option chosen, the costs of the repositories system shall be born by the manufacturing authorisation holders of medicinal products bearing the safety features.[29]

1. Policy option n°3/1 – 'stakeholder governance'

61. Under this policy option the delegated act would define the objective to be achieved and the obligations on the relevant actors (manufacturers, wholesale distributors, pharmacists/retailers) and also set out the legal framework and limits (for example, the obligations to protect personal and commercial data). On the basis of these obligations, this policy option would leave it to the relevant actors to set up the appropriate infrastructure for the repositories system ('stakeholder governance').

62. Thus, the delegated act would define only the key responsibilities, such as:

- The manufacturer would be responsible for ensuring *inter alia*:
  - that the serialisation number is available for authenticity checks, while being secured against illegal infiltration (hacking);
  - that the response from the repositories system is delivered without delay;
  - that the serialisation number is checked out.
- The person dispensing the medicinal product/wholesale distributor (see consultation topic n°3) would be responsible for ensuring *inter alia*
  - that the serialisation number is verified (details depend on the choice made under consultation topic n°3);
  - that data enabling the medicinal product to be traced to the final dispensing point are not made available to the manufacturer (see point 4.1 in this consultation topic).

63. This policy option may be the most cost-efficient as it may create a market that provides best value for money.

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[27] Article 54a(2)(d) of Directive 2001/83/EC.

[28] Article 4 of Directive 2011/62/EU.

[29] Article 54a(2)(e) of Directive 2001/83/EC.

64. This policy option may make it more difficult for Member States to use the information contained in the repositories system for the purposes of reimbursement, pharmacovigilance or pharmacoepidemiology.[30]

2. Policy option n°3/2 – EU governance

65. Policy option n°3/2 is a pan-European repositories system to which all actors are connected, and which is governed by an EU-body (Commission or EMA) ('EU governance').

66. This system would provide a single point to check serialisation numbers in and out. To that extent, it can simplify processes.

67. However, the complexity of the system may be considerable: It would require a central repositories system storing all data from all actors in the supply chain, the simultaneous connection of thousands of actors at the same time, and the instantaneous authentication of individual packs.

3. Policy option n°3/3 – national governance

68. This policy option is the establishment of a system of national repositories to which all actors in the Member State, and actors supplying medicines to the territory of that Member State, are connected. The national repositories would be governed by official national bodies, established by each Member State ('national governance').

69. The national databases would have to be interconnected in order to allow intra-Union trade.

70. The advantages of this policy options are that:

- the number of actors linked to a national repositories system is limited. This might reduce the complexity of the system;

- Member States can select the appropriate characteristics of the national repositories system in view of the national characteristics of the distribution chain.

71. However, the interconnection of systems run by national official bodies might present a challenge. Moreover, a manufacturer supplying medicines to various Member States would have to be connected to a multitude of national repositories.

Consultation item n°8: Please comment on the three policy options set out in points 1 to 3. Where do you see the benefits and disadvantages? Please comment on the costs of each of these policy options. Please quantify your reply, wherever possible. This applies in particular to the estimated one-off costs and running costs for a repositories system. Where possible, please provide information on past experiences with a repositories system at individual company level and at national level (taking into account the experiences of Member States and companies).

[30] Second subparagraph of Article 54a(5) of Directive 2001/83/EC.

4. Other issues related to the repositories system

72. In connection with the repositories system, there are a number of other issues which have to be considered in the delegated act.

4.1. Information of a commercially sensitive nature

73. The Commission is to take due account of the legitimate interests to protect information of a commercially confidential nature.[31] In the context of a repositories system, the following information could be commercially sensitive:

- Information that allows the number of packs manufactured to be established;
- Information that allows the point of dispensation of a pack to be established;
- Information that allows the point of re-packaging of a pack to be established.

Consultation item n°9: Please comment on point 4.1. Are there other items of information which should be taken into consideration when addressing the issue of commercially sensitive information in the delegated act?

74. This information, however, should be made accessible for the national competent authorities in the framework of supervision, controls and investigations.

4.2. Protection of personal data

75. The issue of protection of personal data is explicitly addressed in Directive 2011/62/EU.[32] In any event, the repositories system would *not* contain personal data related to patients, as this is not necessary in order to fulfil the purpose of the unique identifier.

4.3. Re-packaging of medicinal products

76. Article 47a of Directive 2001/83/EC addresses manufacturing activities where the safety features are removed or covered. It obliges *inter alia* the re-packager to replace the safety features with equivalent features. An equivalent safety feature is another unique identifier, which is checked into the repositories system and replaces the original unique identifier.

Consultation item n°10: Please comment on points 4.2 and 4.3. What aspects should be taken into consideration in the delegated act?

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[31] Article 54a(3)(b) of Directive 2001/83/EC.

[32] Article 54a(3)(a) of Directive 2001/83/EC.

D. CONSULTATION TOPIC N°4 - 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

Introduction

77. Directive 2001/62/EU stipulates that medicinal products subject to prescription shall bear the safety features, including the unique identifier, unless they have been listed by the Commission in a delegated act (for the purpose of this concept paper, this list shall be referred to as the 'white list').[33]

78. Medicinal products not subject to prescription shall not bear the safety features, unless they have been listed by the Commission in a delegated act (for the purpose of this concept paper, this list shall be referred to as the 'black list').[34]

79. The 'black list' and the 'white list' are established for the entire EU market. No differentiation is made as regards the national territories of the internal market.

80. For the purposes of ascertaining whether a medicinal product is subject to prescription, the relevant territory is the Member State where the medicinal product is intended to be made available to the final user.

81. At present it is planned to annex the 'black list' and the 'white list' to the delegated act setting out the details related to the unique identifier.

82. In order to draw up the 'black list' and the 'white list', Directive 2011/62/EU stipulates that the following aspects need to be taken into account:

    - The risk of falsified medicines; and
    - The risk arising from falsified medicines (i.e. the potential hazard).[35]

83. More concretely, at least the following criteria (hereafter: 'classification criteria') shall be applied:[36]

    - The *price of the medicinal product*: It is assumed that medicinal products at a very low price are, for economic reasons, less at risk of being falsified. Regarding price, in view of the risk of channelling falsified medicines into the legal supply chain at wholesale distributor level, the gross manufacturer price (i.e. the price to be paid by wholesale distributors) would have to be considered. Moreover, 'high price' being a relative term, it would need to be established against the costs for falsifying a medicinal product. These costs are typically very

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33 First subparagraph of Article 54a(1) of Directive 2001/83/EC.

34 Second subparagraph of Article 54a(1) of Directive 2001/83/EC.

35 Article 54a(2)(b) of Directive 2001/83/EC.

36 Article 54a(2)(b) of Directive 2001/83/EC.

low. Therefore, a manufacturer's gross price of more than 2 EUR could be considered as a 'high price'.

- *The sales volume of the medicinal product*: It is assumed that medicinal products placed on the market in very low volumes are, for economic reasons, less at risk of being falsified. 'Sales volume' being a relative term, it would need to be established against the typical sales volume of medicinal products *per annum* in the EU.

- *The number and frequency of previous incidents of falsified medicines reported in the Union and in third countries:* The number of incidents of falsified medicines detected within the EU, at its borders or in third countries, may be an indicator that a product or a category of product entails a higher risk of falsification. Regarding product categories, point 1 may apply.

- *The specific characteristic of the product:* Medicinal products may have specific characteristics which make the risk of falsification unlikely: One example might be products that are delivered direct from the manufacturer to hospital pharmacies.

- *The seriousness of the conditions intended to be treated:* Falsified medicines usually do not have the same efficacy as the original product: For example, the active substance may not be contained in the falsified medicine, or it may be contained in a higher or lower dosage than the original. Therefore, falsification of these products may have very serious consequences for patients, who will not receive the correct treatment. Examples may include oncology medicines and medicines for cardiovascular diseases.

- *Other potential risks to public health:* Other criteria may be identified in the future for consideration in the assessment.

84. When deciding on the content of the 'black list' and the 'white list', two basic considerations apply:

    - The possibility of exemptions from the general principle laid down by the legislation should be interpreted narrowly. It should not be used as an opportunity to dilute the general principle that all prescription medicines shall bear the safety feature while non-prescription medicines shall not bear the safety feature.

    - The drafting and adoption of the initial delegated act, and of each subsequent amendment, takes around two years. Any listing of medicines, in particular as regards the 'white list', has to be carried out with a eye to future developments.

85. Moreover, regarding the scope of the safety features, it is important to be aware of the following:

    - the EU-scope of the unique identifier is non-optional: a medicinal product which falls within the scope must bear the unique identifier. A medicinal product which falls outside the scope must not have to bear the unique identifier. Thus, there is no 'optional scope' for manufacturers: A manufacturer cannot decide to apply the unique identifier to medicinal products which do not fall within the scope of the safety feature;

- Independently of the EU scope, Member States have the possibility, in respect of medicinal products placed on the market on their territory, to require labelling of the unique identifier on any medicinal product subject to prescription or subject to reimbursement, for the purposes of reimbursement or pharmacovigilance.[37]

1. Identification criteria

86. Directive 2011/62/EU leaves open the criteria for identifying medicinal products to be listed in the 'black list' and the 'white list' (hereafter 'identification criteria'). Four different approaches are put forward for discussion:

- Identification by Anatomical Therapeutical Chemical Code (ATC): This criterion is easy to establish. However, taken on its own it may be insufficient, in view of the classification criteria set out above.

- Identification by brand name: Apart from being a very narrow identification criterion, the main difficulty concerns the differing brand names of identical medicinal products in the EU. In addition, brand names may change. Lastly, there may be a variety of commercial reasons that militate against highlighting individual brands in a delegated act on falsified medicines.

- Identification by the name of the active pharmaceutical ingredient: The difficulty as set out above for the ATC also applies here.

- A flexible approach on a case-by-case basis: This leaves room for some flexibility. This flexibility would facilitate the application of the classification criteria set out above.

Consultation item n°11: Which approach seems the most plausible from your view? Can you think of arguments other than those set out above? Can you think of other identification criteria to be considered?

2. Applying the classification criteria

87. In order to apply the classification criteria in Article 54a(2) of Directive 2001/83/EC consistently, a rough guide might be to adopt a quantified approach. The following should serve as an example of how such a quantified approach could be applied:

Criteria 1: Price	High price: 5 points; Low price: 1 point
Volume	High volume: 5 points; Low volume: 1 point
Criteria 2: Incidents in the EU or third country	Several incidents: 5 points; No incident: 1 point
Criteria 3: Characteristic of the product	Characteristics indicate risk of falsification: 5 points; Characteristics indicate no risk of falsification: 1 point

[37] Second subparagraph of Article 54a(5) of Directive 2001/83/EC.

Criteria 4: Severity of the conditions intended to be treated	Conditions severe: 5 points; Conditions not severe: 1 point
Criteria 5: Other potential risk to public health	Max. 5 points.

On the basis of this scheme, it would be considered that:

- A prescription medicine which has 6 points or less is listed in the 'white list';
- A non-prescription medicine which has more than 10 points is listed in the 'black list'.

88. An approach along these lines would remain within the logic of the legislation (see the introduction to this consultation topic), i.e. as a general rule, it would include prescription medicines in the scope, while excluding non-prescription medicines.

Consultation item n°12: Please comment on the quantified approach set out above.

E. CONSULTATION TOPIC N°5 - OTHER ISSUES

1. Procedures for the notification of medicinal products from the national competent authorities to the Commission

89. The delegated act shall contain procedures for the notification to the Commission of those medicinal products which they judge to be at risk of falsification and those which they deem not to be at such risk, and a rapid system for evaluating and deciding on such notification.[38]

2. Date of application of the delegated act

90. According to Article 2(2)(b) of Directive 2011/62/EU, the date of application of the delegated act is three years after the date of publication of the delegated act.[39]

Consultation item n°13: Please raise any other issue or comment you would wish to make which has not been addressed in the consultation items above.

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[38] Article 54a(2)(c), (4) of Directive 2001/83/EC.

[39] The delegated act is published after the right of opposition by the co-legislators in accordance with Article 121c of Directive 2001/83/EC has expired. On the procedural aspects for delegated acts see Commission Communication COM(2009) 673 - Implementation of Article 290 of the Treaty on the Functioning of the European Union (http://eur-lex.europa.eu/Result.do?checktexts=checkbox&TypeAffichage=sort_key&page=1&idReq=1&Submit22=GO)